



Medtronic Navigation, Inc.  
 826 Coal Creek Circle  
 Louisville, CO 80027  
 www.medtronic.com  
 tel 720.890.3200  
 fax 720.890.3500

May 27, 2015

**URGENT MEDICAL DEVICE CORRECTION NOTIFICATION**  
**Potential for User Injury – Medtronic Navigated Cannulated Taps**

Dear Valued Customer,

At Medtronic, we are committed to continually evaluating and improving the quality and reliability of our processes, products and services. This letter is to notify you of the potential for injury which could occur as a result of cleaning the Medtronic Cannulated Taps.

The following products are covered by this correction notification:

P/N	Description
9734240	Nav 6.5mm Tap (Cannulated)
9734239	Nav 5.5mm Tap (Cannulated)
9734238	Nav 4.5mm Tap (Cannulated)
9734302	6.5mm Tap (Cannulated)
9734300	5.5mm Tap (Cannulated)
9734298	4.5mm Tap (Cannulated)
9734303	7.5mm Tap (Cannulated)
9734301	6.0mm Tap (Cannulated)
9734299	5.0mm Tap (Cannulated)
9734304	8.5mm Tap (Cannulated)
9730944	4.5 mm Cannulated Tap
9730945	5.5 mm Cannulated Tap
9730946	6.5 mm Cannulated Tap
9733182	4.0 mm Cannulated Tap, 1.86P
9733183	4.5 mm Cannulated Tap
9733184	4 mm Cannulated Tap, 1.5P, UCSS
960-347	7.5 Old Round APT (Cannulated Tap-Tip only)
960-345	6.5 Old Round APT (Cannulated Tap-Tip only)
960-344	5.5 Old Round APT (Cannulated Tap-Tip only)
<b>The above cannulated taps are used in the following kits and sets</b>	
9731921	KIT 9731921 INSTRUMENT SPINE BASIC
9735101	INST KIT 9735101 TAP ASM 4.5 G5
9735102	INST KIT 9735102 TAP ASM 5.5 G5
9735103	INST KIT 9735103 TAP ASM 6.5 G5
9735107	INST KIT 9735107 TAP ASM 5.0 G5
9735108	INST KIT 9735108 TAP ASM 6.0 G5

9735109	INST KIT 9735109 TAP ASM 7.5 G5
9735149	INST KIT 9735149 CANNULATED 6.5MM TAP
9735150	INST KIT 9735150 CANNULATED 5.5MM TAP
9735151	INST KIT 9735151 CANNULATED 4.5MM TAP
9735168	INST KIT 9735168 4MM TAP 1.86P
9735169	INST KIT 9735169 4.5MM CANN TAP
9735170	INST KIT 9735170 4MM TAP 1.5P
9734490	INST SET 9734490 LEGACY
9734491	INST SET 9734491 SOLERA STD
9734492	INST SET 9734492 SOLERA DEF UPGRADE
9735469	TAPS 9735469 CD HORIZON SOLERA
9734631	TD SET 9734631 LEGACY STD TAPS/DRIVERS
9734632	TD SET 9734632 SOLERA STD TAPS/DRIVERS
9733370	VERTEX MAX SET, 9733370, NAVIGATED
9734838	KIT 9734838 SOLERA 8.5 CANNULATED TAP

**Description of the issue:**

These taps are reusable devices which were designed for preparing holes for screw placement during spinal procedures. Cannulated taps have the potential to accumulate bone and other tissue in the cannula. Use without a guide wire can increase this possibility. We have received reports of user injuries occurring during the cleaning process of cannulated taps that have bone material in the cannula of the devices.

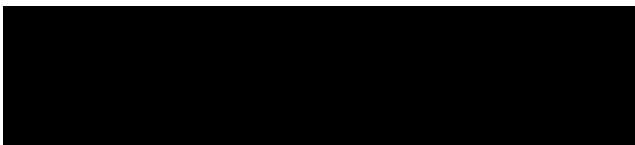
Therefore, we are modifying the instructions for use for the cannulated taps to clearly detail the potential for bone/tissue accumulation in the cannula of the devices if they are used without a guide wire and to caution the user during the cleaning process. If the obstruction in the cannula cannot be removed, the instructions for use indicate that the devices should be considered at the end of their useful life and should be discarded in accordance with your facility procedures and guidelines. Included with this notification is a copy of the revised instructions for use for your review and reference.

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.

Medtronic also offers non-cannulated taps for spinal procedures for those surgeons who may be interested in this option.

If you have further questions regarding this communication, please contact your local Medtronic Navigation Technical Services Representative or call 1-800-595-9709.

Sincerely,



Michael Blasco  
Senior Regulatory Affairs Manager  
Medtronic Navigation

Attachments