

## URGENT – Field Safety Notice

Commercial name of the affected product	Humeral reverse metaphysis +0mm/0°
FSCA-identifier	FSCA 2023-01 – 16/08/2023
Type of action	Recall of specific lot
SRN – single registration number	CH-MF-000033473

### Affected Product

Description	UDI	Reference	Lot
Humeral reverse metaphysis +0mm/0°	07630040706179	04.01.0110	2300354


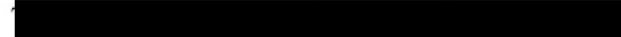
#### 1. Description of advisory:

Medacta International is conducting a removal of one lot of Reference 04.01.0110, Humeral reverse metaphysis +0mm/0°. The lot number listed above was produced with an incorrect positioning of the laser marking indications of the 155° and 145° directly inversed. This could affect the desired range of motion (ROM) and stability. These parameters are evaluated prior to completion of the surgery according to the standard Surgical Technique of the system, therefore no pre-emptive interventions are recommended, however monitoring of the ongoing ROM and stability should be evaluated during the post-operative patient follow-up visits, as per the standard of care.

#### 2. Action to take:

- Return all units of the lot number listed to Medacta International SA
- Forward this notice to all people and organizations potentially affected.

**3. Contact person and return address:**

 Regulatory Affairs Director  
Medacta International SA, Strada Regina, CH-6847 Castel San Pietro, Switzerland  


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

Sincerely,



Regulatory Affairs Director