

Montbonnot, December 8th, 2014

FIELD SAFETY CORRECTIVE ACTION

Medical Device: **Humeral broaches Aequalis Ø 6/6.5**
Item numbers MWA025 - MWA026 - MWA027

All lots are recalled

N/Ref.: FA-TOF-2014-014

Dear Sir or Madam,

This communication is to notify you that we are initiating a voluntary Field Safety Corrective Action related to humeral broaches Aequalis Ø 6/6.5 (item numbers MWA025, MWA026 & MWA027) as a preventive action. We have identified that some of the parts could become more fragile over time resulting in breakage of humeral broaches during surgery.

Your Authority has been informed of this action.

To ensure the highest level of support to our physician customers, all parts should be returned even though scope was identified in lots manufactured before 2005. Devices can still be used until a replacement device has been provided.

Our records indicate that you have received one of the products involved. Therefore, we would ask you to complete the attached acknowledgement form (reference Acknowledgement of Receipt) by which you confirm that you have received this notification and will act in compliance.

Measures to be taken by the user

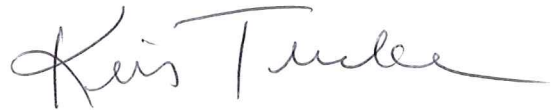
If any of the devices is still in your hospital, we would ask you to:

- Locate and return parts,
- Circulate this information to whom it may concern in the hospital,
- Inform your Tornier Representative of any adverse event and/or report it to Health Authorities as per the MEDDEV 2.12-1 rev.8 regulation.

Your Tornier Representative will contact you to arrange return and to exchange devices impacted by this notice which are still present in your facility.

We apologize for the inconvenience and thank you in advance for your cooperation in this matter.

Regards,



Kris Tucker
Sr. Director, Regulatory Affairs

Acknowledgement of Receipt

Please complete and return to your local Tornier Representative within **15 days**

Identification: FA-TOF-2014-014 – Field Safety Corrective Action - Humeral broaches Aequalis Ø 6/6.5 (Item numbers MWA025 - MWA026 - MWA027)

Hospital: _____
 NAME: _____
 Position: _____
 Address: _____

 Telephone N°: _____

Item Number	Description	Instrument set Box Number	Quantity sent back
	Humeral broaches Aequalis Ø 6/6.5		

I hereby confirm:

- Having received the Field Safety Corrective Action from Tornier relative to the field safety corrective action of humeral broaches Aequalis Ø 6/6.5 and having circulated this information to whom it may concern within the hospital.
- Having checked if any such devices are present in the instrument sets, either in my possession or within a hospital. I have completed the above table accordingly.

Date : _____

Signature : _____