

URGENT – Field Safety Notice

Commercial name of the affected product	Medacta Humeral Anatomical Metaphysis Cementless
FSCA-identifier	FSCA 2019-02 of 04 November 2019
Type of action	Removal

Affected Product

Description	Reference code	Lot numbers
Humeral Anatomical Metaphysis-Cementless – all sizes	From 04.01.0023 to 04.01.0055	From 184523 to 184555, From 1901136 to 1901148, and 1904909

1. Description of advisory:

Inspection of a complaint related device identified that certain lot numbers of the Medacta humeral anatomical cementless metaphysis have a dimensional condition that could limit insertion of the screw used to lock the metaphysis to the humeral diaphysis. To prevent any possible difficulty, Medacta is removing the lot numbers involved. All other lot numbers have been verified as conforming.

2. Possible Patient Harm:

If experienced, this issue would be evident intra-operatively per the standard surgical technique, potentially allowing an alternative component to be used for completion of the surgery. In this case, a patient could be exposed to increased operative time resulting from the need to attain and apply an alternative component or to conduct other mitigating actions at the discretion of the surgeon.

3. Action to take:

- Return all units of the lot numbers listed above to Medacta International SA
- Forward this notice to all people and organizations potentially affected
- Please complete these actions as soon as possible, and within 30 calendar days from receiving this notice

4. Contact person and return address:

Stefano Baj, Regulatory Affairs & Compliance Director
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,

