

URGENT – Field Safety Notice

Commercial name of the affected product	3D Metal B-Cages
FSCA-identifier	FSCA 2022-02 of 15 July 2022
Type of action	Recall from the market of specific lot numbers
SRN – single registration number	Not yet available

Affected Product

Table 1

Description	UDI	Reference code	Lot number
3D Metal B-Cage Ø38 Right	07630971266025	01.35.338R	2008437
3D Metal B-Cage Ø42 Right	07630971266032	01.35.342R	2008438
3D Metal B-Cage Ø46 Right	07630971266049	01.35.346R	2008439
3D Metal B-Cage Ø50 Right	07630971266056	01.35.350R	2008440
3D Metal B-Cage Ø54 Right	07630971266063	01.35.354R	2008441
3D Metal B-Cage Ø58 Right	07630971266070	01.35.358R	2008442
3D Metal B-Cage Ø62 Right	07630971266087	01.35.362R	2008443
3D Metal B-Cage Ø38 Left	07630971266094	01.35.442L	2008444
3D Metal B-Cage Ø42 Left	07630971266100	01.35.446L	2008445
3D Metal B-Cage Ø46 Left	07630971266117	01.35.450L	2008446
3D Metal B-Cage Ø50 Left	07630971266124	01.35.462L	2008447
3D Metal B-Cage Ø54 Left	07630971266131	01.35.438L	2008448
3D Metal B-Cage Ø58 Left	07630971266148	01.35.454L	2008449
3D Metal B-Cage Ø62 Left	07630971266155	01.35.458L	2008450

1. Description of advisory:

During the production of new lots of these devices, we detected the possible presence of manufacturing micro-residuals on the finished devices. Our analysis determined that the lot numbers listed in Table 1 could potentially be affected.

For this reason, we have decided to quarantine all potentially affected items in stock and to remove from the market all the items listed in Table 1.

No other lots of this product have been released on the market other than the ones listed in Table 1.

No associated adverse events have been reported on the devices already implanted.

We have no reason to suspect that these residuals may cause patient harm.

Physicians who have treated patients using the identified lots should continue to follow up on those patients post-operatively according to the physician's 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:

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