Medacta International

FSN 2017-03
Date: 20/Oct/2017

URGENT – Field Safety Notice

Commercial name of the affected product	GMK Hinge System
FSCA-identifier	FSCA 2017-03 of 20/Oct/2017
Type of action	Instruction for Use Advisory Notice

Affected Product

Description	Reference code	Lot numbers
GMK Hinge System	All codes	All Lots

1. Description of advisory:

Medacta has received reports regarding the GMK Hinge System, indicating that sub-optimal alignment of the components can reduce the systems resistance to complications, such as compromised fixation and prosthesis damage or displacement. Based on this an important update to the Instructions for Use (IFU) has been made. The updated IFU, 75.09.083, now includes the following additional Warnings and Precautions:

Demanding anatomical and functional preoperative conditions, individually or together, can present challenges to achieving optimal alignment of components. Poor alignment, as well as insufficient bone support and compromised adjacent anatomy, can cause abnormal and unpredictable stresses on the prosthetic components, which may result in loss of fixation, intra-prosthetic disassembly or prosthetic component fracture. Potentially related preoperative conditions include, but are not limited to, the following:

- **Advanced osteoporosis or insufficient bone stock**
- **Metabolic disorders or systemic medications leading to gradual loss of bone support for the prosthesis (e.g. diabetes mellitus, treatment by steroids, immunosuppressives, etc.)**
- **History of disseminated systemic or local infection**
- **Significant deformations preventing correct fixation or placement of the prosthesis**
- **Tumors of the supporting bone structures**
- **Allergic reactions to the prosthesis materials or cement**
- **Tissue reaction to implant corrosion or wear debris**
- **Functional impairment of the surrounding muscles or of the other joints**

2. Action to take:

- Ensure awareness of all Warnings and Precautions included in the GMK Hinge System IFU, 75.09.083, particularly including the added information listed above.
- 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

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3. Contact person and return address:

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

Sincerely,

Stefano Baj
Regulatory Affairs Manager

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