TORNIER

Montbonnot, 11th August 2014

FIELD SAFETY NOTICE

Medical Device: **Tibial Impactor Salto Talaris (item number MJU361)**

All Lots: 08B821 - 08F242 - 10D348 - 10E707 - 10E706 - 11C698 - 11C816 - 11C817 - 11D742 - 11D741 - 13A651 - 13A766 - 13A984 - 13F734 - 13F733 - 14C340 – 14D410

N/Ref.: FA-TOF-2014-012

Dear Sir or Madam,

Tornier is initiating a voluntary Field Safety Notification related to the instrument Tibial Impactor Salto talaris (item number MJU361).
Complaints have been received which describe a non-optimum grip of tibial inserts with the tibial impactor Salto Talaris which could lead to the fall of the implant.

Our investigations led to the conclusion that only sizes 0 and 1 of the tibial implant are not sufficiently maintained by the tibial impactor which however remains functional. Even if the impactor does not ensure optimal holding of sizes 0 and 1 only of the tibial implant, **it can still safely be used**.

We ask you to be careful when using this tibial impactor for implantation of sizes 0 and 1 of the tibial implants.

You will be informed promptly of the availability of the new design. Our customer service will contact you to arrange return and to exchange devices present in your facility.

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

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

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.

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

Faithfully Yours,

Mireille Lémery
Dir. International Regulatory Affairs
Vigilance representative

Acknowledgement of Receipt

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

Identification: FA-TOF-2014-012 – Field Safety Notice of Tibial Impactor - Salto Talaris (MJU361)

Hospital: _____

NAME: _____

Position: _____

Address: _____

_____

_____

Telephone N°: _____

Item Number	Description	Instrument set Box Number
MJU361	Tibial Impactor – Salto talaris	YKAL13

I hereby confirm:

- Having received the Field Safety Notification from Tornier relative to all lots of Salto Talaris Tibial Impactor and having circulated this information to whom it may concern within the hospital.
- When notified by Tornier, return the devices concerned by this notification for an exchange.

Date : _____ Signature : _____

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