Medtronic

Urgent Field Safety Notice

Neuray® Neurosurgical Patties and Strips
and Merocel® Neurosurgical Pattie and Packing
Labeling Update

September 2017

Medtronic reference: FA776

Dear Customer/Distributor,

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

As part of a notification to all manufacturers of Neurosurgical Patties, Medtronic was informed by the US Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) of a potential 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 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 anterior and posterior, or the appropriate plane, be taken and examined for a missing device. If there are concerns regarding visualization, consult with your local imaging expert to establish the optimal radiographic parameters (e.g., kVp, mAs) for visualization with the imaging equipment."
- "Avoid cutting the patties because fragments without x-ray detectable material may enter the surgical site. Fragments left in the surgical site may result in an unintended adverse reaction."
- "The locator string will not be visible by x-ray as it is not radiopaque. Avoid using the locator strings to remove the patties from the surgical site to prevent detachment."
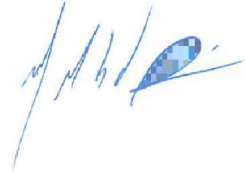
Action:
Read this Product Labeling Update carefully and communicate the precautions to the other users and concerned parties, including X Ray technicians, in your facility.

The Competent Authority of your country has been notified of this action.

Medtronic

We are committed to patient safety and appreciate your prompt attention to this matter. Please do not hesitate to contact your Medtronic representative Tarek Baasiri at00966550606933 if you have any questions regarding the content of this letter.

Sincerely,

Mohammed El Ansari
Sr. BU Manager Restorative therapy group

Appendix A: model numbers of Neuray Neurosurgical Patties and Strips and Merocel Neurosurgical Patties and Packing

Product	CFN	Description
Neuray Neurosurgical Patties and Strips	8003097	PACKING 8003097 NEURAY 200PK 7X38MM
	8003098	PACKING 8003098 NEURAY 200PK 7X76MM
	8003099	PACKING 8003099 NEURAY 200PK 7X7MM
	8004000	PACKING 8004000 NEURAY 200PK 13X13MM
	8004001	PACKING 8004001 NEURAY 200PK 19X19MM
	8004002	PACKING 8004002 NEURAY 200PK 13X25MM
	8004003	PACKING 8004003 NEURAY 200PK 25X25MM
	8004004	PACKING 8004004 NEURAY 200PK 13X38MM
	8004005	PACKING 8004005 NEURAY 200PK 38X38MM
	8004006	PACKING 8004006 NEURAY 200PK 13X51MM
	8004007	PACKING 8004007 NEURAY 200PK 13X76MM
	8004008	PACKING 8004008 NEURAY 200PK 25X76MM
	8004009	PACKING 8004009 NEURAY 200PK 76X76MM
	8004050	PACKING 8004050 NEURAY 200PK 7X152MM
	8004051	PACKING 8004051 NEURAY 200PK 13X152MM
	8004052	PACKING 8004052 NEURAY 200PK 19X152MM
	8004053	PACKING 8004053 NEURAY 200PK 25X152MM
	8004054	PACKING 8004054 NEURAY 200PK 38X152M
	8004055	PACKING 8004055 NEURAY 200PK 50X152MM
	8004056	PACKING 8004056 NEURAY 200PK 76X152MM
	8004057	PACKING 8004057 NEURAY 200PK 89X152MM
Merocel Neurosurgical Patties and Packing	300501	SPONGE 300501 MEROCEL 100PK 1.3 X 1.3CM
	300503	SPONGE 300503 MEROCEL 100PK 1.3 X 2.5CM
	300505	SPONGE 300505 MEROCEL 100PK 1.3 X 5.1CM
	300506	SPONGE 300506 MEROCEL 100PK 1.3 X 7.6CM
	300507	SPONGE 300507 MEROCEL 100PK 2.5 X 2.5CM
	300509	SPONGE 300509 MEROCEL 100PK 2.5 X 5.1CM
	300510	SPONGE 300510 MEROCEL 100PK 2.5 X 7.6CM
	300514	SPONGE 300514 MEROCEL 100PK 8.3 X 8.3CM
	300515	SPONGE 300515 MEROCEL 100PK .7 X 7.6CM
	400611	PACKING 400611 10PK NEUROSURGICAL