Novocure GmbH
Park 6
Root D4
6039 Root
Switzerland

Email:
supportemea@novocure.com
www.novocure.com

October 7, 2020

Urgent Field Safety Notice
Optune
Change of Legal Manufacturer of Novocure and revision of the Patient User Manual for Optune® for all CE Marked product items within EMEA

Dear Sir or Madam,

We hereby provide notice of changes that have been recently made to the Patient's User Manual of Optune, our CE marked treatment kit. These changes are consistent with an advisory notice as defined in ISO 13485: "to provide notice issued by the organization, subsequent to delivery of the medical device, to provide supplementary information".

The changes are as follows:

1. The manufacturer added a precaution to the Patient User Manual stating: "Caution – there is a hazard of falling due to entanglement in the connection cable. You may consider clipping the cable to your belt".

2. Novocure has combined the two existing User Manuals for Optune to one: The previous User Manuals (Optune® User Manual and INE Transducer Arrays User Manual) were combined into one comprehensive User Manual. The new comprehensive User Manual is easier to understand and follow.

Attachment 1 to this notice contains the list all of the changes that were made in the User Manual.

3. Novocure has changed the Legal Manufacturer for its CE marked product items from Novocure LTD to Novocure GmbH. The main reasons for this change are logistical and commercial, and the change has no impact on the use of our products.

New Legal Manufacturer:	**Previous Legal Manufacturer:**
Novocure GmbH	Novocure LTD
Business Village D4	Topaz Building
Park 6/Platz 10	MATAM Center
6039 Root D4	Haifa 3190500
Switzerland	Israel

The following pages provide information on how to identify affected devices and instructions on actions to be taken. Follow the "**Action to be taken by the user**" section of the notice. Customer reply is not required.

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Urgent Field Safety Notice (FSN)

Optune

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Commercial name	Optune
Device model	TFH9100EU–Optune Commercial EU
Device type	Optune is a portable medical device that delivers electric fields called "TTFields" to the brain using transducer arrays. TTFields disrupt cell division, inhibiting tumor growth and potentially causing cancer cells to die.
Primary clinical purpose of device	Optune Treatment Kit is intended for the treatment of patients with newly diagnosed GBM and for the treatment of patients with recurrent GBM. NovoTTF-200A (OptuneTM) Treatment Kit is intended for the treatment of patients with newly diagnosed GBM, after surgery and radiotherapy with adjuvant Temozolomide, concomitant to maintenance Temozolomide. The treatment is intended for adult patients, 18 years of age or older, and should be started more than 4 weeks after surgery and radiation therapy with adjuvant Temozolomide. Treatment may be given together with maintenance Temozolomide (according to the prescribing information in the Temozolomide package insert) and after maintenance Temozolomide is stopped. NovoTTF-200A (OptuneTM) Treatment Kit is intended for the treatment of patients with recurrent GBM who have progressed after surgery, radiotherapy and Temozolomide treatment for their primary disease. The treatment is intended for adult patients, 18 years of age or older, and should be started more than 4 weeks after the latest surgery, radiation therapy or chemotherapy.
Background	During a periodic review of the technical file of Optune INE Transducer Arrays (a product that has been certified in 2007) by Novocure's Notified Body (TUV Rhineland), it was realized that information to prevent potential risk is required. A precaution has been added to the Patient User Manual stating: "Caution – there is a hazard of falling due to entanglement in the connection cable. You may consider clipping the cable to your belt".
Risk	The likelihood of fall due to entanglement in the connection cable is remote. The likelihood of sustaining a serious injury from a fall due to entanglement in the connection cable is remote (0.02%).There have been no incidents of serious injury from a fall due to entanglement in the connection cable in the EEA or Switzerland to date. There have been five reports (0.02%) of serious injury (i.e., fracture or laceration) due to fall caused by entanglement in the device cable to date. All five events occurred in the US.
Action to be taken by the user	Take note of amendment/reinforcement of Instructions For Use (IFU).

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Action being taken by the manufacturer	A precaution has been added to the Patient User Manual stating: "Caution – there is a hazard of falling due to entanglement in the connection cable. You may consider clipping the cable to your belt". Every new patient receives the updated user manual on treatment initiation. Starting on October 7, 2020, all active patients are to be informed about the change in the user manual via Field Safety Notice describing the nature of the change.
Contact Person	Sharon Perez Senior Director Global Medical Safety Email: devicesafety@novocure.com

Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

The undersigned confirms that this Field Safety Notice has also been forwarded to the appropriate European Competent Authorities and the Manufacturer's Notified Body.

Thank you.

Kind Regards,

Sharon Perez

Sharon Perez
Senior Director Global Medical Safety
Novocure

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Attachment 1: Details of changes made to the User Manuals for Optune

i. The previous user manuals for patients (QSD-EUUM-001 and QSD-QR-306) were combined into one comprehensive user manual for Optune system (QSD-EUUM-002), containing all the information required for system use by the patient.

ii. Throughout the document “Temodar” was replaced with “Temozolomide”

iii. Section 3, the following precaution was added: “Caution – there is a hazard of falling due to entanglement in the connection cable. You may consider clipping the cable to your belt”

iv. Section 5 – edited to provide information in a form easily understandable by lay user.

v. Section 12 – added “You may clip the connection cable to your belt”

vi. Section 19 – symbols graphically edited to reflect the exact symbols on the labels. Added symbol for indication that the device is a medical device, per Medical Device Regulation requirement. Added a symbol and explanation “Do not re-sterilize” to explain a new symbol on transducer arrays label.

vii. Section 24 – Applicable standards specified

viii. Section 28 – added clarification for “expected service life” - Expected service life reflects the average time during which the equipment specified below is expected to work without malfunctioning. Please continue using the equipment if it passed its expected service life and do not stop the treatment. Updated the expected service life for device and accessories based on the latest information.

ix. Last page – Manufacturer updated to Novocure GmbH and its address provided.