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Medtronic

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URGENT FIELD SAFETY NOTICE

Medicrea Products – Sterile Packaging Nonconformance

Recall

Affected Products (Refer to Attachment A - FCA Affected Products):					
GRANVIA-C	IMPIX ALIF	IMPIX C+	IMPIX MANTA	IMPIX S	PASS LP
IMPIX 3D	IMPIX ALIF S/A	IMPIX DLIF	IMPIX MANTA+	IMPIX TLIF	

July 2023

Medtronic Reference: FA1335

EU Manufacturer Single Registration Number (SRN): FR-MF-000001866

Dear Customer, Healthcare Professional, Risk Manager:

The purpose of this letter is to advise you that Medtronic is voluntarily recalling specific Medicrea products listed above (see also, **Attachment A - FCA Affected Products**) because the sterile packaging might not conform to Medtronic's specifications. Medicrea products are packaged within a dual-barrier sterile packaging system. Non-conforming packaging may lead to a breach of the sterile barrier. This non-conformance impacts sterile implants (interbody devices, discs, and screws) and sterile instruments for the treatment of degenerative disc disease and deformity for both cervical and thoracolumbar spine.

Issue Description:
Medtronic identified through internal investigation the potential for a product conformity issue which presents as a pinhole in either the inner or outer pouch and therefore may present a risk of compromised sterility (see Figure 1 below). The issue is not lot-specific and potentially impacts any unit from the in-scope product with remaining shelf life.

If the outermost pouch's sterile barrier is compromised, it may increase the risk of sterile field contamination which can lead to infection and therefore may require further medical intervention.

Figure1: Photos of pinhole leaks identified in sterile barrier (circled in marker)

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Historical complaint data was evaluated up to 22-JUN-2023. Based on this evaluation, Medtronic has identified one (1) report that was potentially associated with this issue. However, there is insufficient information in the complaint record to determine if that reported packaging issue can be attributed to the same root cause as the packaging nonconformances at issue in this Field Corrective Action. There was no indication that the device was implanted and there was no reported harm associated with the event.

There are no actions required for patients where the affected products were used during a procedure and patients are asymptomatic. If a patient develops signs or symptoms of infection, the possibility of an infection related to contamination of the affected products should be considered and evaluated. It is the responsibility of the surgeon or healthcare professional to consider how patients treated with these medical devices should be informed.

Product Scope:
Products with a manufacture date before 17-MAR-2023 are impacted. Refer to the attached **Attachment A - FCA Affected Products** for impacted product part numbers and descriptions.

Required Actions:
Our records show that your facility has received the impacted product. Medtronic requests that you immediately take the following actions:

- Identify and quarantine any unused impacted product(s). Refer to the attached ***Attachment A - FCA Affected Products*** for impacted products.
- Return all unused and non-expired product(s) in your inventory to Medtronic following the instructions in the enclosed Customer Confirmation Form. Your Medtronic Sales Representative can assist in returning any affected consignment and loaner inventory, if applicable.
- Complete the Customer Confirmation Form enclosed with this letter (even if you have no product to return), acknowledging that you have received this information.
- This notice should be distributed to all others in your organization who should be aware, or to any organization where the potentially affected devices have been transferred. Please maintain a copy of this notice in your records.

Additional Information:
Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic Representative.

Sincerely,
Medtronic GmbH

Enclosures:
Attachment A: FCA Affected Products
Distributor´s Confirmation Form

Attachement FCA affected model numbers

Product Group	Model Number	Name	GMDN	Class
GRANVIA-C	A13111427	TRIAL KIT FOR GRANVIA-C MEDIUM	58927	IIA
GRANVIA-C	A13112567	TRIAL KIT FOR GRANVIA-C MEDIUM	58927	IIA
GRANVIA-C	A13113456	TRIAL KIT FOR GRANVIA-C SMALL	58927	IIA
GRANVIA-C	A13131516	KIT FOR GRANVIA-C CENTRALIZER SMALL	58927	IIA
GRANVIA-C	A13131789	KIT FOR GRANVIA-C CENTRALIZER MEDIUM	58927	IIA
GRANVIA-C	A13132012	KIT FOR GRANVIA-C CENTRALIZER LARGE	58927	IIA
GRANVIA-C	B13111014	GRANVIA - C CERVICAL DISC PROSTHESIS ON HOLDER MEDIUM	48164	IIB
GRANVIA-C	B13111015	GRANVIA - C CERVICAL DISC PROSTHESIS ON HOLDER MEDIUM	48164	IIB
GRANVIA-C	B13111016	GRANVIA - C CERVICAL DISC PROSTHESIS ON HOLDER MEDIUM	48164	IIB
GRANVIA-C	B13111017	GRANVIA - C CERVICAL DISC PROSTHESIS ON HOLDER MEDIUM	48164	IIB
GRANVIA-C	B13111025	GRANVIA - C CERVICAL DISC PROSTHESIS ON HOLDER LARGE	48164	IIB
GRANVIA-C	B13111026	GRANVIA - C CERVICAL DISC PROSTHESIS ON HOLDER LARGE	48164	IIB
GRANVIA-C	B13111027	GRANVIA - C CERVICAL DISC PROSTHESIS ON HOLDER LARGE	48164	IIB
GRANVIA-C	B13111034	GRANVIA - C CERVICAL DISC PROSTHESIS ON HOLDER SMALL	48164	IIB
GRANVIA-C	B13111035	GRANVIA - C CERVICAL DISC PROSTHESIS ON HOLDER SMALL	48164	IIB
GRANVIA-C	B13111036	GRANVIA - C CERVICAL DISC PROSTHESIS ON HOLDER SMALL	48164	IIB
IMPIX ALIF	B15111209	IMPIX-ALIF	60762	IIB
IMPIX ALIF	B15111212	IMPIX-ALIF	60762	IIB
IMPIX ALIF	B15111409	IMPIX-ALIF	60762	IIB
IMPIX ALIF	B15111412	IMPIX-ALIF	60762	IIB
IMPIX ALIF S/A	B15241415	IMPIX-ALIF S/A	60762	IIB
IMPIX C+	B20240104	PRE-FILLED IMPIX-C ON HOLDER	60762	IIB
IMPIX C+	B20240105	PRE-FILLED IMPIX-C ON HOLDER	60762	IIB
IMPIX C+	B20240106	PRE-FILLED IMPIX-C ON HOLDER	60762	IIB
IMPIX C+	B20240107	PRE-FILLED IMPIX-C ON HOLDER	60762	IIB
IMPIX C+	B20240205	PRE-FILLED IMPIX-C ON HOLDER	60762	IIB
IMPIX C+	B20240206	PRE-FILLED IMPIX-C ON HOLDER	60762	IIB
IMPIX C+	B20240207	PRE-FILLED IMPIX-C ON HOLDER	60762	IIB
IMPIX C+	B20240208	PRE-FILLED IMPIX-C ON HOLDER	60762	IIB
IMPIX DLIF	B16123509	SLIM LATERAL LUMBAR CAGE	60762	IIB
IMPIX DLIF	B16123511	SLIM LATERAL LUMBAR CAGE	60762	IIB
IMPIX DLIF	B16124009	SLIM LATERAL LUMBAR CAGE	60762	IIB
IMPIX DLIF	B16124013	SLIM LATERAL LUMBAR CAGE	60762	IIB
IMPIX DLIF	B16124509	SLIM LATERAL LUMBAR CAGE	60762	IIB
IMPIX DLIF	B16124511	SLIM LATERAL LUMBAR CAGE	60762	IIB
IMPIX DLIF	B16124513	SLIM LATERAL LUMBAR CAGE	60762	IIB
IMPIX DLIF	B16164009	IMPIX-DLIF LUMBAR CAGE	60762	IIB
IMPIX DLIF	B16164013	IMPIX-DLIF LUMBAR CAGE	60762	IIB
IMPIX DLIF	B16165009	IMPIX-DLIF LUMBAR CAGE	60762	IIB
IMPIX DLIF	B16165013	IMPIX-DLIF LUMBAR CAGE	60762	IIB
IMPIX MANTA	A20150407	TRIAL KIT FOR IMPIX-MANTA SMALL	58927	IIA
IMPIX MANTA	A20250407	TRIAL KIT FOR IMPIX-MANTA MEDIUM	58927	IIA
IMPIX MANTA	A20350567	TRIAL KIT FOR IMPIX-MANTA LARGE	58927	IIA
IMPIX MANTA	B20181743	IMPIX-MANTA ON HOLDER SMALL	60762	IIB
IMPIX MANTA	B20181753	IMPIX-MANTA ON HOLDER SMALL	60762	IIB
IMPIX MANTA	B20181763	IMPIX-MANTA ON HOLDER SMALL	60762	IIB
IMPIX MANTA	B20181773	IMPIX-MANTA ON HOLDER SMALL	60762	IIB
IMPIX MANTA	B20181943	IMPIX-MANTA ON HOLDER MEDIUM	60762	IIB
IMPIX MANTA	B20181953	IMPIX-MANTA ON HOLDER MEDIUM	60762	IIB
IMPIX MANTA	B20181963	IMPIX-MANTA ON HOLDER MEDIUM	60762	IIB
IMPIX MANTA	B20181973	IMPIX-MANTA ON HOLDER MEDIUM	60762	IIB
IMPIX MANTA	B20182253	IMPIX-MANTA ON HOLDER LARGE	60762	IIB
IMPIX MANTA	B20182263	IMPIX-MANTA ON HOLDER LARGE	60762	IIB
IMPIX MANTA+	B20171743	PRE-FILLED IMPIX-MANTA ON HOLDER SMALL	60762	IIB

IMPIX MANTA+	B20171753	PRE-FILLED IMPIX-MANTA ON HOLDER SMALL	60762	IIB
IMPIX MANTA+	B20171763	PRE-FILLED IMPIX-MANTA ON HOLDER SMALL	60762	IIB
IMPIX MANTA+	B20171773	PRE-FILLED IMPIX-MANTA ON HOLDER SMALL	60762	IIB
IMPIX MANTA+	B20171943	PRE-FILLED IMPIX-MANTA ON HOLDER MEDIUM	60762	IIB
IMPIX MANTA+	B20171953	PRE-FILLED IMPIX-MANTA ON HOLDER MEDIUM	60762	IIB
IMPIX MANTA+	B20171963	PRE-FILLED IMPIX-MANTA ON HOLDER MEDIUM	60762	IIB
IMPIX MANTA+	B20171973	PRE-FILLED IMPIX-MANTA ON HOLDER MEDIUM	60762	IIB
IMPIX MANTA+	B20172253	PRE-FILLED IMPIX-MANTA ON HOLDER LARGE	60762	IIB
IMPIX MANTA+	B20172263	PRE-FILLED IMPIX-MANTA ON HOLDER LARGE	60762	IIB
IMPIX MANTA+	B20172273	PRE-FILLED IMPIX-MANTA ON HOLDER LARGE	60762	IIB
IMPIX S	B15328071S	Ti OBLIQUE TLIF LUMBAR CAGE	38161	IIB
IMPIX S	B15328073S	Ti OBLIQUE TLIF LUMBAR CAGE	38161	IIB
IMPIX S	B15328074S	Ti OBLIQUE TLIF LUMBAR CAGE	38161	IIB
IMPIX S	B15334072S	Ti OBLIQUE TLIF LUMBAR CAGE	38161	IIB
IMPIX S	B15334073S	Ti OBLIQUE TLIF LUMBAR CAGE	38161	IIB
IMPIX S	B15334074S	Ti OBLIQUE TLIF LUMBAR CAGE	38161	IIB
IMPIX TLIF	B15130607S	IMPIX-TLIF LUMBAR CAGE	60762	IIB
IMPIX TLIF	B15130609S	IMPIX-TLIF LUMBAR CAGE	60762	IIB
IMPIX TLIF	B15130611S	IMPIX-TLIF LUMBAR CAGE	60762	IIB
IMPIX TLIF	B15130613S	IMPIX-TLIF LUMBAR CAGE	60762	IIB
IMPIX TLIF	B15130615S	IMPIX-TLIF LUMBAR CAGE	60762	IIB
IMPIX TLIF	B15900806	LUMBAR TLIF CAGE	60762	IIB
IMPIX TLIF	B15900906	LUMBAR TLIF CAGE	60762	IIB
IMPIX TLIF	B15901006	LUMBAR TLIF CAGE	60762	IIB
IMPIX TLIF	B15901106	LUMBAR TLIF CAGE	60762	IIB
IMPIX TLIF	B15901206	LUMBAR TLIF CAGE	60762	IIB
IMPIX TLIF	B15901306	LUMBAR TLIF CAGE	60762	IIB
PASS LP	B02315535Z	SHORT POST PEDICLE SCREW	61324	IIB
PASS LP	B02315540Z	SHORT POST PEDICLE SCREW	61324	IIB
PASS LP	B02315545Z	SHORT POST PEDICLE SCREW	61324	IIB
PASS LP	B02315550Z	SHORT POST PEDICLE SCREW	61324	IIB
PASS LP	B02316535Z	SHORT POST PEDICLE SCREW	61324	IIB
PASS LP	B02316540Z	SHORT POST PEDICLE SCREW	61324	IIB
PASS LP	B02316545Z	SHORT POST PEDICLE SCREW	61324	IIB
PASS LP	B02316550Z	SHORT POST PEDICLE SCREW	61324	IIB
PASS LP	B02317540Z	SHORT POST PEDICLE SCREW	61324	IIB
PASS LP	B02317545Z	SHORT POST PEDICLE SCREW	61324	IIB
PASS LP	B02317550Z	SHORT POST PEDICLE SCREW	61324	IIB