

**For the attention of the Hospital Director
and the Vigilance Representative**

Montbonnot, France, January 21st 2014

FIELD SAFETY NOTICE

Medical Device:

Radial head Prosthesis MoPyC – Head

Model: small

Catalog number: PTR-H18

Serial number : 0743AMxxx - 5886AMxxx - CB2-425/xx - CB2-243/xx - CB2-244/xx - CB2-245/xx - CB2-146/xx

N/Ref.: RA/020 I

Dear Sir or Madam,

We are initiating a voluntary recall of certain lots of radial head prosthesis MoPyC – head, model small (catalog number. PTR-H18).

We have identified that some lots, manufactured in limit of tolerances, had a risk of rupture slightly more frequent.

These implants are compliant to our specifications; however we engage this action as precautionary measure.

Concerned Competent Authorities have been informed of this action.

Our records indicate that you have received and/or implanted one of the products involved.

Measures to be taken

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,
- 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 local regulation and MEDDEV 2.12-1 rev 8.

Your Tornier Representative will organize the collection and replacement of the devices.

For any further information regarding this event, please contact:

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

Faithfully Yours,



Marielle PUISSAT
Director of Sales Operations



Mireille LEMERY
Dir. Global Regulatory Affairs
Vigilance representative

Acknowledgement of Receipt

Please complete and return to your local Tornier Representative within **7 days**

**Identification: RA/020 I - Radial head Prosthesis MoPyC – small – Catalog Number :
PTR-H18 – SN : 0743AMxxx - 5886AMxxx - CB2-425/xx - CB2-243/xx -
CB2-244/xx - CB2-245/xx - CB2-146/xx**

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

 Telephone N°: _____

Catalog Number	Description	Serial Number	Quantity of devices
PTR-H18	Radial head Prosthesis MoPyC – Head Model : small	0743AMxxx	
PTR-H18	Radial head Prosthesis MoPyC – Head Model : small	5886AMxxx	
PTR-H18	Radial head Prosthesis MoPyC – Head Model : small	CB2-425/xx	
PTR-H18	Radial head Prosthesis MoPyC – Head Model : small	CB2-243/xx	
PTR-H18	Radial head Prosthesis MoPyC – Head Model : small	CB2-244/xx	
PTR-H18	Radial head Prosthesis MoPyC – Head Model : small	CB2-245/xx	
PTR-H18	Radial head Prosthesis MoPyC – Head Model : small	CB2-146/xx	

I hereby confirm:

- Having received the Field Safety Notice from Tornier relative to the recall of one lot of **Radial head Prosthesis, catalogue number: PTR-H18** and having circulated this information to whom it may concern within the hospital.
- Having taken the required measures according to the present notification.

Date : _____

Signature : _____