

URGENT – Field Safety Notice

Commercial name of the affected product GMK Primary PS and GMK Sphere Tibial Inserts
 FSCA-identifier FSCA 2017-02 of 29/Sept/2017
 Type of action Surgical Technique Advisory Notice

Affected Product		
Description	Reference codes	Lot numbers
GMK Sphere Tibial Inserts – all codes	02.12.0XXXFR & 02.12.0XXXFL	All Lots
GMK Primary PS Tibial Inserts – all codes	02.07.0XXXPSF	All Lots

1. Description of advisory:

Medacta has received reports regarding the GMK tibial baseplate screw, involving some cases of post-operative screw back-out, and in fewer cases screw fracture has been reported. In total, the detected world-wide occurrence rate is approximately 0.1 %.

Analysis of these reports identifies the need to emphasize that the current surgical technique includes an important CAUTION that the 3.5 Nm torque limiting screwdriver must be used to guarantee optimal locking of the screw. Please ensure absolute adherence to this and all steps of the surgical technique.

For GMK Sphere, the surgical technique does also stipulate that the screw is optional. Medacta confirms that the tibial baseplate is safe to apply without use of the screw, while it is again emphasized that if the screw is applied it must still be tightened with the 3.5 Nm torque limiting screwdriver specified.

2. Action to take:

- Ensure adherence to the specified surgical technique steps and cautions
- Immediately report any adverse events to Medacta
- Forward this notice to all associated health care professionals and organizations
- Return the attached acknowledgement confirmation as specified

3. Contact person and return address:

Stefano Baj, Regulatory Affairs Manager
 Medacta International SA, Strada Regina, CH-6847 Castel San Pietro, Switzerland
 Tel: +41 (0)91 696 60 60, Fax: +41 (0)91 696 60 66

We apologize for this inconvenience and confirm our commitment to patient safety and surgeon support.

Sincerely,



Stefano Baj
 Regulatory Affairs Manager

Castel San Pietro – October 2, 2017

Subject: Field Safety Notice Acknowledgement of Receipt

Dear sir or madam,

This is to confirm acknowledgement of receipt for a Medacta Field Safety Notice. We thank you in advance for your cooperation, and ask that you please complete and return this document to your local Medacta representative or via one of the following options:

Fax: +41 (0)91 696 60 66

Mail: Regulatory Affairs Manager
Medacta International SA
Strada Regina
CH-6847 Castel San Pietro
Switzerland

ACKNOWLEDGEMENT OF RECEIPT

- I acknowledge receipt of FSN 2017-02 issued by Medacta International SA.
- I understand the notice and have shared it with all applicable associates.

Name, Surname _____

Hospital(s) _____

Signature _____

Date _____