Medtronic

Urgent Field Safety Notice

Medtronic Navigated Solera Screwdrivers

Potential for Instrument Tip Breaking

Updated Instructions For Use

22 September 2015

Medtronic reference: FA674

Dear valued Customer,

This letter is to notify you of the potential for the Navigated Solera Screwdriver tips to break during use and the change to the instructions for use to assist with this issue. This field correction notification impacts products sold by both Medtronic Navigation and Medtronic Spinal and Biologics

Description of the issue:

These screwdrivers are reusable devices which were designed for the placement of screws during spinal procedures. Complaints have been received related to broken, bent or damaged screwdriver tips. The screwdriver tip breaking could result in the extension of the surgery due to the need to find a replacement screwdriver and potentially require extraction of the broken tip from the screw to complete the insertion, or the removal of the tip from the patient.

Under certain use conditions, the torque required to fully seat a pedicle screw may be higher than the screwdriver tip can withstand. Those conditions include:

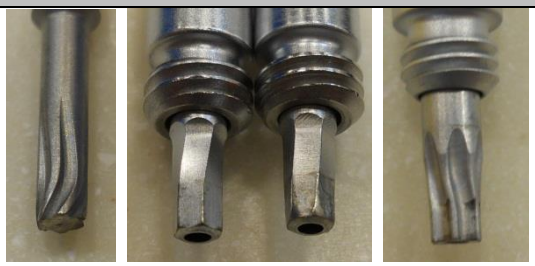
- The hole for the screw not drilled to the proper diameter
- The hole for the screw not tapped adequately, either in the diameter or the length
- Dense bone
- Large diameter screws

Therefore, we are modifying the instructions for use for the navigated screwdrivers to add additional warnings related to the careful inspection of the instruments regularly for damage and the importance of knowledge of the operating procedures, patient selection, and product information. A copy of the updated instructions for use will be sent to you.

Please assure that this information is provided to the personnel within your facility that perform spinal surgeries and also those individuals responsible for cleaning and sterilization of these devices.

The possibility of the driver tip breaking can be increased by the use of an already damaged screwdriver. Although the inspection instructions provided in the instructions for use are adequate, following are some examples of conditions to look for during inspection:

Detail	Example Photo
Tip broken	

Detail	Example Photo
Tip twisted	
Distortion / Deformation	

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

At Medtronic, we are committed to continually evaluating and improving the quality and reliability of our processes, products and services. If you have further questions regarding this communication, please contact your Medtronic Navigation Representative.

Sincerely,

Country/BU manager

Appendix 1: list of affected model numbers

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Model	Description
9735023	DRIVER 9735023 SOLERA 5.5/6.0 MAS
9735024	DRIVER 9735024 SOLERA 5.5/6.0 MAS CAN
9735025	DRIVER 9735025 SOLERA 5.5/6.0 RMAS
9735026	DRIVER 9735026 SOLERA 5.5/6.0 RMAS CAN
9735027	DRIVER 9735027 SOLERA 5.5/6.0 FAS/SAS
9734856	SCREWDRIVER, 9734856, SOLERA STD MAST
9734857	SCREWDRIVER, 9734857, SOLERA RDN MAST
9734279	SCREWDRIVER 9734279 SOLERA STANDARD
9734373	SCREWDRIVER 9734373 SOLERA REDUCTION
The above screwdrivers are used in the following kits and sets sold by Medtronic Navigation:	
9735283	INST SET 9735283 SOLERA 5.5/6.0 DRIVERS
9735283-G02	INST SET 9735283 SOLERA 5.5/6.0 DRVR JP
9734632	TD SET 9734632 SOLERA STD TAPS/DRIVERS
9734647	DRVR KIT 9734647 SOLERA STD DRIVER
9734648	DRVR KIT 9734648 SOLERA REDUCTION DRVR
The following kits are sold by Medtronic Spinal and Biologics:	
9735281	INST KIT 9735281 DRIVER 5.5/6.0 MAS NCAN
9735278	INST KIT 9735278 DRIVER 5.5/6.0 MAS CAN
9735282	INST KIT 9735282 DRIVR 5.5/6.0 RMAS NCAN
9735279	INST KIT 9735279 DRIVER 5.5/6.0 RMAS CAN
9735280	INST KIT 9735280 DRIVER 5.5/6.0 FAS/SAS