

## FIELD SAFETY NOTICE – SMR GLENOSPHERE IMPACTOR/EXTRACTOR

**Product name:** SMR Glenosphere Impactor/Extractor  
**Related FSCA no.:** 02/2015 (related only to product code 9013.74.141)  
**Action type:** Field safety notice to users  
**Date:** 04<sup>th</sup> December 2015

To the kind attention of: Health Directors; Orthopaedic Head Physicians; Orthopaedic Surgeons; Vigilance Directors; Chief Executive Officers (only for Private Facilities)

**Product codes:** 9013.74.140, 9013.74.141  
Device type: Surgical instrument for SMR Reverse and SMR Stemless prosthesis  
**Batch number:** all  
Notes: N/A

### Description of the issue and surgeon information

The instrument *SMR Glenosphere Impactor-Extractor* (product codes: 9013.74.140, 9013.74.141) is used during primary and revision surgeries of the *SMR Reverse* and *SMR Stemless* shoulder prosthesis.

The *SMR Glenosphere Impactor-Extractor* is used to impact the definitive glenosphere into the metal back; the instrument is also used during trial reduction, to position the trial eccentric glenosphere into the metal back, and in revision surgeries where it's necessary to disassemble the previously implanted glenosphere from the metal back.

Picture 1 shows, from right to left, the glenosphere impactor/extractor (whose threaded section is to be inserted and tightened into the glenosphere cavity), the glenosphere, and the connector which guarantees the conical coupling between glenosphere and metal back glenoid.

Picture 1: Insertion of the Glenosphere Impactor-Extractor into the glenosphere with connector.



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Monitoring and analysis of the complaints received on the *SMR Glenosphere Impactor-Extractor* indicate that an improper use of the instrument when impacting the glenosphere can favor the breakage of the threaded section of the instrument intra-operatively.

***Below, are described some important additional instructions to reduce the risk of intra-operative breakage of the instrument.***

***When the SMR Glenosphere Impactor-Extractor is used to impact the definitive glenosphere into the metal back:***

- ***The threaded tip of the instrument must be completely tightened into the apex hole of the glenosphere, before tapping in the morse taper coupling with the mallet; the tightening of the instrument must be stopped only when the surgeon feels high resistance to continue the tightening action.***
- ***When impacting the glenosphere, the mallet must be used along the direction (axis) of the SMR Glenosphere Impactor-Extractor, avoiding as much as possible the onset of unexpected multi-axial forces during impaction.***

***Please refer to picture 2 (red circle and red arrow). If both of the above conditions are not verified, the threaded section of the instruments is subjected to increased unexpected stresses that can lead to its breakage.***

Picture 2: correct use of the instrument.



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### Actions requested to the Surgeons

We kindly ask you to carefully read this Field Safety Notice; we also kindly you to fill out and sign the attached response.

We are available at the e-mail address [medicalcomplaints@limacorporate.com](mailto:medicalcomplaints@limacorporate.com) if you have any question related to this FSN.

### Dissemination of this FSN

This notice needs to be passed on to all these who need to be aware within your organization, or to any organization where the *SMR Glenosphere Impactor-Extractor* has been transferred.

<b>Contact name</b>	
Dr. Ing. Giulio Puppa - Dr. Ing. Michela Zanotto Post Market Surveillance	c/o: Limacorporate S.p.A. Via Nazionale n.52 33038 Villanova di S. Daniele del Friuli (UD)
e-mail: <a href="mailto:medicalcomplaints@limacorporate.com">medicalcomplaints@limacorporate.com</a> fax: +39 0432 945512	

This Field Safety Notice will be submitted to the National Competent Authorities involved and to the Notified Body.

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