



## **NovoTTF™-100L System for Unresectable Malignant Pleural Mesothelioma - Patient Information and Operation Manual**

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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.

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## GLOSSARY

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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 trial – 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 TFields 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

NovoTTF™-100L System– 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 TFields to the chest

TFields – 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

## **WHAT IS THE NOVOTTF-100L SYSTEM AND HOW DOES IT WORK**

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The NovoTTF-100L System 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 the NovoTTF-100L System because you are a good candidate for treatment with the device.

A doctor may prescribe the NovoTTF-100L System to treat a patient with malignant pleural mesothelioma (called “MPM”) which cannot be cured with surgery or radiation.

The NovoTTF-100L System is used together with pemetrexed and cisplatin or carboplatin (types of cancer drugs).

The NovoTTF-100L System 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, the term “NovoTTF-100L System” refers to the Electric Field Generator (also called “the device”), connection cable, transducer arrays, power supply, battery, battery rack and battery charger.

## **CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS**

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### **Contraindications**

Do not use the NovoTTF-100L System if you have an electrical implant. Use of the NovoTTF-100L System together with electrical implants has not been tested and may lead to malfunctioning of the implanted device.

Do not use the NovoTTF-100L System 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 the NovoTTF-100L System 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 the NovoTTF-100L System 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 NovoTTF-100L System 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 NovoTTF-100L System, 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 NovoTTF-100L System 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 NovoTTF-100L System 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 treatment.

Caution - Do not use NovoTTF-100L System 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. NovoTTF-100L System 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 NovoTTF-100L System and transducer arrays will activate metal detectors.

Notice - If you plan to be away from home for more than 1.5 hours, 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 26 of the patient information and operation manual) at all times. This guide is necessary to ensure the NovoTTF-100L system 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 sides 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.

## WHAT ARE THE RISKS OF USING THE NovoTTF-100L SYSTEM?

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Skin irritation is often seen under the transducer arrays when using the NovoTTF-100L System. 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 NovoTTF-100L System 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 NovoTTF-100L System together with cancer drugs, in this clinical study. Only skin irritation was caused by the NovoTTF-100L System. The rest of the medical problems were due to the cancer itself or the cancer drugs used with the device.

Medical Problem	NovoTTF-100L System 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 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



## **WHAT ARE THE BENEFITS OF USING THE NovoTTF-100L SYSTEM?**

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All patients in the clinical study used the NovoTTF-100L together with cancer drugs. Half of the patients using NovoTTF-100L together with cancer drugs lived for more than 18.2 months after their treatment started. Also, 4 out of each 10 patients using NovoTTF-100L together with cancer drugs were alive after two years (42%).

## **WHAT STUDIES HAVE BEEN CONDUCTED WITH THE NovoTTF-100L SYSTEM?**

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A clinical study, referred to as the STELLAR Study, was conducted to evaluate the use of NovoTTF-100L System 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 NovoTTF-100L System. For more information, visit our website: [www.Optune.com](http://www.Optune.com)

## **ABOUT NovoTTF-100L SYSTEM**

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NovoTTF-100L is a portable medical device that delivers electric fields called “TTFIELDS” to the chest using transducer arrays. TTFIELDS are intended to kill cancer cells.

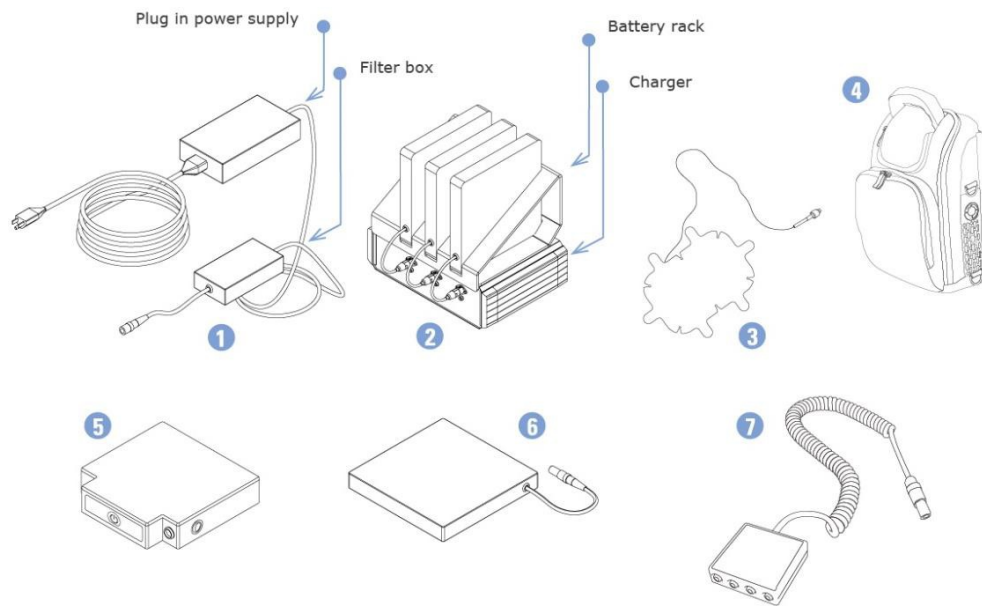
Your doctor has prescribed NovoTTF-100L System for use at home. You may be able to use NovoTTF-100L System on your own, or you may need help from a doctor, family member, or other caregiver. Use NovoTTF-100L System as many hours per day as possible. You can take short breaks for personal needs. When 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 the NovoTTF-100L System. 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 NovoTTF-100L System includes four rechargeable batteries. Each battery will last for up to two hours. 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.

NovoTTF-100L System 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 26). You can also call the 24-hour technical support telephone number (Section 27). 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 NovoTTF-100L

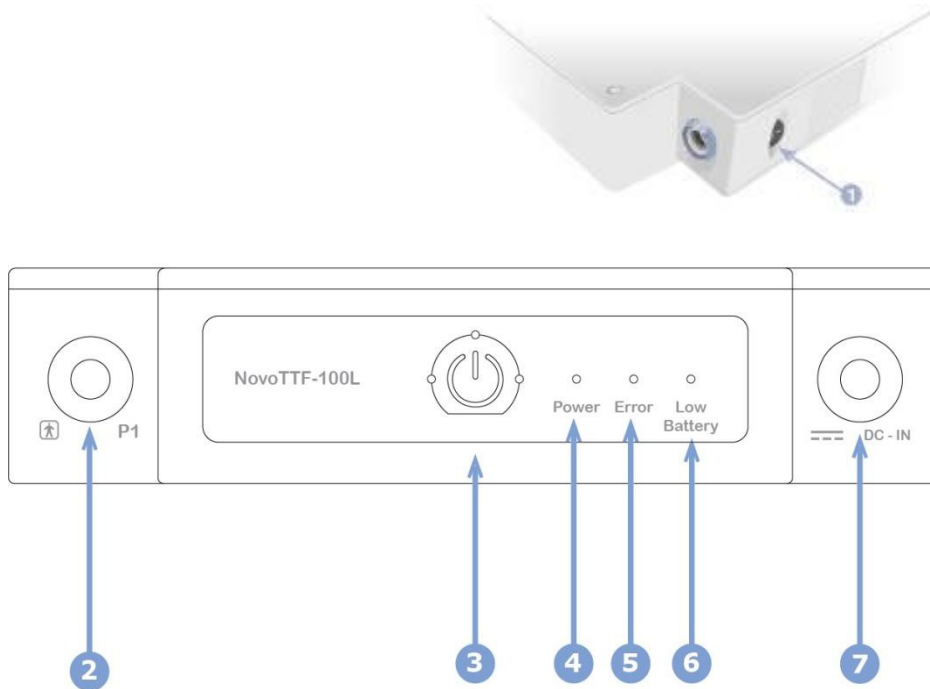


- 1 Power supply
- 2 Charger for portable batteries
- 3 Insulated ILE Transducer Arrays
- 4 Device & battery carrying bag
- 5 NovoTTF-100L electric field generator (the Device)
- 6 Portable battery
- 7 Connection cable & box

## THE DEVICE

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- The NovoTTF-100L System is an automatic system.
- You will need to learn how to place it in a carrying bag, connect a portable battery and operate the system.
- The following controls will allow you to do this:



- 1 NovoTTF-100L power button
- 2 Connection cable socket (P1)
- 3 TTFields ON/OFF button
- 4 Power ON indicator
- 5 Error indicator
- 6 Low Battery indicator
- 7 Battery connector socket

## THE ILE TRANSDUCER ARRAYS

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- 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 the NovoTTF-100L System 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 torso size.
- Your doctor will show you where to place each array on your chest.

## BEFORE YOU BEGIN

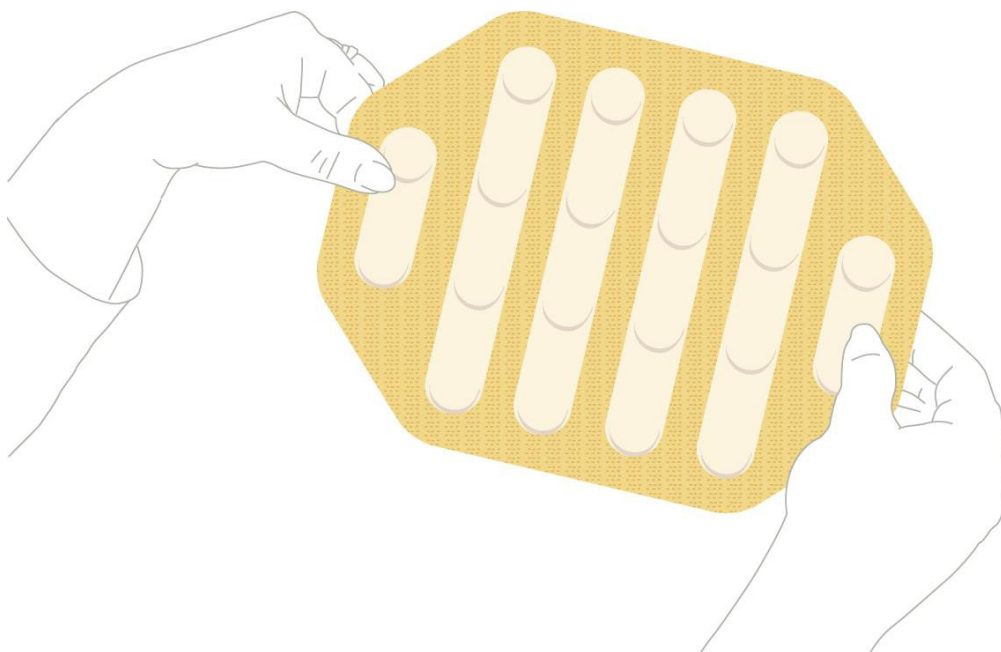
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- You will need four (4) ILE transducer arrays (Sterile) every 3-4 days in order to maintain treatment with the NovoTTF-100L System.
- You will need to make sure you have the right sized transducer arrays for your torso size.
- Make sure you have ample supply of ILE transducer arrays to keep you going until your next visit to your physician.

## REMOVING THE ILE TRANSDUCER ARRAY FROM ITS PACKAGE

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- 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.



## **PREPARING YOUR SKIN FOR TRANSDUCER ARRAY PLACEMENT**

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

## **PLACING THE TRANSDUCER ARRAYS**

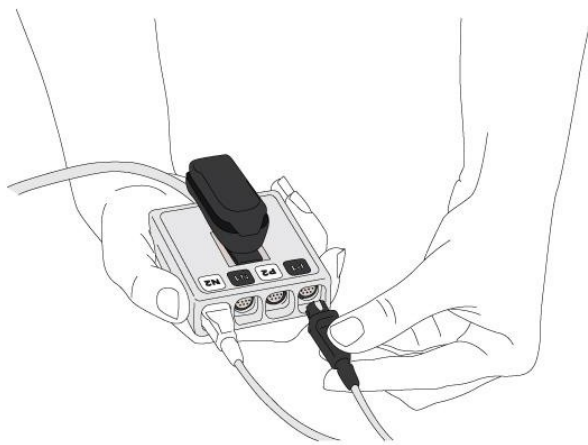
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- Once every 3-4 days (about twice a week) perform the following steps to replace your transducer arrays.
- Remove the transducer arrays already applied to your skin by peeling the medical tape away from your skin.
- Note the black and white color of the transducer array connectors - each pair of the same color will be positioned opposite to each other on your body.
- Remove the transducer array liner from the first transducer array.
- 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.
- Place the other three transducer arrays in the same fashion.
- You will need to ask for assistance from a friend or family member to place the back transducer array(s).
- Press the entire edge of the transducer array tape to your skin.

## CONNECTING THE TRANSDUCER ARRAYS TO THE DEVICE

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- Connect the four black and white Transducer Array connectors to the corresponding black and white coded sockets on the NovoTTF-100L System connection cable.
- Press firmly to verify the connectors are inserted all the way.
- Collect the transducer array wires together and bind with a small piece of tape where convenient.
- You may clip the connection cable clip to your belt.



## STARTING & STOPPING THE DEVICE

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- **To start treatment**, connect a charged battery to the blue battery socket (see section 13) and connect the connection cable to the grey connection cable socket on the device. Both of these connectors are keyed such that they can only be inserted if the arrows on the connectors face up towards the labels on the ports. Turn the power button on the side panel of the device to the ON position.



- Wait approximately 3 seconds for the blue indicators surrounding the TTFIELDS ON/OFF button to stop blinking.
- Press the TTFIELDS ON/OFF button once – this will start treatment.
- The three blue indicators surrounding the TTFIELDS ON/OFF button will light up and remain on for as long as treatment continues.

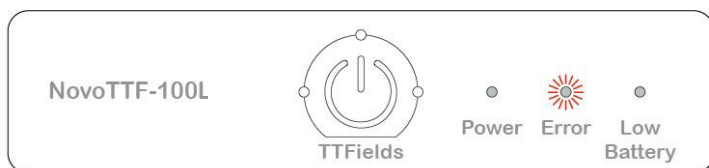




- **Stopping treatment** may be performed in each of the following situations:
- **When the device is running properly:**
  - Press the TTFIELDS button – The three blue indicators surrounding the TTFIELDS ON/OFF button will turn off.

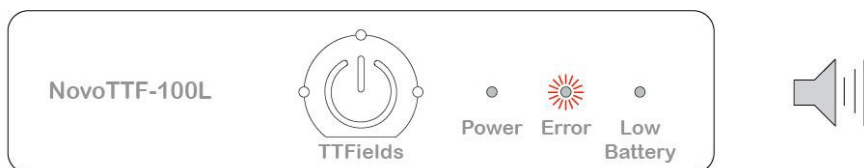


- Turn off the device by turning the power button on the side panel of the device to the OFF position.
- **If TTFIELDS treatment is not started** within 10 minutes of turning the Power button on, a loud intermittent beep will be sounded and the red Error indicator will light up.
  - Press the TTFIELDS button on the front panel in order to stop the alarm sound. The red Error indicator will turn off. Press the TTFIELDS button again in order to start the treatment.



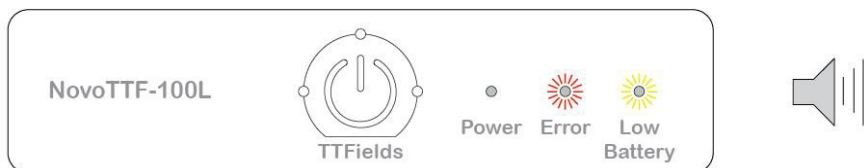
- **When an Error condition occurs:**
  - The device automatically shuts off the TTFIELDS output to the patient, a loud intermittent beep is sounded and the red Error indicator lights up.

- Press the TTFIELDS button on the front panel in order to stop the alarm sound. The red Error indicator will turn off.
- Turn off the device by turning the power button on the side panel of the device to the OFF position.



- **When the Low Battery indicator lights up:**

- When your battery runs out (after about 2-3 hours), an alarm will sound, the TTFIELDS output will shut down and both the yellow Low Battery indicator and red Error indicator will light up.
  - Turn off the device as described above.

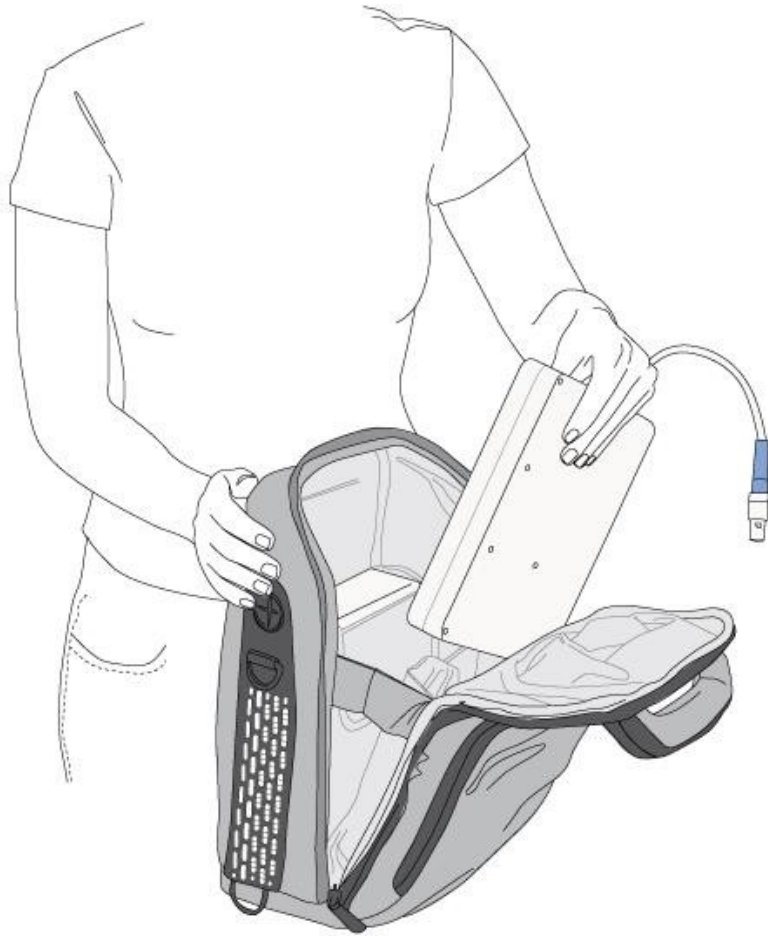


## CONNECTING & DISCONNECTING THE PORTABLE BATTERY

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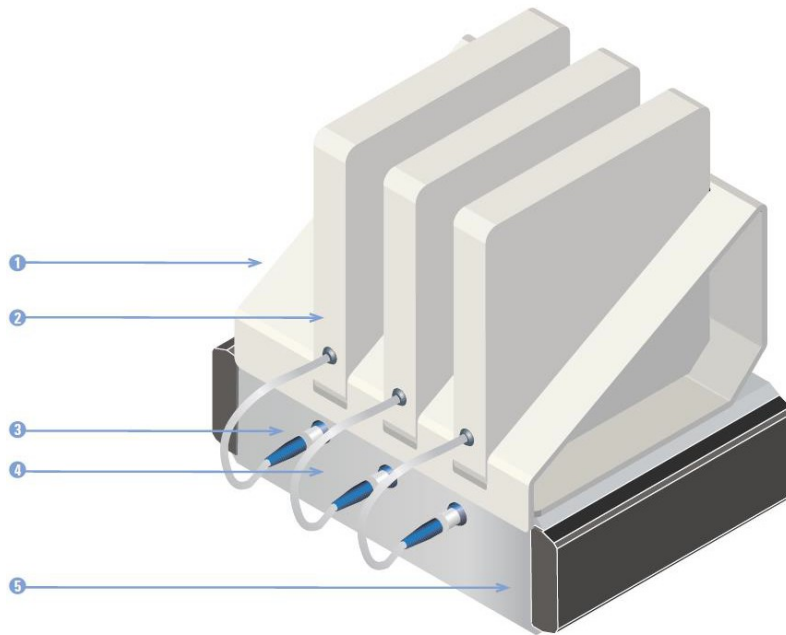
- When the yellow Low Battery indicator lights up, the battery should be replaced according to the following procedure:
- Press the TTFIELDS button once to turn off the alarm sound.
- Turn OFF power switch.
- Disconnect the battery connector from the blue socket on the front panel.
- Make sure to hold the connector as shown.
- Remove the battery from the device bag (do not lift or pull the battery by its cable).
- Insert a fully charged battery into the device bag.
- Connect the battery connector to the blue socket on the front panel.
- Turn power switch ON.
- Start the treatment by pressing the TTFIELDS button on the front panel once.
- Connect the discharged portable battery to its charger for charging.



## CHARGING THE PORTABLE BATTERY

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- Before charging your portable batteries, plug the charger mains cable into an electric socket and turn on the power button located at the back.
- All 3 portable batteries which are not in use should be placed in the charger and their cables connected to the charging sockets at all times.
- Always select a fully charged battery when replacing a battery in the NovoTTF-100L device (the Charge indicator of the battery must be green).
- To remove a battery from the charger, disconnect the battery cable from the charger by pulling its connector from the socket on the charger.
- To recharge a depleted battery, place it in the charger and connect its connector to an available charger socket (the Charge indicator should light up in red).

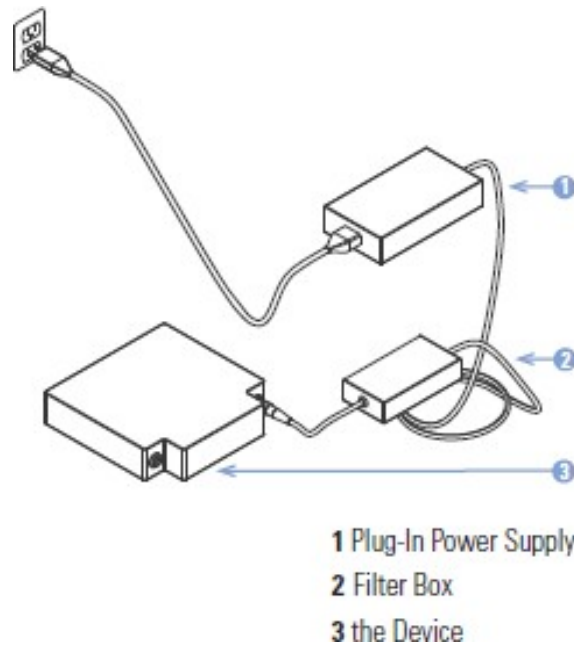


- 1 Portable Battery Rack
- 2 Portable Battery
- 3 Charger Socket
- 4 Charge Indicator
- 5 Charger

## USING THE POWER SUPPLY

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- When portability is not required, the device can be powered from the plug-in power supply. There is no limit to how long the device can operate continuously while using the plug-in power supply.
- The plug-in power supply input is designed to operate on either 120V AC (US) or 230V AC (EU).
- When in use the power supply will become warm.
- When in use, support the filter box so the weight of the box is not hanging on the line from the NovoTTF-100L device.



- **Connecting the Plug-In Power Supply**
  - Stop the device as described in Section 12.
  - Remove the battery connector from the blue socket on the front panel of the device.
  - Plug in the power cord to the plug-in power supply and to the wall outlet.
  - Connect the blue connector on the plug-in power supply line to the blue socket on the front panel of the device where the battery was plugged in.
  - Start the device as described in Section 12.
  - Support the filter box so the weight of the box is not hanging from the line to the blue connector.
  
- **Disconnecting the Plug-In Power Supply**
  - Stop the device as described in Section 12.
  - Remove the blue connector of the plug-in power supply from the blue socket on the front panel of the device.
  - Place a charged portable battery in the device bag.
  - Plug the portable battery connector into the blue socket on the front panel of the device.
  - Start the device as described in Section 12.
  - Store the plug-in power supply for future use.

## DISCONNECTING FROM THE DEVICE

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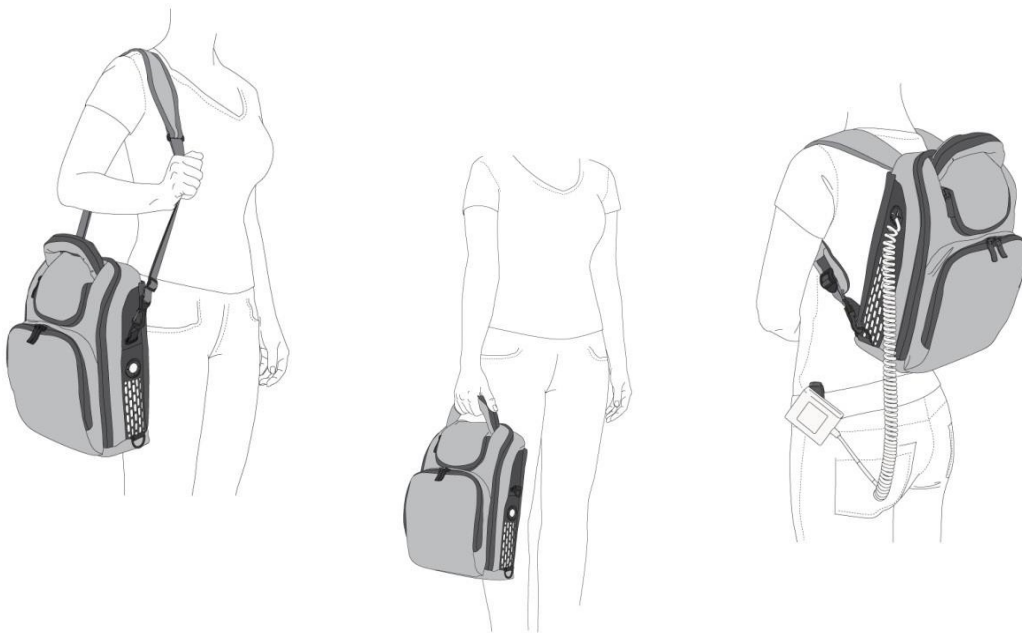
- In order to take a break from treatment you will need to turn off the device and disconnect. There are two options for doing this.
  - The simplest way to disconnect is to disconnect the connection cable from the device. This will require that the connection cable stay attached to the transducer arrays and be carried with you on your break. To accomplish this:
    - Stop TFields.
    - Turn OFF the NovoTTF-100L device
    - Disconnect the connection cable by grasping the connector on the grey sleeve and pulling out.
    - To restart treatment, insert the connection cable connector in the grey connection cable socket.
  - To disconnect from the device without having to keep the connection cable attached to the transducer arrays you will need to disconnect the electrodes from the connection cable box:
    - Stop TFields.
    - Turn OFF the NovoTTF-100L device.
    - Disconnect the transducer array connectors from the connection box by grasping firmly and pulling while gently moving back and forth.
    - To continue treatment, reconnect the transducer arrays to the connection box. Make sure to connect each transducer array to its corresponding color (e.g. white transducer array connector to the white socket). The flat section with the arrow faces up toward the color indicator on the box.
    - When all 4 transducer arrays are connected, restart treatment as described in section 12.












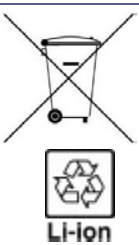



## CARRYING THE DEVICE

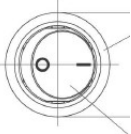







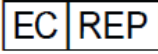

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- Both the device and the portable battery fit in a carrying bag equipped with a carrying handle and a detachable shoulder strap.
- Do not place the device in a bag not intended for use with the NovoTTF-100L device.
- In order to wear the bag, place the strap over your shoulder or use the backpack option
- Grab the snap hook at the end of the strap with your opposite hand.
- Connect the snap hook to the handle as shown.



## 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%
	Atmospheric pressure between 700-1060hPa
	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 is 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
	The novoTTF-100L device and additional parts 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.
 YYYY-MM	Expiration date – do not use beyond this date

	<p>Power ON / OFF switch for the NovoTTF-100L device: When the switch is in the I position the device is ON When the switch is in the O position the device is OFF</p>
	<p>Power ON / OFF switch for the portable battery and overnight battery chargers: 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</p>
	<p>Do not use the ILE Transducer arrays if their packaging is breached.</p>
	<p>The ILE Transducer Arrays are for single use and should not be re-used.</p>
	<p>The ILE Transducer Arrays are sterilized by Gamma irradiation</p>
	<p>Catalogue number</p>
	<p>Serial number</p>
	<p>Class II equipment</p>
	<p>European authorized representative</p>
	<p>Manufacturer information</p>

## **ENVIRONMENTAL CONDITIONS FOR NORMAL OPERATION, STORAGE AND TRANSPORTATION**

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### **Conditions for operation**

- All system components shall be normally used under conditions specified below:
- Mainly for home use.
- For indoor use only (chargers, power supply, battery rack)
- 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/+40°C (23°F/104°F)
- Relative Humidity range: 15-93%
- Ambient pressure range: 700-1060hPa

### **Conditions for storage**

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

### **Conditions for transport**

- Transportation of the device and additional parts shall be possible using air/ground transportation in weather protected conditions as specified below:
- Temperature range: -5°C/+40°C (23°F/104°F)
- Maximal relative humidity 15-93%
- No direct exposure to water
- Transportation of the transducer arrays shall be possible using air/ground transportation in weather protected conditions as specified below:

- Temperature range: 0°C /+40°C (32°F/104°F)
- Maximal relative humidity 15-75%
- No direct exposure to water

## TROUBLESHOOTING

Problem	Possible causes	Actions to be taken
Device alarm on	<ol style="list-style-type: none"> <li>1. Low battery</li> <li>2. Cable becoming loose or disconnected</li> <li>3. Vents being blocked</li> <li>4. Local hot spot on transducer array from laying on a pillow or other insulator</li> <li>5. Poor transducer array contact due to hair growth or other reason</li> <li>6. Device malfunction</li> <li>7. Device is turned ON, but the therapy has not been activated</li> </ol>	<p><b>If Low Battery indicator is on:</b></p> <ol style="list-style-type: none"> <li>1. Replace battery as described above</li> <li>2. Turn ON therapy</li> </ol> <p><b>If the Error indicator lights up but the Low Battery indicator is not lit:</b></p> <ol style="list-style-type: none"> <li>1. Press the TTFields button to stop the alarm</li> <li>2. If three blue lights around the TTFields button light – the therapy has now been activated</li> <li>3. If three blue lights around the TTFields button do not light - Turn OFF power switch</li> <li>4. Check all connections to ensure nothing is loose</li> <li>5. Check vents to make sure they are not blocked</li> <li>6. Make sure transducer arrays are well adhered to the upper torso, add tape if necessary</li> <li>7. Restart treatment</li> <li>8. If alarm persists, turn OFF and call a Novocure representative</li> </ol>
Low Battery indicator remains on after battery replaced	<ol style="list-style-type: none"> <li>1. Charger malfunction</li> <li>2. Battery malfunction</li> <li>3. Device malfunction</li> </ol>	<ol style="list-style-type: none"> <li>1. Replace battery or power supply with a fully charged battery.</li> </ol> <p><b>If problem persists:</b></p> <ol style="list-style-type: none"> <li>1. Turn OFF power switch</li> <li>2. Call Novocure representative</li> </ol>
Device power indicator does not light up after turning ON the device	<ol style="list-style-type: none"> <li>1. Battery dead</li> <li>2. Battery malfunction</li> <li>3. Charger malfunction</li> <li>4. Device malfunction</li> <li>5. Power supply malfunction</li> </ol>	<ol style="list-style-type: none"> <li>1. Replace battery.</li> <li>2. Verify battery or power supply are plugged into the device.</li> <li>3. Verify the power supply is plugged into the mains socket.</li> </ol> <p><b>If problem persists:</b></p> <ol style="list-style-type: none"> <li>1. Turn OFF power switch</li> <li>2. Call Novocure representative</li> </ol>

Problem	Possible causes	Actions to be taken
Any cable detached from transducer array/connection cable/device	<ol style="list-style-type: none"> <li>1. Excess physical force to cables</li> <li>2. Device malfunction</li> </ol>	<ol style="list-style-type: none"> <li>1. Reconnect cable into its socket</li> <li>2. Restart therapy</li> </ol> <p><b>If problem persists:</b></p> <ol style="list-style-type: none"> <li>1. Press TTFields button to stop therapy.</li> <li>2. Turn OFF power switch</li> <li>3. Call Novocure representative</li> </ol>
Device dropped or wet	Incorrect use	<ol style="list-style-type: none"> <li>1. Press TTFields button to stop therapy.</li> <li>2. Turn OFF power switch</li> <li>3. Call Novocure representative</li> </ol>
Device or charger vents blocked by pet hair/dust	Incorrect use	<ol style="list-style-type: none"> <li>1. Return the device/charger to service</li> </ol>
Redness of the skin beneath the transducer arrays	Common side effect	<ol style="list-style-type: none"> <li>1. Use steroid cream prescribed by your doctor when replacing transducer arrays.</li> <li>2. Place transducer arrays in a location shifted by 2 cm from the last location (so the adhesive gel is between the red marks).</li> </ol> <p><b>If the redness gets worse:</b></p> <ol style="list-style-type: none"> <li>1. See your treating doctor</li> </ol>
Blisters beneath the transducer arrays	Rare side effect	See your treating doctor
Itching beneath the transducer arrays	Rare side effect	<ol style="list-style-type: none"> <li>1. Use steroid cream prescribed by your doctor when replacing transducer arrays.</li> <li>2. Place transducer arrays in a location shifted by 2 cm from the last location (so the adhesive gel is between the red marks).</li> </ol> <p><b>If the itching gets worse:</b></p> <ol style="list-style-type: none"> <li>1. See your treating doctor</li> </ol>
Pain beneath the transducer arrays	Rare side effect	<ol style="list-style-type: none"> <li>1. Stop treatment</li> <li>2. See your treating doctor</li> </ol>

## **ASSISTANCE & INFORMATION**

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### **Technical support:**

For technical support call at 1-855-281-9301 (toll free) or email [support@novocure.com](mailto: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 the NovoTTF-100L System**

The system's portable 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 NovoTTF-100L System and transducer arrays will activate metal detectors.



## **MALIGNANT PLEURAL MESOTHELIOMA (MPM)**

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### **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.

NovoTTF-100L System together with cancer drugs

Radiation therapy and surgery can help people with MPM live longer than if they had no treatment. Adding NovoTTF-100L System 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. NovoTTF-100L System leads to skin related problems under the transducer arrays in many people.