AMPLITUDE

Healthcare Facility
Address

To the attention of the vigilance safety officer and orthopaedic surgery departments

Valence, X March 2017

Ref. AMPLITUDE CA 16-03-03

Subject: **Safety Information**
ACOR® primary femoral stem with modular neck and,
INTEGRALE® primary femoral stem with modular neck and,
OPTIMAL® revision femoral stem with modular neck

THIS IS NOT A RECALL

Safety Information:

AMPLITUDE has taken the initiative to issue a safety notice for the primary femoral replacement systems ACOR® with modular neck, INTEGRALE® with modular neck and OPTIMAL® revision femoral stem with modular neck. The purpose of this safety notice is to provide you with information regarding the use of these systems. It is accompanied by the most recent version of the related notice NO151 rev01.

AMPLITUDE would like to emphasize that the patient selection for the implantation of a primary or a revision femoral stem with modular neck system is a key factor. Modular neck femoral stems have been used for many years in hip joint replacement surgery and offer benefits to problems frequently encountered during a femoral replacement, such as the restoration of joint centre with extended modularity options. However, every modular system has a risk of rupture. This is a known complication associated with modular neck systems, and it is most often caused by severe stress on the modular joint when the lever arm between the femoral head and the axis of the femur is important. It is also aggravated by having too much pressure on the joint, due to the overweight of some patients.

For patients with both a large lever arm and a heavy weight, the surgeon must consider surgical options such as the use of a monoblock stem such as ACOR® monoblock stems, or INTEGRALE® monoblock, combined with a suitable femoral head for primary surgeries or an INTEGRALE® revision stem for revision surgeries.

Some ruptures have been reported for certain combinations of modular necks and femoral heads. Additional mechanical tests determining the endurance of the proximal stem geometry have been conducted on the modular neck stems according to standard ISO 7206 -6: 2013 in order to determine which combinations of necks and heads should be subjected to usage restrictions.

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These restrictions cover combination bans as well as admissible patient weight limits. These are explained in detail in the following table:

		Femoral heads				
		Short neck	**Medium neck**	**Long neck**	**Extra long neck**	**Extra extra long neck**
L/M neck	Lateralised and medialised versions	✓	✓	✓	✗	✗
Ante/retro neck	Anteverted and retroverted versions	✓	✓	✓	✓	✗
L/M+ neck	Lateralised version	Maximum patient weight 90kg	Maximum patient weight 90kg	Maximum patient weight 90kg	✗	✗
	Medialised version	✓	✓	✓	✗	✗
L/M+10.5 neck	Lateralised and medialised versions	Maximum patient weight 90kg	Maximum patient weight 90kg	✗	✗	✗

Indication in future notices associated with the devices in question.

✓ Validated combination

✗ Combination presenting a risk of rupture

The surgical technique and the IFU have been updated with these recommendations. An interim solution is implemented temporarily for device which do not have the new IFU yet: the updated IFU and a warning label have been added onto the packaging of the device.

Consequences and risks for the patient:

Following the results of the mechanical tests, there is a low risk of rupture of the connection between the body of the stem and the modular neck for the stems combining the L/M+ or L/M+10.5 necks when the patient weighs more than 90kg. It is recommended not to use a head/neck combination which is marked "X" in the previous table.

We recommend you perform the normal care and follow up for the patients implanted with AMPLITUDE components concerned by this safety notice.

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Devices in question:

Our traceability data indicates that your hospital has been delivered some of the implants related to this safety information:

Reference	Description
	Modular neck with taper 10/12
1-0106701	Lateral / Medial modular neck – 10/12 Taper
1-0106702	Ant / Retro 8° modular neck – 10/12 Taper
1-0106703	High lateral / High medial modular neck – 10/12 Taper
1-0106704	+10.5 Lateral / Medial modular neck – 10/12 Taper
	Modular neck with taper 12/14
1-0191001	Lateral / Medial modular neck – 12/14 Taper
1-0191002	High lateral / High medial modular neck – 12/14 Taper
1-0191003	Ant / Retro 8° modular neck – 12/14 Taper
1-0191004	+10.5 Lateral / Medial modular neck – 12/14 Taper

Measures to be undertaken by the users:

- Observe the head/neck combination restrictions described in the previous table according to the weight of the patient;
- Report any adverse reactions observed with these devices to AMPLITUDE and/or to the local national Health and Security Agency.

Other information:

The French Health Agency (ANSM) has been informed of this safety information.

We would like to thank you for your help and collaboration in the implementation of this safety action. We apologise for any inconvenience it may cause and we thank you for your understanding.

[redacted]
[redacted] / vigilance@amplitude-ortho.com

AMPLITUDE

AMPLITUDE Gmbh
Am Neuen Graben 15
55576 Zotzenheim
Allemagne

To the attention of the Director

Valence, 04 April 2017

Ref. AMPLITUDE CA 16-03-03

Subject: **Safety Information**
ACOR® primary femoral stem with modular neck and,
INTEGRALE® primary femoral stem with modular neck and,
OPTIMAL® revision femoral stem with modular neck

THIS IS NOT A RECALL

Dear Partner,

AMPLITUDE initiates a modular neck's safety notice.

Safety Information:

AMPLITUDE has taken the initiative to issue a safety notice for the primary femoral replacement systems ACOR® with modular neck, INTEGRALE® with modular neck and OPTIMAL® revision femoral stem with modular neck. The purpose of this safety notice is to provide you with information regarding the use of these systems. It is accompanied by the most recent version of the related notice NO151 rev01.

AMPLITUDE would like to emphasize that the patient selection for the implantation of a primary or a revision femoral stem with modular neck system is a key factor. Modular neck femoral stems have been used for many years in hip joint replacement surgery and offer benefits to problems frequently encountered during a femoral replacement, such as the restoration of joint centre with extended modularity options. However, every modular system has a risk of rupture. This is a known complication associated with modular neck systems, and it is most often caused by severe stress on the modular joint when the lever arm between the femoral head and the axis of the femur is important. It is also aggravated by having too much pressure on the joint, due to the overweight of some patients.

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Some ruptures have been reported for certain combinations of modular necks and femoral heads. Additional mechanical tests determining the endurance of the proximal stem geometry have been conducted on the modular neck stems according to standard ISO 7206 -6: 2013 in order to determine which combinations of necks and heads should be subjected to usage restrictions.

Service Clients-France
Porte du Grand Lyon
01700 Neyron - France
Tél. : +33 (0)4 37 85 19 19
Fax : +33 (0)4 37 85 19 18

Customer Service-Export
11, cours Jacques Offenbach
Zone Mozart 2
26000 Valence - France
Tél. : +33 (0)4 75 41 91 69
Fax : +33 (0)4 75 41 87 42

E-mail :
amplitude@amplitude-ortho.com
Internet :
www.amplitude-ortho.com

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These restrictions cover combination bans as well as admissible patient weight limits. These are explained in detail in the following table:

		Femoral heads				
		Short neck	Medium neck	Long neck	Extra long neck	Extra extra long neck
L/M neck	Lateralised and medialised versions	✓	✓	✓	✗	✗
Ante/retro neck	Anteverted and retroverted versions	✓	✓	✓	✓	✗
L/M+ neck	Lateralised version	Maximum patient weight 90kg	Maximum patient weight 90kg	Maximum patient weight 90kg	✗	✗
	Medialised version	✓	✓	✓	✗	✗
L/M+10.5 neck	Lateralised and medialised versions	Maximum patient weight 90kg	Maximum patient weight 90kg	✗	✗	✗

Indication in future notices associated with the devices in question.

✓ Validated combination

✗ Combination presenting a risk of rupture

Devices in question:

Reference	Description
	Modular neck with taper 10/12
1-0106701	Lateral / Medial modular neck – 10/12 Taper
1-0106702	Ant / Retro 8° modular neck – 10/12 Taper
1-0106703	High lateral / High medial modular neck – 10/12 Taper
1-0106704	+10.5 Lateral / Medial modular neck – 10/12 Taper
	Modular neck with taper 12/14
1-0191001	Lateral / Medial modular neck – 12/14 Taper
1-0191002	High lateral / High medial modular neck – 12/14 Taper
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The communication for the users is detailed in the attached safety notice mail template.

As part of the safety notice procedure and according to contractual arrangements, we ask you to:

- Conduct local regulatory notification to the competent authority. Deliver the FSCA form if applicable (Europe),
- Inform the sub distributors and/or healthcare facilities using the attached mail if applicable.

We thank you to acknowledge receipt of this mail by sending back the attached form fully completed to AMPLITUDE Regulatory Affairs department.

The French Health Agency (ANSM) has been informed of this safety information.

We remind you that any adverse event when using these devices must be declared to the national competent authority and AMPLITUDE.

We apologize for the inconvenience it may cause and thank you for your understanding.

[redacted]

[redacted] vigilance@amplitude-ortho.com

Attachments :

- Acknowledge receipt form
- FSN mail template in English.

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Porte du Grand Lyon
01700 Neyron - France
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amplitude@amplitude-ortho.com
Internet :
www.amplitude-ortho.com

AMPLITUDE

SAFETY NOTICE: MODULAR NECKS

Acknowledge receipt form – please complete and return by e-mail, fax or mail to:

AMPLITUDE - Service Affaires Réglementaires
11, Cours Jacques Offenbach - ZA Mozart 2
26000 VALENCE – France

Fax : +33 4-75-41-41-78

vigilance@amplitude-ortho.com

AMPLITUDE Gmbh
Am Neuen Graben 15
55576 - Zotzenheim
Allemagne

Department :

Date :

I acknowledge to have received and taken into consideration the safety notice procedure about modular necks.
I commit to conduct the safety notice over my market and to notify the local competent authority as applicable. It is recommended to get receiving signatures of the safety notice mail from the places of use because the competent authorities can demand the transmission proofs.

Name and function:

Signature :

Service Clients-France
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