

FIELD SAFETY NOTICE

Object: **Field Safety Notice regarding the MoPyc Radial Head Prosthesis**

Ref/No.: **FA TOF-2016-035**

Person responsible for follow-up: **Alice SIAUD-SIMOENS – +33(0)4 56 52 43 28**

Please note that this is not a recall, product return is not necessary.

Dear Sir or Madam,

This letter aims to inform you that Tornier initiated a Field Safety Notice about the reported risk of misuse with MoPyc Radial Head Prosthesis during the impaction step of the neck into the stem component leading potentially to disassembly of the system post-operatively.

The complaints analyses have shown that the root cause is related to some impaction practices that are not compliant with that described in the surgical technique.

This letter is intended to emphasize an essential point of the surgical technique of the MoPyc Radial head prosthesis describing the correct impaction technique.

1. With the orientation tip correctly inclined, use it to impact the neck:

Seat the neck to the stem by applying a force distally while rocking the orientation tip a few degrees. A proper seating of the neck to the stem will make the patient's hand supinate and pronate when gently rocking the orientation tip. If rocking the orientation tip does not make the hand rotate, this means that the initial locking has not been completed. If so, perform this whole step again (no locking can be obtained by an inappropriate cleaned and dried surfaces).

2. Arm and forearm are firmly maintained by an assistant. With a hammer, give 2 to 3 series of 3 straight hits on the silicon part of the orientation tip.
3. Check the head is not disassembled from the neck. Vibrations generated by the neck / stem impactions may disassemble the head from the neck. Check the correct head / neck assembly applying a manual strength on the head. In case of head disassembly, remove the neck from the stem, take the head and the neck off, clean the surfaces



Impaction of the neck into the stem

with alcohol, re-assemble the neck with the head according to the technique described previously, and then impact again the neck into the stem.

Finally, in order to simplify the technique and to reduce the risk of misuse, we decided to develop a new impactor for guaranteeing the assembly between the neck and the stem.

By that time, we kindly remind to strictly follow the impaction steps of the neck into the stem as described in the current surgical technique to ensure strong assembly of the system.

Actions to be taken by the user

Since your institution has the concerned devices, from now on we would ask you to:

- Distribute this Field Safety Notice to whom it may concern,
- Complete and sign the attached Acknowledgment of Receipt form and return it to us within 15 working days.
- Maintain awareness internally with respect to this Field Safety Notice,
- Inform us of any adverse event and/or report them to the Competent Authorities in accordance with current regulations and in compliance with MEDDEV 2.12-1.

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

For any further information, please contact:

Sabrina ZERUAL
International Product Manager – Upper Limbs
+ 33 (0)6 63 83 64 24

We would like to thank you for your cooperation and trust in our company,
Sincerely.



Maud ANDRIOLLO
Vigilance Representative

FA TOF 2016 035 – Field Safety Notification

Acknowledgment

Please complete this acknowledgment and send it back to us within **15 days**
by fax on +33 (0)4 76 61 35 33 or by email to alice.siaud-simoens@wright.com

Institution / Company Name: _____

NAME: _____

Position: _____

Address: _____

Telephone No.: _____

By completing and returning this form, I confirm that I have received and read this information notice.

Date : _____

Signature : _____