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 CEREVERM® breast implants and sizers (prefilled and inflatable).

CONCERNED PRODUCT FOR RECALL

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

REASON FOR RECALL

Following the CE mark suspension for regulatory reasons, the CEREVERM® 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 CEREVERM® 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 CEREVERM® 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 CEREVERM® 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: