

URGENT FIELD SAFETY NOTICE

Screw Module used with the ATLANTIS® and Premier Anterior Cervical Plate Systems Serial Numbers Affected: 176-503, 176-504, and 1860503, All Lots

Medtronic Reference: FA545

August 2012

Dear Hospital Administrator, OR Manager, and Risk Manager

This letter is to inform you that we are recalling the Screw Module (“Screw Caddy”) used with the ATLANTIS® Anterior Cervical Plate System and the Premier Anterior Cervical Plate System, part numbers 176-504, 176-503, and 1860503.

The Screw Caddy is not an implant. It is a polymer block used to hold screws for spinal surgery. It was discovered that the measurement gauge located on the lower corner of the caddy may be out of specification, which could cause a screw to be measured improperly. An incorrect gauge could measure a screw to be approximately 1mm shorter than its actual length.

No patient injuries have been reported to date. However, using an inappropriately long screw could cause irreversible neurologic injury if it penetrated the vertebral body.

A replacement Screw Caddy will be provided to you. In the meantime, you can confirm the length of ATLANTIS® or Premier Screws by referencing the chart below by Part Number:

PREMIER®	ATLANTIS®	ATLANTIS®	Implant Size	PREMIER®	ATLANTIS®	ATLANTIS®	Implant Size
6860010	876-010	876-310	4.0mm x 10mm	6860017	876-017	876-317	4.0mm x 17mm
6860011	876-011	876-311	4.0mm x 11mm	6860018	876-018	876-318	4.0mm x 18mm
6860012	876-012	876-312	4.0mm x 12mm	6860019	876-019	876-319	4.0mm x 19mm
6860013	876-013	876-313	4.0mm x 13mm	6860020	876-020	876-320	4.0mm x 20mm
6860014	876-014	876-314	4.0mm x 14mm	6860053	876-053	876-353	4.5mm x 13mm
6860015	876-015	876-315	4.0mm x 15mm	6860055	876-055	876-355	4.5mm x 15mm
6860016	876-016	876-316	4.0mm x 16mm	6860057	876-057	876-357	4.5mm x 17mm

If they have not already done so, your Sales Representative will be contacting you to facilitate the return of any Screw Caddies you may have. Please disseminate this information to additional personnel within your facility as appropriate.

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

We sincerely apologize for this inconvenience. If you need assistance, or if you have any related questions or concerns, please do not hesitate to contact your Medtronic Sales Representative (**insert local contact number**). We apologize for this inconvenience, but this action is necessary to assure that our high standard of quality is maintained.

Sincerely,