



«Etablissement_Livr»
«Adresse_1_Livr»
«CP_Livr» «Ville_Livr»

To local vigilance system manager

For release to :

- The CEO ;
- The chief of orthopaedics surgical unit ;
- In charge of the medical device pharmacy;
- To whoever may be concerned

Montrouge, July the 16th, 2015

Field Safety Notice : 2015-03

Subject : Combinations between Optimum and Optimum AC femoral stems size 0 and Titanium modular necks from Ceram Concept

Madam, Sir,

Reasons:

During preliminary tests to update Ceram Concept femoral stems endurance and performance characteristics following ISO 7206-4:2010, results revealed some combinations could not fulfill requirements of new standard version.

Combinations concerned are the following:

- Optimum size 0 (reference OPTI 0) femoral modular stem with titanium short or medium varus-valgus 15° neck (reference C0007 and C0008);
- Optimum AC size 0 (reference OPTIC 0) femoral modular stem with titanium short or medium varus-valgus 15° neck (reference C0007 and C0008).

Associated potential hazards:

In light of preliminary results, it is possible above combinations don't reach clinical performances (early break of the stem at distal part).

Ceram Concept wants to specify, since Optimum modular stem has been commercialized in April 2008 and Optimum AC in March 2009, none incident has been reported on these combinations.

Potential hazard associated is low

Recommendations:

We recommend to surgeons who implanted one, or several, of these combinations to be vigilant during patient following visit in order to detect any eventual break beginning.

We also recommend to surgeon not to implant one of these combinations anymore.

Our Vigilance contact (Mr Jean Claude PEYRONNY +33 1 49 65 50 31) or our Quality Manager (Mrs Sandrine GUERN +33 1 49 65 43 59) remain at your disposal for any complementary information.

We remind you, by the way, the need to declare to sanitary authorities, vigilance department, all incidents concerning these devices.

Sincerely,

Vigilance contact
Jean Claude PEYRONNY

Company Manager
Olivier GENTIEN



AKNOWLEDGMENT

SAFETY FIELD NOTICE 2015-03

(Please complete this form to avoid unnecessary reminders)

Etablissement : _____

I received notice from Ceram Concept informing me following combinations could not to fulfill ISO 7206-4 version 2010 requirements:

- Optimum size 0 (reference OPTI 0) femoral modular stem with titanium short or medium varus-valgus 15° neck (reference C0007 and C0008);
- Optimum AC size 0 (reference OPTIC 0) femoral modular stem with titanium short or medium varus-valgus 15° neck (reference C0007 and C0008).

I sent this notice to all concerned persons within our institution

Contact name : _____

Function : _____

Phone : _____

E-mail : _____

Date : ____/____/____

Signature and stamp :

Thank you for returning this form by fax or e-mail to Sandrine Guern (+33 1 49 85 96 62 – sg@ceramconcept.com).