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MEDICAL VISION AUSTRALIA PLASTIC & COSMETIC

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6th March 2014

Medical Device Recall and Marketing Stop
Cereform Breast Implants and Corresponding Sizers
TGA Ref # RC-2014-RN-00161-1

Dear Valued Client,

Following our previous notification in February by phone and email I would like to provide you with further information on our decision to recall from the market and issue a marketing stop in regards to Cereform Breast Implants and Corresponding Sizers manufactured by Cereplas, France.

As mentioned in our last notification the French regulatory body, Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM) after an inspection of the manufacturing facility determined that the validation of the sterilisation provider was not consistent with the requirements of international regulatory standards. Therefore, sterility of the Cereform Breast Implants and Corresponding Sizers cannot be fully assured.
Cereplas was in the process of validating a new sterilisation provider but due to the lengthy process of such validation Cereplas did not meet the deadline set by the French regulatory body ANSM resulting in suspension of the CE certificate on the 10th February 2014. The suspension remains in place until the sterilisation validation with the new provider is completed and accepted by ANSM.

Following the suspension of the CE certificate ANSM requested that all non-implanted Cereform products be recalled in France clearly stating **the recall was based on the licensing and regulatory issue and NOT a "sanitary" (safety) issue.**

Please note that there is no evidence in Australia or overseas to suggest any issues with the products already implanted.
As we strive to provide you with the best possible products and appropriate regulatory reassurances, in the absence of the current CE certification we feel it would be in the best interest of Australian patients to completely alleviate any fear of product safety, therefore until the CE certification is reinstated we have decided to remove **all non implanted stock from the Australian market and return it to Cereplas, France.**
All stock in Australia is under our control and is currently being prepared for shipment to France.

This action has been undertaken after consultation with the Therapeutic Goods Administration. For any further information please do not hesitate to contact us on info@medicalvision.com.au or 1300 661 559

Best regards

Stan Z. Racic
Director

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