

Montbonnot, December 30, 2019

ADVISORY NOTICE

Subject: **Aequalis Ascend Flex Humeral Stems**

Our/Ref.: FA-WMG-2019-005

Devices concerned: See Attachment A for full listing.

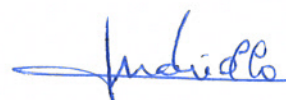
Dear Sir or Madam,

As you know, following the Safety Information you received last November, communicated in cooperation with the ANSM, small amounts of packaging debris have been identified on a very limited number of Aequalis Ascend Flex humeral stems.

We carried out a first series of tests aimed at identifying the origin of the particles. Additional tests are being carried out, on ANSM's request, to ensure that there is no safety concern. As a precautionary measure and although no complaints or safety concern have been reported in this regard, it was decided, in cooperation with the ANSM, to suspend the implantation of Aequalis Ascend Flex humeral humeral stems, pending the analysis of the results.

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 Vanessa Garroux:
vanessa.garroux@wright.com



Maud ANDRIOLLO
Vigilance Representative

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
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
Long Cemented Humeral stem	DWF708A
	DWF708B
	DWF708C
	DWF709A
	DWF709B
	DWF709C
	DWF712A
	DWF712B
	DWF712C
	DWF713A
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