



Type de document : FORMULAIRE
Référence : FR7-E-001.V1
Date d'application : 27/05/13
Page : Page 1 sur 1
COURRIER DE RAPPEL DE PRODUITS

Document Qualité

N° d'enregistrement : EN7-E-001-110214-GRAND EXPORT

INFORMATION FOR PRODUCT RECALL

In Saily lez Cambrai, 11/02/14

Dear Sir,

The company CEREPLAS with the Agence Nationale de Sécurité du Médicament et des produits de santé (ANSM) agreement, starts a product recall on **non-implanted** CEREFORM® breast implants and sizers (prefilled and inflatable).

CONCERNED PRODUCT FOR RECALL

- CEREFORM® Round breast implants
- CEREFORM® Anatomical breast implants
- CEREFORM® Aptima breast implants
- CEREFORM® Round prefilled sizers
- CEREFORM® Anatomical prefilled sizers
- CEREFORM® Aptima prefilled sizers
- CEREFORM® Round inflatable sizers
- CEREFORM® Anatomical prefilled sizers

REASON FOR RECALL

Following the CE mark suspension for **regulatory reasons**, the CEREFORM® breast implants and corresponding sizers are subject to a marketing stop. As a consequence, from today on, the use of these medical devices is suspended until the validation of a new sterilization.

RISK FOR THE USERS AND/OR PATIENTS

This decision has not been taken following a sanitary issue. **Therefore, there is NO CONFIRMED RISK concerning the products already implanted.**

DECIDED CORRECTIVE ACTION

CEREPLAS is actually working on the validation of a new sterilization with another supplier.

PROCEDURE TO FOLLOW - ELEMENTS TO SEND BACK TO CEREPLAS

All CEREFORM® breast implants and corresponding sizers (prefilled and inflatable) have to be sent back to CEREPLAS.

Please follow the following procedure:

- 1- For CEREPLAS to be assured that you have received this document, we are asking you to send us back a dated signed copy by email (carine.leporcq@cereplas.com)
- 2- You have to make sure that all the non-implanted CEREFORM® breast implants and corresponding sizers (prefilled and inflatable) on your territory are in your possession (getting back stocks from your customers, ...)
- 3- Make an inventory of all the non-implanted CEREFORM® breast implants and corresponding sizers (prefilled and inflatable) on your territory.
- 4- Send us the signed inventory with a signed commitment letter showing that you will avoid all use and that you will send us all products.
- 5- Contact the International sales department to organize the shipment of the products back to us.

CEREPLAS SIGNATURE

Name, Family name : LELEU David
Position : Director
Date : 02/12/2014
Signature :

DISTRIBUTOR'S SIGNATURE

Name, Family name :
Position :
Date :
Signature :