



Medtronic[®]

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Medtronic Navigation Cannulated Taps
Release of Updated Instructions For Use

August 2015

Medtronic reference: FA650 Phase II

Dear valued Customer,

In May 2015 you were notified that Medtronic was in the process of updating the Instructions For Use of the Medtronic Navigation Cannulated Taps because these devices have the potential to accumulate bone and other tissue in the cannula especially when used without a guide wire.

As a follow up to the May 2015 communication, Medtronic is now distributing the updated Instructions For Use for the model numbers listed in appendix 1 to all users of these devices.

Please ensure that the updated Instructions For Use are provided to the personnel within your facility that perform spinal surgeries and also those individuals responsible for cleaning and sterilization of these devices.

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.

Sincerely,

Keith Taverner
Regulatory Affairs Manager UK & Ireland

- Appendix 1: list of affected model numbers
- Appendix 2: APT Tips IFU in local language
- Appendix 3: Navigated Vertex Max Drill Set IFU in local language
- Appendix 4: NavLock™ Tracker Instruments IFU in local language



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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



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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