Medtronic

Urgent Field Safety Notice

Braive™ Break-off Set Screw

Product Code: 777501000

Recall

April 2021

Medtronic Reference FA973

Dear Customer,

Medtronic is voluntarily recalling two lots of the Braive™ Break off Set Screw that are impacted by a thread profile defect due to a manufacturing issue. Please review the information contained in this letter, quarantine any affected product in your inventory for return and replacement by Medtronic, and sign and return the customer confirmation form included with this letter.

Issue Description:

Medtronic has identified a thread profile defect that can result in difficulty engaging and tightening the Braive™ break-off set screws used with the Braive™ Growth Modulation System. This issue is limited to the following two lots of set screws, which may be in loaner kits.

Product Name	Product Number	Lot Number
Braive™ Break off Set Screw	777501000	CT20L012
Braive™ Break off Set Screw	777501000	CT20L020

Potential Health Hazard:

The defect with the thread profile can result in difficulty engaging and tightening the set screw into the Fixed Angle Screw (FAS). This difficulty tightening the set screw could result in increased surgical time.

Testing is currently ongoing to determine if any long-term system impact may result from this issue. If testing indicates a potential impact to system performance or patient safety, Medtronic will provide a follow-up communication within the next two months with relevant information and any patient management recommendations as necessary.

Medtronic reports indicate intraoperative delays have occurred due to this issue. As of the date of this letter, no reports of additional patient injury, beyond increased surgical time, have been attributed to this issue.

Required Actions:

1) Identify, segregate, and quarantine any impacted product (listed above) within your inventory.
2) Return the impacted product to Medtronic. Your Medtronic Sales Representative can assist in facilitating the return of product as necessary.
3) Please maintain a copy of this notice in your records.
4) Please share this communication within your organization, with other organizations where affected devices have been transferred, and any other associated organizations that may be impacted by this action.

Additional Information:

The Competent Authority of your country has been notified of this action. If you have any questions, please contact your Medtronic representative.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter.

Sincerely,

Medtronic