

FIELD SAFETY NOTICE FOR EUROPEAN MARKET SMR GRAFT CUTTER

Product name: SMR Graft Cutter
Related FSCA no.: 05/2017
Action type: Field safety notice to users
Date: 22nd November 2017

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

Product code: 9013.75.443
 Device type: Surgical instrument for SMR bone grafting technique
Batch number: all
 Notes: N/A

Intended use of the instrument

The instrument *SMR Graft Cutter* (product code: 9013.75.443) is used during surgeries of the *SMR Anatomic* and *Reverse* shoulder prosthesis with glenoid grafting technique. The intended use of the glenoid bone grafting instruments is to enable the preparation of the bone graft to restore the glenoid anatomy. They are used in combination with the SMR Axioma TT Metal Back glenoid.

The *SMR Graft Cutter* is used to cut the bone graft during the preparation phase. The instrument is connected to the power tool and inserted into the prepared hole of the humeral head. The graft cutter has a hook with a blade; the blade allows to take the bone graft. When the adaptor of the graft cutter is in contact with the bone, the hook of the graft cutter will come out to cut the bottom part of the bone graft. Picture 1 shows the graft cutter during the cutting phase in the native humeral head.



Picture 1 - Preparation of the bone graft using the SMR Graft Cutter.

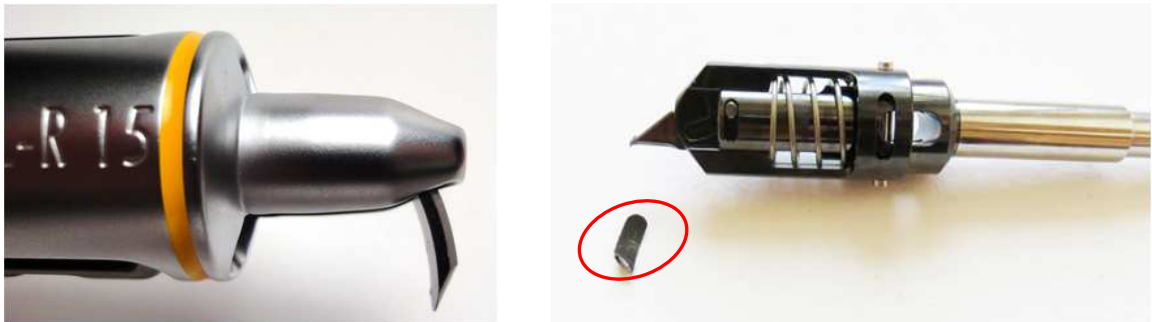
Limacorporate spa

Sede Legale: Via Nazionale, 52 ♦ 33038 Villanova di San Daniele ♦ Udine – Italy ♦ T. +39 0432 945511 ♦ F. +39 0432 945512
 ♦ info@limacorporate.com ♦ www.limacorporate.com ♦ REA Nr. 173824 ♦ Cap. Soc. Euro 09.854.675,00 i.v. ♦ C.F. e P. IVA IT01427710304

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Description of the issue and surgeon information

Monitoring and analysis of the complaints received on the *SMR Graft Cutter* indicate that an improper use of the instrument, when cutting the graft, can favor the deformation or breakage of the blade of the instrument intra-operatively with respect to the not deformed one, as per Picture 2 below.



Picture 2 – Comparison between a not-deformed blade (left) and a broken blade (right) of the graft cutter.

Even if no adverse effects for patients were reported for all the similar complaints received up to date, Limacorporate decided to provide some important additional instructions (in red bold character below) to reduce the risk of intra-operative deformation or breakage of the blade.

The *additional* indications reported in red, below, will be introduced in the SMR Axioma TT Metal Back glenoid bone grafting Surgical Technique.

“In bone grafting technique, using autograft from the patient is preferable whenever available. When using allograft, please follow the instructions provided by the processor.”

When the SMR Graft Cutter is used to cut the bone graft:

“Connect the graft cutter to the power tool and insert it into the prepared hole in the humeral head. When the stopper of the adaptor for the graft cutter is in contact with the humerus bone, the hook of the graft cutter will come out to cut the bottom part of the graft by applying pressure (Picture 1). Please note that this operation must be performed gradually while reaming in order to allow a progressive and precise cut of the graft, so do not force the hook to come out if the graft cutter is not rotating but push instead gently the instrument while reaming. Ensure the graft is fully in contact with the humerus bone before starting the cutting operation. Once the cut has been performed, remove the graft cutter.

“Note: the graft cutter is for preparing cancellous bone grafts only.”

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If the above instructions are not followed, the blade section of the instrument is subjected to increased unexpected stresses that can lead to its bending or breakage.

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, to be sent to the following email address: pms@limacorporate.com.

We are available at the same e-mail address mentioned above if you have any question related to this FSN.

Dissemination of this FSN

This notice needs to be passed on to all those who need to be aware within your organization, or to any organization where the *SMR Graft Cutter* has been transferred.

Contact name

Dr. Ing. Giulio Puppa – Dr. Ing. Michela Zanotto
Post Market Surveillance

e-mail: pms@limacorporate.com
fax: +39 0432 945512

c/o:

Limacorporate S.p.A.
Via Nazionale n.52
33038 Villanova di S. Daniele del Friuli (UD)

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


Roberto Gabetta
Regulatory Manager
Limacorporate S.p.A

Limacorporate spa

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