FCA# 17-04-19-01

NEURAY ® SURGICAL PATTIES AND STRIPS

MEROCEL ® NEUROSURGICAL PATTIES AND PACKING

INFORMATION FOR USE MODIFICATIONS

ATTACHMENT C

Customer Letter

Medtronic

PRODUCT LABELING UPDATE NOTICE

NEURAY® SURGICAL PATTIES AND STRIPS

MEROCEL® NEUROSURGICAL PATTIES AND PACKING

September 2017

Dear Valued Customer/Distributor:

The purpose of this letter is to advise you that Medtronic is updating our Instructions For Use ("IFU") via a Product Labeling Update Notice for the Neuray® and Merocel® Neurosurgical patties.

Issue Description:

As part of a notification to all manufacturers of Neurosurgical Patties, Medtronic Xomed was informed by the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) of a potential postmarket safety concern associated with the use of neurosurgical patty devices.

The potential safety concern identified by the FDA "is related to clinical consequences when some patties, which are designed to be x-ray detectable or radiopaque to assist with post-procedural removal in the event of a missing device, are not visible during x-ray imaging."

To address this potential concern, Medtronic is including additional information in the Instructions For Use regarding these issues to further clarify the use of these devices to health care practitioners. The updated Instructions for Use provided includes the precautions that will help reduce the potential for clinical consequences when some neurosurgical patties, which are designed to be x-ray detectable or radiopaque to assist with post-procedural removal in the event of a missing device, are not visible during x-ray imaging.

Therefore, Medtronic is including the following *precautions:*

• "Count all devices before and after the procedure prior to surgical closure. In the event a device cannot be located; an x-ray can be used to locate the devices. Only the radiopaque markers are visible on imaging. The size and position of the radiopaque markers may impact their visibility."

• "It is recommended that at least three views, using the optimal parameters for the imaging (x-ray) equipment, at a variety of angles (e.g., 45 degrees, 22.5 degrees, and 0 degree angles) for

Medtronic

[redacted]

CC: Chairman of Medical Board and relevant HODs

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Customer Confirmation Form

PRODUCT LABELING UPDATE NOTICE

NEURAY ® SURGICAL PATTIES AND STRIPS

MEROCEL ® NEUROSURGICAL PATTIES AND PACKING

For completion by Medtronic Customers Only – Please complete all fields below and return immediately

Note: The addressee may continue to receive reminders of this notice until a response is received.

By signing this form, I confirm that I have read the Product Labeling Update Notice Letter, dated September 2017 from Medtronic regarding Neuray® and Merocel® Neurosurgical patties.

The letter and information for Use (IFU) booklet provided is a Product Labeling Update Notice that describes the safety concerns of a potential postmarket safety issue associated with the use of neurosurgical paddie devices. We are asking you to please take the following steps concerning the communication of this Product Labeling Update Notice:

Return Instructions:
Please review your inventory for product affected by this issue as listed on the attached affected Models and Lot Numbers list and perform the following:

1.) Read this Product Labeling Update Notice carefully, and communicate the issue and recommendations to the other users and concerned parties including X Ray technicians, in your facility;

2.) Complete and return the attached "Acknowledgement Form" indicating your receipt, review and further communication (as necessary) of this Product Labeling Update Notice within your organization.

For questions related to this communication, please contact your Medtronic representative.

Please share this notification with others in your organization as appropriate. If product within the scope of this notification has been forwarded to another facility, please alert the facility of this notification. Please maintain a copy of this notice in your records.

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In the event, you no longer manage the Neurosurgical patties affected by this Product Labeling Update Notice, please provide a detailed explanation in the space below so that Medtronic's records can be updated accordingly. Thank you.

Note: The addressee may continue to receive reminders of this notice until a response is received.

By signing this form, I confirm that I have read the Product Labeling Update Notice Letter, dated **11 September**, from Medtronic regarding Neuray and Merocel Neurosurgical patties, strips and packings and taken appropriate action.

Please complete and sign the form as indicated below and return to Medtronic Representative.

Customer Name (Print): _____ Date:
(First Name, Last Name)

Customer Title (Print): _____

Customer Signature and stamp (ink): _____

Facility name and stamp (ink): _____

Telephone: _____

Comments/notes**:** _____

For questions, please contact your Medtronic Representative.