

# RESTORIGIN<sup>™</sup> Sx

A Natural Next-Generation Tissue Barrier

## Frequently Asked Questions

- Q:** What is Restorigin Sx?
- A:** A placental tissue membrane designed to serve as a soft tissue covering, internal wound covering & protective barrier for a variety of surgical demands. The Restorigin Sx family is derived from human placental tissues consisting of amnion and amnion/chorion. It is used to maintain a barrier between adjacent tissues, implants or structures following surgery.
- Q:** What are the indications for Restorigin Sx?
- A:** Restorigin Sx is intended for use as a wound or soft tissue covering and protective barrier.
- Q:** How is Restorigin Sx regulated?
- A:** Restorigin Sx is regulated as a Human Cellular and Tissue Product (HCT/P) under section 361 of the Public Health Service Act (PHS Act). There is no pre-market approval required.
- Q:** What are the benefits of having an amnion and amnion/chorion membrane option?
- A:** The primary difference in the tissue options is the thickness of the membrane which translates to customizable sizing, choice of handling characteristics and duration of time in the body.
- Q:** What is the shelf life of Restorigin Sx?
- A:** Restorigin Sx can be stored for up to 5 years at ambient temperature.
- Q:** Does it matter if placental tissue is terminally sterilized?
- A:** Restorigin Sx is sterilized using electron beam technology. Terminal sterilization offers an additional layer of safety and test results show no change in the makeup of the tissue.<sup>1</sup>
- Q:** I have heard that chorion has an immune response. Do you have data that suggests otherwise?
- A:** 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 has no reported history of an immune response. In addition, the chorion membrane represents the outer shell of the placenta, which is not rejected by the mother.<sup>2,3</sup>
- Q:** What type of procedures would you place Restorigin Sx with epithelial side up?
- A:** Based on physician usage, when the graft is being used as an internal wound covering, the epithelial side should be placed towards the wound bed.

**Q:** Can Restorigin Sx be tacked down?

**A:** Yes, Restorigin Sx Medium and Restorigin Sx Thin can be gently tacked in place.

**Q:** Should Restorigin Sx be hydrated prior to use?

**A:** 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, but it does make handling the tissue more challenging.

**Q:** Can Restorigin Sx be over hydrated, if so what would happen?

**A:** Too much irrigation post implantation should be avoided because it could potentially cause the graft to shift from its position.

**Q:** For internal wounds how long does it take for Restorigin to reincorporate?

**A:** For internal wounds, a single layer of amnion has been shown to take at least 6-12 weeks to resorb in previous animal studies.<sup>4</sup> Restorigin Sx Medium, which contains an amnion and a chorion layer, is expected to persist over a considerably longer period in the body because the thickness of the chorion layer is 2-4 times that of the amnion layer.

**Q:** Can Restorigin Sx be used as a nerve wrap or a dural covering?

**A:** Yes, it can be used as a nerve wrap or dural covering.<sup>5,6,7</sup> Based on physician usage, the epithelial side should be placed up in these types of applications.

1. Restorigin Post Sterilization Growth Factor Data on file.

2. Veenstra van Nieuwenhoven AL et al. The immunology of successful pregnancy. Human Reproduction Update. 2003; 9:347-357.

3. U.eta M et al. Immunosuppressive properties of human amniotic membrane for mixed lymphocyte reaction. Clin Exp Immunol. 2002; 129:464-470.

4. Tao H, Fan H. Implantation of amniotic membrane to reduce postlaminectomy epidural adhesions. Eur Spine J. 2009; 18:1202-12.

5. Meng H et al. Assessment of processed human amniotic membrane as a protective barrier in rat model of sciatic nerve injury. Neuroscience Letters. 2011; 496:48-53.

6. Mligliche N et al. Extracellular matrix of human amnion manufactured into tubes as conduits for peripheral nerve regeneration. J Biomed Mater Res. 2002; 63:591-600.

7. Tomita T et al. New Dried Human Amniotic Membrane Is Useful as a Substitute for Dural Repair Skull Base Surgery. J Neurol Surg B Skull Base. 2012; 73:302-307.

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