

# Product Fact Sheet

## Tumor Treating Fields (TTFields)

- TTFields are low-intensity alternating electric fields that are frequency-tuned to specifically interact with dividing tumor cells.
  - TTFields specifically target and directly disrupt dividing tumor cells, inhibiting tumor growth and possibly causing affected cancer cells to die while sparing normal, healthy cells.
- Optune® and NovoTTF-100L™ are wearable and portable cancer treatments that deliver TTFields.

## Optune in Glioblastoma (GBM)

- Optune is an FDA-approved treatment for GBM, the most common and deadliest type of primary brain cancer.
  - Optune is the first FDA-approved treatment in more than a decade for newly diagnosed GBM.
  - Optune received FDA approval in newly diagnosed GBM in 2015. The FDA previously approved Optune in 2011 for the treatment of recurrent GBM. Optune was approved under the Premarket Approval (PMA) pathway.
  - More than 10,000 patients with GBM have started Optune.
- For patients with newly diagnosed GBM, Optune has proven to extend survival and maintain quality of life.
  - A large clinical trial showed that the survival rate with Optune + TMZ vs TMZ alone was significantly higher at the 2-year landmark analysis (43% vs 31%) and remained higher at 5 years (13% vs 5%)
    - In a 5-year follow up, people on Optune + TMZ lived longer across all groups analyzed regardless of well-being, age, gender and how much of the tumor was removed.
    - Patients using Optune + TMZ in the study were also able to maintain their mental, emotional, and physical well-being longer than those on chemotherapy alone for up to one year.

## NovoTTF-100L in Unresectable Malignant Pleural Mesothelioma

- The NovoTTF-100L system is FDA approved for the first-line treatment of unresectable, locally advanced or metastatic, malignant pleural mesothelioma (MPM), a rare cancer with a poor prognosis.
  - NovoTTF-100L is the first FDA-approved treatment in MPM in over 15 years.
  - NovoTTF-100L for MPM is classified as a Humanitarian Use Device (HUD), approved under the Humanitarian Device Exemption (HDE). The HDE pathway was created to encourage companies to innovate in rare diseases with underserved patient populations.



- A clinical trial showed that NovoTTF-100L and pemetrexed + cisplatin/carboplatin may help people with MPM extend their lives and prevented tumor growth.
  - MPM patients who received NovoTTF-100L with platinum-based chemotherapy experienced median overall survival of 18.2 months.
  - 97% percent of patients (n=72) with at least one follow-up CT scan performed experienced clinical benefit, either partial response or stable disease.
  - More than half of patients enrolled in STELLAR trial who used NovoTTF-100L + platinum-based chemotherapy were still alive at 1 year.
    - At year 1: 62% of patients (N=80)
    - At Year 2: 42% of patients (N=80)

## Additional background

- Because TTFields do not enter the bloodstream like a drug, they did not increase chemotherapy related side effects in clinical trials. The most common ( $\geq 10\%$ ) adverse events seen when using Optune alone were skin irritation from device use and headache.
- Optune and NovoTTF-100L are wearable and portable so continuous treatment with both can be received almost everywhere.
- Optune and NovoTTF-100L deliver treatment to the region of the tumor via 4 adhesive patches called transducer arrays. These arrays are applied to the shaved skin and are connected to the device and battery.

## Indications for Use

The NovoTTF-100L System 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.

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.

## Important Safety Information

### Contraindications

Do not use the NovoTTF-100L System 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 the NovoTTF-100L System 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 the NovoTTF-100L System for MPM or Optune for GBM in patients known to be sensitive to conductive hydrogels. Skin contact with the gel used with the NovoTTF-100L System 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

The NovoTTF-100L System and Optune can only be prescribed by a healthcare provider that has completed the required certification training provided by Novocure®.

The most common ( $\geq 10\%$ ) adverse events involving the NovoTTF-100L System in combination with chemotherapy in patients with MPM were anemia, constipation, nausea, asthenia, chest pain, fatigue, device skin reaction, pruritus, and cough.

Other potential adverse effects associated with the use of the NovoTTF-100L System 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 site reaction and skin breakdown/skin ulcer.

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

The most common ( $\geq 10\%$ ) 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 the NovoTTF-100L System and Optune treatment.

Do not prescribe the NovoTTF-100L System or Optune for patients that are pregnant, you think might be pregnant or are trying to get pregnant, as the safety and effectiveness of NovoTTF-100L System and Optune in these populations have not been established.

Please [click here](#) to see the NovoTTF-100L Instructions For Use (IFU) for complete information regarding the device's indications, contraindications, warnings, and precautions.

Please [click here](#) to see the Optune IFU for complete information regarding the device's indications, contraindications, warnings, and precautions.

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