



Medtronic[®]

Medtronic Ireland Ltd
Unit GA,
Swords Business Campus,
Balheary Road, Swords
Co. Dublin
Tel. 353 1 511 1400
Fax 353 1 872 2077
vat IE 9513488W

Urgent Field Safety Notice

Medtronic Navigation Cannulated Taps Updated Instructions For Use

May 2015

Medtronic reference: FA650

Dear valued Customer,

You are receiving this communication because our records indicate you have received one or more Medtronic Navigation Cannulated Taps. This letter is to notify you of the potential for injury which could occur as a result of cleaning these devices. Please see appendix 1 for the model numbers that are affected by this notification.

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. A copy of the updated instructions for use will be sent to you within the next 2 months.

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 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 Sales Representative directly or via Customer Service Department Tel no: 353 1 511 1400.

Sincerely,

Regulatory Affairs Manager UK & Ireland



Medtronic

Medtronic Ireland Ltd
Unit GA,
Swords Business Campus,
Balheary Road, Swords
Co. Dublin
Tel. 353 1 511 1400
Fax 353 1 872 2077
vat IE 9513488W

Appendix 1: list of affected model numbers

Appendix 1: list of affected model numbers

| Model Number | 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) |

| The above referenced cannulated taps are included in the kits and sets listed below. | |
|---|--|
| 963-720 | INST 963-720 APT SET FN |
| 9730262 | INST 9730262 SET, PASSIVE APT |
| 9731426 | INSTRUMENT SET, 9731426 NAVIGATED LUMBAR |
| 9731921 | KIT 9731921 INSTRUMENT SPINE BASIC |
| 9732733 | PACKAGE, 9732733, SYNERGY NEW USER |
| 9733370 | VERTEX MAX SET, 9733370, NAVIGATED |
| 9734490 | INST SET 9734490 LEGACY |
| 9734491 | INST SET 9734491 SOLERA STD |
| 9734492 | INST SET 9734492 SOLERA DEF UPGRADE |
| 9734520 | INST KIT 9734520 NAVLOCK LGY BASIC SPINE |
| 9734625 | INST KIT 9734625 NAVLOCK LGY BASIC SPINE |



Medtronic[®]

Medtronic Ireland Ltd
Unit GA,
Swords Business Campus,
Balheary Road, Swords
Co. Dublin
Tel. 353 1 511 1400
Fax 353 1 872 2077
vat IE 9513488W

| | |
|---------|--|
| 9734631 | TD SET 9734631 LEGACY STD TAPS/DRIVERS |
| 9734632 | TD SET 9734632 SOLERA STD TAPS/DRIVERS |
| 9734838 | KIT 9734838 SOLERA 8.5 CANNULATED TAP |
| 9734901 | INST KIT 9734901 UNV NVLCK LGY BSC SPINE |
| 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 |
| 9735469 | TAPS 9735469 CD HORIZON SOLERA |