

URGENT FIELD SAFETY NOTICE Multigen Plus H System

Product name: Multigen Plus H Knee System
FSCA number: 01/2021
Action type: Voluntary Field Safety Notice on medical device
Date: 07/05/2021

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

Product: **Multigen Plus H System**
Device type: implantable devices for Multigen Plus H knee
prosthesis
Notes: /

Products information

Multigen Plus H is a hinged knee prosthesis system indicated for revision cases.

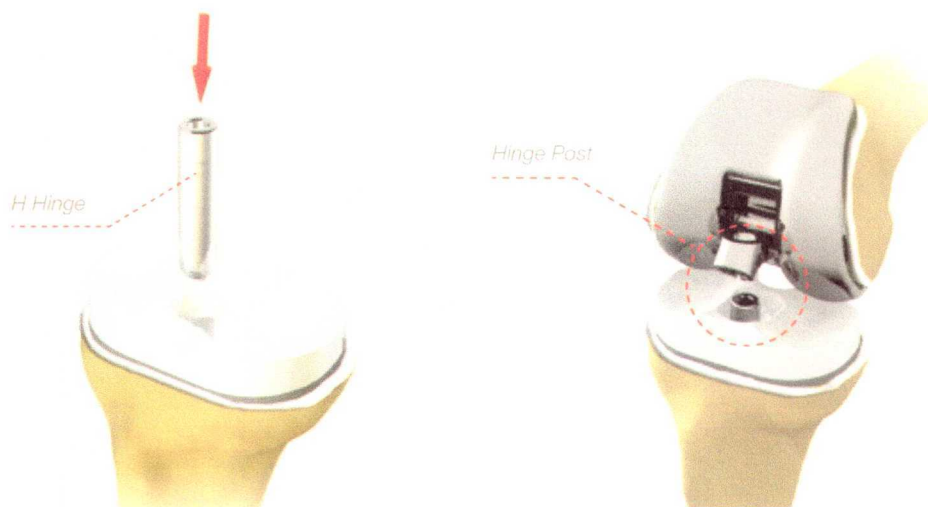


Figure 1: Multigen Plus H

URGENT FIELD SAFETY NOTICE

Multigen Plus H System

Problem description

Following the close monitoring of the complaints on the Multigen Plus H System, Lima Corporate decided to issue a voluntary Field Safety Notice to all the Multigen Plus H users to increase their awareness on the current Multigen Plus H surgical technique.

The Post Market Surveillance data collected by Lima Corporate, highlighted cases of post-operative loosening and/or breakage of the locking screw used to finalize the conical coupling between the hinge post of the femoral component and the hinge (please refer to figure 1 for the details of the components). The investigations performed, showed that the missing achievement of a complete conical coupling between the hinge post and the hinge might occur if the current surgical technique is not carefully followed.

To ease the intra-operative assembly of the hinge, in the past Lima Corporate introduced additional dedicated instruments, contained in the Addendum set with code 9066.51.000. The surgical technique was updated accordingly.

The use of the Addendum set is mandatory and users must always refer to the updated version of the surgical technique, which specifies step by step how to reach the proper coupling.

In addition to this Field Safety Notice, Lima Corporate has taken the following measures to increase users awareness:

- introduction of an additional warning in the Multigen Plus H surgical technique, to highlight that the use of the addendum set is mandatory;
- definition of a new training program: the Multigen Plus H users will be contacted by a Lima local representative to schedule a training session.

Furthermore, Lima Corporate would like to underline that the presence of a Lima representative in the Operating Room is strongly recommended for all the future Multigen Plus H surgeries.

The surgeons are advised to continue monitoring the patients according to the standard clinical follow-up protocol and to act accordingly.

Action to be taken

We kindly ask You to:

1. Carefully read the content of this Field Safety Notice;
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;

Limacorporate spa

URGENT FIELD SAFETY NOTICE
Multigen Plus H System

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
Regulatory Manager
Lima Corporate SpA

