Medtronic
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Urgent Medical Device Correction
Catalyft™ PL & PL40 Expandable Interbody System
Cage Loss of Lordosis
(Update to IFU and Surgical Technique Guide)

September 2025

Dear Risk Manager,

The purpose of this letter is to provide information related to Medtronic's Catalyft™ PL & PL40 expandable interbody system and reports of loss of lordosis, which may also be described as *loss of height* or *collapse*. This notification is to inform you of the potential for loss of lordosis and ensure that you are aware of updates that Medtronic is making to the surgical technique and the addition of certain adverse events to the instructions for use (IFU). The associated products are listed in Table 1 and loaner sets are identified in Table 2.

The Catalyft™ PL & PL40 implant is designed to be inserted into the disc space in a closed position, then expanded to the desired lordosis as an adjunct to fusion procedures. These implants have either an inline straight tip, which is known as the "PL" implant, or a hockey stick-shaped tip, which is known as the "PL40" implant.

Issue Description:
Medtronic has evaluated reports of post implantation loss of lordosis. While loss of implant lordosis and/or subsidence is a known risk associated with expandable interbody implants, Medtronic's investigation has identified labeling updates that can further mitigate this risk for loss of lordosis to occur. Medtronic has confirmed that the Catalyft™ PL & PL40 expandable interbody system meets its design and manufacturing specifications and can continue to be used.

Potential Health Hazard:
The majority of complaints reporting Catalyft™ PL & PL40 loss of lordosis received by Medtronic were asymptomatic findings detected on routine post operative imaging. Associated with reports of loss of lordosis, some patients have had revision surgery due to pain or pseudoarthrosis. The use of a Catalyft™ PL & PL40 expandable interbody system without following the device's IFU and surgical technique could result in potential adverse events such as loss of lordosis, migration, subsidence and/or neurological injury.

Labeling Updates
Instructions (IFU) Guide
The potential for loss of lordosis and subsidence associated with Catalyft™ PL & PL40 is being added to the Adverse Events section of the IFU.

Surgical Technique Guide

The following are a summary of the updates to the surgical technique guide that can help reduce the potential for loss of lordosis:

- The Catalyft™ PL & PL40 device is designed to be placed anteriorly in the disc space, with the anterior tip of the device sitting on the anterior apophyseal ring.
- The Catalyft™ PL & PL40 is designed to be under compression in situ. Ensure proper loading and optimal endplate surface contact by:
    - Applying adequate torque while expanding the implant so that ideally the torque handle clicks.
    - If the cage has been expanded to the surgeon's desired lordosis without the torque handle clicking, posterior compression should be performed to maximize endplate engagement and implant loading. Fluoroscopy confirmation is recommended to confirm that the final implant lordosis matches the patient's segmental lordosis.
- The cage size should be maximized to ensure endplate engagement and cage loading. (e.g. if a 9 mm trial/shaver fits into the disc space, then a 9 mm device should be used.)
- The Inserter should be stabilized using gentle downward pressure during implant expansion to maintain the desired final implant placement.
- After the cage is placed and expanded, posterior compression should be applied using compressors or capped rods to achieve lordosis and maximize the amount of bony endplate contact along the length of the device.
- After posterior compression, additional torque may be applied to further expand the cage for maximum endplate contact.
- Confirm device position and endplate alignment with intra-operative imaging.

Customer Actions:

- Share this notification within your facility with clinical users of the Catalyft™ PL & PL40 system.
- Complete the enclosed Customer Acknowledgement Form. When complete please return the form to neuro.quality@medtronic.com.

Medtronic Actions:
Medtronic is updating the Surgical Technique Guide and Instruction for Use.

Patient Management Recommendations:

The Catalyft™ PL & PL40 expandable interbody system should be selected only for patients meeting the criteria described in the product's indications.

For patients already implanted with Catalyft PL or PL40 devices, no additional actions are needed beyond standard post operative management to ensure normal healing and fusion. If a device is found to have a loss of lordosis, the patient's overall medical condition should be considered in determining the course of care.

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Associated Products:

Table 1: Product List (Affected Geographies: Americas, APAC, EMEA)

CFN	Material/ UPN	Material Description
6068073	00763000246693 00763000529567	SPACER 6068073 CATALYFT PL SHORT 7MM
6068076	00763000246709 00763000529574	SPACER 6068076 CATALYFT PL LONG 7MM
6068093	00763000246723 00763000529581	SPACER 6068093 CATALYFT PL SHORT 9MM
6068096	00763000246730 00763000529598	SPACER 6068096 CATALYFT PL LONG 9MM
6068113	00763000246754 00763000529604	SPACER 6068113 CATALYFT PL SHORT 11MM
6068116	00763000246761 00763000529611	SPACER 6068116 CATALYFT PL LONG 11MM
6069073	00763000246785 00763000868963	SPACER 6069073 CATALYFT PL40 SHORT 7MM
6069076	00763000246792 00763000529628	SPACER 6069076 CATALYFT PL40 LONG 7MM
6069093	00763000246815 00763000868970	SPACER 6069093 CATALYFT PL40 SHORT 9MM
6069096	00763000246822 00763000529635	SPACER 6069096 CATALYFT PL40 LONG 9MM
6069113	00763000246846 00763000868987	SPACER 6069113 CATALYFT PL40 SHORT 11MM
6069116	00763000246853 00763000529642	SPACER 6069116 CATALYFT PL40 LONG 11MM

Table 2: Loaner Sets and affected Distribution Geography

Loaner Set	Description	Distribution Geography
SPS03143	CATALYFT PL IMPLANT SET	USA
SPS03144	CATALYFT PL 40 IMPLANT SET	USA

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Additional Information:

Please maintain a copy of this notice in your records and ensure it is passed on to those who need awareness within your organization. Adverse events or quality problems experienced with this product should be reported to Medtronic and the FDA MedWatch Adverse Event Reporting program via:

- Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm
- FDA telephone at 1-800-FDA-1088 (1-800-332-1088)

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 sales representative.

Sincerely,

Alison Webster
VP Quality, Medtronic Cranial and Spinal Technologies