

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.

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

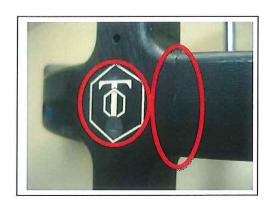
Vigilance Representative Substitute

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 <u>15 days</u>

Identification:		FA-TUS-2015-003 — Field Safety Noti Targeting Jig ref. 9020060	ce Aequalis® IM Nail
	Hospital: NAME: Position: Address:		
	Telephone N°:		
	Item Number	Description	Instrument set Box number
	9020060	Aequalis® IM Nail Targeting Jig	YKAD102/
<ul> <li>I hereby confirm:</li> <li>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.</li> <li>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.</li> </ul>			
Date .		Signature :	