

URGENT – Field Safety Notice

Commercial name of the affected product	NextAR Shoulder – Surgical Technique
FSCA-identifier	FSCA 2022-03 of 24 October 2022
Type of action	Correction – Warning added to Surgical Technique
EC Rep SRN – Single Registration Number	IT-AR-000022505

Affected Document

Table 1

Description	Document Reference code	Revision Numbers
NextAR Shoulder System Surgical Technique	99.81NEXTAR.12 (not for US market) 99.81NEXTAR.12US (for US market only)	Rev.02 and previous

1. Description of advisory:

The following Warning has been added to the Surgical Technique for NextAR Shoulder, advising verification of suitable patient conditions prior to placement of the NextAR Shoulder Target Holder:

WARNING

Target fixation requires adequate coracoid bone stability. Osteoporosis, weakness of the coracoid process, or other deficiencies, could lead to adverse events including bone fracture. Verify that the coracoid bone and relevant patient conditions are suitable before proceeding.

The updated Surgical Technique is attached to this document and can be found at: resources.medacta.com

2. Action to take:

- Transmit this communication all end-users, ensuring it is fully understood.
- Verify acknowledgment through end-user signature on the attached receipt.
- Return all the signed receipts to the Regulatory Department of Medacta International.

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 Director