



Field Safety Notice - RECALL

«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, December the 29th, 2017

Field Safety Notice: 2017-02

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

Reasons:

During tests to update Ceram Concept femoral stems endurance and performance characteristics following ISO 7206-6:2014, results revealed some combinations could not fulfill requirements of new standard version.

Following these results, here is the compatibility table for Optimum stem and Optimum Ac with titanium's neck updated :

Necks	Optimum and Optimum AC size 0	Optimum and Optimum AC size 1 to 8
C0001 - CDC	X	X
C0002 – CDM	X	X
C0003 – CDL	X	X
C0004 – CVV8C	X	X
C0005 – CVV8M	X	X
C0006 – CVV8L		
C0007 – CVV15C		X
C0008 – CVV15M		X
C0009 – CAR8C	X	X
C0010 – CAR8M	X	X
C0011 – CAR8L	X	X
C0012 – CAR14C	X	X
C0013 – CAR14M	X	X

Legend of the table:

X	Allowed combination
	unauthorized combination according to ISO 7206-6 :2014
	unauthorized combination according to ISO standard ISO 7206-4 :2010

CERAMCONCEPT France

204, avenue Marx Dormoy

92120 Montrouge

Tel : 01 49 65 43 59

Fax : 01 49 85 96 62



Associated potential hazards:

In view of these results, it is possible that the combinations above do not reach their clinical performance:

the combination of a modular neck varus-valgus 8 ° long 10-12 (ref C0006) with an Optimum stem an Optimum AC stem presents a risk of premature rupture of the modular neck.

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.

Actions to be implemented:

1. Send this Field Safety Notice to surgeons of your establishment ;
2. Check that you have the following reference in your stock :

C0006 – Modular neck varus-valgus 8° long 10-12 6° Titanium

3. If you do not have this reference return the acknowledgment page 3 completed to the following email address: mv@ceramconcept.com.
4. If you have this reference:
 - a. Place it in non-conform product area;
 - b. Prepare a carton with isolated products and acknowledgment page 3 completed;
 - c. Call Ceram Concept France +33 (0)1 49 65 43 59 in order to organize the shipment.

other subject:

We remind you of the necessity to report any adverse event to the ANSM by mail to the address materiovigilance@ansm.sante.fr

ANSM (French health authorities) have been informed about this Field Safety.

Please accept our apologies for the inconvenience and thank you for your understanding.

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CEO
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AKNOWLEDGMENT

SAFETY FIELD NOTICE 2017-02

(Please complete this form to avoid unnecessary reminders)

Establishment : _____

I sent this notice 2017-02 to all concerned persons within our institution.

- I have no modular neck ref: C0006 in stock;
- I have in my stock one or more modular neck C0006 with batch number following and I return it to Ceram Concept France:

Reference	Batch Number	Quantity
C0006		

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).

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