Medtronic

Urgent Field Safety Notice

VERTEX SELECT® MULTI AXIAL SCREW (MAS)
Model 6958838 lot H5517628
Recall

April 2020

Medtronic reference: FA910

Dear Healthcare Professional,

The purpose of this letter is to inform you that Medtronic is voluntarily retrieving a specific lot of product code 6958838 of VERTEX SELECT® MULTI AXIAL SCREW (MAS), see below table. Our records show that this product has been received by your facility.

Product Information		
Product Name	**Product Number**	**Lot Number**
VERTEX SELECT® 4.0 X 38MM MULTI AXIAL SCREW	6958838	H5517628

Issue Description
Medtronic has been made aware of a potential mislabeled or misrepresented product overall length of the VERTEX SELECT® MAS. The screw may be undersized. The VERTEX SELECT® MAS, product number 6958838, was determined to be incorrectly assembled with a shorter bone screw component. The VERTEX SELECT® 4.0 X 38MM MAS specifies a 38MM length screw when the actual screw length aligns with 34MM screw length requirements.

The risk associated of an undersized screw related to this issue could result in reduced stability of the construct. If the undersized condition is discovered pre-operatively or intraoperatively, a minor adjustment to surgery due to location of placement may result in surgical delay. Long term harm may include potential construct failure resulting in revision surgery; however, this risk is likely low and is mitigated by following the surgical technique for this product system.

The surgical technique identifies correct screw lengths and multiple checks to select, identify and confirm the screw size prior to implanting the screw. Additionally, screw length measuring instruments should be used such as a Pedicle Feeler Probe or Depth Gauge. Also, the risk is further mitigated by the use of an imaging system to facilitate confirmation of screw position using radiographs or intraoperative fluoroscopy.

To date, Medtronic has not received any reports of patient harm attributed to this issue. If you have already implanted products affected by this recall, we recommend you monitor the patient according to the standard hospital or clinician protocol in lieu of the previously communicated potential adverse events.

Actions
- Identify and quarantine all unused affected products in your inventory.
- Return all unused affected products in your inventory to Medtronic. Your Medtronic Representative can assist you in the return and replacement of this product as necessary.
- This notice needs to be forwarded to all those who need to be aware within your organization and to any organization where the affected product may have been transferred. Please maintain a copy of this notice in your records.

The Competent Authority of your country has been notified 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, please contact your Medtronic Representative.

Sincerely,

Local / BU Manager