

URGENT FIELD SAFETY NOTICE Modular Femoral stems restriction for use

Product name: Modulus, Modulus-R, Revision, Revision LR stems
FSCA number: 04/2019
Action type: Voluntary Field Safety Notice on medical device
Date: 02nd of August 2019

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: Cementless hip stems (Modulus, Modulus-R,
Revision) + Cemented hip stems (Revision LR)

Lot number: All the lot numbers manufactured starting from
18/06/2019

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 modular femoral stems (Modulus, Modulus-R, Revision, Revision LR) have to be 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.

Since the market introduction of the modular femoral stems involved (Revision stems are sold since 1996, Modulus stems since 2001, Revision LR stems since 2008, Modulus-R stems since 2013), a low number of complaints has been reported to LimaCorporate in a very long in vivo clinical history.

Stating that more than 37.000 Revision stems and more than 20.300 Modulus stems sold worldwide and that, according to the PMS data, all the safety or performance issues involving a Modulus and Revision code have been analyzed (and corrected) over time, the aim of this Field Safety Notice is to simply provide to the users information about the relevant changes in the Instruction for Use always provided with our products.

When applying the current mechanical standards retrospectively to our modular femoral stems, we had to conclude the following:

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- 1) Starting from 18th June 2019, weight limitations - previously not existing - need to be introduced for Modulus Taper A and Revision LR. See Table 1 for details:

Hip system	Stem Type	Sizes	Type	NEW IFU Weigh limitations [Kg] starting from 18 th June 2019
MODULUS&REVISION SYSTEMS	MODULUS Taper A	All sizes	TAPER A	48 Kg
	MODULUS Taper B	All sizes	TAPER B	NO LIMIT
	REVISION LR	All sizes	-	60 Kg

Table 1 – weight limitations for Modulus Taper A and Revision LR highlighted in red.

- 2) Starting from 18th June 2019, restriction for use only with #S, #M and #L femoral heads for Modulus, Modulus-R, Revision, Revision LR necks need to be introduced. Possible coupling with size XL femoral heads previously allowed for Modulus, Modulus-R and Revision necks is eliminated. See Table 2 for details:

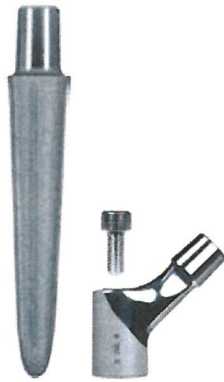

DEVICE	OLD IFU	NEW IFU new coupling limitation starting from 18 th June 2019
MODULUS & MODULUS- R	Allowed combination between femoral heads and femoral necks: <ul style="list-style-type: none"> • Only the sizes S, M and L can be coupled with femoral necks #L (125° and 135°); • Only the sizes S, M, L and XL can be coupled with femoral necks #S (125° and 135°). 	Allowed combination between femoral heads and femoral necks: only the sizes S, M and L can be coupled with femoral necks (125° and 135°).
REVISION	Allowed combination between Femoral heads and Revision femoral necks: <ul style="list-style-type: none"> • only the sizes S, M and L can be coupled with lateralized Revision necks (#L); • only the sizes S, M, L and XL can be coupled with standard Revision necks (#S). 	Allowed combination between Femoral heads and Revision femoral necks: only the sizes S, M and L can be coupled with Revision necks.
REVISION LR	There was no limitation because REVISION LR had generic IFU for articular prosthesis.	Allowed combination between Femoral heads and Revision LR femoral necks: only the sizes S, M and L can be coupled with Revision LR necks.

Table 2 – restriction for use only with size S,M,L femoral heads for Modulus, Modulus-R, Revision, Revision LR femoral necks.

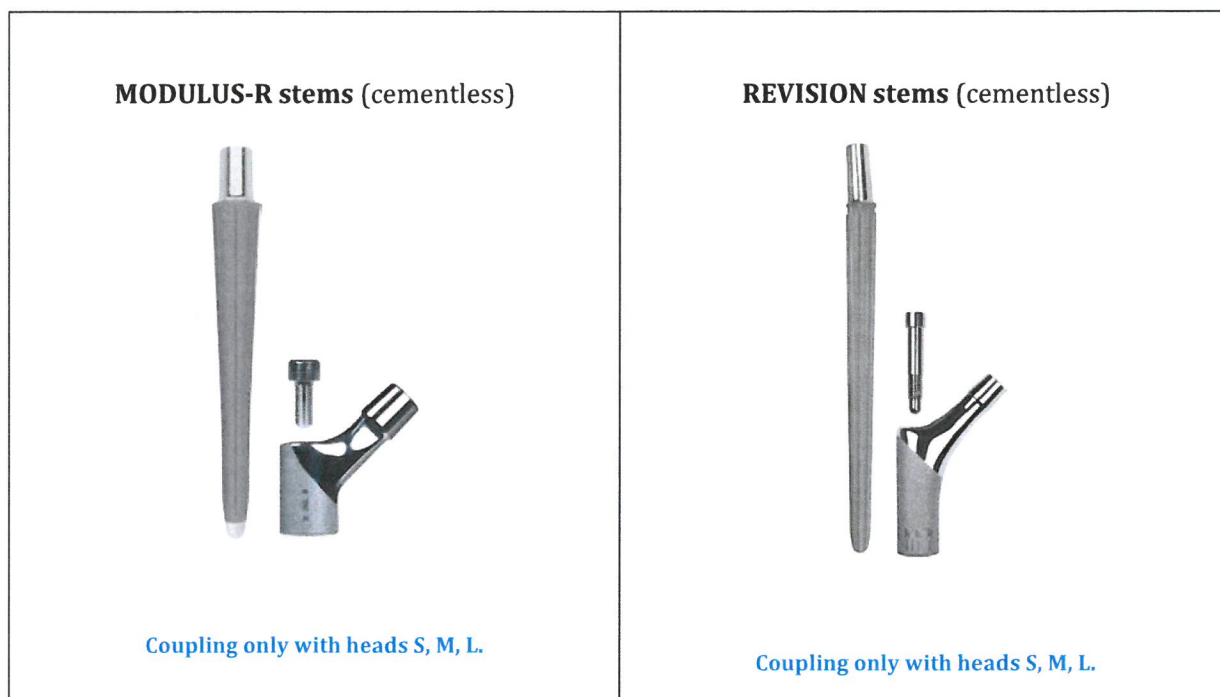
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The Instruction for Use (IFU) valid for Modulus, Modulus-R, Revision and Revision LR femoral stems have been adapted accordingly.

Please, see the summary below for an immediate and clear understanding of weight limitations/restriction for use involving Modulus, Modulus-R, Revision and Revision LR femoral stems:

MODULUS stems (cementless)	REVISION-LR stems (cemented)
 <p data-bbox="395 1411 555 1444">TAPER A: 48Kg</p> <p data-bbox="379 1467 571 1500">TAPER B: No limit</p> <p data-bbox="303 1523 646 1556">Coupling only with heads S, M, L.</p>	 <p data-bbox="1013 1422 1173 1456">All sizes: 60Kg</p> <p data-bbox="917 1478 1268 1512">Coupling only with heads S, M, L.</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.

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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 Modulus, Modulus-R, Revision and Revision LR stems codes.

MODULUS	
COD.	DESCRIPTIONS
Modular Stems (Ti6Al4V)	
4310.15.010	Dia. 13 mm, Taper A
4310.15.020	Dia. 14 mm, Taper A
4310.15.030	Dia. 15 mm, Taper A
4310.15.045	Dia. 16 mm, Taper B
4310.15.050	Dia. 17 mm, Taper B
4310.15.060	Dia. 18 mm, Taper B
4310.15.070	Dia. 19 mm, Taper B
4310.15.080	Dia. 20 mm, Taper B
4310.15.090	Dia. 21 mm, Taper B
4310.15.100	Dia. 22 mm, Taper B
4310.15.110	Dia. 23 mm, Taper B
4310.15.120	Dia. 24 mm, Taper B
4310.15.130	Dia. 25 mm, Taper B
4310.15.140	Dia. 26 mm, Taper B
Necks with Screw (Ti6Al4V) CCD 125°	
7590.15.010	S - Taper A (Standard version)
7590.15.020	L - Taper A (Standard version)
7590.15.030	S - Taper B (Standard version)
7590.15.040	L - Taper B (Standard version)
7590.15.050	S - Taper B (Large version)
7590.15.060	L - Taper B (Large version)
Necks with Screw (Ti6Al4V) CCD 135°	
7595.15.010	S - Taper A (Standard version)
7595.15.020	L - Taper A (Standard version)
7595.15.030	S - Taper B (Standard version)
7595.15.040	L - Taper B (Standard version)
7595.15.050	S - Taper B (Large version)
7595.15.060	L - Taper B (Large version)

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MODULUS R	
<i>COD.</i>	<i>DESCRIPTIONS</i>
Femoral stem (Ti6Al4V)	
4330.15.160	Dia.16 mm
4330.15.170	Dia.17 mm
4330.15.180	Dia.18 mm
4330.15.190	Dia.19 mm
4330.15.200	Dia.20 mm
4330.15.210	Dia.21 mm
4330.15.220	Dia.22 mm
4330.15.230	Dia.23 mm
4330.15.240	Dia.24mm
4330.15.250	Dia.25 mm
4330.15.260	Dia.26 mm

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REVISION SYSTEM	
COD.	DESCRIPTIONS
Modular Stems (Ti6Al4V)	
3810.15.010	Dia. 14 mm, L. 140 mm
3810.15.020	Dia. 14 mm, L. 200 mm
3811.15.010	Dia. 15 mm, L. 140 mm
3811.15.020	Dia. 15 mm, L. 200 mm
3812.15.010	Dia. 16 mm, L. 140 mm
3812.15.020	Dia. 16 mm, L. 200 mm
3813.15.010	Dia. 17 mm, L. 140 mm
3813.15.020	Dia. 17 mm, L. 200 mm
3814.15.010	Dia. 18 mm, L. 140 mm
3814.15.020	Dia. 18 mm, L. 200 mm
3815.15.010	Dia. 19 mm, L. 140 mm
3815.15.020	Dia. 19 mm, L. 200 mm
3816.15.010	Dia. 20 mm, L. 140 mm
3816.15.020	Dia. 20 mm, L. 200 mm
3817.15.010	Dia. 21 mm, L. 140 mm
3817.15.020	Dia. 21 mm, L. 200 mm
3818.15.010	Dia. 22 mm, L. 140 mm
3818.15.020	Dia. 22 mm, L. 200 mm
3819.15.010	Dia. 23 mm, L. 140 mm
3819.15.020	Dia. 23 mm, L. 200 mm
3820.15.010	Dia. 24 mm, L. 140 mm
3820.15.020	Dia. 24 mm, L. 200 mm
3821.15.010	Dia. 25 mm, L. 140 mm
3821.15.020	Dia. 25 mm, L. 200 mm
3822.15.010	Dia. 26 mm, L. 140 mm
3822.15.020	Dia. 26 mm, L. 200 mm
Necks with Locking Screw (Ti6Al4V) - Taper 12/14	
7515.15.005	H. 50 mm
7515.15.010	H. 60 mm
7515.15.020	H. 70 mm
7515.15.030	H. 80 mm
7515.15.040	H. 90 mm
7515.15.050	H. 100 mm
7515.15.060	H. 110 mm

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Lateralized necks with Locking Screw (Ti6Al4V) - Taper 12/14	
7515.15.105	H. 50 mm - lateralized
7515.15.110	H. 60 mm - lateralized
7515.15.120	H. 70 mm - lateralized
7515.15.130	H. 80 mm - lateralized
7515.15.140	H. 90 mm - lateralized
7515.15.150	H. 100 mm - lateralized
7515.15.160	H. 110 mm - lateralized

REVISION - LR	
<i>COD.</i>	<i>DESCRIPTIONS</i>
LR Stem for Large Resection (Ti6Al4V)	
3838.15.130	Dia 12 x 130 mm
3840.15.130	Dia 14 x 130 mm
3842.15.130	Dia 16 x 130 mm
3838.15.165	Dia 12 x 165 mm
3840.15.165	Dia 14 x 165 mm
3842.15.165	Dia 16 x 165 mm
3840.15.200	Dia 14 x 200 mm
3842.15.200	Dia 16 x 200 mm
LR Modular Spacer (Ti6Al4V)	
3801.15.060	Spacer H 60 mm
3801.15.120	Spacer H 120 mm

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