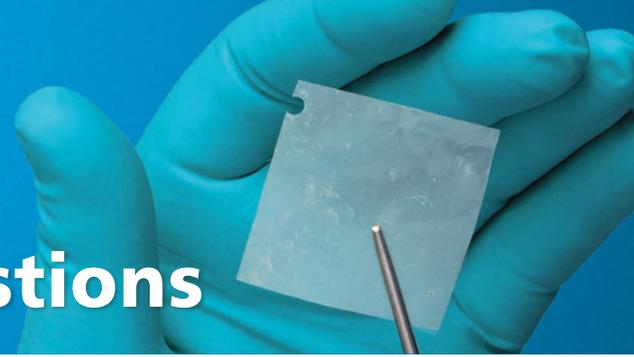
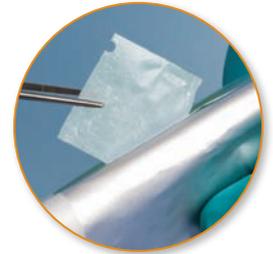


Frequently Asked Questions



1. What is VersaShield?

A thin hydrophilic amniotic membrane designed to serve as a wound covering & protective barrier for a variety of surgical demands. VersaShield is derived from the human placental layers amnion and chorion. It is used to maintain a tissue plane between adjacent tissues or structures following surgery.



2. What are the indications for VersaShield?

VersaShield is intended for use as a wound or soft tissue covering, or protective barrier.

3. How is VersaShield Regulated?

VersaShield is regulated as a Human Cellular and Tissue Product (HCT/P). There is no pre-market approval required.

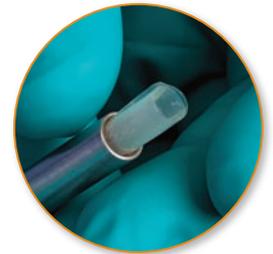


4. What are the benefits of an amnion and chorion bi-layer membrane versus amnion only?

The chorion membrane is added to reinforce the graft. It improves the handling properties of the graft during implantation and helps support a longer residence time in the body post-implantation.

5. What is the shelf life of VersaShield?

VersaShield can be stored for up to 3 years at ambient temperature.

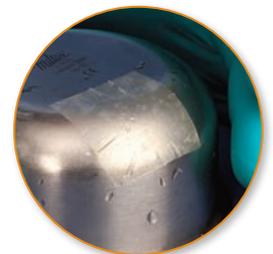


6. Does it matter if amnion is terminally sterilized?

VersaShield is not terminally sterilized. It has been well-documented that terminal sterilization may have an adverse effect on soft tissue allografts which can reduce their efficacy¹⁻⁴. The graft is aseptically processed and passes USP <71> Sterility Test.

7. I have heard that chorion has an immune response. Do you have data that suggests otherwise?

The chorion membrane from this graft is from the non-vascularized portion of the placenta. It is immune privileged, similar to the amnion membrane, and therefore will not illicit an immune response. In addition, the chorion membrane represents the outer shell of the placenta, which is not rejected by the mother⁵⁻⁷.



8. What type of procedures would you place the graft with amnion side facing up? What type of procedures would you want to place the amnion side down?

When the graft is being used as wound covering, the amnion side should be placed towards the wound bed. When the graft is being used as a protective barrier the amnion side should be placed up towards the side of potential inflammation or scar tissue formation.

9. Can VersaShield be sutured or tacked down?

Yes, VersaShield can be gently sutured, however VersaShield does not have suture retention strength so it should only be used for tacking in place.

10. Should VersaShield be hydrated prior to use?

The tissue can be applied in its dry form. If needed, the tissue can be hydrated with sterile saline or sterile water prior to implantation.

11. Can VersaShield be over hydrated, if so what would happen?

Too much irrigation post implantation could potentially cause the graft to shift from its position and should be avoided.

12. For internal wounds how long does it take for VersaShield to reincorporate?

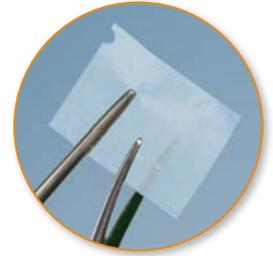
For internal wounds, a single layer of amnion has been shown to take at least 6-12 weeks to resorb in previous animal studies⁸. VersaShield which contains an amnion layer and a chorion layer, is expected to persist over a considerably longer period in the body since the thickness of the chorion layer is two to four times that of the amnion layer.

13. Can VersaShield be used as a nerve wrap or a dural covering?

Yes, it can be used as a nerve wrap or dural covering⁹⁻¹¹. The amnion side should be placed up in these types of applications.

14. How often does VersaShield have to be reapplied?

For external wounds, factors such as the wound type and location, as well as the overall patient health will determine how many applications of VersaShield will be needed.



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