Electronic Certificate

Version: 1 . 0

Document Number: US-OPT-03472

Document Name: Approval Letter

Country: United States

Product: Malignant Pleural Mesothelioma

Type: Material

Sub Type: HCP

Classification: Marketing

Certification Statement
We certify that the final electronic form of this material is in accordance with the regulations set forth by the health authority for the country of this document, and is a fair and truthful presentation of the facts about the product.

Role	Signature
David Blazina - Legal Approval (dblazina@novocure.com)	Meaning: As the Legal, I approve this document for use. Date: 07-May-2020 11:58:50 GMT+0000
Kory Gardner - Complete Quality Control Check (KGardner@novocure.com)	Meaning: As the Final Reviewer, I approve this document for use. Date: 08-May-2020 15:12:20 GMT+0000

May 23, 2019

Novocure, Ltd.
% Jonathan Kahan
Regulatory Counsel
Hogan Lovells US LPP
555 13th Street, NW
Washington, District of Columbia 20004

Re: H180002
HUD Number: DEV 2017-0381
Trade/Device Name: NovoTTF™-100L System
Product Code: QGZ
Filed: October 23, 2018
Amended: November 14, 2018, November 27, 2018, March 8, 2019

Dear Jonathan Kahan:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your humanitarian device exemption (HDE) application for the NovoTTF™-100L System. This device is indicated for the treatment of adult patients with unresectable, locally advanced or metastatic, malignant pleural mesothelioma (MPM) to be used concurrently with pemetrexed and platinum-based chemotherapy. We are pleased to inform you that the HDE is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm identifies combination product submissions.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device and insofar as the sale and distribution of the device are restricted to oncologists and surgical oncologists. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and probable benefit of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at 9 months for the transducer arrays. This is to advise you that the protocol you used to establish this expiration dating is considered an approved

protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.108 and 21 CFR 814.39(a)(7).

Continued approval of the HDE is contingent upon the submission of periodic reports, required under 21 CFR 814.126, at intervals of one year (unless otherwise specified) from the date of approval of the original HDE. This report, identified as "Annual Report" and bearing the applicable HDE reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.126.

In addition to the above an HDE holder is required to maintain records of the names and addresses of the facilities to which the humanitarian use device (HUD) has been shipped, correspondence with reviewing institutional review boards (IRBs), as well as any other information requested by a reviewing IRB or FDA.

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final Unique Device Identification (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). For more information on these requirements, please see the UDI website, http://www.fda.gov/udi.

Before making any change affecting the safety or probable benefit of the HDE device, you must submit an HDE supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.108 and 814.39 except a request for a new indication for use of a humanitarian use device (HUD). A request for a new indication for use for an HUD shall comply with the requirements set forth in 21 CFR 814.110 which includes obtaining a new designation of HUD status for the new indication for use and submission of an original HDE application in accordance with §814.104. The application for the new indication for use may incorporate by reference any information or data previously submitted to the agency.

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52 for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm and on combination product postmarketing safety reporting is available at (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm).

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the postmarketing safety reporting requirements (21 CFR 4, Subpart B) for combination products, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

FDA has determined that this device meets the conditions of either (I) or (II) under section 520(m)(6)(A)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This device may be sold for an amount that exceeds the costs of research and development, fabrication, and distribution of the device (i.e., for profit) as long as the number of devices distributed in any calendar year does not exceed the annual distribution number (ADN). The ADN for this device is determined to be 24,000. This ADN was calculated based on the estimated number of NovoTTF-100L devices needed per patient in a year. You must immediately notify the agency by submitting an HDE amendment (21 CFR 814.126) whenever the number of devices shipped or sold in a year exceeds the ADN. FDA may also inspect the records relating to the number of your devices distributed during any calendar year. See section 520(m)(6)(B) of the FD&C Act. If you notify the FDA that the ADN has been exceeded, or if FDA discovers through an inspection that the ADN has been exceeded, then you are prohibited to sell your device for profit for the remainder of the year. See section 520(m)(6)(D) of the FD&C Act. If additional information arises regarding the ADN for your device, you may submit an HDE supplement (21 CFR 814.108) requesting that FDA modify the ADN based upon this additional information. See section 520(m)(6)(C) of the FD&C Act.

CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your HDE by making available, among other information, a summary of the safety and probably benefit data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the HDE number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a HDE. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this HDE submission with a copy of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted, unless otherwise specified, to the address below and should reference the above HDE number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Rachana Visaria at 240-402-5628 or Rachana.Visaria@fda.hhs.gov.

Sincerely,

Michael J. Ryan -S

for Malvina Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Description of the Optune Lua® system

Discuss Optune Lua with your next patient

Optune Lua overview

- For the first-line **treatment of unresectable, locally advanced or metastatic, MALIGNANT PLEURAL MESOTHELIOMA (MPM)**, the FDA has approved Optune Lua together with pemetrexed + cisplatin or carboplatin[1,2]
- When using Optune Lua, **loco-regional delivery of Tumor Treating Fields (TTFields) via transducer arrays** provides antimitotic activity directly at the site of the malignancy[1]

How Optune Lua is used

- Transducer arrays are applied to the torso and need to be replaced at least twice per week (every 4 days at most) to help minimize the risk of skin irritation[3]
- Portable for use during normal daily activities[3]
  - Patients should avoid activities that may result in Optune Lua or the transducer arrays becoming wet, as this may cause damage[3]
- It is recommended to use TTFields continuously, averaging at least 18 hours a day[1,4]
- Patients should refer to the Skin Care Guidelines for specific information regarding taking care of their skin and array placement instructions

Introducing the second-generation Optune Lua system[3]

Second-generation Optune Lua system

Optune Lua is a wearable, portable treatment for MPM and has been redesigned for carrying comfort and usability. Note that the Optune Lua system is[1,3]:

More compact

- Smaller-profile carrying case with easy-grip texture

More convenient

- Weighs half as much and now has 5 different ways to carry the device, including a backpack and shoulder strap

Equipped with smart technology

- Battery indicator alerts patients to change battery, and light sensor auto-dims for night use

Note: Transducer arrays are customized based on gender, body type, and tumor location.

How Optune Lua works

Optune Lua is a noninvasive, antimitotic cancer treatment for MPM that delivers TTFields. TTFields are low-intensity (1-3 V/cm) alternating electric fields tuned to a specific frequency (150 kHz) to disrupt cancer cell division in solid tumors.[1]

TTFields disrupt cell division through physical interaction with key molecules during multiple phases of mitosis.[1,5]

Visit OptuneLua.com/hcp for more information

Caution: Federal law restricts this device to sale by or on the order of a physician. Humanitarian Device. Authorized by Federal Law for use in the treatment of adult patients with unresectable, locally advanced or metastatic, malignant pleural mesothelioma concurrently with pemetrexed and platinum-based chemotherapy. The effectiveness of this device for this use has not been demonstrated.

Please see the complete Important Safety Information for Optune Lua on the back and the Optune Lua Instructions For Use (IFU) for complete information regarding the device's indications, contraindications, warnings, and precautions at OptuneLua.com/hcp.

OPTUNE LUA®

Indications For Use

Optune Lua® is indicated for the treatment of adult patients with unresectable, locally advanced or metastatic, malignant pleural mesothelioma (MPM) to be used concurrently with pemetrexed and platinum-based chemotherapy.

Important Safety Information

Contraindications

Do not use Optune Lua in patients with implantable electronic medical devices such as pacemakers or implantable automatic defibrillators, etc. Use of Optune Lua together with implanted electronic devices has not been tested and may lead to malfunctioning of the implanted device.

Do not use Optune Lua in patients known to be sensitive to conductive hydrogels. Skin contact with the gel used with Optune Lua may commonly cause increased redness and itching, and may rarely lead to severe allergic reactions such as shock and respiratory failure.

Warnings and Precautions

Optune Lua can only be prescribed by a healthcare provider that has completed the required certification training provided by Novocure®.

The most common (≥10%) adverse events involving Optune Lua in combination with chemotherapy were anemia, constipation, nausea, asthenia, chest pain, fatigue, medical device site reaction, pruritus, and cough.

Other potential adverse effects associated with the use of Optune Lua include: treatment related skin toxicity, allergic reaction to the plaster or to the gel, electrode overheating leading to pain and/or local skin burns, infections at sites of electrode contact with the skin, local warmth and tingling sensation beneath the electrodes, muscle twitching, medical device site reaction and skin breakdown/skin ulcer.

If the patient has an underlying serious skin condition on the chest, evaluate whether this may prevent or temporarily interfere with Optune Lua treatment.

Do not prescribe Optune Lua for patients that are pregnant, you think might be pregnant or are trying to get pregnant, as the safety and effectiveness of Optune Lua in these populations have not been established.

Please see the Optune Lua Instructions For Use (IFU) included in the Information Kit for complete information regarding the device's indications, contraindications, warnings, and precautions.

References: 1. Optune Lua. Instructions For Use for Unresectable Malignant Pleural Mesothelioma. Novocure; 2021. **2.** FDA Approves the NovoTTF-100L™ System in Combination with Chemotherapy for the Treatment of Malignant Pleural Mesothelioma [press release]. St. Helier, Jersey: Business Wire; May 23, 2019. **3.** Optune Lua. Patient Information and Operation Manual for Unresectable Malignant Pleural Mesothelioma. Novocure; 2021. **4.** Ceresoli GL, Aerts JG, Dziadziuszko R, et al. Tumour Treating Fields in combination with pemetrexed and cisplatin or carboplatin as first-line treatment for unresectable malignant pleural mesothelioma (STELLAR): a multicentre, single-arm phase 2 trial. *Lancet Oncol*. 2019;20(12):1702-1709. **5.** Kirson ED, Gurvich Z, Schneiderman R, et al. Disruption of cancer cell replication by alternating electric fields. *Cancer Res*. 2004;64(9):3288-3295.

novocure®

OPTUNE LUA®

Optune Lua®—For unresectable, locally advanced or metastatic, MALIGNANT PLEURAL MESOTHELIOMA (MPM)[1]

ENTER AN EXCITING ERA IN SURVIVAL

Indications For Use

Optune Lua® is indicated for the treatment of adult patients with unresectable, locally advanced or metastatic, malignant pleural mesothelioma (MPM) to be used concurrently with pemetrexed and platinum-based chemotherapy.

Selected Important Safety Information

Contraindications

Do not use Optune Lua in patients with implantable electronic medical devices such as pacemakers or implantable automatic defibrillators, etc. Use of Optune Lua together with implanted electronic devices has not been tested and may lead to malfunctioning of the implanted device.

Do not use Optune Lua in patients known to be sensitive to conductive hydrogels. Skin contact with the gel used with Optune Lua may commonly cause increased redness and itching, and may rarely lead to severe allergic reactions such as shock and respiratory failure.

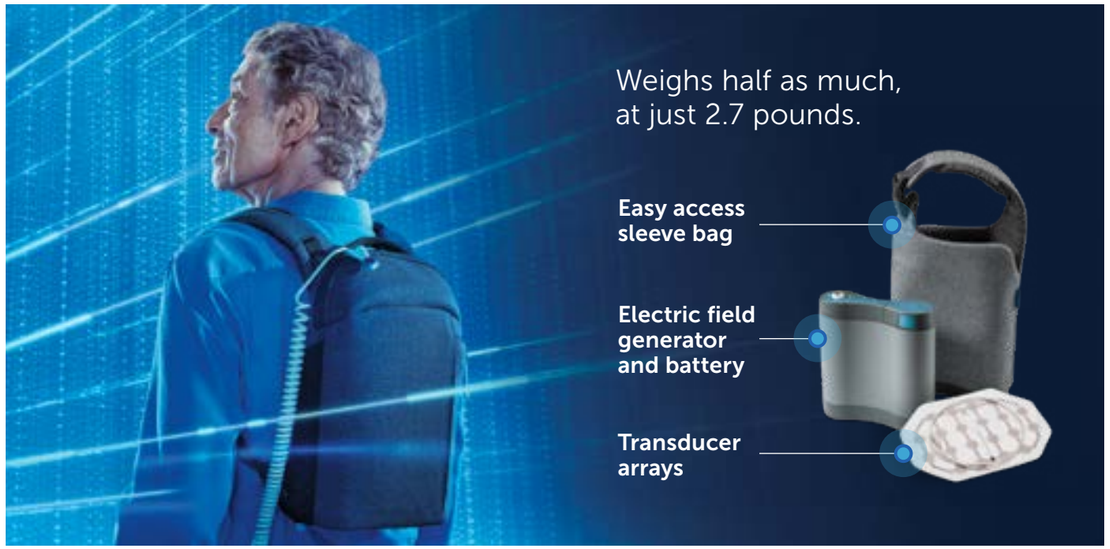
Please see the Important Safety Information for Optune Lua throughout and on page 10 and the Optune Lua Instructions For Use (IFU) for complete information regarding the device's indications, contraindications, warnings and precautions at OptuneLua.com/hcp.

Caution: Federal law restricts this device to sale by or on the order of a physician. Humanitarian Device. Authorized by Federal Law for use in the treatment of adult patients with unresectable, locally advanced or metastatic, malignant pleural mesothelioma concurrently with pemetrexed and platinum-based chemotherapy. The effectiveness of this device for this use has not been demonstrated.

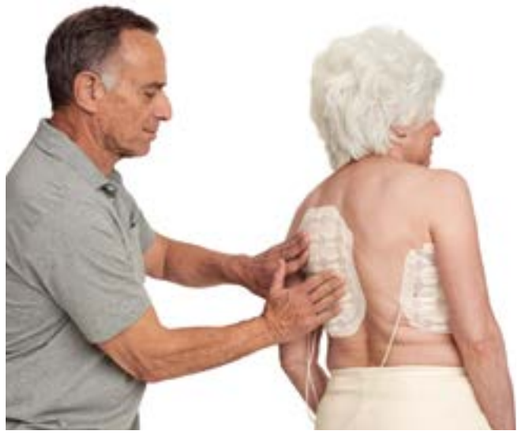
OPTUNE LUA®

Optune Lua® is a wearable and portable treatment for MPM[1,2]

FDA-approved, second-generation device—smaller, lighter, and designed to better fit your patient's everyday life



Loco-regional delivery of Tumor Treating Fields (TTFields) via transducer arrays provides antimitotic activity directly at the site of the malignancy[1]



- TTFields are added to pemetrexed + cisplatin or carboplatin systemic therapies
- The size and placement of arrays are customized based on gender, body type, and tumor location
- It is recommended that Optune Lua is turned on at least 75% of the time (18 hours per day)[1]
  - Patients have flexibility to decide which times of the day are best for them, including at night when sleeping[2]

Novocure® will provide a customized map for array placement based on patient-specific measurements and tumor location (determined via CT scans).
FDA, US Food and Drug Administration; CT, computed tomography; MPM, malignant pleural mesothelioma.

Optune Lua allows patients to go about their daily routine while continuously receiving treatment for MPM[3]

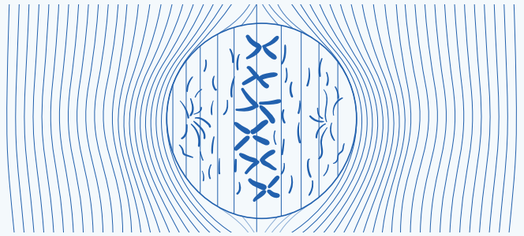
Optune Lua is a noninvasive, antimitotic cancer treatment for MPM[1]

Optune Lua delivers TTFields

- Optune Lua is a noninvasive, antimitotic cancer treatment for MPM that delivers Tumor Treating Fields (TTFields). TTFields are electric fields that continuously and selectively disrupt cancer cell division in solid tumors
  - TTFields disrupt cell division through physical interaction with key molecules during multiple phases of mitosis[1,4]

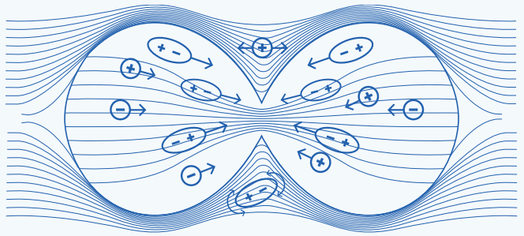
TTFields target dividing cells, leading to apoptosis[1,4]

Metaphase – Uniform electric fields (TTFields)



- Disrupt alignment of highly polarized tubulin subunits[4]
- Disrupt microtubule spindle formation during mitosis and may ultimately lead to apoptosis[4,5]

Telophase – Nonuniform electric fields



- A change in cell shape during telophase causes a nonuniform electric field[4,6]
- Polar components move toward cleavage furrow[4]
- Cell cannot divide properly, which may ultimately lead to apoptosis[4,5]

MPM, malignant pleural mesothelioma; TTFields, Tumor Treating Fields.

Selected Important Safety Information

Warnings and Precautions

Optune Lua can only be prescribed by a healthcare provider that has completed the required certification training provided by Novocure®.

The most common (≥10%) adverse events involving Optune Lua in combination with chemotherapy were anemia, constipation, nausea, asthenia, chest pain, fatigue, medical device site reaction, pruritus, and cough.

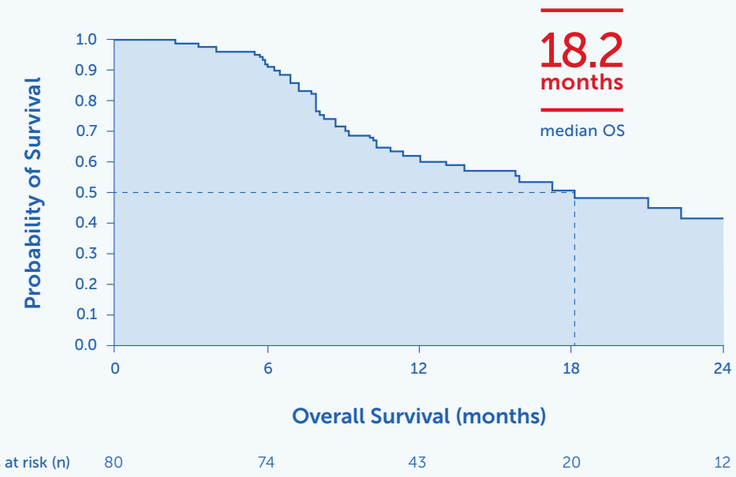
OPTUNE LUA®

An exciting era in overall survival (OS) starts with Optune Lua®

STELLAR Clinical Results: Patients who used Optune Lua as first line together with pemetrexed + cisplatin or carboplatin achieved 18.2 months median OS with no added systemic AEs[1,3]

STELLAR: Primary endpoint

Optune Lua and pemetrexed + cisplatin or carboplatin median OS analysis



Kaplan-Meier OS curve for the 80 study patients (95% CI, 12.1-25.8).

Study design

The STELLAR study was a prospective, single-arm, phase 2 trial to study the safety and efficacy of Optune Lua first line in patients with unresectable, locally advanced or metastatic, MPM (N=80). Patients were ≥18 years of age, had an ECOG performance status of 0-1, and at least 1 measurable or evaluable lesion according to mRECIST for MPM. Patients received continuous TTFields to the thorax at a frequency of 150 kHz for at least 18 hours/day and concomitant chemotherapy every 21 days for up to 6 cycles.*

*Concomitant chemotherapy used in the STELLAR study was a combination of pemetrexed and platinum-based chemotherapy.

AEs, adverse events; ECOG, Eastern Cooperative Oncology Group; MPM, malignant pleural mesothelioma; mRECIST, modified Response Evaluation Criteria In Solid Tumors; TTFields, Tumor Treating Fields.

Selected Important Safety Information

Other potential adverse effects associated with the use of Optune Lua include: treatment related skin toxicity, allergic reaction to the plaster or to the gel, electrode overheating leading to pain and/or local skin burns, infections at sites of electrode contact with the skin, local warmth and tingling sensation beneath the electrodes, muscle twitching, medical device site reaction and skin breakdown/skin ulcer.

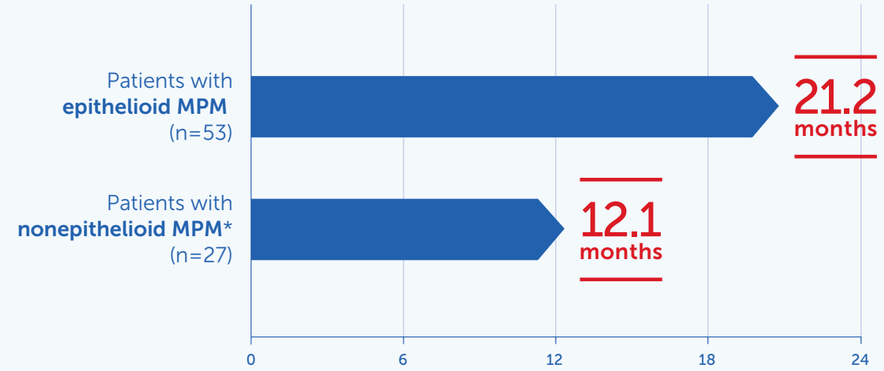
Median OS across MPM histologies

Optune Lua and pemetrexed + cisplatin or carboplatin median OS results shown across histologies[1,3]

- 21.2 months median OS in 66% of patients with epithelioid histology (2/3 of participants) and 12.1 months in 34% of less responsive, harder-to-treat nonepithelioid histology (1/3 of patients)*

STELLAR: OS across histologies

Optune Lua and pemetrexed + cisplatin or carboplatin median OS across histologies



*Nonepithelioid histology includes sarcomatoid or biphasic and unknown tumor pathology.

Baseline patient characteristics

The STELLAR study included male (84%) and female (16%) patients with a median age of 67 years who had locally advanced (84%) and metastatic (16%) tumor stage. Tumor histology included epithelioid (66%), sarcomatoid or biphasic (26%), and unknown (8%). ECOG performance status for all patients was 0 (56%) or 1 (44%).

ECOG, Eastern Cooperative Oncology Group; MPM, malignant pleural mesothelioma; OS, overall survival.

OPTUNE LUA®

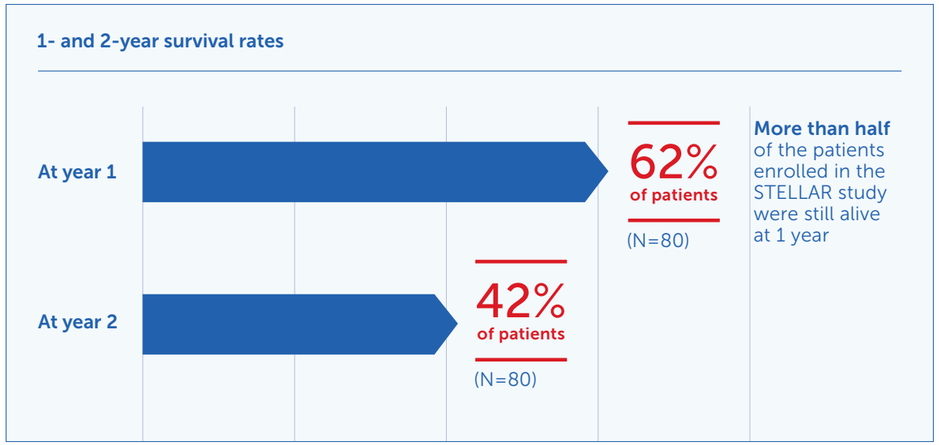
STELLAR: Secondary endpoints

Progression-free survival (PFS)[1]

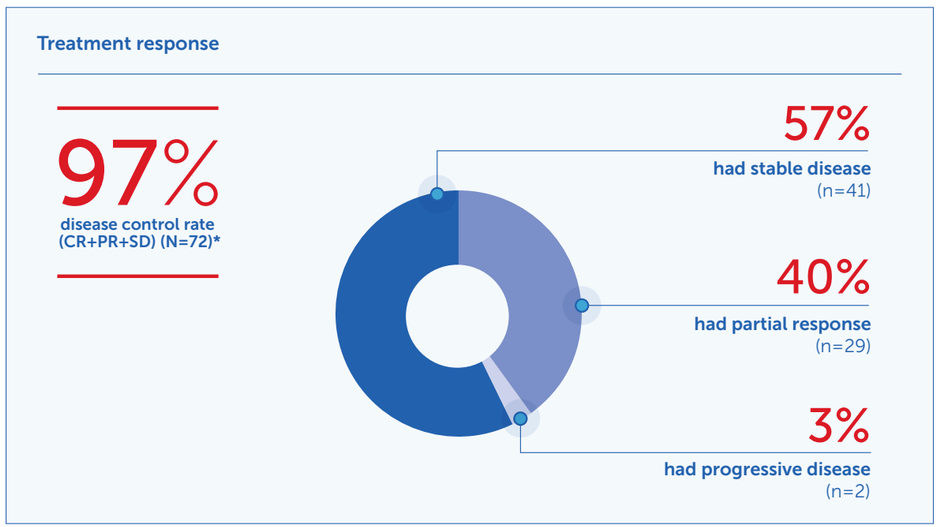
Patients using Optune Lua® together with pemetrexed + cisplatin or carboplatin as first-line treatment (N=80) achieved 7.6 months median PFS.

- 95% CI, 6.7-8.6, across all patients treated

Survival rates[1,3]



Radiological response rate[1,3]



*In patients with at least one follow-up CT scan performed and were evaluable for response according to mRECIST criteria.

CR, complete response; CT, computed tomography; mRECIST, modified Response Evaluation Criteria In Solid Tumors; PR, partial response; SD, stable disease.

No systemic AEs were considered to be related to the use of Optune Lua

Mild-to-moderate skin irritation was the only device-related side effect with Optune Lua[1,3]

Severe (Grade 3-4) AEs by body system seen in >1 patient:

System organ class/ preferred term	Optune Lua and pemetrexed + cisplatin or carboplatin (N=80)
Number of patients with ≥1 AE	**32 (40%)**
Blood and lymphatic system disorders	**18 (23%)**
Anemia	9 (11%)
Leukopenia	3 (4%)
Neutropenia	7 (9%)
Thrombocytopenia	4 (5%)
Cardiac disorders	**3 (4%)**
Pericardial effusion	2 (3%)
Gastrointestinal disorders	**3 (4%)**
Vomiting	2 (3%)

System organ class/ preferred term	Optune Lua and pemetrexed + cisplatin or carboplatin (N=80)
General disorders and administration site conditions	**6 (8%)**
Fatigue	3 (4%)
Infections and infestations	**2 (3%)**
Investigations	**2 (3%)**
Respiratory, thoracic, and mediastinal disorders	**4 (5%)**
Dyspnea	2 (3%)
Skin and subcutaneous tissue disorders	**4 (5%)**
Medical device site reaction (rash beneath transducer arrays)	4 (5%)

- The only AE attributed to Optune Lua use was skin irritation (71% of patients); 66% mild-to-moderate and 5% severe[1,3]
- No SAEs were considered related to device use

AEs, adverse events; SAEs, serious adverse events.

Selected Important Safety Information

If the patient has an underlying serious skin condition on the chest, evaluate whether this may prevent of temporarily interfere with Optune Lua treatment.

Do not prescribe Optune Lua for patients that are pregnant, you think might be pregnant or are trying to get pregnant, as the safety and effectiveness of Optune Lua in these populations have not been established.

OPTUNE LUA®

Optune Lua® has the same mechanism of action as Optune®[1,7,8]

Optune, which has been approved for glioblastoma multiforme (GBM) since 2011, offers real-world experience and clinical evidence delivering Tumor Treating Fields (TTFields) in patients with both recurrent and newly diagnosed GBM[9]

MORE THAN **20,000 PATIENTS** HAVE BEEN TREATED WITH TTFIELDS IN GBM SINCE THE FDA APPROVAL OF OPTUNE IN 2011[7,10]

In newly diagnosed patients with GBM, the addition of Optune + maintenance temozolomide (TMZ) **significantly improved PFS and OS with QoL maintained over time**[9,10,*,†]

In recurrent GBM, patients treated with Optune experienced **similar efficacy, improved cognitive and emotional functioning, and fewer systemic AEs** compared with physician's choice of chemotherapy[8,12,‡]

- Optune was approved under the Premarket Authorization (PMA) pathway[13]

Optune Lua for MPM is FDA approved under the Humanitarian Device Exemption (HDE) pathway and is classified as an Humanitarian Use Device (HUD)[1,3]

- An HDE may be granted if:
  - The device will not expose patients to an unresectable or significant risk of illness or injury, and the probable benefit to health from use of the device outweighs the risk of injury or illness from its use while taking into account the probable risks and benefits of currently available devices or alternative forms of treatment[14]
  - The device would not be available to a person with the disease or condition in question without the HDE[14]
  - The device is designed to treat or diagnose a disease or condition that affects not more than 8,000 individuals in the United States[14]

*Patient-reported QoL data collected per EORTC QLQ-C30 at baseline and Months 3, 6, 9, and 12. The 30-question survey covered 5 daily-functioning domains (physical, role, social, emotional, and cognitive).[9,11]

†EF-14 was a prospective, randomized, open-label, phase 3 clinical trial that was designed to evaluate the efficacy and safety of TTFields + TMZ vs maintenance TMZ in patients newly diagnosed with supratentorial GBM who completed radiation therapy and adjuvant TMZ. Patients (N=695) were randomized in a 2 to 1 ratio to receive either TTFields + TMZ or TMZ alone. Treatment began 4 to 7 weeks after the end of chemotherapy and radiation therapy. The specific objectives of the study included: PFS (primary endpoint), overall survival (powered secondary endpoint), 1- and 2-year survival rate, overall response rate, QoL, and safety.[8]

‡EF-11 was a prospective, randomized, open-label, phase 3 clinical trial that was designed to evaluate the efficacy and safety of TTFields as a monotherapy vs physician's best choice for chemotherapy (including bevacizumab) in patients with supratentorial recurrent GBM. The best available therapy was prescribed according to local practice and depending on prior treatment exposure. Adult patients (N=237) were randomized in a 1:1 manner to either TTFields or chemotherapy. The primary endpoint was OS. Secondary objectives included: PFS, 1-year survival rate, radiological response rate, QoL, and safety.[8]

AEs, adverse events; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer core quality of life questionnaire; FDA, US Food and Drug Administration; OS, overall survival; PFS, progression-free survival; QoL, quality of life.

Selected Important Safety Information

Contraindications

Do not use Optune Lua in patients known to be sensitive to conductive hydrogels. Skin contact with the gel used with Optune Lua may commonly cause increased redness and itching, and may rarely lead to severe allergic reactions such as shock and respiratory failure.

nCompass® is an award-winning* support program with comprehensive services

For patients using Optune Lua, nCompass partners with your patients and your practice every step of the treatment journey—offering customized support based on patient and caregiver needs

We are committed to identifying resources and programs to minimize the cost of Optune Lua for patients

- Support your patients and your practice through the reimbursement process, starting with an investigation of benefits

Support includes

- **In-person device education**
- **Resources and tips for using Optune Lua**
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OPTUNE LUA®

Important Safety Information

Indications For Use

Optune Lua® is indicated for the treatment of adult patients with unresectable, locally advanced or metastatic, malignant pleural mesothelioma (MPM) to be used concurrently with pemetrexed and platinum-based chemotherapy.

Optune® is intended as a treatment for adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme (GBM).

Optune with temozolomide is indicated for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery, and completion of radiation therapy together with concomitant standard of care chemotherapy.

For the treatment of recurrent GBM, Optune is indicated following histologically- or radiologically-confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted.

Important Safety Information

Contraindications

Do not use Optune Lua in patients with MPM with implantable electronic medical devices such as pacemakers or implantable automatic defibrillators, etc. Do not use Optune in patients with GBM with an implanted medical device, a skull defect (such as, missing bone with no replacement), or bullet fragments. Use of Optune together with skull defects or bullet fragments has not been tested and may possibly lead to tissue damage or render Optune ineffective.

Use of Optune Lua for MPM or Optune for GBM together with implanted electronic devices has not been tested and may lead to malfunctioning of the implanted device.

Do not use Optune Lua for MPM or Optune for GBM in patients known to be sensitive to conductive hydrogels. Skin contact with the gel used with Optune Lua and Optune may commonly cause increased redness and itching, and may rarely lead to severe allergic reactions such as shock and respiratory failure.

Warnings and Precautions

Optune Lua and Optune can only be prescribed by a healthcare provider that has completed the required certification training provided by Novocure®.

The most common (≥10%) adverse events involving Optune Lua in combination with chemotherapy in patients with MPM were anemia, constipation, nausea, asthenia, chest pain, fatigue, medical device site reaction, pruritus, and cough.

Other potential adverse effects associated with the use of Optune Lua include: treatment related skin toxicity, allergic reaction to the plaster or to the gel, electrode overheating leading to pain and/or local skin burns, infections at sites of electrode contact with the skin, local warmth and tingling sensation beneath the electrodes, muscle twitching, medical device site reaction and skin breakdown/skin ulcer.

The most common (≥10%) adverse events involving Optune in combination with chemotherapy in patients with GBM were thrombocytopenia, nausea, constipation, vomiting, fatigue, convulsions, and depression.

The most common (≥10%) adverse events related to Optune treatment alone in patients with GBM were medical device site reaction and headache. Other less common adverse reactions were malaise, muscle twitching, and falls related to carrying the device.

If the patient has an underlying serious skin condition on the treated area, evaluate whether this may prevent or temporarily interfere with Optune Lua and Optune treatment.

Do not prescribe Optune Lua or Optune for patients that are pregnant, you think might be pregnant or are trying to get pregnant, as the safety and effectiveness of Optune Lua and Optune in these populations have not been established.

References

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Please see the Important Safety Information for Optune Lua on page 10 and the Optune Lua Instructions for Use (IFU) for complete information regarding the device's indications, contraindications, warnings, and precautions at OptuneLua.com/hcp.

Please see the Optune Instructions for Use (IFU) for complete information regarding the device's indications, contraindications, warnings, and precautions at Optune.com/IFU.

OPTUNE LUA®

Optune Lua®—For unresectable, locally advanced or metastatic, MALIGNANT PLEURAL MESOTHELIOMA (MPM)[1]

ENTER AN EXCITING ERA OF SURVIVAL

Optune Lua together with pemetrexed + cisplatin or carboplatin showed encouraging overall survival (OS) results in the STELLAR clinical study with no added systemic AEs[1,3]

OptuneLua.com/hcp

Median OS

18.2 months

Median OS with no added chemotherapy-related side effects was achieved in patients using Optune Lua first line together with pemetrexed + cisplatin or carboplatin[1,3]

No added systemic AEs

No added systemic AEs were considered to be related to the use of Optune Lua.[1]

- The only AE attributed to Optune Lua use was skin irritation (71% of patients); 66% mild-to-moderate and 5% severe[1,3]
- No SAEs were considered related to device use[1,3]

Median OS shown across histologies

21.2 months

in 66% of patients with **epithelioid** histology (n=53)[1]

12.1 months

in 34% of patients with **nonepithelioid** histology (n=27)[1]

nCompass®

AWARD SUPPORT PROGRAM WINNING

nCompass® is an award-winning support program with comprehensive services for your patients using Optune Lua

nCOMPASS®

Call us:
1-855-281-9301 (toll-free)

Or email:
support@novocure.com

AEs, adverse events; SAEs, serious adverse events.

Important Safety Information

Optune Lua and Optune® can only be prescribed by a healthcare provider that has completed the required certification training provided by Novocure®.

Please see the Important Safety Information for Optune Lua on page 10 and the Optune Lua Instructions for Use (IFU) for complete information regarding the device's indications, contraindications, warnings, and precautions at OptuneLua.com/hcp.

Depictions of patients and caregivers are actor portrayals.

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OPTUNE LUA®

Meet the nCompass® team members assisting you and your patients from prescription through treatment

HCP Points of Contact

HCP Coordinator (HCPC)

- Manages prescription process and supportive documentation
- Updates your practice on your patient's prescription status, as desired

Case Manager

- Works with your patient's insurance plan and identifies resources and programs to minimize the cost for Optune Lua®, regardless of their financial status

Patient Points of Contact

Care Coordinator (CC)

- Provides 24/7 technical support via phone or email
- Manages supply reorders for delivery to patients
- Offers travel resources and tips

Device Support Specialist (DSS)

- Provides live ongoing education and support to your patients
- Sends monthly Optune Lua usage reports to your practice and provides tips to your patients to help optimize their time on Optune Lua

nCompass® offers services to help your patients start Optune Lua®

Optune Lua Prescription and Benefits Review

- Your office completes an Optune Lua Prescription Form and sends all supportive documentation
- Supportive documentation and prescription are processed*
- Benefits investigation begins on behalf of your patient

Resource Kit and Array Layout

- Your patient receives a resource kit that contains tools to help prepare them for starting Optune Lua and integrating it into their lives
- Customized array layout map and measurements are sent to your practice prior to treatment initiation

Welcome Calls

- CC makes Welcome Call(s) to patient or caregiver, to help familiarize them with Optune Lua and discuss their out-of-pocket costs

Starting Optune Lua

- DSS delivers Optune Lua to your patient's home or your practice and provides in-person training at treatment start*
- DSS informs your practice once your patient initiates Optune Lua

*No-contact, and virtual options also available

nCompass provides ongoing support and education, as needed, throughout treatment

*It is important to note that incomplete prescriptions will be returned for updating.

Indications For Use

Optune Lua® is indicated for the treatment of adult patients with unresectable, locally advanced or metastatic, malignant pleural mesothelioma (MPM) to be used concurrently with pemetrexed and platinum-based chemotherapy.

Important Safety Information

Contraindications

Do not use Optune Lua in patients with implantable electronic medical devices such as pacemakers or implantable automatic defibrillators, etc. Use of Optune Lua together with implanted electronic devices has not been tested and may lead to malfunctioning of the implanted device.

Do not use Optune Lua in patients known to be sensitive to conductive hydrogels. Skin contact with the gel used with Optune Lua may commonly cause increased redness and itching, and may rarely lead to severe allergic reactions such as shock and respiratory failure.

Warnings and Precautions

Optune Lua can only be prescribed by a healthcare provider that has completed the required certification training provided by Novocure®.

The most common (≥10%) adverse events involving Optune Lua in combination with chemotherapy were anemia, constipation, nausea, asthenia, chest pain, fatigue, medical device site reaction, pruritus, and cough.

Other potential adverse effects associated with the use of Optune Lua include: treatment related skin toxicity, allergic reaction to the plaster or to the gel, electrode overheating leading to pain and/or local skin burns, infections at sites of electrode contact with the skin, local warmth and tingling sensation beneath the electrodes, muscle twitching, medical device site reaction and skin breakdown/skin ulcer.

If the patient has an underlying serious skin condition on the chest, evaluate whether this may prevent or temporarily interfere with Optune Lua treatment.

Do not prescribe Optune Lua for patients that are pregnant, you think might be pregnant or are trying to get pregnant, as the safety and effectiveness of Optune Lua in these populations have not been established.

Please visit OptuneLua.com to see the Optune Lua Instructions For Use (IFU) for complete information regarding the device's indications, contraindications, warnings, and precautions.

nCompass® Support Basics

What do I do if my patient receives unfavorable letters from their insurance company (eg, denial letters)?

Your patient should not be concerned by these documents, as they are commonly sent. nCompass will continue to work with your patient's insurance company. Please have your patient reach out to nCompass regarding specific insurance questions.

Can an nCompass team member interact with my patient before a prescription is written?

Yes. Patients and caregivers can ask questions about Optune Lua® by calling nCompass, even without a prescription. A Device Support Specialist (DSS) may educate your patient considering Optune Lua by addressing any potential equipment or lifestyle questions.

What supporting documents should I include as part of the prescription?

Supporting documents needed to process the prescription include: face/demographics sheet; copy of patient insurance card; medical records (history and physical); clinical notes; and patient's computed tomography (CT Scan).

nCOMPASS®

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nCompass®: an award-winning support program with comprehensive services for your patients using Optune Lua®

Reimbursement assistance

- Supports your patients and your practice through the reimbursement process, starting with an investigation of benefits

Customized support based on patient or caregiver needs, including

- In-person device education
- Resources and tips for using Optune Lua
- Technical support via phone
- Reordering supplies

Contact nCompass for all your patients' Optune Lua support needs

24 HRS

Call us any time of day:
1-855-281-9301 (toll-free)

@

Or email us:
support@novocure.com

Novocure is not permitted to provide medical advice to patients. All patients with medical questions will be referred back to their healthcare provider.

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nCOMPASS®

Partnering with your patients and practice at every step of the journey

This brochure highlights the nCompass services available to help your patients using the Optune Lua® System

Caution: Federal law restricts this device to sale by or on the order of a physician. Humanitarian Device. Authorized by Federal Law for use in the treatment of adult patients with unresectable, locally advanced or metastatic, malignant pleural mesothelioma concurrently with pemetrexed and platinum-based chemotherapy. The effectiveness of this device for this use has not been demonstrated.

Instructions for Use

for Unresectable Malignant Pleural Mesothelioma

This manual is intended for physicians prescribing the use of Optune Lua™. Additional information is found in the following materials:

- Patient Information and Operation Manual
- Clinical Practice Guidelines: layout optimization in thoracic malignancies

Caution: Federal law restricts this device to sale by or on the order of a physician Humanitarian Device. Authorized by Federal Law for use in the treatment of adult patients with unresectable, locally advanced or metastatic, malignant pleural mesothelioma concurrently with pemetrexed and platinum based chemotherapy. The effectiveness of this device for this use has not been demonstrated.

Table of contents

Indications for Use

Optune Lua™ is indicated for the treatment of adult patients with unresectable, locally advanced or metastatic, malignant pleural mesothelioma (MPM) to be used concurrently with pemetrexed and platinum-based chemotherapy.

Contraindications, Warnings and Precautions

Contraindications

Do not use Optune Lua if you have implantable electronic medical devices including a pacemaker, implantable automatic defibrillator, etc. Use of Optune Lua together with implanted electronic devices has not been tested and may lead to malfunctioning of the implanted device.

Do not use Optune Lua if you are known to be sensitive to conductive hydrogels like the gel used on electrocardiogram (ECG) stickers or transcutaneous electrical nerve stimulation (TENS) electrodes. In this case, skin contact with the gel used with Optune Lua may commonly cause increased redness and itching, and rarely may even lead to severe allergic reactions such as shock and respiratory failure.

Warnings

Warning – Use Optune Lua only after receiving training from qualified personnel, such as your doctor, a nurse, or other medical personnel who have completed a training course given by Novocure (the device manufacturer). Ask to see a certificate signed by Novocure that says they completed a training course. Your training will include a detailed review of this manual and practice in the use of the system. In addition, you will be trained in what to do if there are problems with treatment. Use of Optune Lua without receiving this training can result in breaks in treatment and may rarely cause increased skin irritation, open sores on your chest or back, allergic reactions or even an electric shock.

Warning - In case of skin irritation, which appears as redness under the transducer arrays (a mild rash), use high potency topical steroids (hydrocortisone cream) when replacing transducer arrays. This will help relieve your skin irritation. If you do not use this cream, the skin irritation can become more serious and may even lead to skin break down, infections, pain and blisters. If this happens, stop using the topical steroid cream and contact your doctor. Your doctor will supply you with an antibiotic cream to use when replacing transducer arrays. If you do not use this cream, your symptoms may continue and your doctor may ask you to take a break from treatment until your skin heals.

Warning - All servicing procedures must be performed by qualified and trained personnel. If you attempt to open and service the system alone you may cause damage to the system. You could also get an electric shock by touching the inner parts of the device.

Precautions

Caution - Do not use any parts that do not come with Optune Lua, or that were not sent to you by the device manufacturer or given to you by your doctor. Use of other parts, manufactured by other companies or for use with other devices, can damage the device. This may lead to a break in treatment.

Caution - Do not use Optune Lua if any parts look damaged (torn wires, loose connectors, loose sockets, cracks or breaks in the plastic case). Use of damaged components can damage the device, and cause a break in treatment.

Caution - Do not wet the device or transducer arrays. Getting the device wet may damage it, preventing you from receiving treatment for the right amount of time. Getting the transducer arrays very wet is likely to cause the transducer arrays to come loose from your skin. If this happens, the device will turn off and you will need to change the transducer arrays.

Caution - Before connecting or disconnecting the transducer arrays, make sure that the Optune Lua power switch is in the OFF position. Disconnecting transducer arrays with the device power switch in the ON position may cause a device alarm to go off, and could damage the device.

Caution - If you have an underlying serious skin condition on the chest, discuss with your doctor whether this may prevent or temporarily interfere with Optune Lua treatment.

Caution - Do not use Optune Lua if you are pregnant, you think you might be pregnant, or are trying to get pregnant. If you are a woman who is able to get pregnant, you must use birth control when using the device. Optune Lua was not tested in pregnant women. It is unknown what side effects the device may cause if you are pregnant or if it will be effective.

Notices

Notice - Optune Lua and transducer arrays will activate metal detectors.

Notice - If you plan to be away from home for more than 1 hour, carry an extra battery and/or the power supply with you in case the battery you are using runs out. If you do not take a spare battery and/or the power supply you may have a break in your treatment.

Notice - Make sure you have at least 12 extra transducer arrays at all times. This will last you until the next transducer array shipment arrives. Remember to order more transducer arrays when there are at least 12 extra transducer arrays left. If you do not order transducer arrays in time you may have a break in your treatment.

Notice - Batteries may weaken over time and need to be replaced. You will know this has happened when the amount of time the device can run on a fully charged battery begins to shorten. For example, if the low battery indicator light flashes within only 1 hour from the start of treatment, replace the battery. If you do not have replacement batteries when your batteries run out, you may have a break in your treatment.

Notice - You should carry the Troubleshooting Guide (Section 25 of the patient information and operation manual) at all times. This guide is necessary to ensure Optune Lua works properly. If you do not work the system correctly you may have a break in your treatment.

Notice - Do not block the device vents located on the front and back of the device. Blocking the vents may cause the device to overheat and turn off, leading to a break in treatment. If this happens, unblock the vents, wait 5 minutes and restart the device. In case the vents are blocked with pet hair or dust, return the device for service.

Notice - Do not block the battery charger vents located on the sides of the battery chargers. Blocking the vents may cause the charger to overheat. This could prevent your batteries from charging. In case the vents are blocked with pet hair or dust, return the charger for service.

Notice - Before using a transducer array, make sure its package is sealed by gently rubbing the package between thumb and pointer finger on all four sides. The package should be closed on all sides. There should be no openings in the package seal. If the package is not sealed, the transducer array may be damaged. A damaged transducer array will not work properly and may cause the device to turn off.

Notice - The transducer arrays are for single use and should not be taken off your body and put back on again. If you put a used transducer array back on your chest again, it may not stick well to your skin and the device could turn off.

Notice - Keep the device out of the reach of children and pets.

Notice - The device has a cord that may cause tripping when connected to an electric socket.

Description

Optune Lua for the first-line treatment of unresectable, locally advanced or metastatic, malignant pleural mesothelioma, is a portable, battery or power supply operated device which produces alternating electrical fields, called tumor treatment fields ("TTFields") within the human body. TTFields are applied to the patient by electrically- insulated surface transducer arrays. TTFields disrupt the rapid cell division exhibited by cancer cells[1].

Optune Lua is comprised of two main components: (1) an Electric Field Generator (the Optune Lua device); and (2) ILE Insulated Transducer Arrays (the transducer arrays). In addition, the following components are also included in Optune Lua: power supply, battery, battery charger, connection cable and carrying bag.

Treatment parameters are preset by Novocure such that there are no electrical output adjustments available to the patient. The patient must learn to change and recharge depleted device batteries and to connect to an external power supply overnight. In addition, the transducer arrays need to be replaced at least two times per week (every 4 days at most) and the skin re-shaved in order to maintain optimal contact. Patients carry the device in an over-the-shoulder bag or backpack and receive continuous treatment without changing their daily routine.

1 Mitotic Spindle Disruption by Alternating Electric Fields Leads to Improper Chromosome Segregation and Mitotic Catastrophe in Cancer Cells. Giladi M, et al. Sci Rep. 2015 Dec 11;5:18046. doi: 10.1038/srep18046.

Principles of Operation

Optune Lua produces TTFields within the human body through transducer arrays placed on the chest. TTFields disrupt the rapid cell division exhibited by cancer cells.

TTFields harness electric fields to arrest the proliferation of tumor cells and to destroy them. TTFields technology takes advantage of the special characteristics and geometrical shape of dividing cells, which make them susceptible to the effects of the TTFields. These special fields alter the tumor cell polarity at an intermediate frequency (on the order of 100-300 kHz). The frequency used for a particular treatment is specific to the cell type being treated (e.g., 150 kHz for MPM).

In contrast, the TTFields have not been shown to have an effect on cells that are not undergoing division. Since most normal adult cells proliferate very slowly, if at all, they are hypothesized to be little affected by the TTFields. Testing demonstrates no differences between treated and control animals in histology of the major internal organs (including the lungs), blood examination, cardiac rhythm, body temperature, or in animal behavior. In addition, because the fields alternate so rapidly, they have no effect on normal quiescent cells nor do they stimulate nerves and muscles. It is noted that, because TTFields are only applied to the chest, they have no effect on rapidly proliferating cells in the rest of the body. The intensities of the electric fields within the tissues are very small and do not result in any meaningful increase in tissue temperature.

The above mechanisms of action are consistent with the extensive research regarding the effects of TTFields. These results demonstrate both disruption of cell division up to complete cessation of the process, as well as complete destruction of the dividing cells. It is important to note that all the described effects can be obtained by fields of low intensity such that they are not accompanied by any significant elevation of temperature.

Preclinical Data

TTFields have been shown in vitro to inhibit cancer cell replication during mitosis without any systemic side effects. At intensities of approximately 1 V/cm, TTFields can be frequency-tuned to inhibit different cancer cell types (i.e., the smaller the cell, the higher the frequency needed), due to disruption of microtubule polymerization and physical disruption of cell integrity at the cleavage plane during telophase[2].

Specifically, TTFields have been shown to inhibit mesothelioma cells in vitro at a frequency of 150 kHz and an intensity of 1 V/cm. Based on realistic finite element mesh simulations, Novocure has concluded that intended TTFields intensities can be generated in the lungs of large animals and humans.

Using a model developed to simulate the growth kinetics of a malignant tumor, the minimal treatment course duration for TTFields has been determined to be approximately 4 weeks to reach tumor stabilization. Stopping treatment prior to completion of a 4 week treatment course will most likely lead to continued tumor growth and appearance of symptoms within approximately 1-2 weeks.

2 Kirson, E. D., Z. Gurvich, et al. (2004). "Disruption of cancer cell replication by alternating electric fields." Cancer Res 64(9): 3288-95.

Clinical Data

UNRESECTABLE MALIGNANT PLEURAL MESOTHELIOMA (MPM)

Potential Adverse Effects of the Device on Health

Below is a list of the potential adverse effects (i.e., complications) associated with the use of the device.

- Treatment related skin toxicity
- Allergic reaction to the plaster or to the gel
- Electrode overheating leading to pain and/or local skin burns
- Infection at the sites of electrode contact with the skin
- Local warmth and tingling sensation beneath the electrodes
- Medical device site reaction
- Muscle twitching
- Skin breakdown / skin ulcer

Clinical Study in Unresectable MPM

Study Design: The study was a prospective, single-arm study evaluating pemetrexed and cisplatin or carboplatin in combination with TTFields in patients with untreated unresectable malignant pleural mesothelioma. The study was conducted at 13 sites in Europe.

The following were the objectives of the study:

To prospectively determine the overall survival of malignant pleural mesothelioma subjects treated with Optune Lua in combination with pemetrexed and cisplatin or carboplatin.

To collect evidence of the safety of TTFields applied to subjects with malignant pleural mesothelioma using Optune Lua.

Eligibility Criteria: The inclusion and exclusion criteria for the trial were as follows:

Inclusion Criteria

- Pathological or histological evidence of mesothelioma.
- ≥ 18 years of age
- TNM Stage IV, Not candidate for curative treatment (surgery or radiotherapy)
- At least 4 weeks since major surgery
- At least one measurable or evaluable lesion according to modified RECIST criteria for malignant pleural mesothelioma
- ECOG Performance Status (PS) of 0-1.
- Life expectancy of at least 3 months.
- Participants of childbearing age must use effective contraception as indicated by the investigator
- All subjects must sign written informed consent.
- Able to operate Optune Lua independently or with the help of a caregiver.

Exclusion Criteria

a. Previous chemotherapy or radiation;
b. Prior malignancy requiring anti-tumor treatment or concurrent malignancy;
c. Significant co-morbidities within 4 weeks prior to enrollment, resulting in the following laboratory findings:
    - Significant liver function impairment:
    - AST or ALT >3 times the upper limit of normal
    - Total bilirubin >1.5 upper limit of normal
    - Significant renal impairment (serum creatinine >1.7 mg/dL);
    - Coagulopathy (as evidenced by PT or APTT >1.5 times control in subjects not receiving anticoagulants);
    - Thrombocytopenia (platelet count < 100 x 103/μL);
    - Neutropenia (absolute neutrophil count < 1.5 x 103/μL);
    - Anemia (Hb <10 g/dL);
    - Severe acute infection;
d. Significant comorbidity expected to affect patient's prognosis or ability to receive the combined therapy:
    - History of significant cardiovascular disease unless the disease is well controlled. Significant cardiac disease includes second/third degree heart block; significant ischemic heart disease; poorly controlled hypertension; congestive heart failure of the New York Heart Association (NYHA) Class II or worse (slight limitation of physical activity; comfortable at rest, but ordinary activity results in fatigue, palpitation or dyspnea).
    - History of arrhythmia that is symptomatic or requires treatment. Patients with atrial fibrillation or flutter controlled by medication are not excluded from participation in the trial.
    - Active infection or any serious underlying medical condition that would impair the ability of the patient to receive protocol therapy.
    - History of any psychiatric condition that might impair the patient's ability to understand or comply with the requirements of the study or to provide consent.
e. Untreated brain metastases. Asymptomatic, pretreated brain metastases not requiring steroids are allowed;
f. Implanted pacemaker, defibrillator or other electrical medical devices;
g. Known allergies to medical adhesives or hydrogel;
h. Pregnant or breastfeeding (all patients of childbearing potential must use effective contraception method during the entire period of the study based on the recommendation of the investigator or a gynecologist);
i. Admitted to an institution by administrative or court order.

Study Procedures:

Patients received pemetrexed based doublet in combination with TTFields. For the purpose of this study 3 weeks (21 days) was considered one treatment cycle. Chemotherapy: Treating investigators could choose one of the following regimens: pemetrexed/cisplatin, or pemetrexed/carboplatin. Pemetrexed was administered intravenously at a dose of 500 mg/m^2 day with either cisplatin 75 mg/m^2 intravenously on day 1 or carboplatin intravenously at a dose of AUC 5 on day 1. Cycles were repeated every 21 days for up to 6 cycles in the absence of progression or unacceptable toxicity. In the event of chemotherapy toxicities, dose modifications could be employed.

Optune Lua: Continuous TTFields for at least 18 hours/day applied to the thorax with output parameters of 150 kHz with two sequential, field direction at a maximal intensity of 1414mA RMS. TTFields were administered until radiological disease progression according to the Modified RECIST criteria for malignant pleural mesothelioma, or unacceptable toxicity based on investigator assessment. There was no dose modification for TTFields but treatment interruptions could occur if recommended by investigator. In the case of chemotherapy discontinuation due to toxicity or the completion of 6 chemotherapy cycles, TTFields therapy could be continued until disease progression or unacceptable toxicity.

Follow-up

All patients were seen every 3 weeks until disease progression. At each visit patients underwent: physical examination, performance status assessment, complete blood count, serum chemistry, adverse event collection, concomitant medication recording and device compliance assessment. CT of the chest and MRI and/or bone scan (if clinically indicated) were performed every 6 weeks until progression. Assessment of local and distant disease progression was performed per the modified RECIST criteria version 1.1. The protocol specified a minimum follow-up of 12 months.

Patients were seen at an outpatient clinic for an additional visit 30 days following treatment discontinuation. Physical examination and blood tests were performed during the visit. Patient performance status and adverse events were documented at this visit. Subsequently, patients were followed monthly for survival by telephone (unless a clinical visit was performed). Patient date of death was captured in the CRFs.

Analysis: The trial endpoints were analyzed in the intent to treat population which included 80 patients.

Protocol Deviations:

Major protocol deviations were defined as deviations that have the potential to influence the primary endpoints of the study. There were no major protocol deviations in the trial.

Subject Characteristics and Treatment Details: 80 subjects with unresectable MPM were enrolled in the study. Eight patients (10%) were lost to follow up before completing the required minimum of 12 months follow up. Baseline characteristics and treatment details in the ITT population were as follows:

Characteristics	Optune Lua/Chemotherapy (N=80)
Age (Years)	
n	80
Mean (SD)	64.8 (9.28)
Median (range)	67.0 (27-78)
Sex, No. (%)	
Female	13 (16%)
Male	67 (84%)
Ethnicity, No. (%)	
Caucasian	80 (100%)
Smoking, No. (%)	
Current Smokers	8 (10%)
Former Smokers	37 (46%)
Never Smokers	35 (44%)
Tumor pathology, No. (%)	
Epithelioid	53 (66%)
Sarcomatoid/Biphasic	21 (26%)
Unknown	6 (8%)
Performance status (ECOG), No. (%)	
0	45 (56%)
1	35 (44%)
Visual Analog Pain Scale at Baseline	
Mean (SD)	15.1 (20.68)
Median (range)	5.0 (0-93)

Treatment Details

Number of TTFields Cycles	
Mean (SD)	8.7 (6.08)
Median (range)	8.0 (2-41)
Number of Chemotherapy Cycles	
Mean (SD)	4.6 (1.81)
Median (range)	6.0 (1-7)
Usage (percentage Optune Lua use per treatment cycle)	
n	72
Median (range)	68.0 (2-91)
Patients with treatment breaks (>=24 hours), No. (%)	70 (88%)
Number of treatment breaks (>=24 hours)	
n	70
Median (range)	6.0 (1-75)
Duration of treatment breaks (>=24 hours) (Days)	
n	70
Median (range)	2.6 (1-101)

Results:

Primary Endpoint: Overall Survival

The median overall survival in the trial was 18.2 months (95%CI 12.1-25.8). The Kaplan Meier overall survival curve for the 80 study patients is shown in Figure 1 below.

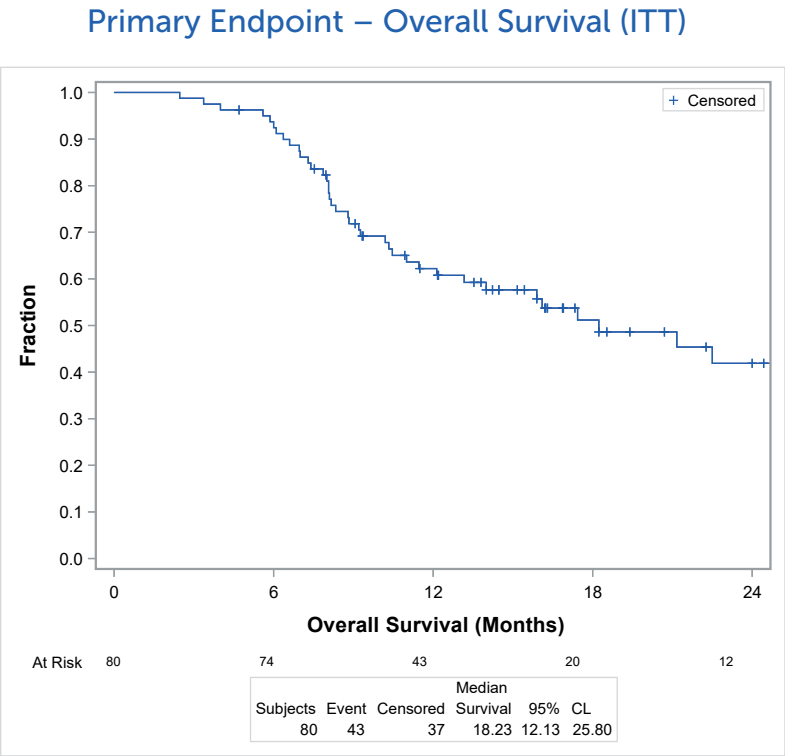

Figure 1: Median OS in STELLAR Study

Patients with epithelioid histology have previously been shown to have better outcomes than those with non-epithelioid histology. OS in the current study also favored patients with epithelioid versus non-epithelioid histology (median OS 21.2 months versus 12.1 months, respectively).

Secondary Endpoints:

Progression Free Survival

The median PFS in the study was 7.6 months (95% CI 6.7-8.6). The Kaplan Meier PFS curve for the 80 study patients is shown in Figure 2 below.

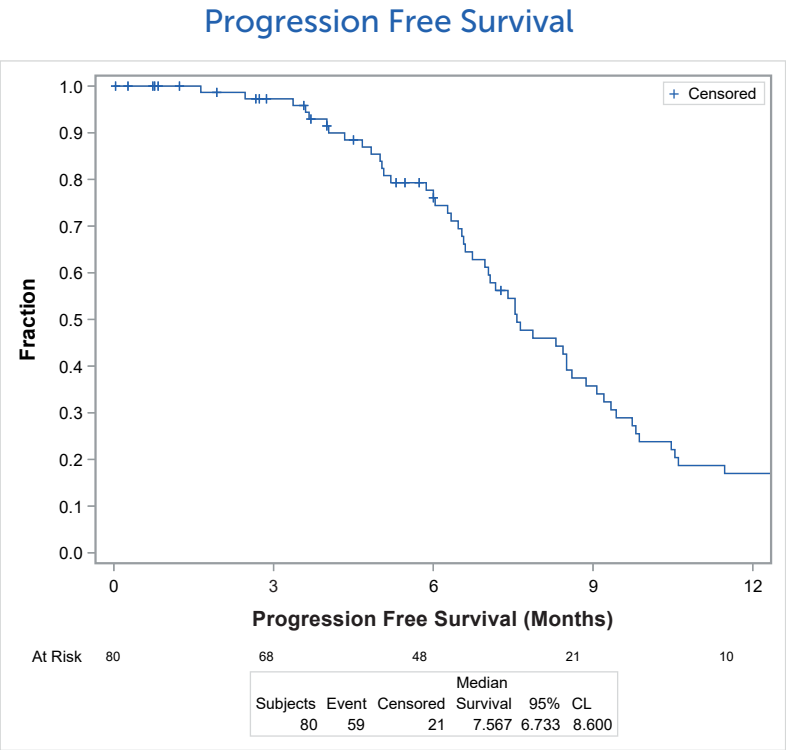

Figure 2: Median PFS in STELLAR Study

PFS in the current study also favored patients with epithelioid versus non-epithelioid histology (median PFS 8.3 months versus 6.5 months, respectively).

One-year and two-year survival rate

1-year survival in the study was 62% (95%CI 50%-72%). 2-year survival in the study was 42%.

Radiological Response Rate

Seventy two patients in the trial had at least one follow up CT scan performed. Of these patients, 29 (40%) experienced a partial response, 41 stable disease (57%) and 2 (3%) patients progressed at their first follow up scan. This represents a disease control rate of 97%.

Summary of Results

Endpoint	Optune Lua / Pemetrexed / Platinum (n=80)
Overall survival	
Median OS, months (95% CI)	18.2 (12.1-25.8)
Survival rate % (95% CI)	
1-year	62.2% (50.3- 72.0)
2-year	41.9% (28.0 ; 55.2)
Progression free survival	
Median PFS, months (95% CI)	7.6 (6.7-8.6)
Available best response, No. (%)	72 (90)
Complete Response	0 (0)
Partial Response	29 (40)
Stable Disease	41 (57)
Progressive Disease	2 (3)
Disease control rate (CR+PR+SD)	70 (97)

Safety Results: A total of 32 patients (40%) reported severe (grade 3-4 adverse events in the trial). None of the grade 3-4 adverse events were considered related to Optune Lua by any of the investigators except for 5% grade 3 skin irritation.

Severe (Grade 3-4) Adverse Events by Body System and Severity seen in > 1 patient

System Organ Class	n=80
Preferred Term	
Number of Patients with >=1 AE	32 (40%)
Blood and lymphatic system disorders	18 (23%)
Anemia	9 (11%)
Leukopenia	3 (4%)
Neutropenia	7 (9%)
Thrombocytopenia	4 (5%)
Cardiac disorders	3 (4%)
Pericardial effusion	2 (3%)
Gastrointestinal disorders	3 (4%)
Vomiting	2 (3%)
General disorders and administration site conditions	6 (8%)
Fatigue	3 (4%)
Infections and infestations	2 (3%)
Investigations	2 (3%)
Respiratory, thoracic and mediastinal disorders	4 (5%)
Dyspnea	2 (3%)
Skin and subcutaneous tissue disorders	4 (5%)
Medical Device Site Reaction (rash beneath transducer arrays)	4 (5%)

The only AEs attributed to use of Optune Lua are the known skin irritation seen in 66% of patients in this study (5% severe). No SAEs were considered related to device use.

Conclusions: Optune Lua is a portable, battery operated device which delivers TTFields to patients with unresectable previously untreated MPM. The results of the trial in MPM showed that Optune Lua, when added to pemetrexed and cisplatin or carboplatin, leads to a median OS of 18.2 months and a median PFS of 7.6 months. No increase in systemic adverse events is seen when Optune Lua treatment is added to pemetrexed and a platinum based chemotherapy. The only common device-related AE was skin irritation seen beneath the transducer arrays in 66% percent of patients. The majority of these events were mild to moderate with only 5% of patients experiencing severe skin irritation.

Directions for Use

Detailed directions for use for Optune Lua for MPM can be found in:
The Optune Lua Patient Information and Operation Manual for MPM QSD-QR-390

Guidelines for ILE transducer array placement can be found in:
Clinical Practice Guidelines: layout optimization in thoracic malignancies

Abbreviations

AE – Adverse event

MPM – Malignant Pleural Mesothelioma

ITT – Intent-to-Treat. This analysis population includes all randomized subjects.

kHz – kilo hertz; number of cycles per second

Optune Lua – A portable, battery, or power supply, operated device for delivering 150 kHz TTFields to the lungs of patients with MPM

OS – Overall survival

PFS – Progression free survival

Radiological Response Rate - sum of complete and partial radiological response rates

Disease Control Rate – sum of stable disease, complete and partial radiological response rates

TTFields – Tumor Treating Fields: Low intensity (1-3 V/cm), intermediate frequency (100-300 kHz), alternating electric fields, delivered using insulated transducer arrays to the region of the body inflicted with a solid tumor. The fields have been shown in vitro to arrest the replication of tumor cells by disrupting the proper formation of the microtubule spindle and by dielectrophoretic disruption of cell integrity during late telophase

V/cm – Volts per centimeter; the unit of intensity measurement of electric fields

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Bibliography

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Kirson, E. D., Z. Gurvich, et al. (2004). "Disruption of cancer cell replication by alternating electric fields." Cancer Res 64(9): 3288-95.

novocure®

Document number: QSD-QR-391. Version 1.

OPTUNE LUA™

[Should be put on official letterhead – all instructions are written in red font to provide guidance. Red font text should be wholly deleted before submission to IRB]

SAMPLE CONSENT FORM FOR THE USE OF OPTUNE LUA®

This consent form is provided to explain the risks and benefits associated with the therapy you have been prescribed, Optune Lua®. Optune Lua is a therapy approved by the United States Food and Drug Administration ("FDA", or the "Agency"), as a Humanitarian Use Device ("HUD") under the Humanitarian Device Exemption ("HDE") pathway.

Optune Lua is indicated for the treatment of adult patients with unresectable, locally advanced or metastatic, malignant pleural mesothelioma ("MPM") to be used concurrently with pemetrexed and platinum-based chemotherapy.

While this is an approved therapy and not an investigational product, please take your time reviewing the information contained within this form before you consent to its use.

TITLE: Humanitarian Use Device: Optune Lua

HDE#: H180002

PRIMARY PHYSICIAN:

Name:
Department:
Address:
Telephone Number (with Area Code):

SECONDARY PHYSICIAN(S):

Names of all secondary physicians authorized to use the device:
Department:
Address:
Telephone Number (with Area Code)

What is a Humanitarian Use Device?

A Humanitarian Use Device is a device used to diagnose or treat a disease or condition that affects no more than 8,000 individuals in the United States per year and for which no comparable device or therapy is available.

What is a Humanitarian Device Exemption?

The HDE approval pathway for medical devices is similar to the Premarket Approval ("PMA") pathway, but the device in question is exempted from demonstrating effectiveness under the

Federal Food, Drug, and Cosmetic Act ("FDCA"). FDA will grant approval for a HUD under the HDE pathway if the Agency determines that the device will not expose patients to an unreasonable or significant risk of illness or injury, and the probable benefit to health from use of the device outweighs the risk of injury or illness from its use.

Why is this procedure being done?

You are being asked to consent to the use of Optune Lua because your doctor has determined that **[provide rationale for use here]**.

What will be involved with the use of this device?

Optune Lua creates low-intensity, wave-like electric fields called Tumor Treating Fields or TTFields that may slow or stop cancer cells from dividing and may destroy them. TTFields are delivered through adhesive patches called transducer arrays, which are placed on the upper body as instructed by a trained professional. Transducer arrays will need to be replaced at least twice per week to help minimize the risk of skin irritation.

Optune Lua allows you to get continuous treatment almost anywhere while going about your daily activities. It is recommended that Optune Lua be turned on at least 75% of the time (18 hours per day) to get the best response from your treatment.

What are the Risks From this Procedure?

[Provide risks you think are appropriate. This can include information from the STELLAR clinical trial, or our important safety information. We strongly suggest you mention mild to moderate skin irritation, but defer to what you believe is important to disclose. Example disclosure below]

There may be adverse events or side effects that are currently unknown with use of Optune Lua, and it is possible that certain of these unknown risks could be permanent, serious or life threatening. Based on the results of prior research studies on this device and experience with its approved use, the possibility of adverse events or side effects from use of Optune Lua and chemotherapy include medical device site reaction, pruritis, anemia, constipation, nausea, asthenia, chest pain, fatigue, and cough.

What are the Benefits of this Procedure?

[Provide benefits you think are appropriate. This can include information from the STELLAR clinical trial. Example statement provided below.]

In a clinical trial, patients receiving Optune Lua with chemotherapy had a median overall survival of 18.2 months. The median progression free survival across all patients in the trial was 7.6 months.

The survival rate of patients in the clinical trial at 1 and 2 years were 62% and 42% respectively.

There was a 97% disease control rate in patients with at least one follow-up CT scan performed (n=72). Of the 72 patients who were evaluated, 40% of patients had a partial response and 57% had stable disease.

What are Alternative Treatments or Procedures Available?

FDA-approved therapies include:

- Pemetrexed + cisplatin (chemotherapy) for patients with unresectable MPM
- Nivolumab + ipilimumab (immunotherapy) for patients with previously untreated unresectable MPM

Will my insurance provider or I be charged for the costs of this device or any procedure associated with its clinical use?

You or your insurance provider will be responsible for any costs or charges associated with the use of Optune Lua. All other costs relating to your normal care will be billed in the usual manner. Optune Lua is not an experimental device.

However, because this is a new device, it is possible that your insurance carrier will refuse to pay for the device. If your insurance carrier refuses to pay, you will be responsible for the cost of the device and your treatment, but if eligible, you can apply for financial assistance from Novocure. The Novocure nCompass™ support team will work with your insurance plan to help minimize the cost of Optune Lua, regardless of your financial situation. Please call 855-2819301 or email support@novocure.com for more information.

In the event you believe you have suffered a procedure-related injury or illness, you should contact **[Provide Dr. Name and contact]**. A procedure-related injury is an injury caused by the procedure(s) rather than an injury attributable to your underlying disease or condition.

If physical injury resulting from your participation in this procedure should occur, medical treatment will be available to you, including first aid, emergency treatment and follow-up care as needed. You or your insurance carrier may be billed for the cost of any such medical treatment in the ordinary manner.

Who will have access to my identifiable information related to the use of this device?

In addition to the physicians listed on the first page of this authorization (consent) form and their clinical staff, the following individuals will or may have access to your identifiable information: **[Provide list here]**.

In addition, authorized representatives of the manufacturer of the device, Novocure, will have access to your identifiable information to, as examples: assist health care professionals in providing you with medical treatment or services; so that the products and services provided may be billed to and payment may be collected; to contact you regarding product delivery, maintenance, in-service, or pick-up; and as required by law.

Your data may also be sent to domestic and foreign drug regulatory agencies if you should suffer an adverse event related to the device. You have the right to look at your health data at your doctor's office and to ask for corrections of any kind to any of your data that is wrong.

If you do not sign this approval form, you will not be able to receive Optune Lua. You can change your mind and revoke this approval at any time by contacting **[Insert appropriate contact]**. Once you revoke your approval, no new personal health information will be collected; however, the doctor or facility may continue to use the health information that was provided before you withdrew your approval as required.

Signature page to follow

Agreement to Participate

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this treatment protocol and the physician listed on the first page of this form will answer future questions.

(Patient's Signature)

(Date)

PHYSICIAN'S CERTIFICATION

I certify that the nature and purpose, the potential benefits and possible risks associated with Optune Lua and its proposed use have been explained to the above individual and that any questions about this information have been answered.

(Physician's Signature)

(Date)

Optune Lua™ for Unresectable Malignant Pleural Mesothelioma -

Patient Information and Operation Manual

Caution: Federal law restricts this device to sale by or on the order of a physician Humanitarian Device. Authorized by Federal Law for use in adult patients with unresectable, locally advanced or metastatic, malignant pleural mesothelioma (MPM) concurrently with pemetrexed and platinum-based chemotherapy.

The effectiveness of this device for this use has not been demonstrated.

Contents

1 Glossary

Cancer – abnormal cell division that spreads without control

Carboplatin – a type of cancer drug used to treat MPM

Chemotherapy – medication used to destroy cancer cells

Cisplatin – a type of cancer drug used to treat MPM

Clinical study – a research study that involves people

Contraindications – situations when a treatment should not be used

CT scan – a procedure that uses radiation to create pictures of areas inside the body

Electric Field Generator (the device) – a portable device for delivering TTFields to the lungs of patients with MPM

Local – in one part of the body

Malignant Pleural Mesothelioma (MPM) – a type of cancer which affects the linings of the lungs

Optune Lua™ Treatment Kit – the Electric Field Generator and other parts including batteries, charger, connection cable, transducer arrays, power supply and carrying bag

Pemetrexed – a type of cancer drug used to treat MPM

Progression – when cancer comes back after being treated

Radiation – a treatment involving x-rays used to kill tumor cells

Steroids – When used on the skin, a medication that can reduce inflammation

Systemic – throughout the body

Topical – on the surface of the skin

Transducer Array – adhesive bandages that hold insulated ceramic discs that deliver TTFields to the chest

TTFields – Tumor Treating Fields: Alternating electric fields, delivered using transducer arrays to the part of the body with a solid tumor. The fields have been shown to destroy tumor cells

Tumor – an abnormal growth of tissue

2 What is Optune Lua and How Does It Work

Optune Lua is indicated for the treatment of adult patients with unresectable, locally advanced or metastatic, malignant mesothelioma (MPM) to be used concurrently with pemetrexed and platinum-based chemotherapy.

Your doctor has prescribed Optune Lua because you are a good candidate for treatment with the device.

A doctor may prescribe Optune Lua to treat a patient with malignant pleural mesothelioma (called "MPM") which cannot be cured with surgery or radiation.

Optune Lua is used together with pemetrexed and cisplatin or carboplatin (types of cancer drugs).

Optune Lua is a portable device. It produces electric fields, called tumor treatment fields ("TTFields"). Transducer arrays connected to the device deliver TTFields to your chest. The TTFields are intended to destroy lung cancer cells.

The device and battery are carried in a shoulder bag. You should use them as much as you can.

In this manual, "Optune Lua Treatment Kit" refers to the Electric Field Generator (also called "the device"), connection cable, transducer arrays, power supply, battery, and battery charger.

3 Contraindications, Warnings and Precautions

Contraindications

Do not use Optune Lua if you have an electrical implant. Use of Optune Lua together with electrical implants has not been tested and may lead to malfunctioning of the implanted device.

Do not use Optune Lua if you are known to be sensitive to gels like the gel used on electrocardiogram (ECG) stickers or transcutaneous electrical nerve stimulation (TENS) electrodes. In this case, skin contact with the gel used with Optune Lua may commonly cause increased redness and itching, and rarely may even lead to severe allergies such as a fall in blood pressure and breathing difficulty.

Warnings

Warning – Use Optune Lua only after receiving training from qualified personnel, such as your doctor, a nurse, or other medical personnel who have completed a training course given by Novocure (the device manufacturer). Ask to see a certificate signed by Novocure that says they have completed the training course.

Your training will include a detailed review of the patient manual and practice in the use of the system. In addition, you will be trained in what to do if there are problems with treatment. Use of Optune Lua without receiving this training can result in breaks in treatment and may rarely cause increased skin irritation, open sores on your chest or back, allergic reactions or even an electric shock.

Warning - In case of skin irritation, which appears as redness under the transducer arrays (a mild rash), use high potency topical steroids (hydrocortisone cream) when replacing transducer arrays. This will help relieve your skin irritation. If you do not use this cream, the skin irritation can become more serious and may even lead to skin break down, infections, pain and blisters. If this happens, stop using the topical steroid cream and contact your doctor. Your doctor will supply you with an antibiotic cream to use when replacing transducer arrays. If you do not use this cream, your symptoms may continue and your doctor may ask you to take a break from treatment until your skin heals.

Warning - All servicing procedures must be performed by qualified and trained personnel. If you attempt to open and service the system alone you may cause damage to the system. You could also get an electric shock by touching the inner parts of the device.

Precautions

Caution - Do not use any parts that do not come with the Optune Lua Treatment Kit, or that were not sent to you by the device manufacturer or given to you by your doctor. Use of other parts, manufactured by other companies or for use with other devices, can damage the device. This may lead to a break in treatment.

Caution - Do not use the Optune Lua Treatment Kit if any parts look damaged (torn wires, loose connectors, loose sockets, cracks or breaks in the plastic case). Use of damaged components can damage the device, and cause a break in treatment.

Caution - Do not wet the device or transducer arrays. Getting the device wet may damage it, preventing you from receiving treatment for the right amount of time. Getting the transducer arrays very wet is likely to cause the transducer arrays to come loose from your skin. If this happens, the device will turn off and you will need to change the transducer arrays.

Caution - Before connecting or disconnecting the transducer arrays, make sure that the Optune Lua power switch is in the OFF position. Disconnecting transducer arrays with the device power switch in the ON position may cause a device alarm to go off, and could damage the device.

Caution - If you have an underlying serious skin condition on the chest, discuss with your doctor whether this may prevent or temporarily interfere with Optune Lua treatment.

Caution - Do not use Optune Lua if you are pregnant, you think you might be pregnant, or are trying to get pregnant. If you are a woman who is able to get pregnant, you must use birth control when using the device. Optune Lua was not tested in pregnant women. It is unknown what side effects the device may cause if you are pregnant or if it will be effective.

Notices

Notice - The Optune Lua device and transducer arrays will activate metal detectors.

Notice - If you plan to be away from home for more than 1 hour, carry an extra battery and/or the power supply with you in case the battery you are using runs out. If you do not take a spare battery and/or the power supply you may have a break in your treatment.

Notice - Make sure you have at least 12 extra transducer arrays at all times. This will last you until the next transducer array shipment arrives. Remember to order more transducer arrays when there are at least 12 extra transducer arrays left. If you do not order transducer arrays in time you may have a break in your treatment.

Notice - Batteries may weaken over time and need to be replaced. You will know this has happened when the amount of time the device can run on a fully charged battery begins to shorten. For example, if the low battery indicator light flashes within only 1 hour from the start of treatment, replace the battery. If you do not have replacement batteries when your batteries run out, you may have a break in your treatment.

Notice - You should carry the Troubleshooting Guide (Section 24 of the patient information and operation manual) at all times. This guide is necessary to ensure Optune Lua works properly. If you do not work the system correctly you may have a break in your treatment.

Notice - Do not block the device vents located on the front and back of the device. Blocking the vents may cause the device to overheat and turn off, leading to a break in treatment. If this happens, unblock the vents, wait 5 minutes and restart the device. In case the vents are blocked with pet hair/dust, return the charger for service.

Notice - Do not block the battery charger vents located on the sides of the battery chargers. Blocking the vents may cause the charger to overheat. This could prevent your batteries from charging. In case the vents are blocked with pet hair/dust, return the device for service.

Notice - Before using a transducer array, make sure its package is sealed by gently rubbing the package between thumb and pointer finger on all four sides. The package should be closed on all sides. There should be no openings in the package seal. If the package is not sealed, the transducer array may be damaged. A damaged transducer array will not work properly and may cause the device to turn off.

Notice - The transducer arrays are for single use and should not be taken off your body and put back on again. If you put a used transducer array back on your chest again, it may not stick well to your skin and the device could turn off.

Notice - Keep the device out of the reach of children and pets.

Notice - The device has a cord that may cause tripping when connected to an electric socket.

4 What Are the Risks of Using Optune Lua?

Skin irritation is often seen under the transducer arrays when using Optune Lua. This will look like a red rash, small sores or blisters on your chest. In general, this will not cause skin damage that cannot be fixed.

The irritation can be treated with steroid cream or by moving the transducer arrays. If you do not use steroid cream, the skin irritation could become more serious. This may lead to open sores, infections, pain and blisters. If this happens, stop using the steroid cream and contact your doctor.

In a clinical study of Optune Lua together with cancer drugs used to treat your kind of lung cancer, the device led to skin irritation in about two thirds of 80 patients (66%). Most of these cases were not severe and were treated with topical creams. Only a handful of patients (5%) had severe skin irritation.

The table below shows how often severe medical problems occurred in patients using Optune Lua together with cancer drugs, in this clinical study. Only skin irritation was caused by Optune Lua. The rest of the medical problems were due to the cancer itself or the cancer drugs used with the device.

Medical Problem	Optune Lua together with Cancer Drugs
Lower white and red blood cell counts	18 out of 80 subjects (23%)
General disorders	6 out of 80 subjects (8%)
Rash under device transducer arrays and other skin problems	4 out of 80 subjects (5%)
Breathing disorders	4 out of 80 subjects (5%)
Vomiting and Ulcer	3 out of 80 subjects (4%)
Heart disorders	3 out of 80 subjects (4%)
Infections	2 out of 80 subjects (3%)
Muscle disorders	1 out of 80 subjects (1%)
Kidney disorders	1 out of 80 subjects (1%)
Liver disorders	1 out of 80 subjects (1%)

Below is a list of the potential adverse effects (i.e., complications) associated with the use of Optune Lua:

- Treatment related skin toxicity
- Allergic reaction to the plaster or to the gel
- Electrode overheating leading to pain and/or local skin burns
- Infection at the sites of electrode contact with the skin
- Local warmth and tingling sensation beneath the electrodes
- Medical device site reaction
- Muscle twitching
- Skin breakdown / skin ulcer

5 What Are the Benefits of Using Optune Lua?

All patients in the clinical study used Optune Lua together with cancer drugs. Half of the patients using Optune Lua together with cancer drugs lived for more than 18.2 months after their treatment started. Also, 4 out of each 10 patients using Optune Lua together with cancer drugs were alive after two years (42%).

6 What Studies Have Been Conducted With Optune Lua?

A clinical study, referred to as the STELLAR Study, was conducted to evaluate the use of Optune Lua in conjunction with cancer drugs to treat unresectable (unable to be removed via surgery) malignant pleural mesothelioma. The study included 80 subjects.

Half of the patients using lived for more than 18.2 months after their treatment started and half of the patients did not experience growth of their MPM for more than 7.6 months after their treatment started.

Local skin problems under the transducer arrays were seen in 57 of 80 patients in the study (red rash, small sores or blisters). This was expected. None of these cases of skin problems caused damage to the skin that could not be fixed. The irritation went away after being treated with steroid cream and moving the transducer arrays. Only 4 subjects had severe skin problems.

These problems led to stopping treatment in 3 subjects. In all cases, the rash went away after stopping treatment.

Ask your doctor for more details about the clinical studies of Optune Lua. For more information, visit our website: www.Optunelua.com

7 About Optune Lua

Optune Lua is a portable medical device that delivers electric fields called "TTFields" to the chest using transducer arrays. TTFields are intended to kill cancer cells.

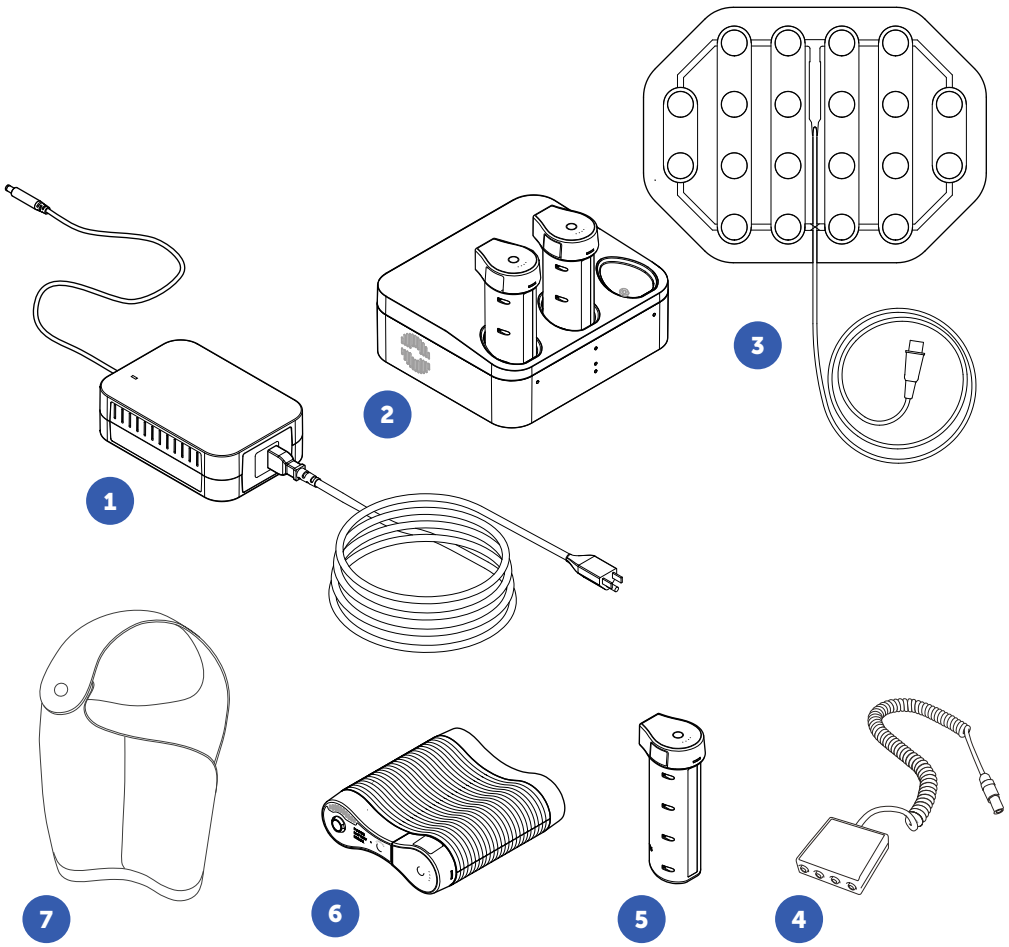
Your doctor has prescribed Optune Lua for use at home. You may be able to use Optune Lua on your own, or you may need help from a doctor, family member, or other caregiver. Use Optune Lua as many hours per day as possible. You can take short breaks for personal needs. When starting treatment, your doctor or a representative from Novocure will teach you how to use the device, replace transducer arrays, recharge and replace batteries, and plug in the device. Your Novocure representative will also teach you what to do if an alarm beeps and will give you a telephone number to call for technical support. After this short training, with the help of a family member or care provider if needed, you will be able to properly use Optune Lua. You will also be able to change the batteries, charge the batteries and replace the transducer arrays as needed.

The device can be carried when you are using a battery. You can continue your normal daily life while carrying the device in a shoulder bag. The Optune Lua Treatment Kit includes four rechargeable batteries. Each battery will last for about one hour. For sleeping, or other times when you plan to stay in the same place for a while, plug the device into a standard wall outlet.

Optune Lua does not need regular maintenance. The device also does not have any settings for you to change. The only things you need to do are check that the device has a power supply (a charged battery or is plugged into the wall) and turn it ON and OFF. If the device is not working, an alarm will beep. A Troubleshooting Guide is provided in this manual (Section 24). You can also call the 24-hour technical support telephone number (Section 25).

Change the transducer arrays at least twice a week. Keep treatment breaks to a minimum. You can interrupt treatment for personal needs such as bathing, exercise, or any time you need a planned treatment break. You will need to stop treatment (turning the device OFF) to replace the transducer arrays. To take a shower, unplug the transducer arrays from the device (leave the transducer arrays on your chest) and wrap your chest with a waterproof wrapping so it does not get wet. You can take a full shower and wet your entire body when you are not wearing the transducer arrays (for example, when you have taken them off but before replacing them with a new pair).

Overview of the Optune Lua Treatment Kit

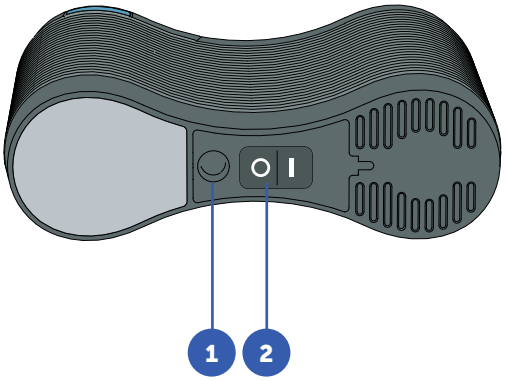


1.	Power Supply	(SPS9200)
2.	Battery Charger	(ICH9100)
3.	ILE Transducer Array	(Small: ILE1010, Large: ILE1030)
4.	Connection Cable	(CAD9100)
5.	Battery	(IBH9200)
6.	Optune Lua™ electric field generator – the device	(TFT9200)
7.	Shoulder Bag and Strap	

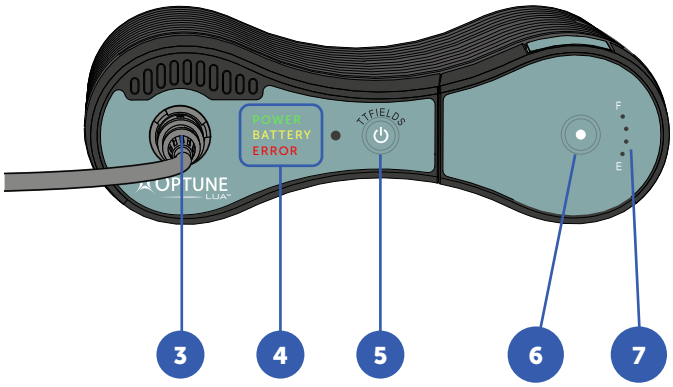
8 The Device

- Optune Lua is an automatic system.
- You will need to learn how to place it in a carrying bag, connect a battery and operate the system.
- The following controls will allow you to do this:

Back



Front



1. Power Supply Port
2. Optune Lua Power Switch
3. Connection Cable (CAD) Socket
4. POWER / BATTERY / ERROR Indicators
5. TTFields ON / OFF Button
6. Battery Test Button
7. Battery Gauge

9 The ILE Transducer Arrays

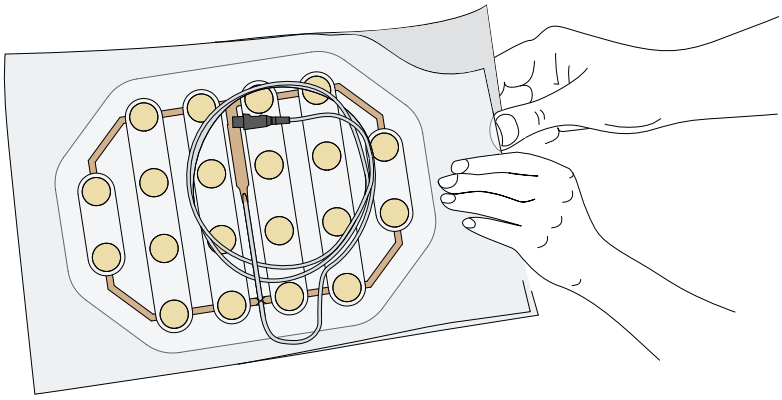
- An ILE Transducer Array is an adhesive patch which delivers Tumor Treating Fields to the chest.
- The ILE transducer arrays are supplied sterile and are to be used with Optune Lua only.
- ILE transducer arrays come in two sizes – small and large. You should use either large or small transducer arrays on the chest and upper abdomen, back and both sides of your thorax, depending on your body size.
- Your doctor will show you where to place each array on your chest.

10 Before You Begin

- You will need four (4) ILE transducer arrays (Sterile) every 3-4 days in order to maintain treatment with Optune Lua.
- You will need to make sure you have the right sized transducer arrays for your body size.
- Make sure you have ample supply of ILE transducer arrays to keep you going until your next visit to your physician.

11 Removing The ILE Transducer Array From Its Package

- Open the see-through envelope of four (4) ILE transducer arrays by gently pulling apart the opposing edges of the envelope. Hold the transducer array as shown in the illustration.



12 Preparing Your Skin For Transducer Array Placement

1. Wash your skin on the chest abdomen back and flanks using a gentle soap.
2. Remove any remnant adhesive from your skin from prior transducer arrays by wiping with baby oil.
3. If you have any hair on your torso, shave your entire torso using an electric shaver. Make sure no stubble is left.
4. Wipe your skin with 70% Alcohol (medical grade – any manufacturer).
5. If the skin is red, apply the steroid cream prescribed to you by your physician.
6. If you have any sores on your skin treat them as instructed by your treating physician.
7. Wait at least 30 minutes and gently wipe your skin again with 70% Alcohol to facilitate adhesion of the transducer arrays to your skin.

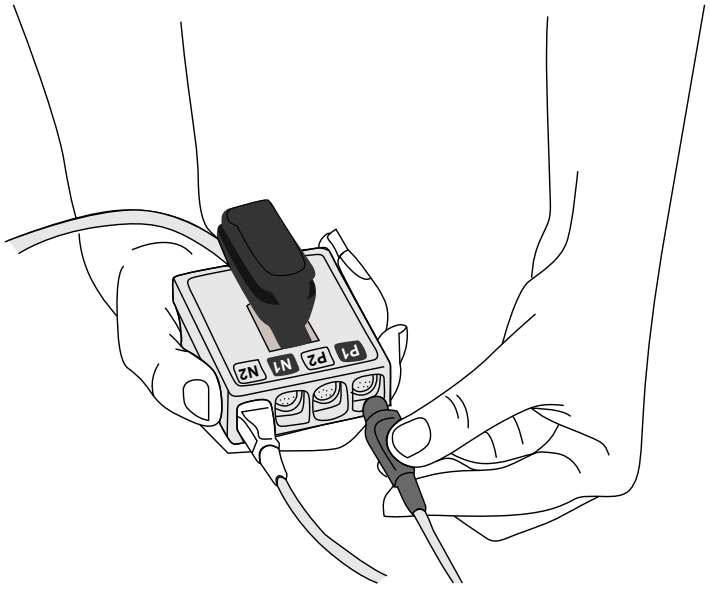
13 Placing the Transducer Arrays

Once every 3-4 days (about twice a week) perform the following steps to replace your transducer arrays. Note, if this is the first time you use the ILE Transducer Arrays, ignore the first step (removal).

1. Remove the transducer arrays already applied to your skin by peeling the medical tape away from your skin.
2. Note the black and white color of the transducer array connectors - each pair of the same color will be positioned opposite to each other on your body.
3. Remove the transducer array liner from the first transducer array.
4. Place the transducer array on your chest in the same location as before but shifting the transducer array 2 cm to avoid areas of redness.
5. Place the other three transducer arrays in the same fashion.
6. You will need to ask for assistance from a friend or family member to place the back transducer array(s).
7. Press the entire edge of the transducer array tape to your skin.

14 Connecting the Transducer Arrays to the Device

1. Connect the four black and white Transducer Array connectors to the corresponding black and white coded sockets on the Optune Lua connection cable.
2. Press firmly to verify the connectors are inserted all the way.
3. Collect the transducer array wires together and bind with a small piece of tape where convenient.
4. You may clip the connection cable clip to your belt.

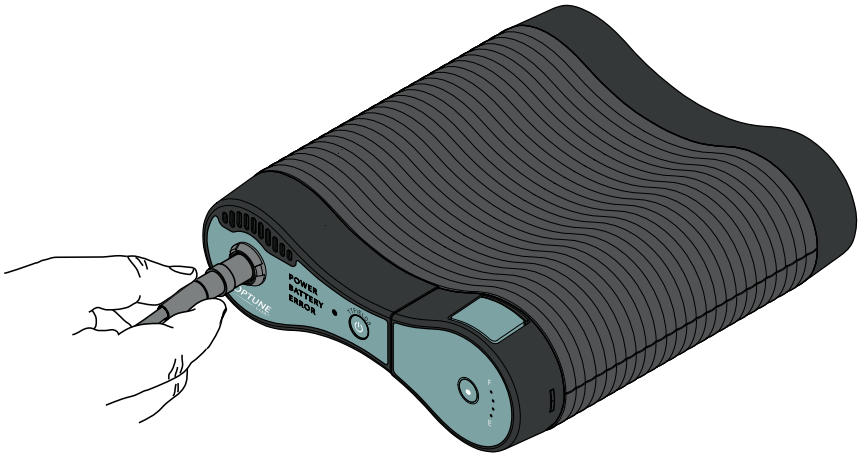


15 The Connection Cable

The connection cable is the coiled, stretchy cord that runs from the connection box to the device. The four transducer array connectors (two blacks and two whites) are plugged into the connection box. The black and white coding matches with the transducer array position on the body.

Follow the instructions to connect to the device:

1. Verify that the arrow on the connection cable facing up and is aligned with the arrow on the connector socket of the device and plug in the connection cable.
2. Push in the connector until you hear a snap. It indicates that the connector is in its place.

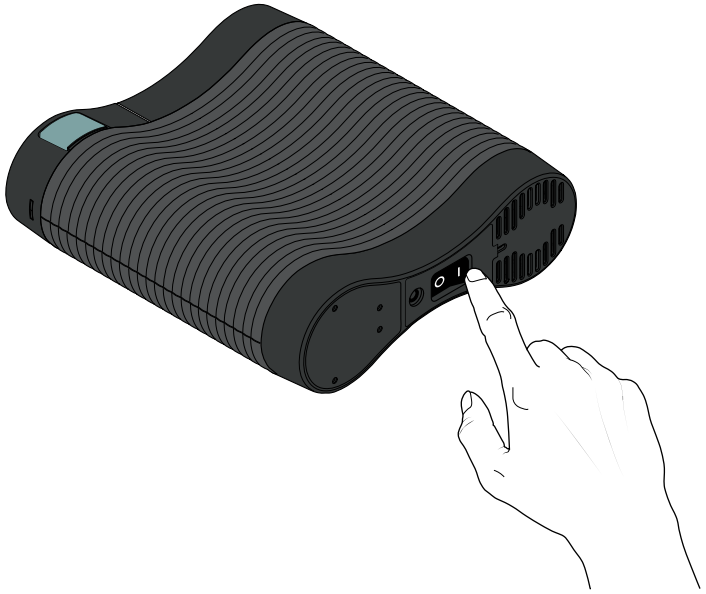


16 Starting and Stopping the Device

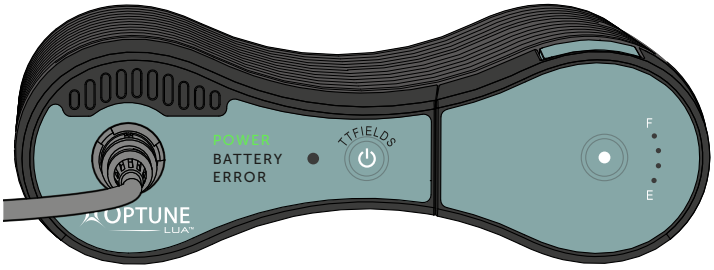
To start treatment:

The Transducer Arrays should be attached to your body.

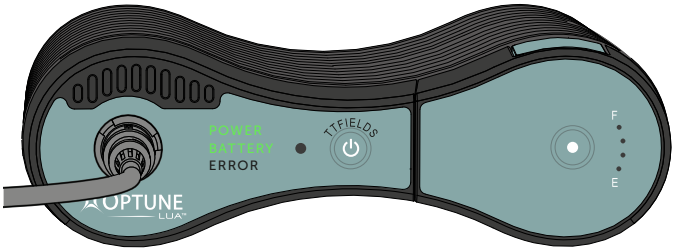
1. Plug the transducer arrays into the connection cable box (see Sections 14 and 15).
2. Plug the connection cable into the device, aligning connector arrow with socket arrow (see Section 15).
3. Connect a power source - either a charged battery (Section 17) or a power supply (Section 19) to the device.
4. Turn ON the device by using the power switch.



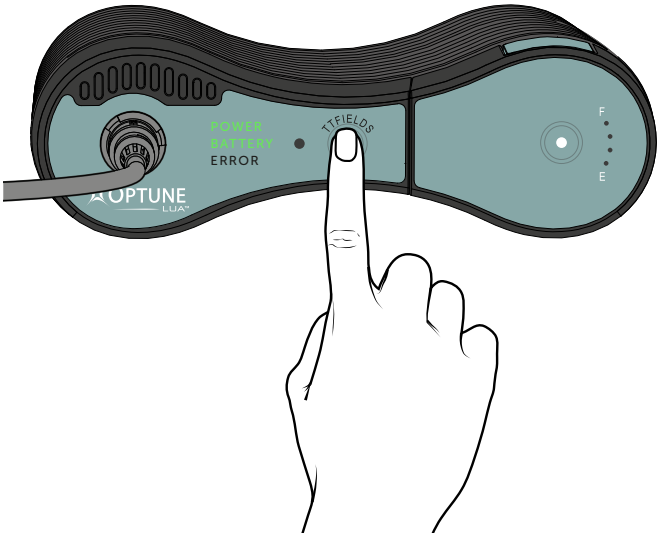
5. Wait about 10 seconds for the self-check to be completed, until the green "POWER" indicator illuminates.



NOTE: If a charged battery is installed (and no power supply is connected), the green "BATTERY" indicator illuminates. If the device is connected to the power supply, it will be operated from the power supply and the "BATTERY" indicator will turn off.



6. Activate TTFields by pressing the TTFields ON/OFF button.



The "TTFIELDS" indicator, above the TTFields ON/OFF button, should illuminate in blue and stay on while the treatment is ON.

NOTE:

If the blue indicator doesn't illuminate, then the treatment is OFF and you should check the setup and restart the procedure. If, after this, the indicator lights do not light up, refer to the Troubleshooting Guide (Section 24). If you still have problems, contact Novocure technical support (Section 25).

The green, blue and yellow indicators automatically dim in a dark room. The red "ERROR" indicator illumination level is permanent.

If the TTFields button isn't pressed within about 10 minutes after the device is turned ON, a notification signal alarm sounds along with a flashing blue "TTFIELDS" indicator, indicating that the therapy is OFF. This is a reminder to start the therapy. The TTFields button should be pressed once to silence the alarm and again to start the therapy. The blue "TTFIELDS" indicator will then illuminate.

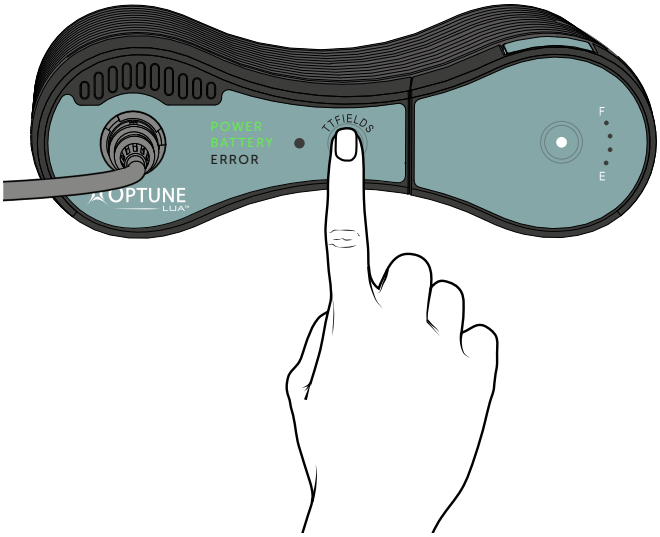
To stop treatment:

Stopping treatment may be performed in each of the following situations:

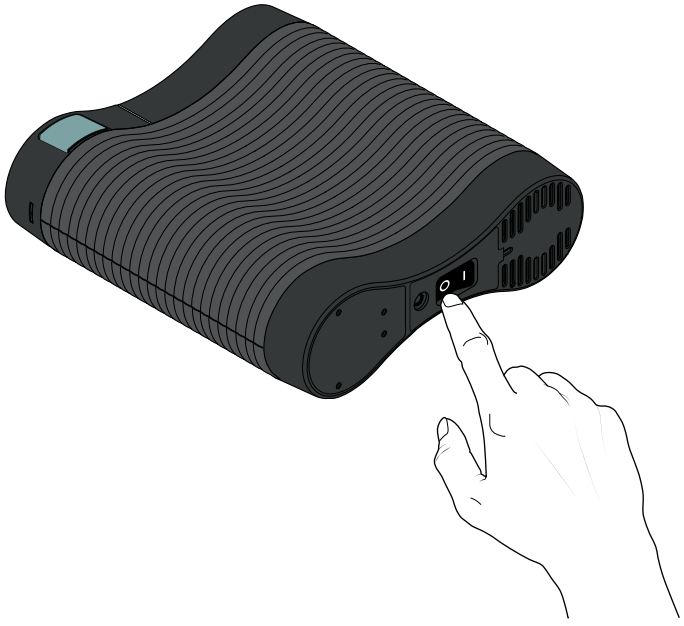
A. When the device is running properly, and you would need to take a break:

1. Stop treatment by pressing TTFields button. TTFields therapy stops, indicated by the blue "TTFIELDS" indicator turn OFF.

   NOTE: Device power is still ON.



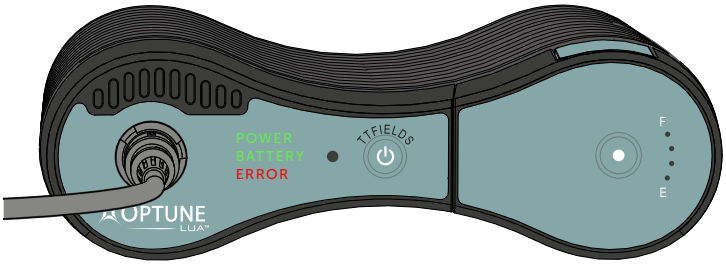
2. Turn OFF the device by using the power switch.



B. If an error occurs:

If an error occurs, the device stops the treatment and sounds a loud beeping alarm. The red "ERROR" indicator illuminates (as shown below).

1. Press TTFields button to stop the alarm. The red "ERROR" indicator will turn OFF. If the alarm sound persists, proceed to the next step to silence the alarm.
2. Turn OFF the device by using the power switch.

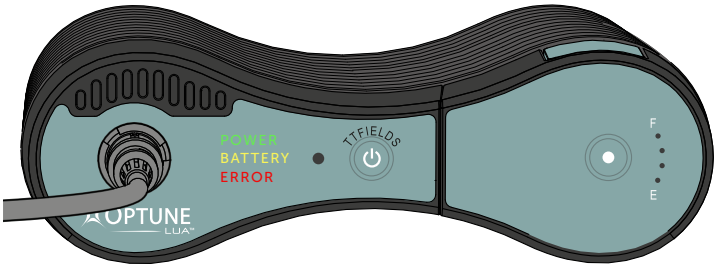


C. If the Low BATTERY Indicator lights up:

When your battery runs out (after about one hour), the TTFields output will shut down (device stops the treatment) and an alarm will sound.

NOTE: The alarm sound is identical to alarm that the device sounds when an error occurs. However, in this case, both the yellow "BATTERY" and red "ERROR" indicators light up.

1. Press the TTFields button to stop the alarm. The red "ERROR" indicator turns OFF.
2. Turn OFF the device by using the power switch.
3. Replace the battery (see Section 17).

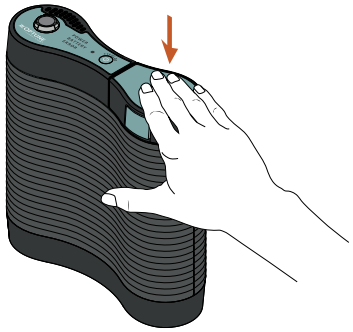


17 Connecting and Disconnecting the Battery

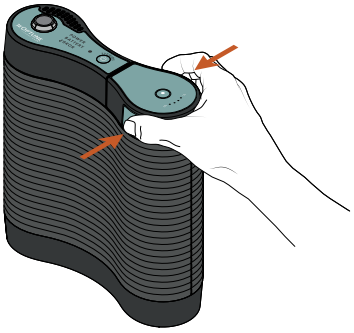
The Optune Lua Treatment Kit is provided with four rechargeable batteries. Optune Lua operation requires one battery at a time. The other three batteries should stay in the battery charger.

If you plan to be away from home for more than one hour, carry extra batteries.

1. Slide the battery into the device.
2. Gently push the battery down until a click is heard, indicating it is fully latched.
   NOTE: Take care not to drop the battery in place or force it into the battery slot.
3. Replace the battery each time it runs out (when the green "BATTERY" indicator turns yellow)



Gently press down to lock the battery in place.



To remove the battery from the slot, press both blue buttons on the sides of the battery and lift up.

Recharge the batteries in the charger (Section 18) for two to four hours. The batteries will keep most of their charge after being removed from the charger for several days but eventually will lose their charge. It will not hurt the batteries to keep them in the charger after they are fully charged so you can leave them there if they are not needed.

You can charge and use the batteries many times for about six to nine months. Over time, the length of time that the batteries can run the device (before the yellow low BATTERY indicator illuminates and the alarm beeps) will get shorter. If the time from treatment start with a full battery to low battery alarm, audible alarm sounds and the red "ERROR" indicator illuminates falls below 50 minutes contact technical support (Section 25) to get replacement batteries.

The battery light will turn from green to yellow when the battery charge falls below a threshold. This is an indication that the battery should be changed soon. The treatment will continue to run while the yellow low BATTERY indicator is illuminated until the audible alarm sounds and the red "ERROR" indicator illuminates. Once this happens the treatment will stop and the device must be turned off and the battery replaced.

When the "BATTERY" indicator turns yellow, there are two ways to continue your treatment:

A. Option one:

To be used if near the direct wall power supply, allows you to connect the power supply without interrupting therapy. This can be used before the battery is completely depleted, and before the device has alarmed. Follow the instructions:

1. Plug in the wall power supply to back of the Optune Lua device (Section 19). Treatment continues while Device indicator indicates that it is no longer operated by battery power.
2. Push the two blue buttons on both battery sides and remove it by sliding outside from device.
3. Charge the removed battery (Section 18).
4. Continue the treatment using the wall power supply.

B. Option Two:

If you are not near a wall power supply, follow the instructions to replace the battery:

NOTE: If the battery is totally depleted, start from step 2

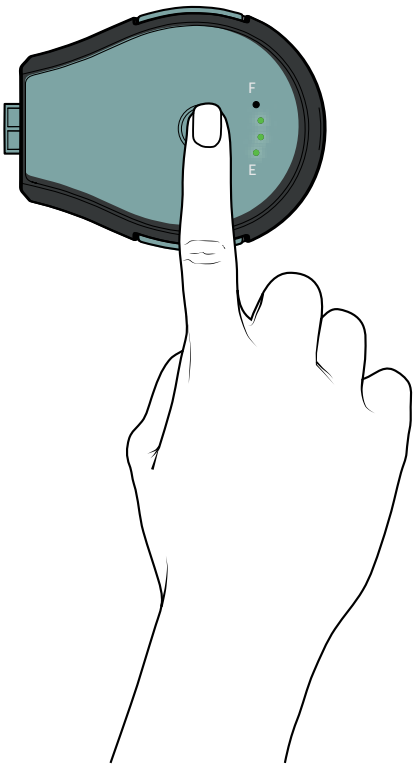
1. Press the TTFields button to stop the treatment.
2. Turn OFF the device by using the power switch (on the back side of the device).
3. Push the two blue buttons on both battery sides and remove it by sliding outside from device.
4. Select another fully charged battery.
5. Slide the fully charged battery into the device.
6. Gently push the battery down until a click is heard, indicating it is fully latched.
7. See the next section to check the battery gauge.
8. Turn ON the device by using the power switch and wait about 10 seconds until the device completes with the self-check.
9. Start treatment by pressing the TTFields button (Section 16).
10. Insert the used battery into the battery charger for recharging (Section 18).

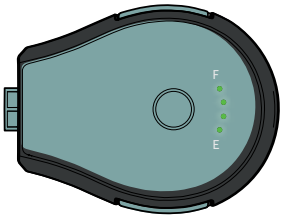
18 Charging the Battery

Checking the Battery Gauge

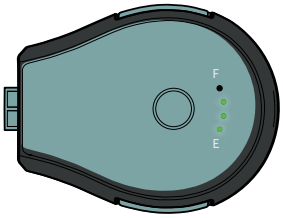
While you are using Optune Lua, you may want to check how much energy is left in your battery. Checking the battery will not interfere with, or stop, your treatment.

To check the battery capacity, press once on the button on the top of the battery. The battery capacity will be indicated by the lighted gauge to the right of the button. The gauge reads from Full (F) to Empty (E) like a gas gauge in a car.

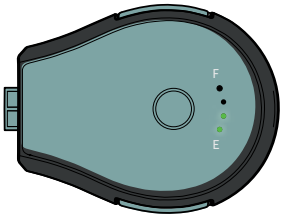




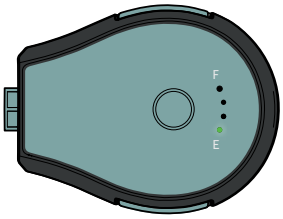
Full charge



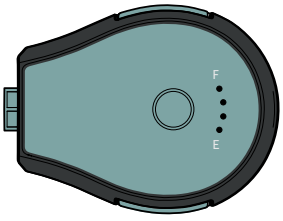
75% charge



50% charge



25% charge



Empty

The battery charger recharges used batteries. The battery charger uses power from a standard wall outlet. Each battery sits in a slot that connects it directly to the charger.

Before charging the batteries, plug the charger power cord into a standard wall outlet and turn ON the power switch at the charger rear side. The front lights of the charger will come on during a self-check then the small light in the center of the front panel will light up green indicating power is applied.

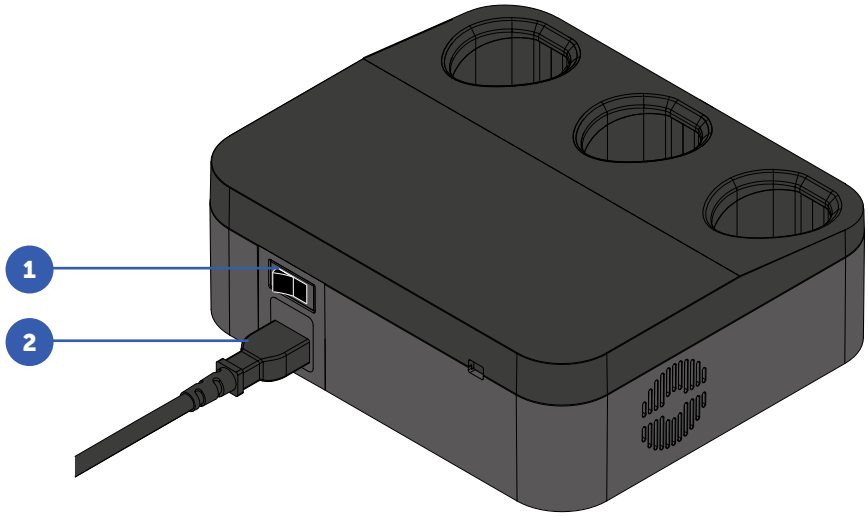
To recharge a used battery:

1. Place the used battery in one of the three openings in the top of the charger. Slide the battery in until it is fully in place.
2. The light directly in front of the opening where the battery is plugged in will illuminate flashing green. This indicates the battery is charging. The green light will flash faster once the battery has been charged to 95% of its capacity. You can also check the battery gauge while charging to get information regarding the amount of charge in the battery.
3. When the battery is fully charged (about 2 to 4 hours), the charge light will turn from flashing green to solid green. The solid green light will disappear upon removal of the battery or the disconnection of the charger from the standard wall outlet.

If a light on the front panel turns red, this indicates that there is a fault with the battery or charger and you should contact technical support for assistance. Do not use a battery if it creates a red light on the charger.

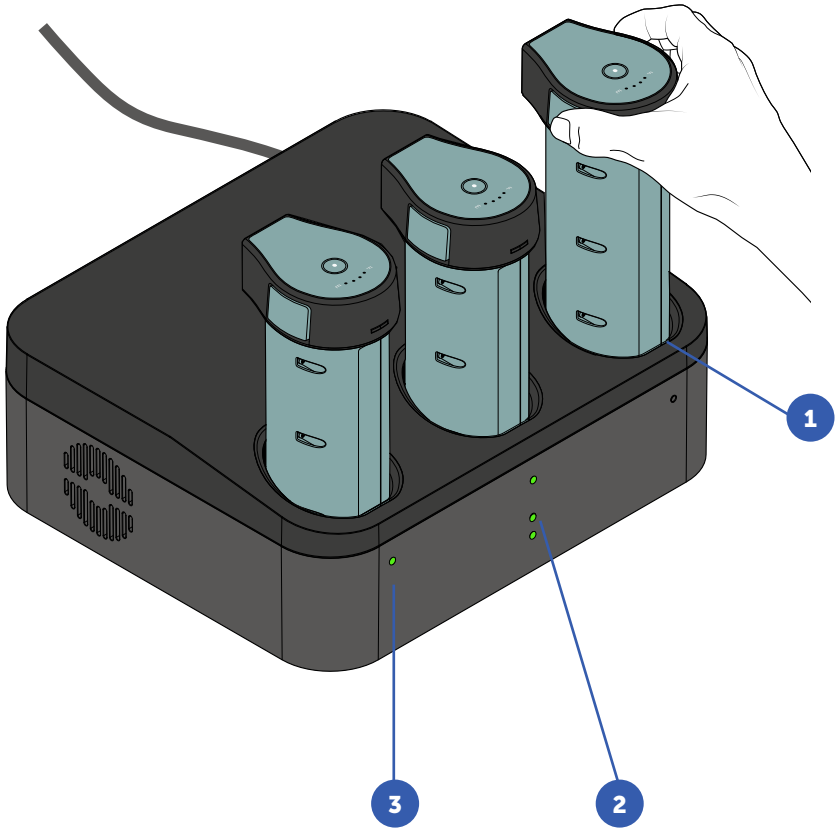
Keep the batteries in the charger even after they are fully charged. This will not harm the batteries.

1. Power Switch
2. Power Cord



Battery Charger Rear View Showing the Power Switch and Where the Power Cord Connects

1. Battery Charging Slot
2. Charger Power Indicator
3. Battery Charge Indicator



Front view of the battery charger showing how the batteries are inserted into the charger

NOTE: The charger is not intended for use in the presence of flammable mixtures.

19 Using the Plug-In Power Supply

When you plan to stay in one place for a while, like when you are sleeping, you may use the plug-in power supply instead of the batteries. Unlike the batteries, there is no limit to how long the device can work when you use the plug-in power supply. The plug-in power supply will work with either US (120 VAC) or European (230 VAC) outlets.

NOTE: It is normal for the power supply to become warm when in use. If the power supply becomes too hot to touch, unplug it and contact technical support (Section 25).

When the device has a battery in, and is also connected to the wall power supply, it will utilize the wall power supply as the preferred power source. When the wall power cord is plugged in while the device is operated from the battery, the device will automatically switch from battery power to wall supply power.

Connecting the Plug-In Power Supply

1. Plug in the power supply cord into a standard wall outlet.

NOTE:

You do not need to remove the battery from the device to use the wall power supply.

Please note that a battery in the device will not charge while the device is plugged into the wall power supply.

If the TTFields are activated, you do not need to turn them OFF.

2. Plug the power supply connector into the power supply port, located on the back side of the device (next to the power switch).
3. If the TTFields are already activated, the device will automatically switch to wall power supply without interruption of the treatment.
4. If the device is OFF, turn ON the power switch and wait about 10 seconds until the device completes with the self-check. Then, Push the TTFields button to start the treatment (as described in Section 16).

To Disconnect the Plug-In Power Supply and Go Back to Battery Power

Ensure that a charged battery is properly inserted in the device before removing the wall power supply. If the TTFields are activated, you need to turn them OFF before removing the wall power supply. The device will shut down and restart using battery power once the power supply is removed. In that case you will be required to push the TTFields button to start the treatment (as described in Section 16), after the self-check is completed.

1. Remove the power supply connector from the back side of the device. After about eight seconds, the "BATTERY" indicator on the front panel illuminates.
2. Store the plug-in power supply for future use.

20 Disconnecting from the Device

There are two ways to unplug the device in order to take a break from treatment:

- To unplug the connection cable from the device.
- To unplug the four transducer arrays from the connection cable.

To Unplug the Connection Cable from the Device

1. Stop treatment by pressing the TTFields button.
2. Turn OFF the device by using the power switch.
3. Hold the connector latch-sleeve and pull out the connection cable from the socket.

CAUTION! Do not pull on the cord!

You may now move around without the device, but you will still be connected to the connection cable and box.

To start treatment again after your break:

1. Plug the connection cable into the port with the arrows pointing up.
2. Turn ON the device by using the power switch. Wait about 10 seconds until the device completes with the self-check.
3. Activate TTFields by pressing the TTFields button.

To Unplug the Transducer Arrays from the Connection Cable

To take a break from treatment and completely disconnect from the device, unplug the transducer arrays from the connection cable box. The four transducer arrays are plugged into the connection cable box (as described in Section 14). The connection cable remains plugged into the device socket.

1. Stop treatment by pressing the TTFields button.
2. Turn OFF the Optune Lua device by using the power switch.
3. Unplug the four transducer arrays from the connection box by pulling their connectors.

NOTE: You may have to wiggle the transducer array connectors gently to remove them. Do not pull on the cord.

To restart treatment:

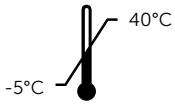
1. Plug the four transducer arrays into its matching color (black or white) in the connection box.
2. Turn ON the device by using the power switch and wait about 10 seconds until the device completes with the self-check.
3. Activate TTFields by pressing the TTFields button.

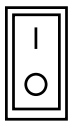
21 Carrying the Device

Both the electric field generator and the battery fit in a carrying bag. The bag can be carried in one of three ways: by the handle on top or over the shoulder/ cross-body with a carrying strap attached, or as a backpack as shown below.

NOTE: Do not place the device in a different bag. Optune Lua has a fan on the inside that needs air flow. The bag that comes with the device is designed to allow for proper air flow. If you put the device in a bag without proper air flow, it could overheat and stop the treatment. If this happens, you will hear an alarm.

22 Glossary of Graphic Symbols

	Consult the instructions for use for important cautionary information such as warnings and precautions
	Date of Manufacturing
	Fragile – handle with care
	Follow instructions for use
	Do not expose to temperatures below -5°C or above 40°C
	Do not expose to humidity below 15% or above 93%
	Do not enter rooms with high humidity or danger of direct exposure to water while wearing the device. Do not use the device if not within its carrying bag. Do not expose the device to direct rain.
	The charger and power supply are for indoor use only
	Batteries are Lithium Ion. Contact technical support to arrange for proper disposal of batteries that are used up or no longer in use
	Optune Lua (device, additional parts and transducer arrays) should be kept away from extreme heat and sources of radiation
	BF type applied part – symbolizes the part which comes in contact with the patient Applied part – part of the ME equipment that in normal use necessarily comes into physical contact with the patient for ME equipment or an ME system to perform its function.
	Expiration date – do not use beyond this date

	Power ON / OFF switch for the device and battery charger: When the switch is in the I position the device is ON and will light up green. When the switch is in the O position the device is OFF
	Do not use the ILE Transducer arrays if their packaging is breached.
	The ILE Transducer Arrays are for single use and should not be re-used.
	The ILE Transducer Arrays are sterilized by Gamma irradiation
	Do not resterilize
	Batch code
	Catalogue number
	Serial number
	Class II equipment per IEC 60601-1
Rx only	Prescription device
	Manufacturer information: Novocure GmbH, Park 6, CH-6039 Root D4, Switzerland
IP21	Protects persons against access to hazardous parts with fingers. Protects the equipment inside the enclosure against ingress of solid foreign objects of 12.5 mm in diameter or greater. Protects the equipment inside the enclosure against ingress of vertical falling water drops.
IP22	Protects persons against access to hazardous parts with fingers. Protects the equipment inside the enclosure against ingress of solid foreign objects of 12.5 mm in diameter or greater. Protects the equipment inside the enclosure against ingress of vertical falling water drops when enclosure is tilted up to 15°.

23 Environmental Conditions For Operation, Storage and Transportation

Conditions for operation

All system components shall be normally used under conditions specified below:

- Mainly for home use.
- For indoor use only (charger and power supply)
- Not for use in shower, bath tub or sink, or in heavy rain
- Not for use in presence of flammable mixtures
- Can be dropped on floor, there shall be no safety hazard, not expected to function anymore

Conditions of visibility: any

Cleaning: all system components can be periodically cleaned with damp cloth, to remove dust and regular soil.

Physical operation conditions for all system components:

- Temperature range: -5°C to +40°C (23°F to 104°F)
- Relative Humidity range: 15-93%
- Ambient pressure range: 700-1060hPa

Conditions for storage

- Temperature range: -5°C to +40°C (23°F to 104°F) for the device and additional parts
- Temperature range: 5°C to +27°C (41°F to 80°F) for the transducer arrays

Conditions for transport

Transportation of the device, ILE Transducer Arrays and additional parts shall be possible using air/ground transportation in weather protected conditions as specified below:

- Temperature range: -5°C to +40°C (23°F to 104°F)
- Maximal relative humidity 15-93%
- No direct exposure to water

Expected Service Life

- Optune Lua device – 12 months
- Connection cable – 11 months
- Power supply – 5 years
- Battery – 11 months (or until the expiration date)
- Charger – 7 years
- ILE Transducer Arrays have an expiration date. Please do not use the arrays after the expiration date.

24 Troubleshooting

Note, when calling your device support specialist or the technical support line, please have the serial number of the equipment accessible

Problem	Possible causes	Actions to be taken
Device POWER indicator does not light up after turning ON the device	1. Device not connected to power source 2. Battery depleted 3. Battery malfunction 4. If power supply – not properly plugged into the wall 5. Device malfunction 6. Power supply malfunction	1. If on battery – check battery gauge to verify it is not depleted. If it is – replace with a charged battery or to power supply 2. Verify both the device and the power source are properly connected and re-try 3. Evaluate the integrity of all connectors. Nothing should appear to be damaged or broken in any way 4. If device cannot be powered on by either the battery or the wall power supply or if anything appears to be damaged do not use the device 5. Call technical support at 855.281.9301
Any cable detached from transducer array/ connection cable/ device	1. Too much physical force to cables 2. Device malfunction	1. Silence the notification signal by pressing the TTFields button 2. Evaluate the connectors. If intact – reconnect and re-start therapy 3. If anything appears damaged or cannot be properly connected do not try to use the device 4. Call technical support at 855.281.9301
Device dropped or wet	Incorrect use	1. Press TTFields button to stop therapy 2. Turn OFF power switch 3. Disconnect from power 4. Call technical support at 855.281.9301

Problem	Possible causes	Actions to be taken
Device alarm on, and low BATTERY indicator is yellow	1. Low battery 2. Device is turned ON, but the therapy has not been activated	1. Replace battery as described above in Section 17 2. Turn ON treatment 3. Press the TTFields button to stop the alarm 4. Wait a few seconds then press the TTFields button again 5. If the blue lights around the TTFields button light up – the therapy has now been activated If the notification signal recurs within a few minutes: 1. Silence the notification signal and power the device down completely 2. Disconnect all equipment and make sure that nothing appears to be damaged or broken. If something is – replace the damaged item before trying to power the device back 3. Re-connect all equipment in proper order and power the device back up. Verify the self-check is completed and press the TTFields button 4. Check vents on device to make sure they are not blocked 5. If lying down, get up and move your body 6. Make sure transducer arrays are well stuck to the body, add tape if needed 7. Restart treatment 8. If alarm keeps going, turn OFF the device and call technical support at 855.281.9301

Problem	Possible causes	Actions to be taken
Device alarm is flashing, the "TTFIELDS" indicator above the TTFields button will flash blue and audio sound 3 very short beeps, stops for 2.5 seconds and beeps 3 times again	Therapy Timeout	The notification alarm on the device will sound if it is powered on for about 10 minutes, but therapy is not initiated. This is a reminder to start therapy and does not indicate a malfunction. 1. Silence the notification alarm by pressing the TTFields button then wait a few seconds and press the TTFields button again to initiate treatment. The blue indicator around the TTFields button will illuminate to indicate therapy is now on 2. If you encounter further alarms please review the following troubleshooting descriptions in this section.
Low BATTERY indicator remains on after battery replaced	1. Charger malfunction 2. Battery malfunction 3. Device malfunction	1. Replace battery with an additional charged battery 2. If problem is not fixed – call technical support at 855.281.9301
When powering on the device a continuous notification alarm sounds and all lights remain on indefinitely. Device does not complete the self-check.	1. Device is too hot 2. Device malfunction 3. Power Source Malfunction	1. Power the device off completely using the power switch 2. Verify the device is not hot to the touch 3. Connect the device to a different power source and try powering on again 4. If device cannot be powered on by either the battery or the wall power supply or if anything appears to be damaged, please contact technical support

Problem	Possible causes	Actions to be taken
Redness of the skin beneath the transducer arrays	Common side effect	1. Use steroid cream prescribed by your doctor when replacing transducer arrays. 2. Place transducer arrays in a location shifted by 3/4 of an inch (2 cm) from the last location (so the adhesive gel is between the red marks). If the redness gets worse: 1. See your treating doctor
Blisters beneath the transducer arrays	Rare side effect	See your treating doctor
Itching beneath the transducer arrays	Rare side effect	1. Use steroid cream prescribed by your doctor when replacing transducer arrays. 2. Place transducer arrays in a location shifted by 3/4 of an inch (2 cm) from the last location (so the adhesive gel is between the red marks). If the itching gets worse: 1. See your treating doctor
Pain beneath the transducer arrays	Rare side effect	1. Stop treatment 2. See your treating doctor

25 Assistance and Information

Technical support:

For technical support call at 1-855-281-9301 (toll free) or email support@novocure.com.

Call or email technical support for help with operation of the system, troubleshooting alarms, or to get replacement parts or transducer arrays.

Clinical support:

If you feel any change in your health or any side effects from the treatment call your doctor right away.

Traveling with Optune Lua

The system's batteries contain lithium ion material and are restricted from being checked as luggage for passenger aircraft travel. They can be carried in the passenger cabin. Please contact nCompass™ Support if you have questions related to travel restrictions.

Note: The Optune Lua device and transducer arrays will activate metal detectors.

26 Disposal

Please contact Novocure to arrange for proper disposal of used transducer arrays.
Do not throw them in the trash.

27 Malignant Pleural Mesothelioma (MPM)

What is Cancer of the Linings of the Lungs?

In simple terms, lung cancer is a growth of cells that form a tumor in the lungs. MPM is a type of lung cancer that develops from the linings of the lungs. Just like any other form of cancer, these tumors can spread to other parts of the lungs and even to the rest of the body. Even before the tumor grows and spreads, it could cause problems breathing, coughing, bleeding and other problems. Symptoms of lung cancer depend on where and how big the tumor is.

About 3,000 patients in the U.S. are diagnosed with MPM every year. MPM is usually caused by exposure at work to asbestos. MPM is a very serious disease. Less than 5% of patients with MPM are alive after 5 years even using the best available treatments.

Can Cancer of the Linings of the Lungs Be Treated?

There are currently four main options to treat MPM:

Surgery – Few patients can be cured by taking out all of the tumor

Radiation – Following surgery, some patients have radiation therapy

Cancer Drugs – most MPM patients take cancer drugs. There are several approved drugs to treat MPM.

Optune Lua together with cancer drugs

Radiation therapy and surgery can help people with MPM live longer than if they had no treatment. Adding Optune Lua to cancer drugs may help people with MPM to live longer than with cancer drugs alone. Surgery, radiation and cancer drugs have side effects. These side effects include pain, hair loss, skin irritation, nausea, vomiting, loss of appetite, effects related to breathing, and tiredness. Optune Lua leads to skin related problems under the transducer arrays in many people.

28 Emitted Radiation and Electromagnetic Compatibility

The Optune Lua device and the accompanying battery charger (ICH9100) and power supply (SPS9200) need special precautions regarding EMC and need to be installed and put into service according to the EMC information provided below.

Portable and mobile RF communications equipment can affect the Optune Lua System and the accompanying battery charger.

The Optune Lua device (TFT9200) should be used with the following cables and additional parts only:

1. connection cable (CAD9100)
2. ILE Transducer Arrays (ILE1010; ILE1030; ILE1010W; ILE1030W)
3. battery (IBH9200)
4. power supply (SPS9200)
5. Battery charger (ICH9100)
6. Unshielded AC mains cables for indoor use only with a maximal length of 1.5m

The use of accessories, parts and cables other than those specified may result in increased EMISSIONS or decreased IMMUNITY of the Optune Lua System.

Table 1 – Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC EMISSIONS – for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emissions		
The Optune Lua system is intended for use in the electromagnetic environment specified below. The customer or the user of the Optune Lua should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Optune Lua system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Optune Lua Treatment Kit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic emissions		
The ICH9100 charger and the SPS9200 power supply are intended for use in the electromagnetic environment specified below. The customer or the user of the ICH9100 charger and the SPS9200 power supply should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The ICH9100 charger and the SPS9200 power supply use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ICH9100 charger and the SPS9200 power supply are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Warning: The Optune Lua System, the ICH9100 charger and the SPS9200 power supply should not be used adjacent to or stacked with other equipment.

Table 2 – Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC IMMUNITY – for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
The Optune Lua (model NovoTTF-200T) system is intended for use in the electromagnetic environment specified below. The customer or the user of the Optune Lua should assure that it is used in such an environment.			
Emissions test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact, ± 2 kV, ± 4 kV, ±8 Kv, ± 15 kV air	±8 kV contact, ± 2 kV, ± 4 kV, ±8 Kv, ± 15 kV air	The relative humidity should be at least 5%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/output lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0,5 kV, ±1 kV line to line ± 0,5 kV, ± 1 kV, ±2 kV line to ground	± 0,5 kV, ±1 kV line to line ± 0,5 kV, ± 1 kV, ±2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The ICH9100 charger and the SPS9200 power supply are intended for use in the electromagnetic environment specified below. The customer or the user of the ICH9100 charger and the SPS9200 power supply should assure that they are used in such an environment.			
Emissions test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact, ± 2 kV, ± 4 kV, ±8 Kv, ± 15 kV air	±8 kV contact, ± 2 kV, ± 4 kV, ±8 Kv, ± 15 kV air	The relative humidity should be at least 5%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/output lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0,5 kV, ±1 kV line to line ± 0,5 kV, ± 1 kV, ±2 kV line to ground	± 0,5 kV, ±1 kV line to line ± 0,5 kV, ± 1 kV, ±2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles h) Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level = 120V and 230V			

Table 3 – Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC IMMUNITY – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The Optune Lua treatment kit is intended for use in the electromagnetic environment specified below. The customer or the user of the Optune Lua treatment kit should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz (table 8.5.1) 10 V/m	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz 10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the NovoTTF-200T treatment kit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \frac{6}{E}\sqrt{P}$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Optune Lua treatment kit is used exceeds the applicable RF compliance level above, the Optune Lua treatment kit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Optune Lua treatment kit.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The ICH9100 charger and the SPS9200 power supply are intended for use in the electromagnetic environment specified below. The customer or the user of the ICH9100 charger and the SPS9200 power supply should assure that they are used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz (table 8.5.1) 10 V/m	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz 10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the ICH9100 charger and the SPS9200 power supply, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \frac{6}{E}\sqrt{P}$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m. Field strengths from fixed RF transmitters, as deter-mined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ICH9100 charger and the SPS9200 power supply are used exceeds the applicable RF compliance level above, the ICH9100 charger and the SPS9200 power supply are should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ICH9100 charger and the SPS9200 power supply.			

Normal operation: The Optune Lua System is working properly when the blue LED surrounding the TTFields button are lit and no notification signal sounds. The ICH9100 charger is working properly when all the LEDs are lit. The SPS9200 power supply is working properly when the blue LEDs surrounding the TTFields button on Optune Lua System are lit and no notification signal sounds.

Table 4 – Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEM – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m						
	380 – 390MHz	430 – 470MHz	704 – 787MHz	800 – 960MHz	1700 – 1990MHz	2400 – 2570MHz	5100 – 5800MHz
The Optune Lua is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Optune Lua can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Optune Lua as recommended below, according to the maximum output power of the communications equipment.							
0.2	0.3	0.3	0.3	0.3	0.3	0.3	0.3
1.8	0.3	0.3	0.3	0.3	0.3	0.3	0.3
2	0.3	0.3	0.3	0.3	0.3	0.3	0.3
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.							
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.							

www.OptuneLua.com

Document number: QSD-QR-390 Version 1

nCOMPASS™

novocure®

Complete patient support every step of the way

AWARD-WINNING SUPPORT PROGRAM

Award-winning support for users and their caregivers

Meet nCompass™ Care Coordinator, Kate

Your Care Coordinator will be your first contact from nCompass.

From your first question about the Optune Lua™ System and throughout your treatment, a Care Coordinator, like Kate, provides customized phone support based on your needs. They can provide resources and discuss:

- Optune Lua and how it works
- Benefits and side effects of Optune Lua
- How nCompass will work with your insurance plan to minimize your cost for Optune Lua, regardless of your financial situation
    - The cost of Optune Lua is different for each person and is based on income, insurance, and other factors

Once you've started Optune Lua, your Care Coordinator will provide phone support throughout treatment and be available 24/7 for:

- Reordering supplies
- Questions about Optune Lua
- Technical support
- Travel tips and resources

Important Safety Information

What is Optune Lua™ approved to treat?

Optune Lua is a wearable, portable, FDA-approved device indicated for the treatment of adult patients, with unresectable, locally advanced or metastatic, malignant pleural mesothelioma (MPM) to be used together with standard chemotherapy (pemetrexed and platinum-based chemotherapy).

Who should not use Optune Lua?

Optune Lua is not for everyone. Talk to your doctor if you have:

- **An implanted electronic medical device including a pacemaker, implantable automatic defibrillator, etc.** Optune Lua has not been tested in people with implanted electronic devices, which may cause the devices not to work properly
- **A known sensitivity to conductive hydrogels** (the gel on the arrays placed on the upper body like the ones used on EKGs). When Optune Lua comes into contact with the skin, it may cause more redness and itching or may rarely cause a life-threatening allergic reaction

Do not use Optune Lua if you are pregnant or are planning to become pregnant. It is not known if Optune Lua is safe or effective during pregnancy.

What should I know before using Optune Lua?

Optune Lua should only be used after receiving training from qualified personnel, such as your doctor, a nurse, or other medical staff who have completed a training course given by Novocure®, the maker of Optune Lua.

- Do not use any parts that did not come with Optune Lua sent to you by Novocure or given to you by your doctor
- Do not get the device or transducer arrays wet
- Please be aware that Optune Lua has a cord that may cause tripping when connected to an electric socket
- If you have an underlying serious skin condition on the upper body, discuss with your doctor whether this may prevent or temporarily interfere with Optune Lua treatment

What are the possible side effects of Optune Lua?

Most common side effects of Optune Lua when used together with chemotherapy were low red blood cell count, constipation, nausea, tiredness, chest pain, fatigue, skin irritation from device use, itchy skin, and cough.

Other potential adverse effects associated with the use of Optune Lua include: treatment related skin irritation, allergic reaction to the plaster or to the gel, electrode overheating leading to pain and/or local skin burns, infections at sites of electrode contact with the skin, local warmth and tingling sensation beneath the electrodes, muscle twitching, medical device site reaction and skin breakdown/skin ulcer.

Talk to your doctor if you have any of these side effects or questions.

Please visit OptuneLua.com for Optune Lua Instructions For Use (IFU) for complete information regarding the device's indications, contraindications, warnings, and precautions.

Caution: Federal law restricts this device to sale by or on the order of a physician. Humanitarian Device. Authorized by Federal Law for use in the treatment of adult patients with unresectable, locally advanced or metastatic, malignant pleural mesothelioma concurrently with pemetrexed and platinum-based chemotherapy. The effectiveness of this device for this use has not been demonstrated.

nCompass™ team members support you from the start and throughout your treatment with Optune Lua

Educational Materials

To help you prepare for treatment, educational resources and tools will be delivered to you after your prescription is sent to Novocure®

Welcome Call

You will receive a call from your Care Coordinator to discuss next steps and answer your questions

Starting Optune Lua

To get you started, your DSS provides training to you and your caregivers

Ongoing Support

nCompass provides ongoing support and education, as needed, throughout treatment

Your Device Support Specialist (DSS) will provide in-person support to get you started.

A DSS, like Matt, will call you to make an appointment to start Optune Lua. At this start visit, your DSS will:

- Deliver Optune Lua and the supplies you need
- Demonstrate how to use the device, supplies, and accessories

Your DSS will provide support throughout treatment either in person or by phone and will contact you to:

- Review your time on Optune Lua each month
- Check in on your experience
- Offer tips and resources

Meet nCompass™ DSS, Matt

Your nCompass™ team is available 24/7 to:

- Troubleshoot and resolve technical issues
- Reorder supplies
- Offer resources and tips for using Optune Lua
- Answer ongoing questions*

For questions, troubleshooting, and supplies

Call us 24/7:
1-855-281-9301 (toll free)

Email us:
support@novocure.com

Translation is available in over 240 languages.

For more information, visit **OptuneLua.com**

nCOMPASS™

*nCompass cannot provide you with medical advice. Consult with your doctor for medical-related questions.

Patient images reflect the health status of the patient(s) at the time each photo was taken.

All images feature actor portrayals.

OPTUNE LUA™

A guide to skin care and transducer array placement

Optune Lua™ is FDA approved for malignant pleural mesothelioma (MPM)*

Inside you will find helpful tips for taking care of your skin during your treatment.

Optune Lua is a wearable, portable, FDA-approved device indicated for the treatment of adult patients, with unresectable, locally advanced or metastatic, malignant pleural mesothelioma (MPM) to be used together with standard chemotherapy (pemetrexed and platinum-based chemotherapy).

Caution: Federal law restricts this device to sale by or on the order of a physician. Humanitarian Device. Authorized by Federal Law for use in the treatment of adult patients with unresectable, locally advanced or metastatic, malignant pleural mesothelioma concurrently with pemetrexed and platinum-based chemotherapy. The effectiveness of this device for this use has not been demonstrated.

*FDA approved under the Humanitarian Device Exemption pathway.

Please see pages 14 and 15 for full Important Safety Information.

What is Optune Lua™?

Optune Lua + chemotherapy is an FDA-approved treatment for people who have malignant pleural mesothelioma (MPM)* that cannot be treated with surgery or radiation

In a recent clinical study,* Optune Lua + chemotherapy

- May have helped people with MPM live longer
  - Survival rate at 1 year was **62%** of patients
  - Survival rate at 2 years was **42%** of patients
- Helped tumors shrink or stop growing
- Optune Lua is not a medicine and does not enter the bloodstream
- In the clinical study, the only side effect related to Optune Lua use was skin irritation seen in 71% of people (66% mild-to-moderate and 5% severe)
  - Most skin irritation is reversible and can be treated with topical ointments, creams, or solutions prescribed by your doctor

*In a clinical study, Optune Lua was used with chemotherapy (pemetrexed and platinum-based chemotherapy) in 80 untreated patients with unresectable (unable to be removed via surgery) MPM.

How Optune Lua works

Optune Lua works by creating Tumor Treating Fields (TTFields), which are electric fields that disrupt cancer cell division.

Using 4 adhesive patches called arrays, TTFields therapy is delivered right into the area of your body where the cancer is located. TTFields may destroy some cancer cells completely and have not been shown to affect healthy cells.

Optune Lua is wearable and portable–so continuous treatment with TTFields can be received almost anywhere.

Selected Important Safety Information

Optune Lua should only be used after receiving training from qualified personnel, such as your doctor, a nurse, or other medical staff who have completed a training course given by Novocure®, the maker of Optune Lua.

Please see pages 14 and 15 for full Important Safety Information.

OPTUNE LUA™

How can I prepare my skin for placing arrays?

Materials you will need

- Gentle soap and water for cleaning your upper body before placing arrays
- Electric shaver, if needed, to remove hair from your upper body before placing arrays
- Gauze
- Baby oil
- A few clean washcloths
- Steroid cream (if prescribed by your doctor for irritated skin)
- 4 unopened arrays and array layout
- Towel
- Array applicator

For skin preparation, follow these simple steps:

Remove any existing hair from your upper body using an electric shaver. Make sure no stubble is left.

- Removing hair will help the arrays stick to your skin

Wash your upper body using warm water, a washcloth, and gentle soap.

- Or you can take a full shower if you prefer

See pages 12 and 13 for showering instructions and what to do if skin irritation occurs.

Selected Important Safety Information

Most common side effects of Optune Lua™ when used together with chemotherapy were low red blood cell count, constipation, nausea, tiredness, chest pain, fatigue, skin irritation from device use, itchy skin, and cough.

Please see pages 14 and 15 for full Important Safety Information.

How will I know if my arrays are right for me?

The size and placement of your arrays have been customized just for you

Where you put the arrays on your body matters. Each person's body is a different shape and size and may have cancer cells in different locations. You (and your caregiver) will receive training to show you where to place the arrays on your upper body.

Make sure your caregiver is available to help you when placing arrays on your upper body

OPTUNE LUA™

How do I place arrays on my body?

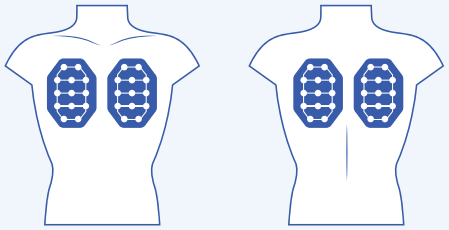
Follow these simple steps:

1 Make sure you have 4 arrays ready to place on your body. You will use 2 black and 2 white array connectors.

2 Remove the array liner from the first array.

3 Refer to the customized array layout map to guide where to place your arrays. Place your arrays as instructed to you by a Novocure® Support Specialist. You may use the Array Applicator* that has been supplied.

Sample array placement



Note: Your array placement may vary. This may include the placement of arrays on your sides.

On pages 8-9, follow the instructions on how to use the Array Applicator to easily place new arrays onto your skin.

*Using the Array Applicator is optional.

Selected Important Safety Information

Optune Lua™ is not for everyone. Talk to your doctor if you have:

- **An implanted electronic medical device including a pacemaker, implantable automatic defibrillator, etc.** Optune Lua has not been tested in people with implanted electronic devices, which may cause the devices not to work properly.

Please see pages 14 and 15 for full Important Safety Information.

4 Place the other 3 arrays in the same way.

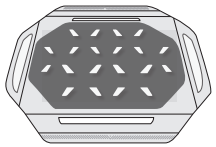
5 You can wear your clothes as normal over the attached arrays.

Do not place arrays over metal or ports (such as any access points in which you put medicine directly into your blood)

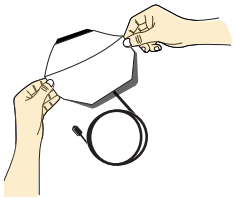
OPTUNE LUA™

How do I use the Array Applicator to place arrays on my skin?*†

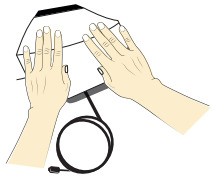
Follow these simple steps:



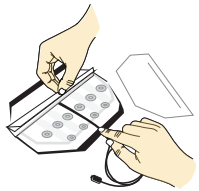
1 Select the applicator size to match the size of the array you are using. Place the applicator on a hard, flat surface. Make sure the inner black patch is facing upward.



2 Remove the array from its packaging. Place it on the applicator with the fabric side facing the black patch. The removable liner should be facing you.



3 Apply medium pressure on the array so it attaches to the black patch.



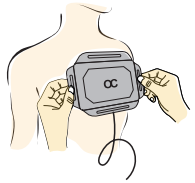
4 Place one hand on the cord. With your other hand, slowly peel the removable liner off the back of the array.

You can reuse the Array Applicator for placing additional arrays on your body

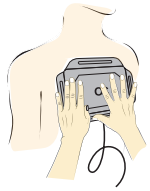
Things to know:

*Keep the Array Applicator in its bag when not in use.
†Clean the Array Applicator by rinsing it with cold water and mild soap. Do not tumble dry. Lay in a shaded place to dry, keeping it away from direct heat.

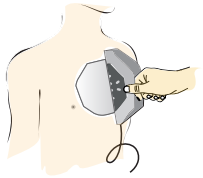
Please see pages 14 and 15 for full Important Safety Information.



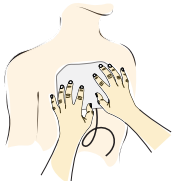
5 Use the applicator to place the array on the skin. Follow the array layout map that has been provided to you.



6 Apply pressure on the applicator. Make sure that the transducers and the edges of the array fabric stick to the skin.



7 Starting from the side, gently remove the applicator.



8 Apply pressure again on the array to ensure full contact.

- Place the other 3 arrays in the same way

- Please refer to your customized array layout map for instructions on where to place each array
- A small and/or large Array Applicator will be provided

Selected Important Safety Information

Do not use Optune Lua™ if you are pregnant or are planning to become pregnant. It is not known if Optune Lua is safe or effective during pregnancy.

OPTUNE LUA™

What about replacing my arrays?

Replace your arrays about twice a week to help reduce the risk of skin irritation

- Make sure you have 4 new arrays with you when it is time to replace them
- You will need to replace your arrays at least twice per week (every 4 days at most)
- You may need to replace the arrays more often if warmer weather or physical activity is causing you to sweat

When replacing your arrays, follow these simple steps:

1. Place the new arrays on your body in the same way you've already been instructed, **except this time**, shift arrays about 0.75 inches. Ask your Novocure® Support Specialist for the correct way to shift your arrays.

2. When you replace the arrays again, shift them back to their original location. Repeat this process each time you replace your arrays.

Do not throw used arrays in the trash

Please contact nCompass™ support at **1-855-281-9301** or at **support@novocure.com** to arrange for proper disposal.

Please see pages 14 and 15 for full Important Safety Information.

How do I remove arrays from my body?

Follow these simple steps:

1. Using gauze, wipe the edges of the arrays you are removing with baby oil. This will help loosen the adhesive so removing the arrays is easier.

2. Remove the arrays by gently peeling them off your skin.

3. Remove any remaining adhesive from your skin by wiping again with baby oil.

4. Wash your upper body using warm water, a washcloth, and gentle soap. This will clear any baby oil left behind on your skin before you apply new arrays. See page 12 for showering instructions.

5. Dry skin completely with a soft towel.

The adhesive will loosen on your skin the longer you wear your arrays*

*If the arrays come loose, the device alarm will sound as a reminder to change your arrays. Frequently changing arrays may prevent this.

Selected Important Safety Information

Optune Lua™ is not for everyone. Talk to your doctor if you have:

- **A known sensitivity to conductive hydrogels** (the gel on the arrays placed on the upper body like the ones used on EKGs). When Optune Lua™ comes into contact with the skin, it may cause more redness and itching or may rarely cause a life-threatening allergic reaction

OPTUNE LUA™

How do I wash my body while being treated with Optune Lua™?

There are 2 ways to clean your upper body

A sponge bath with your arrays still on

- Unplug the arrays from Optune Lua
- Cover the unplugged arrays and wires that are still attached to you. Do this by placing a towel around your upper body to prevent the arrays from getting wet*

A full shower with your arrays completely removed

- Unplug the arrays from Optune Lua
- Take a normal shower once your arrays have been unplugged and completely removed from your body*

*Leave Optune Lua outside the bathroom while taking a sponge bath or a full shower.

How can I help prevent infection?

There are additional steps you can take to help reduce the risk of infection

- Wash your hands with gentle soap and water before applying and removing your arrays
  - Your caregiver should do the same
- Clean your electric shaver after every shave

Selected Important Safety Information

Other potential adverse effects associated with the use of Optune Lua include: treatment related skin irritation, allergic reaction to the plaster or to the gel, electrode overheating leading to pain and/or local skin burns, infections at sites of electrode contact with the skin, local warmth and tingling sensation beneath the electrodes, muscle twitching, medical device site reaction and skin breakdown/skin ulcer.

Please see pages 14 and 15 for full Important Safety Information.

What should I do if skin irritation occurs?

Look for signs of skin irritation so you can seek proper treatment from your doctor

Contact your doctor if you experience swelling, redness, excessive itching, or other skin-related symptoms.

Your doctor may prescribe topical ointments, creams, or solutions to treat skin irritation. These treatments can help ensure you can continue using Optune Lua without having to take a break.

You can help reduce your risk for developing skin irritation by changing your arrays at least twice per week (every 4 days at most).

What if I have open areas or sores on my skin?

Notify your doctor

- Follow your doctor's instructions to clean the area and apply the topical ointment, cream, or solution you've been instructed to use
- Wait at least 30 minutes for the ointment, cream, or solution to absorb into your skin. After 30 minutes, wash the area gently with a clean washcloth and dry thoroughly before placing arrays

OPTUNE LUA™

Important Safety Information

What is Optune Lua™ approved to treat?

Optune Lua is a wearable, portable, FDA-approved device indicated for the treatment of adult patients, with unresectable, locally advanced or metastatic, malignant pleural mesothelioma (MPM) to be used together with standard chemotherapy (pemetrexed and platinum-based chemotherapy).

Who should not use Optune Lua?

Optune Lua is not for everyone. Talk to your doctor if you have:

- **An implanted electronic medical device including a pacemaker, implantable automatic defibrillator, etc.** Optune Lua has not been tested in people with implanted electronic devices, which may cause the devices not to work properly
- **A known sensitivity to conductive hydrogels** (the gel on the arrays placed on the upper body like the ones used on EKGs). When Optune Lua comes into contact with the skin, it may cause more redness and itching or may rarely cause a life-threatening allergic reaction

Do not use Optune Lua if you are pregnant or are planning to become pregnant. It is not known if Optune Lua is safe or effective during pregnancy.

What should I know before using Optune Lua?

Optune Lua should only be used after receiving training from qualified personnel, such as your doctor, a nurse, or other medical staff who have completed a training course given by Novocure®, the maker of Optune Lua.

- Do not use any parts that did not come with Optune Lua sent to you by Novocure or given to you by your doctor
- Do not get the device or transducer arrays wet
- Please be aware that Optune Lua has a cord that may cause tripping when connected to an electric socket
- If you have an underlying serious skin condition on the upper body, discuss with your doctor whether this may prevent or temporarily interfere with the Optune Lua treatment

What are the possible side effects of Optune Lua?

Most common side effects of Optune Lua when used together with chemotherapy were low red blood cell count, constipation, nausea, tiredness, chest pain, fatigue, skin irritation from device use, itchy skin, and cough.

Other potential adverse effects associated with the use of Optune Lua include: treatment related skin irritation, allergic reaction to the plaster or to the gel, electrode overheating leading to pain and/or local skin burns, infections at sites of electrode contact with the skin, local warmth and tingling sensation beneath the electrodes, muscle twitching, medical device site reaction and skin breakdown/skin ulcer.

Talk to your doctor if you have any of these side effects or questions.

Please visit OptuneLua.com to see the Optune Lua Instructions For Use (IFU) for complete information regarding the device's indications, contraindications, warnings, and precautions.

Get support every step of the way with nCompass™

We know that starting Optune Lua™ doesn't just impact how you treat MPM. It can impact your entire way of life, and that can be a lot to deal with—that's where nCompass comes in. Our support team is here to help you adjust to life with Optune Lua, and we're available 24/7.

nCompass can*:

- Provide information on Optune Lua and how it works
- Answer questions about how Optune Lua may help treat your MPM
- Work with your insurance plan and identify resources that may help minimize your cost
- Provide tips and resources on how to make Optune Lua a part of your daily life
- Set up delivery of Optune Lua and provide training to you and your caregivers
- Set up additional Optune Lua training at any time if you need it
- Reorder supplies, such as arrays or extra batteries
- Provide support and answer questions 24/7

*nCompass and Novocure® cannot provide medical advice. Consult with your doctor for medical-related questions.

Call us:
1-855-281-9301 (toll-free)

Or email:
support@novocure.com

nCOMPASS™

Support is available in over 240 languages.

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novocure®

OPTUNE LUA™

All images feature actor portrayals.

Understanding Optune Lua™

The first FDA-approved* treatment for malignant pleural mesothelioma (MPM) in over 15 years

Find information about the benefits, side effects, and answers to frequently asked questions about Optune Lua.

Optune Lua in addition to chemotherapy is approved to treat people with unresectable, locally advanced or metastatic, malignant pleural mesothelioma (MPM).

Caution: Federal law restricts this device to sale by or on the order of a physician. Humanitarian Device. Authorized by Federal Law for use in the treatment of adult patients with unresectable, locally advanced or metastatic, malignant pleural mesothelioma concurrently with pemetrexed and platinum-based chemotherapy. The effectiveness of this device for this use has not been demonstrated.

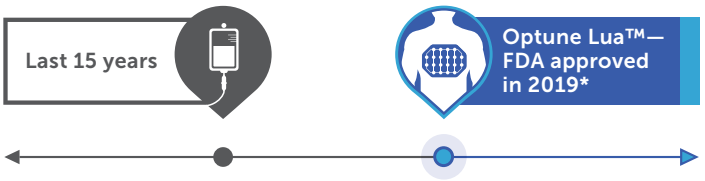
*FDA approved under the Humanitarian Device Exemption pathway.

Please see pages 10 and 11 for full Important Safety Information.

OPTUNE LUA™

How is malignant pleural mesothelioma (MPM) treated?

Until recently, treatment for MPM had been limited



Until 2019, people who could not have surgery would only be treated with chemotherapy.

Optune Lua + chemotherapy† is an FDA-approved treatment for people with MPM who could not be treated with surgery.

Optune Lua is approved to treat unresectable, locally advanced or metastatic, MPM to be used together with standard chemotherapy.†

If you need help understanding the medical language used above, see page 3.

Optune Lua is used together with chemotherapy†

Optune Lua + **Standard chemotherapy**

Optune Lua is not a medicine and does not enter the bloodstream. When used with chemotherapy, the most common device-related side effect was skin irritation.

*FDA approved under the Humanitarian Device Exemption pathway.
†Pemetrexed and platinum-based chemotherapy.

Please see pages 10 and 11 for full Important Safety Information.

Explore Optune Lua

Optune Lua is designed with you in mind

Small, light, and weighs just 2.7 pounds.

Optune Lua weighs less than most laptop computers.

Sometimes medical language is hard to understand. The following may help:

Unresectable means that a tumor is not able to be removed with surgery.

Locally advanced means that tumors have spread into nearby tissues, organs, or lymph nodes in the areas around where the cancer originally formed.

Metastatic means the cancer has spread from where the cancer originally formed to other tissues or organs in the body.

Malignant pleural mesothelioma (MPM) is a type of cancer that affects the lining of the lungs. It is malignant, which means abnormal cells divide without control and spread to nearby cells.

Selected Important Safety Information

Optune Lua is not for everyone. Talk to your doctor if you have:

- **An implanted electronic medical device including a pacemaker, implantable automatic defibrillator, etc.**

Optune Lua™ might help you live longer

A recent clinical study* showed that using Optune Lua + chemotherapy provided:

SURVIVAL RATE AT 1 YEAR — **62%** of patients

SURVIVAL RATE AT 2 YEARS — **42%** of patients

*In a clinical study, Optune Lua was used with chemotherapy (pemetrexed and platinum-based chemotherapy) in 80 untreated patients with unresectable (unable to be removed via surgery) MPM.

Most people who used Optune Lua + chemotherapy† saw their MPM shrink or stop growing:

57% had tumors that stopped growing

40% had tumors that shrank

97% of patients had tumors that shrank or stopped growing

†In a study where 72 patients had at least 1 follow-up CT scan performed.

Please see pages 10 and 11 for full Important Safety Information.

Does Optune Lua cause side effects?

- Optune Lua is not a medicine and does not enter the bloodstream
- In the clinical study, the only side effect related to Optune Lua use was skin irritation seen in 71% of people (66% mild-to-moderate and 5% severe)
  - Most skin irritation is reversible and can be treated with topical ointments, creams, or solutions prescribed by your doctor

Selected Important Safety Information

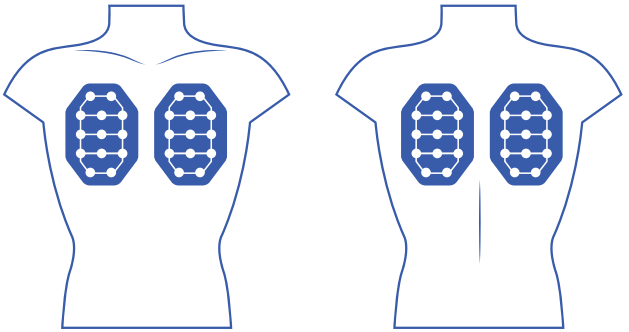
Most common side effects of Optune Lua when used together with chemotherapy were low red blood cell count, constipation, nausea, tiredness, chest pain, fatigue, skin irritation from device use, itchy skin, and cough.

How Optune Lua™ works

Optune Lua works by creating Tumor Treating Fields (TTFields), which are electric fields that disrupt cancer cell division

Using 4 adhesive patches called arrays, TTFields therapy is delivered right into the area of your body where the cancer is located. TTFields may destroy some cancer cells completely and have not been shown to affect healthy cells.

Sample placement of arrays



Where you put the arrays on your body matters. Each person's body is a different shape and size and may have cancer cells in different locations. You (and your caregiver) will receive training to show you how and where to place the arrays on your upper body.

Note: Your array placement may vary. This may include the placement of arrays on your sides.*

- A Skin Care Guidelines brochure is available with more details about how to take care of your skin and place arrays on your body

Download the Skin Care Guidelines brochure at **OptuneLua.com/skincare**

*An Array Applicator will be provided to help place arrays onto your skin. Using the Array Applicator is optional.

Selected Important Safety Information

Optune Lua should only be used after receiving training from qualified personnel, such as your doctor, a nurse, or other medical staff who have completed a training course given by Novocure®, the maker of Optune Lua.

Please see pages 10 and 11 for full Important Safety Information.

Frequently asked questions

Can I wear my Optune Lua™ while I'm sleeping?

Yes. You can set the device on the nightstand next to your bed.

What will I feel when using Optune Lua?

You may experience a warm feeling or sensation, which is normal.

Why do I have to shave my upper body while using Optune Lua?

The arrays need to be applied directly to your skin to work properly. Even a small amount of hair growth can prevent the arrays from making good contact with your skin.

How do I shower or bathe while I use Optune Lua?

There are 2 ways to clean your upper body:

A sponge bath with your arrays still on

- Unplug the arrays from Optune Lua
- Cover the unplugged arrays and wires that are still attached to you by placing a towel around your upper body to prevent the arrays from getting wet*

A full shower with your arrays completely removed

- Unplug the arrays from Optune Lua
- Take a normal shower once your arrays have been completely removed from your body*

*Leave Optune Lua outside the bathroom while taking a sponge bath or a full shower.

Please see pages 10 and 11 for full Important Safety Information.

What should I do if my arrays get wet?

Getting the arrays wet can cause them to come loose and interfere with contact to your skin. If this happens, the alarm may sound and the device may turn off. If at any time the arrays become wet or loosen, they should be changed.

How long should I use Optune Lua?

- You should turn on Optune Lua at least 75% of the time (averaging 18 hours per day), even at night while you are sleeping
  - You can plan ahead for important events (like a wedding) where you do not wish to use the device. This can be done by using Optune Lua for more hours prior to the event
- You can decide which times of the day are best for you to use Optune Lua
- You should not stop treatment with Optune Lua unless you have been instructed to do so by your doctor

How often do I have to replace my arrays?

You should replace your arrays at least twice per week (every 3-4 days) to help minimize the risk of skin irritation.

For answers to more questions you may have, please visit: **OptuneLua.com/FAQs**

Selected Important Safety Information

Do not use Optune Lua if you are pregnant or are planning to become pregnant. It is not known if Optune Lua is safe or effective during pregnancy.

Important Safety Information

What is Optune Lua™ approved to treat?

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- Do not get the device or transducer arrays wet
- Please be aware that Optune Lua has a cord that may cause tripping when connected to an electric socket
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Talk to your doctor if you have any of these side effects or questions.

Please visit OptuneLua.com to see the Optune Lua Instructions For Use (IFU) for complete information regarding the device's indications, contraindications, warnings, and precautions.

OPTUNE LUA™

Get support every step of the way with nCompass™

We know that starting Optune Lua™ doesn't just impact how you treat MPM. It can impact your entire way of life, and that can be a lot to deal with—that's where nCompass comes in. Our support team is here to help you adjust to life with Optune Lua, and we're available 24/7.

nCompass can*:

- Provide information on Optune Lua and how it works
- Answer questions about how Optune Lua may help treat your MPM
- Work with your insurance plan and identify resources that may help minimize your cost
- Provide tips and resources on how to make Optune Lua a part of your daily life
- Set up delivery of Optune Lua and provide training to you and your caregivers
- Set up additional Optune Lua training at any time if you need it
- Reorder supplies, such as arrays or extra batteries
- Provide support and answer questions 24/7

*nCompass and Novocure® cannot provide medical advice. Consult with your doctor for medical-related questions.

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nCOMPASS™

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OPTUNE LUA™