

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.

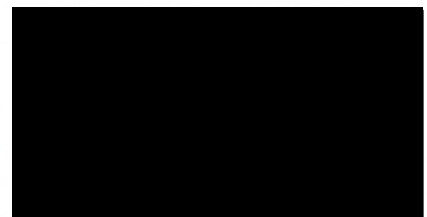
Dear Sir or Madam,

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



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
	DWF709A
	DWF709B
	DWF709C
Long Cemented Humeral stem	DWF712A
	DWF712B
	DWF712C
	DWF713A
	DWF713B
	DWF713C
	DWF714A
	DWF714B
	DWF714C
	DWF715A
	DWF715B
	DWF715C
	DWF716A
	DWF716B
	DWF716C
	DWF717A
	DWF717B
	DWF717C
	DWF718A
	DWF718B
	DWF718C
	DWF719A
	DWF719B
	DWF719C

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,

This communication is to notify you that we are initiating an Advisory Notice related to Aequalis Ascend Flex stems.

Reason for the Advisory Notice:

During shipping, it is possible for the Aequalis Ascend Flex humeral stem to become unseated or otherwise move within its internal packaging restraints. Movement within the packaging may cause the product to rub against the PETG blister shipping container causing the transfer of PETG material from the blister container to the stem. PETG material on the stem is detectable by visual inspection and will appear as a white film or white particles to the unaided eye. See Attachment A for photographs.

Potential risks for the patient:

Wright Medical is recommending that stems that have white film or particles like the photographs in Attachment A not be implanted. Such stems can be returned to Wright Medical for a replacement. Wright Medical recommends 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.

Intended Use:

The AEQUALIS ASCEND FLEX Convertible Shoulder System is intended for use as:

- A replacement of shoulder joints in primary anatomic or primary reverse.
- A replacement of other shoulder joint devices in case of revisions, if sufficient bone stock remains.
- The AEQUALIS ASCEND FLEX Convertible Shoulder System also allows for conversions from anatomic to reverse shoulder prosthesis in case of revision.

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

Actions to be taken by the user:

- Ensure backup stem product is available in the operating room or is easily accessible prior to beginning surgery.
- Visually examine the stem after removing the stem from its packaging.
- If white film or particles are seen on the stem as pictured in Attachment A, immediately remove the implant and anything it touches from the sterile field. Replace the stem with a backup stem that lacks visible white film or particles.
- If no packaging material is visible on the stem, you may proceed with the implantation procedure.
- Report the discovery of any stems with packaging material to Wright Medical.
- Distribute this Field Safety Notice to whom it may concern,
- Maintain awareness internally with respect to this Field Safety Notice,
- Inform us of any adverse event and/or report them to the Competent Authorities in accordance with current regulations and in compliance with MEDDEV 2.12-1.

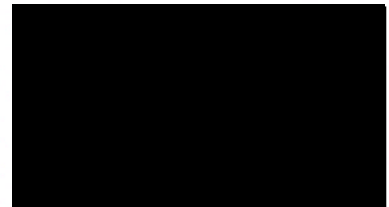
Your Health Authority has been informed of this action.

For any further information, please contact your local representative.

We are taking every measure to satisfy you and we are grateful for your understanding and cooperation.

We thank you for working with us and for your continued trust in our company.

Yours faithfully.



FA WMG 2019 005 – Advisory Notice

Acknowledgment of receipt

Please complete this acknowledgment of receipt and return it within **7 days**
to **Field-Action@wright.com**

Hospital / Company's name: _____

NAME: _____

Function: _____

Address: _____

Phone number: _____

I hereby confirm that I have received the Advisory 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:

Images of PETG Debris on Ascend Flex Stems

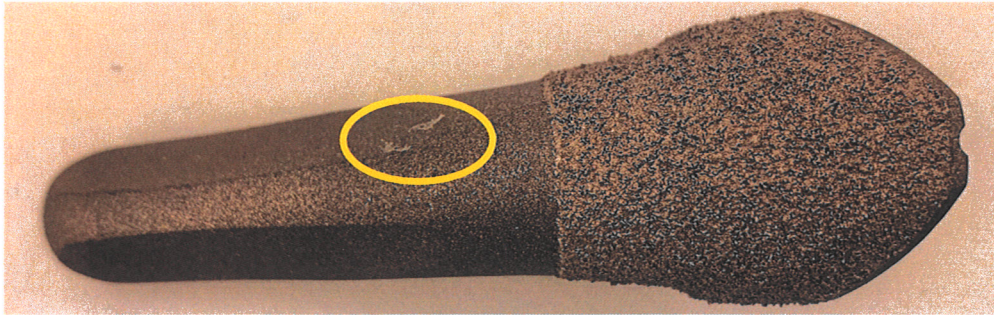


Figure 1. PETG Debris on PTC Stem (Film)

Debris appears as a film of thin, plastic flakes.



Figure 2. PETG Debris on PTC Stem (Particles)

Debris appears as small, white particles.



Figure 3. PETG Debris on Cemented Stem (Film)

Debris appears as a thin film or smudge on the stem.

Attachment B:
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
	DWF709A
	DWF709B
	DWF709C
Long Cemented Humeral stem	DWF712A
	DWF712B
	DWF712C
	DWF713A
	DWF713B
	DWF713C
	DWF714A
	DWF714B
	DWF714C
	DWF715A
	DWF715B
	DWF715C
	DWF716A
	DWF716B
	DWF716C
	DWF717A
	DWF717B
	DWF717C
	DWF718A
	DWF718B
	DWF718C
	DWF719A
	DWF719B
	DWF719C