

FIELD SAFETY NOTICE - RECALL

Subject: **FSCA – Pin guides non sterile**

Our/Ref.: FA-WMG-2019-002

Person in charge of the follow-up: **Alice SIAUD-SIMOENS –** XXXXXXXXXX

Devices concerned:

Product description	Catalog numbers	Lots
Aequalis™ Perform guide pin non sterile	MWE157	18B792
Aequalis guide pin non sterile	MWB319	18C696
Tornier Instrument non sterile	MJU093	18D493 19A141

Dear Sir or Madam,

This communication is to notify you that we are initiating a voluntary Field Safety Corrective Action related to some lots of non-sterile pin guides.

Reason for the Field Safety Notice

We have identified a potential risk of insufficient cleaning of the device. As a result, some pin guides may have (randomly) some traces of black residues

As part of our policy of continuous monitoring and transparency for our customers, and although no adverse event related to this issue has been reported to date, we would like to inform you of our preventive action.

The purpose of this notification is to provide healthcare professionals with information regarding the withdrawal of lots and the possible risks associated with the use of this device.

Since the detection of this issue, we have immediately taken actions to ensure the cleanliness of the products for the next manufacturing batches.
Only the recalled batches are affected by this issue.

Potential risks for the patient

A local inflammatory reaction limited at the implant site or adverse effects on tissues could occur in the first week following the surgery.

Since this is potential risk, and no adverse events have been reported so far to us, no additional specific action is recommended with regard to patients.

For non-implantable devices, regular post-operative follow-up after surgery is sufficient to detect a possible adverse event.

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

Actions to be taken by the user

If any of the devices are still in your hospital, we would ask you to:

- Quarantine affected devices,
- Complete the attached form by which you confirm that you have received this notification and will act in compliance,
- Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action,
- 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.

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

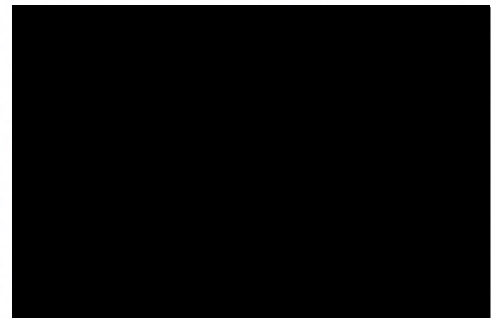
For any further information, please contact:

Product	Contact Name
Aequalis™ Perform guide pin non sterile (MWE157)	Sylvie Saint Preux sylvie.saint-preux@wright.com
Aequalis guide pin non stérile (MWB319)	Romain Huon romain.huon@wright.com
Tornier Instrument non sterile (MJU093)	Mark McMillan mark.mcmillan@wright.com

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 2018 008 – Rappel

Acknowledgment of receipt

Please complete this acknowledgment of receipt and return it within **7 days**
04.76.61.35.33 or mail to [alice.siaud-simoens @wright.com](mailto:alice.siaud-simoens@wright.com)

Hospital / Company's name: _____

NAME: _____

Function: _____

Address: _____

Phone number: _____

No Part / Batch	Reference	Name	Quantity Returned

I certify that:

- I have received from the company Tornier the notice concerning the field action # **FA-WMG-2018-008** and have released it to the involved persons.
- I have checked the presence in stock of the concerned devices and proceed to their quarantine. Thus I fill up in the above table.
- If not, I have identified in the above table the organisms where devices have been distributed.

Date: _____

Signature: _____