TORNIER

Montbonnot, June 29, 2015

FIELD SAFETY NOTICE

Objet : **Aequalis® IM Nail Targeting Jig ref. 9020060**

Lots: All lots

(DB0114069, DB0114349, CA46096, CA216052, DB0111264001, DB0112016, DB0113102)

N/Ref. : FA-TUS-2015-003

Dear Sir or Madam,

Tornier has initiated a voluntary Field Safety Corrective Action for the Aequalis® IM Nail Targeting Jig (ref. 9020060) due to several reports that the targeting jig mast is separating from the jig boom. Any separation will impact alignment and can affect the ability to fixate the screws.

There has been no impact to a patient to-date; however, a design change to the product is necessary. Tornier has decided to exercise precautionary measures by instituting a voluntary recall to avoid any further occurrences.

Our analysis indicates that the incidence of separation occurring during a case is low (0.3%) and the ability to recognize the separation prior to using the jig to treat a patient further reduces the potential patient risk.

Until product replacement, the jig needs to be inspected prior to every case to ensure there is no visible separation (see page 3). If there is any separation during surgery, the targeting jig can still be used for all surgical steps except for targeting. For this step, we have included a Surgical Technique Addendum (ref. CAW-7939) to obtain alignment if this should be necessary.

Our representatives will work with you to ensure you understand how separation appears on the jig and are familiar with this surgical technique (see addendum) for your upcoming cases.

We will be supporting all cases from our internal inventory versus consignment to ensure that the targeting jigs are inspected between each case and those that have separation are contained. If this problem is detected on your guide, we recommend to quarantine it and to contact your representative in order to organize the provision of the replacement part.

TORNIER SAS
161, rue Lavoisier. 38334 Montbonnot Cedex. France
Tél. : 33 (0)4 76 61 35 00. Fax : 33 (0)4 76 61 35 33. www.tornier.com
SAS au capital de 35 043 008 €. SIRET 070 501 275 000 21. RCS 070 501 275. Code APE 3250 A
Siège social : 161, rue Lavoisier. 38330 Montbonnot Saint Martin. France

Concerned Competent Authorities as well as Health Care providers have been informed of this action.

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:

- Circulate this information to whom it may concern in the hospital,
- Maintain awareness of this notice internally until the return has been arranged within your facility,
- 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.

If you have any questions please contact:

Vanessa GARROUX
International Senior Product Manager - Upper Extremity
+ 33 (0)7 60 90 39 40

We regret any inconvenience this recall may cause you and thank you in advance for your cooperation.

Faithfully Yours,

Maud Andriollo
Vigilance Representative Substitute

Gerard Sheehan
Quality Director

Inspection procedure for the jig (REF. 9020060)

Compliant jig (no separation)

Non compliant jig (separated)

Acknowledgement of Receipt

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

Identification: **FA-TUS-2015-003 – Field Safety Notice Aequalis® IM Nail Targeting Jig ref. 9020060**

Hospital: _____

NAME: _____

Position: _____

Address: _____

_____

_____

Telephone N°: _____

Item Number	Description	Instrument set Box number
9020060	Aequalis® IM Nail Targeting Jig	YKAD102/ _____

I hereby confirm:

- Having received the field safety notice from Tornier relative to the recall of all lots of Aequalis® IM Nail Targeting Jig and having circulated this information to whom it may concern within the hospital.
- Having checked if we had any such devices in the instrument sets. I quarantined them or I mentioned the device is not currently in the hospital. I have completed the above table accordingly.

Date : _____ Signature : _____

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