



INFORMATIVE NOTE

You can view this note on CEREPLAS webpage

www.cereplas.com/questions.html

Following the recent events about the Poly Implants Protheses implants, and in order to offer full transparency, CEREPLAS wishes to bring out several precisions on CEREFORM[®] range technical characteristics.

SITUATION

It is important to be reminded that these sanitary issues are the sole result of voluntary and hidden malevolence. For the last months, the numerous clinical complications linked to known conception and quality problems, has led the AFSSAPS (French Agency for Medical Devices Sanitary Security) to conduct an inspection in the said company's premises.

Nevertheless, this very serious fraud should not mask the quality and manufacturing improvements brought to breast implants these last years.

CEREPLAS RAW MATERIAL

CEREPLAS clarifies that **CEREFORM breast implants are CE certified** and have been going through 20 biocompatibility tests and 12 mechanical tests to obtain the certificate (**Refer to Annex 1**).

Strict controls are led by our provider (*Nusil Technology; leader in the implantable medical silicones field*) on each new material lot in order to strictly correspond to our specifications. Moreover, the materials we use have all been homologated by the FDA (*Food and Drug Administration*) (**Refer to Annex 2**).

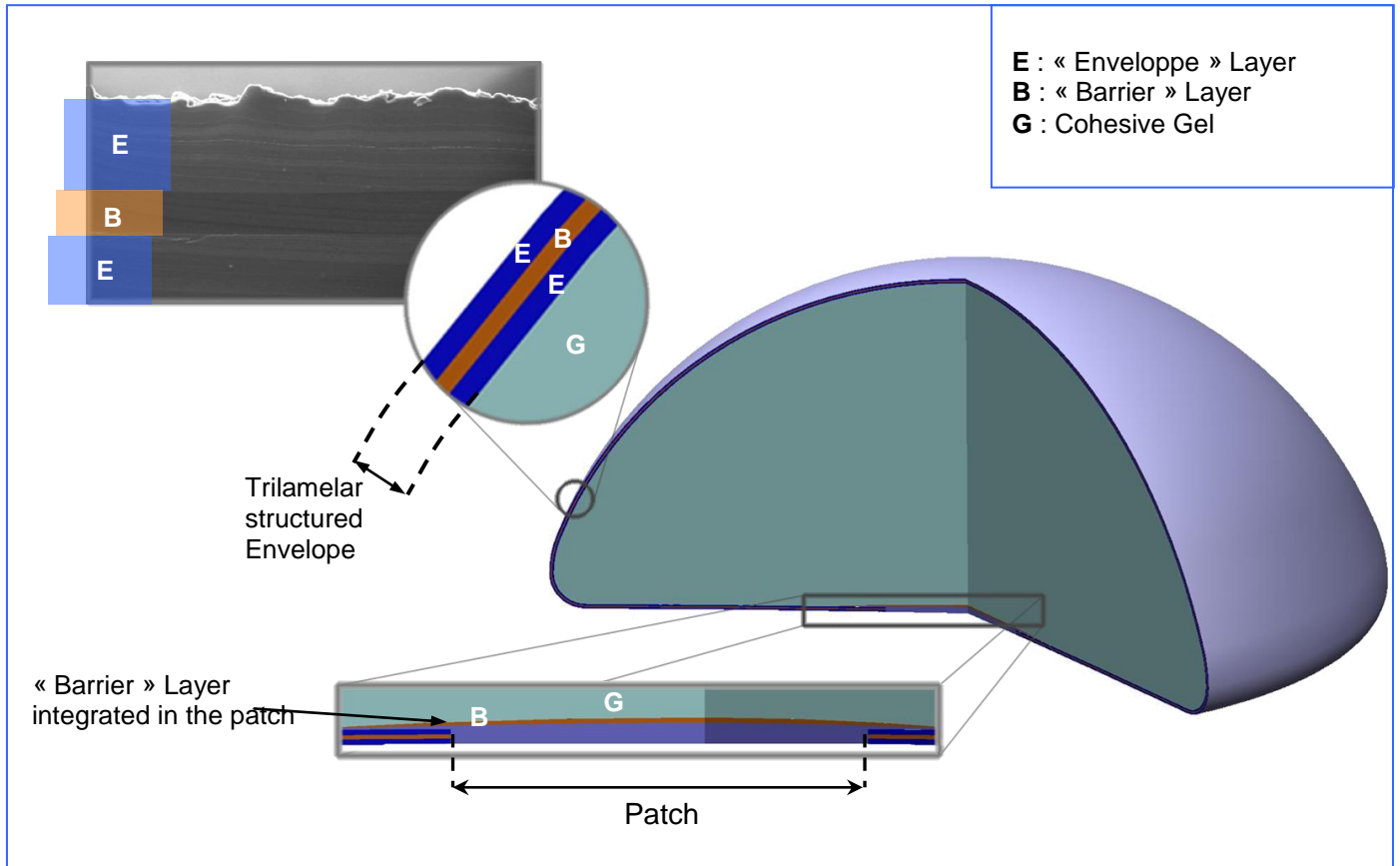
CEREFORM® BREAST IMPLANTS TECHNICAL CHARACTERISTICS

CEREFORM® breast implants envelope contains **a group of medical grade silicone layers called « barrier layer »**. This « barrier » silicone has been developed and optimised for the specific aim of limiting at best the silicone gel particules movement through the envelope.

Our implants patch also contains a group of « barrier layers » in order to limit the perspiration phenomena in all parts of the implant.

Our implants are filled with a **medical grade reticulated silicone cohesive gel** appeasing all inflammatory risk in case of envelope rupture.

The implant mechanical performances and the compatibility between the gel and the envelope are also closely watched through regular stability studies and quality controls. This allows us to state that **the gel we use does not make our envelope fragile**.



CONTROLS MADE ON CEREFORM® IMPLANTS

In order to master our production and for product conformity, **our implants are controlled individually** :

- 12 points thickness control
- Patch self reticulating seal control
- Implant visual controls in several steps of the manufacturing process
- Sealing blisters control
- Sterilisation parameters control
- Post sterilisation visual control

The implants are manufactured in an ISO 7 type clean room (or « class 10 000 ») in which atmospheric parameters (temperature, pressure and hygrometry) are controlled. Moreover, 25 weekly microbiological controls are made to master our working environment cleanliness which is validated again every year by an independent agency.

CEREFORM[®] IMPLANTS CERTIFICATION AND CE MARK

The company CEREPLAS is **ISO 13485 certified** and respects the **European Directives 93/42/CEE and 2007/47/CE** requirements for medical devices. This is the reason why our breast implants do have the CE mark. ***(Refer to Annex 3).***

In order to attest its products conformity with the current regulations, CEREPLAS is annually audited. These quality audits are made by the Organisme Notifié français LNE/G-Med (French Notified Body). It is appointed by the Ministry of Health and is known for its severe methods. The aim of these audits is to control our activities in relation to medical devices and in particular our traceability system and our strict mastery of our raw materials.

To this day, the company CEREPLAS has never been presented with any non conformity which could endanger the integrity of its products or of the raw material it uses. Our raw materials are traced from their manufacturing to their transformation. Our traceability system allows us also to track back precisely at each moment the manufacturing process of a given implant.

This informative note by CEREPLAS is meant to bring you objective elements which will attest our products quality and conformity. With these precisions, we hope to show you once again that CEREPLAS main goal has, is and will always be the patient's security.

In order to illustrate this note, CEREPLAS warmly welcomes you to come and see our production facility in France at your convenience. Please contact our exclusive distributor to schedule a visit.

Hoping this letter has shown our seriousness and our products quality, CEREPLAS and its distributors' network are fully at your disposal to answer all your questions. Contact us directly at questions@cereplas.com

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USEFUL LINKS



<http://www.cereplas.com>

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<http://www.nusil.com/products/healthcare/unrestricted/index.aspx>



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