

URGENT FIELD SAFETY NOTICE
Monolithic cementless and cemented stems restriction for use

Product name: FRIENDLY, H-MAX C, LOGICA MIRROR, SL
(cementless and cemented)
FSCA number: 06/2019
Action type: Voluntary Field Safety Notice on medical device
Date:

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

Codes: See Attachment 1

Device type: Monolithic Cementless hip stems (SL) + Cemented
hip stems (FRIENDLY, H-MAX C, LOGICA MIRROR,
SL)

Lot number: All the lot numbers manufactured starting from
03/08/2019

Notes: /

LimaCorporate's mission has always been to offer innovative and safe solutions to assist orthopedic surgeons in restoring the emotion of movement. As part of our product quality assurance process, it was identified that instruction for use related to LimaCorporate monolithic cementless and cemented femoral stems were reviewed in order to be aligned with the requirements posed by the ISO standards aimed at promoting global harmonization on mechanical testing matter related to orthopedic implants.

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When applying the current mechanical standards retrospectively to our monolithic cementless and cemented stems, we had to conclude the following:

- Starting from 3rd August 2019, weight limitations - previously not existing - need to be introduced for some sizes of FRIENDLY, H-MAX C, LOGICA MIRROR and SL monolithic stems. See Table 1 for details:

| HIP STEMS | Product | STEM sizes involved | Type | PATIENT MASS limitation [KG] in IFU <i>Starting from 03/08/2019</i> |
|------------|---------------|---------------------|----------|--|
| CEMENTED | FRIENDLY | #1→#2 | STD, LAT | 66 |
| | H-MAX C | #9→#10 | STD, LAT | 66 |
| | LOGICA MIRROR | #0→#1 | - | 66 |
| | SL | #02 | - | 63 |
| CEMENTLESS | SL | #02 | - | 63 |

Table 1 – weight limitations for some sizes of FRIENDLY, H-MAX C, LOGICA MIRROR and SL monolithic stems.

The Instruction for Use (IFU) valid for monolithic cementless and cemented femoral stems have been adapted accordingly.

Stating that:

- All the monolithic femoral stems have a very long history of presence on the market (> 10 years for all devices under assessment, with the only exception of H-MAX C femoral stems, which have a shorter history (> 7 years);
- Low number of medical complaints were reported to LimaCorporate despite the long in vivo experience (history of presence on the market >25 years in some cases);
- No changes have been made in the prosthesis design nor in the manufacturing process





the devices under assessment can be considered mechanically safe.

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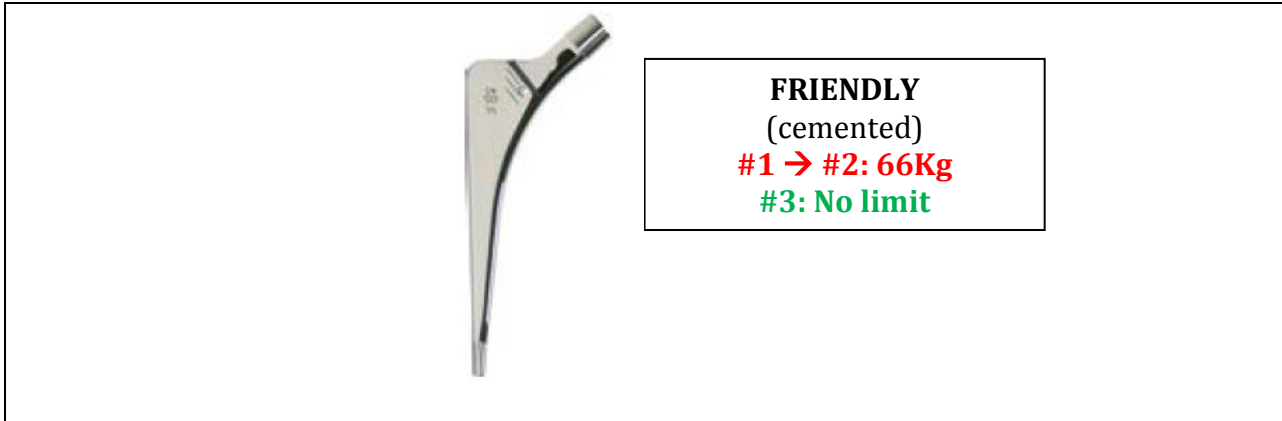
Aim of this Field Safety Notice is to simply provide information about the relevant changes in the Instruction for Use always provided with our products.

Please, see the summary below for an immediate and clear understanding of weight limitations introduced for some sized of Lima monolithic cemented stems:

| | | | |
|---|---|---|--|
|  | <p>SL (cementless) #02: 63Kg #0→#8: No limit</p> |  | <p>H-MAX C (cemented) #9→#10: 66Kg #11→#18: No limit</p> |
|  | <p>SL (cemented) #02: 63Kg #0→#8: No limit</p> |  | <p>LOGICA MIRROR (cemented) #0→#1: 66Kg #2→#5: No limit</p> |

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Action to be taken

We kindly ask You to:

1. 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, or to any organization where the devices involved have been received

This Field Safety Notice will be also sent to the Competent Authorities of the Countries involved in this Field Safety Corrective Action.

Roberto Gabetta
Regulatory Manager
LimaCorporate SpA

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Attachment 1

List of Monolithic cementless and cemented stems involved

| SL Self Locking Femoral Stems | |
|--|--------------------|
| COD. | DESCRIPTIONS |
| Partially Coated Stems - Cementless (Ti6Al4V + PoroTi) - Taper 12/14 | |
| 3515.21.003 | Width 4.5 mm, # 02 |
| Cemented Stems (Ti6Al4V) - Taper 12/14 cemented Stems (Ti6Al4V) - Taper 12/14 | |
| 3515.15.003 | Width 4.5 mm, # 02 |

| FRIENDLY Femoral Stems | |
|--|--------------|
| COD. | DESCRIPTIONS |
| Stems (FeCrNiMnMoNbN) - Taper 12/14 | |
| 4110.07.220 | # 1 - 125° |
| 4110.07.230 | # 2 - 125° |
| 4110.07.320 | # 1 - 132° |
| 4110.07.330 | # 2 - 132° |

| H-MAX C Femoral Stem | |
|---|--------------|
| COD. | DESCRIPTIONS |
| Standard stem (FeCrNiMnMoNbN) – Taper 12/14 | |
| 4260.07.090 | #9 |
| 4260.07.100 | #10 |
| Lateralized stem (FeCrNiMnMoNbN) – Taper 12/14 | |
| 4261.07.090 | #9 |
| 4261.07.100 | #10 |

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| LOGICA | |
|--|---------------------|
| <i>COD.</i> | <i>DESCRIPTIONS</i> |
| STANDARD Stems with Centralizer (FeCrNiMnMoNbN) - Taper 12/14 | |
| 3710.07.005 | #0 |
| 3710.07.010 | #1 |

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RESPONSE FORM

**Monolithic Cementless and Cemented femoral stems – restriction for use
To be completed, signed and sent to Limacorporate urgently.**

Please check the following box:

I have read and understood the instructions provided in this Field Safety Notice.

Person name: _____

Structure name: _____

Signature: _____

Please fax or e-mail completed response form to:
Dr.Eng Federica Malvaso
E-mail: pms@limacorporate.com
Fax: +39 0432 945512