



ADVISORY NOTICE - URGENT

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

To person responsible for implantable devices stock

To broadcast to :

- Surgery area ;
- all relevant persons.

Montrouge, December the 1st 2017

Advisory notice : 2017-01

Object : batch number and expiration date mistake for Must Delta cup.

Reasons :

A mistake occurred during coding of a Must Delta cup batch. Some information provided by the barcode, printed on product labels, are wrong :

- Expiration date ;
- batch number.

Only barcode is wrong, information readable on stuck labels, or on labels inserted into the box, are correct.

Associated potential risks :

Products entered in stock via barcode reading, then implanted, are traceable with a bad batch number. Traceability is broken.

The mistake on expiration date doesn't induce potential risks.



Actions to enforce :

We ask to persons responsible for implantable devices stock to correct information concerning Must Delta D 50 (36/44) in their software as follow:

	Wrong encoded information	Correct information
Expiration date	2022-09-10	2022-09-00
Batch number	03479	1003479

After action implementations, please return to Ceram Concept France acknowledgement of receipt you can find at page 3 of the present notice.

Other information :

The italian Ministry of Health have been informed of this notice.

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

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ACKNOWLEDGMENT OF RECEIPT

ADVISORY NOTICE 2017-01

(In order to avoid any useless relaunching, thank you for filling in this form)

Healthcare institution name : _____

I read the advisory notice 2017-01 from Ceram Concept France informing me that barcode of Must Delta cup batch n°1003479 is wrong and I corrected information as explained in the notice.

I broadcasted this notice to all relevant persons inside my healthcare institution.

Contact name : _____

Fonction : _____

Phone : _____

E-mail : _____

Date : ____/____/____

Signature and stamp :

Please return this form to Sandrine Guern (sg@ceramconcept.com)