URGENT FIELD SAFETY NOTICE

SMR TT hybrid glenoid Std - Peg S

Product name:	SMR TT Hybrid glenoid Std - Peg S
Device Type	Shoulder glenoid fossa prosthesis
FSCA number:	04/2023
Action type:	Urgent Field Safety Notice on medical device
Date:	08/02/2023
Single Registration Number (SRN)	IT-MF-000010690
To the kind attention of:	Health Directors; Orthopaedic Head Physicians; Orthopaedic Surgeons; Vigilance Directors; Chief Executive Officers (only for Private Facilities); Distributors

Product information

Product code	*Product description*	*Product lot number*	*Sterilization number*	*Unique Device Identification (UDI-DI):*
1379.59.210	SMR TT Hybrid glenoid Std - Peg S	2206565	2200094	08033390121798

Table 1: Product information

Problem description

Following a complaint from the market, LimaCorporate became aware of a non-conformity affecting one specific lot number of SMR TT Hybrid glenoid.
In details, the SMR TT Hybrid glenoid with the product information reported in Table 1, has been manufactured without the tantalum markers.
The tantalum markers are the spheres embedded in the peripheral polyethylene pegs, to allow the radiographic assessment of the pegs position. See Figure 1:

Figure 1: tantalum markers position on TT Hybrid glenoid

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REA Nr. 173824 / Cap. Soc. Euro 9.868.179,30 i.v. / C.F. e P. IVA IT01427710304

This Field Safety Notice is issued to the Hospitals that received/implanted at least one of the affected devices, to inform the users about the non-conformity and to recall the items still on the market, following the assessment by the Coordinating Competent Authority.

Please be informed that, according to the clinical evaluation performed, the non-conformity under assessment has no impact on the product safety and clinical practice as in the absence of the markers on already implanted devices, a correct radiographic assessment of the hybrid glenoid position can still be performed by the evaluation of the joint space, central TT peg position and cement mantel observation.

Action to be taken

We kindly ask You to:

1. Check your stock to locate and quarantine the affected devices. Devices must be sent back to LimaCorporate **within 15 days** together with a hard copy of the attached Response Form.

2. Fill out, sign and send the attached Response Form to the email address pms@limacorporate.com, as a confirmation that You have read and acknowledged the content of this FSN.

If needed, please address any inquiry on this FSN to the email address medicalcomplaints@limacorporate.com.

Dissemination of this FSN

This notice needs to be passed on all those who need to be aware within your organization. This Field Safety Notice will be sent to the Competent Authorities of the Countries involved in this Field Safety Corrective Action.

Roberto Gabetta
Person Responsible for
Regulatory Compliance
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