



Montbonnot, 28 January 2020

## FIELD SAFETY NOTICE

Subject: **Aequalis Ascend Flex Humeral Stems**

Ref.: FA-WMG-2019-005 (Update for action)

Devices concerned: See Attachment A for full listing.

Dear Sir or Madam,

As you know, following the Field Safety Notice you received last November communicated by Tornier, small amounts of PETG packaging debris have been identified on a very limited number of Aequalis Ascend Flex humeral stems.

The Field Safety Notice issued by Tornier in November 2019 recommended to examine the stem for potential PETG packaging debris upon removal from its packaging. Stems that have white film or particles of packaging debris should not be implanted. Those could be returned to Wright Medical for a replacement. We also recommended that back up stems be available during surgery in the event a stem with packaging debris is found, so that replacing the stem with a new stem that does not have PETG packaging debris will not lengthen operating time.

We have clearly identified the origins of the debris and have carried out testing to confirm that there is no safety concern. Preliminary review of those results suggests that the Aequalis Ascend Flex humeral stems are safe for patients. However, while the results of these tests are being further analyzed, as a precautionary measure and although no safety concerns have been reported in this regard in Switzerland, Swissmedic, Swiss Agency for Therapeutic Products has asked Wright Medical / Tornier to comply with a request for **suspension of implantations of Aequalis Ascend Flex humeral stems** in Switzerland.

We will of course inform you as soon as possible, once the additional tests have been completed, of the follow-up to be given both for resuming implantations and if necessary for monitoring implanted patients.

If you have any questions, please contact Maud Andriollo: [maud.andriollo@wright.com](mailto:maud.andriollo@wright.com)

**Maud ANDRIOLLO**  
Vigilance Representative

## **Acknowledgement of receipt**

**FA-WMG-209-005 (Update for action) – Field Safety Notice of 28 January 2020**

Please complete this acknowledgment of receipt and return it within **7 days**  
to [Field-Action@wright.com](mailto:Field-Action@wright.com)

Hospital / Company's name: .....

NAME: .....

Function: .....

Address: .....

Phone number: .....

I hereby confirm that I have received the Field Safety Notice from Tornier relating to this action regarding the Aequalis Ascend Flex stems and have distributed it to whom it may concern.

Date: .....

Signature: .....

**Attachment A:**  
**List of affected Products**

Product Description	Catalog Numbers
Standard PTC Humeral stem	DWF601A
	DWF601B
	DWF601C
	DWF602A
	DWF602B
	DWF602C
	DWF603A
	DWF603B
	DWF603C
	DWF604A
	DWF604B
	DWF604C
	DWF605A
	DWF605B
	DWF605C
	DWF606A
	DWF606B
	DWF606C
	DWF607A
	DWF607B
	DWF607C
	DWF608A
	DWF608B
	DWF608C
	DWF609A
	DWF609B
	DWF609C
Long PTC Humeral stem	DWF611A
	DWF611B
	DWF611C
	DWF612A
	DWF612B
	DWF612C
	DWF613A
	DWF613B
	DWF613C
	DWF614A
	DWF614B
	DWF614C
	DWF615A
	DWF615B
	DWF615C
	DWF616A
	DWF616B
	DWF616C
	DWF617A
	DWF617B
	DWF617C
	DWF618A
	DWF618B
	DWF618C

Product Description	Catalog Numbers
Long PTC Humeral stem	DWF619A
	DWF619B
	DWF619C
Standard Cemented Humeral stem	DWF702A
	DWF702B
	DWF702C
	DWF703A
	DWF703B
	DWF703C
	DWF704A
	DWF704B
	DWF704C
	DWF705A
	DWF705B
	DWF705C
	DWF706A
	DWF706B
	DWF706C
	DWF707A
	DWF707B
	DWF707C
	DWF708A
	DWF708B
	DWF708C
Long Cemented Humeral stem	DWF709A
	DWF709B
	DWF709C
	DWF712A
	DWF712B
	DWF712C
	DWF713A
	DWF713B
	DWF713C
	DWF714A
	DWF714B
	DWF714C
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	DWF719B
	DWF719C