



Montbonnot, March 17, 2020

## ADVISORY NOTICE

### **UPDATE**

Subject: **Aequalis Ascend Flex Humeral Stems**

Our/Ref.: FA-WMG-2019-005 (**UPDATE VERSION**)

Devices concerned: See Attachment A for full listing.

Dear Sir or Madam,

On December 30, 2019, based on a precautionary principle, we voluntarily decided, in cooperation with the health authorities, to suspend implantation of the Aequalis Ascend Flex humeral stems in the current packaging. We are aware of no evidence of increased risk to patients who received implants in this packaging.

We are now pleased to announce that we expect Aequalis Ascend Flex humeral stems in the new packaging to be CE marked and available for the Swiss market as early as next week.

With a view to resume implantations of the Aequalis Ascend Flex prosthesis in its new packaging as soon as possible, we are preparing to arrange the return of all Ascend Flex humeral stems available in your hospital in the current packaging in conjunction to deploying the new packaging.

#### **Actions to be taken by the user**

If any of the Ascend Flex humeral stem devices in current packaging are still in your hospital, we would ask you to complete the attached form confirming you have received this notification

Concerned Competent Authorities and Health Care providers and been informed of this action.

Our records indicate that you have received the above-mentioned products.

We will contact you to arrange return and to exchange devices concerned by this notice which are still present in your facility.

If you have any questions, please contact your local representative.

**Maud ANDRIOLLO**  
Vigilance Representative

# TORNIER



**Acknowledgement of receipt**

**FA-WMG-209-005 (Update for action) – Field Safety Notice of 16 MAR 2020**

Please complete this acknowledgement 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	Product Description	Catalog Numbers
Standard PTC Humeral stem	DWF601A	Long PTC Humeral stem	DWF619A
	DWF601B		DWF619B
	DWF601C		DWF619C
	DWF602A	Standard Cemented Humeral stem	DWF702A
	DWF602B		DWF702B
	DWF602C		DWF702C
	DWF603A		DWF703A
	DWF603B		DWF703B
	DWF603C		DWF703C
	DWF604A		DWF704A
	DWF604B		DWF704B
	DWF604C		DWF704C
	DWF605A		DWF705A
	DWF605B		DWF705B
	DWF605C		DWF705C
	DWF606A		DWF706A
	DWF606B		DWF706B
	DWF606C		DWF706C
	DWF607A		DWF707A
	DWF607B		DWF707B
DWF607C	DWF707C		
DWF608A	DWF708A		
DWF608B	DWF708B		
DWF608C	DWF708C		
DWF609A	DWF709A		
DWF609B	DWF709B		
DWF609C	DWF709C		
Long PTC Humeral stem	DWF611A	Long Cemented Humeral stem	DWF712A
	DWF611B		DWF712B
	DWF611C		DWF712C
	DWF612A		DWF713A
	DWF612B		DWF713B
	DWF612C		DWF713C
	DWF613A		DWF714A
	DWF613B		DWF714B
	DWF613C		DWF714C
	DWF614A		DWF715A
	DWF614B		DWF715B
	DWF614C		DWF715C
	DWF615A		DWF716A
	DWF615B		DWF716B
	DWF615C		DWF716C
	DWF616A		DWF717A
	DWF616B		DWF717B
	DWF616C		DWF717C
DWF617A	DWF718A		
DWF617B	DWF718B		
DWF617C	DWF718C		
DWF618A	DWF719A		

# TORNIER



	DWF618B
	DWF618C

	DWF719B
	DWF719C