URGENT FIELD SAFETY NOTICE

Product name: SMR Glenoid TT MB Peg S-R Medium, Long, X-Long
FSCA number: 03/2023
Action type: Voluntary Field Safety Notice on medical device
Date: 15 February 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)

Device type: Shoulder glenoid peg

Product information

Product code	*Version*	*Product description*	*Lot Number*	*Unique Device Identification (UDI-DI)*
1375.14.652	00	GLENOID PEG TT S-R Medium	ALL	80333903S038GA
1375.14.653	00	GLENOID PEG TT S-R Long	ALL	80333903S038GA
1375.14.654	00	GLENOID PEG TT S-R X-Long	ALL	80333903S038GA

Table 1 – List of Glenoid TT Peg compatible with SMR TT Augmented 360 baseplates

Version (00) of the product can be always identified on top right position of the Glenoid Peg TT label. In the label example below, version is highlighted though a red circle:

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

Problem description
Internal investigation led Lima Corporate discover a SMR TT Augmented 360 baseplate component (part number 1375.15.**522**) was coupled with a Glenoid TT Peg SMALL-R #M - part number 1375**.14.652**, despite the warning on TT peg label reports "*Couple only with baseplate 1375.15.**605** - 1375.15.**650***" as per Figure 1 below:

Figure 1 – Warning on GLENOID PEG TT S-R Medium

The same warning is included for all the product codes listed in Table 1.
Further investigation revealed coupling of SMR Glenoid TT Peg S-R Medium, S-R Long, S-R X-Long and Augmented 360 baseplate is a **on label combination**.
Correct information about compatibility of the components is made available to the final users thought **SMR TT Augmented 360 baseplate Instructions For Use**, **Surgical Technique** and **labels**.

It was evaluated that, in the most likely case scenarios, the surgery - both primary and revision procedures - can be completed without adverse effect for the patient.
There is a remote event that:

- In case of primary procedure, the user would like to couple a Glenoid Peg TT S-R medium, S-R Long or X-Long with a SMR TT Augmented 360 baseplate and is stopped by confusion reading the labels. A second stage operation later is needed;
- In case of revision surgery, the user would like to couple a Glenoid Peg TT S-R medium, Long or X-long with a SMR TT Augmented 360 baseplate and is stopped by confusion reading the labels. With no alternatives, the user may choose bone graft only and a second stage operation later.

Stating that:

- SMR TT Augmented 360 baseplate cannot be used without SMR Glenoid TT MB Peg;
- Instructions For Use + Surgical Technique + Warning on labels related to SMR TT Augmented 360 baseplate provide to the users the correct compatibility information;
- Current warning on Glenoid Peg TT S-R Medium, S-R Long, S-R X-Long does not allow for incorrect coupling: it limits compatibility with respect to what is actually on label;

- No complaints from SMR TT Augmented 360 baseplate users have ever been reported to LimaCorporate about scenarios described above despite SMR TT Augmented 360 glenoid baseplate is marketed since 2019.

LimaCorporate would like to recommend TT Augmented 360 baseplate users to refer to IFUs, Surgical Technique and Warning on TT Augmented 360 baseplate labels **ONLY** when choosing to couple a SMR TT Augmented 360 baseplate with Glenoid Peg TT codes listed in Table 1.

Action to be taken

We kindly ask You to:

1. Carefully read the content of this Field Safety Notice to be aware you need to refer to IFUs, Surgical Technique and Warning on TT Augmented 360 baseplate labels **ONLY** when choosing to couple a SMR TT Augmented 360 baseplate with Glenoid Peg TT codes listed in Table 1;
2. Fill out, sign and send the attached Response Form within 15 days to the email address pms@limacorporate.com. The Form confirms that You have read and acknowledged the content of this FSN.

For any inquiry on this FSN, please email to medicalcomplaints@limacorporate.com.

Dissemination of this FSN

This notice needs to be passed on to all of those who need to be aware on it within your organization.
This Field Safety Notice is sent to the applicable regulatory authorities of the countries involved in the Field Safety Corrective Action (ref. 03/2022).

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