



RESTORIGIN[™] Sx
A Natural Next-Generation Tissue Barrier

Post Sterilization Growth Factor Data
for Amniotic Membrane

Restorigin Sx is a family of novel placental tissue allografts in membrane forms

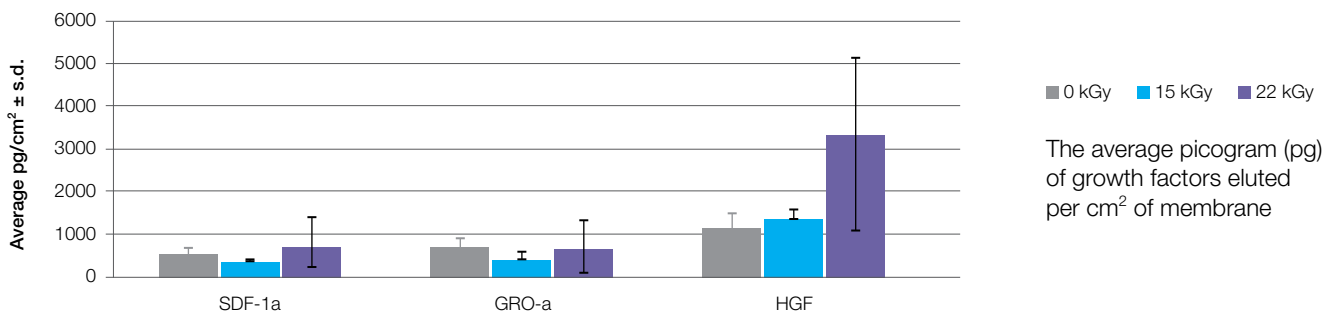
Placental tissues have been shown clinically and scientifically to support soft tissue repair by acting as a physical barrier and covering, protecting new and repaired tissue from the surrounding environment.^{1,2,3} All Restorigin Sx allografts are derived from tissues acquired from living, healthy donors after full-term pregnancy and a scheduled Cesarean section. They have been minimally processed and preserved to maintain the inherent properties of the placental tissues. Restorigin Sx tissues are processed in accordance with the standards and regulations set forth by the Food and Drug Administration (FDA) and the American Association of Tissue Banks (AATB). Our processes have been developed to preserve the placental tissues' inherent characteristics, including the extracellular matrix and growth factors.

Methods

1. The amniotic membranes were collected from consenting mothers, cleaned, dehydrated, cut and packaged in an ISO Class 5 environment.
2. Validation testing was completed on the amniotic membranes and verified that the VDMax 15 method for substantiation of 15 kGy of E-beam exposure achieves a Sterility Assurance Level (SAL) of 10^{-6} .
3. Amniotic membranes were sterilized using electron beam technology.
4. Growth factors were eluted from the membranes for 24 hours in Dulbecco's Modified Eagle Medium (DMEM) with 10% fetal bovine serum (FBS).
5. The supernatant from the elution was assayed for several growth factors, the predominant factor analyzed was Hepatocyte Growth Factor (HGF).
6. Growth factor concentration was determined by MagPix followed by analysis with Milliplex[®] Analyst.

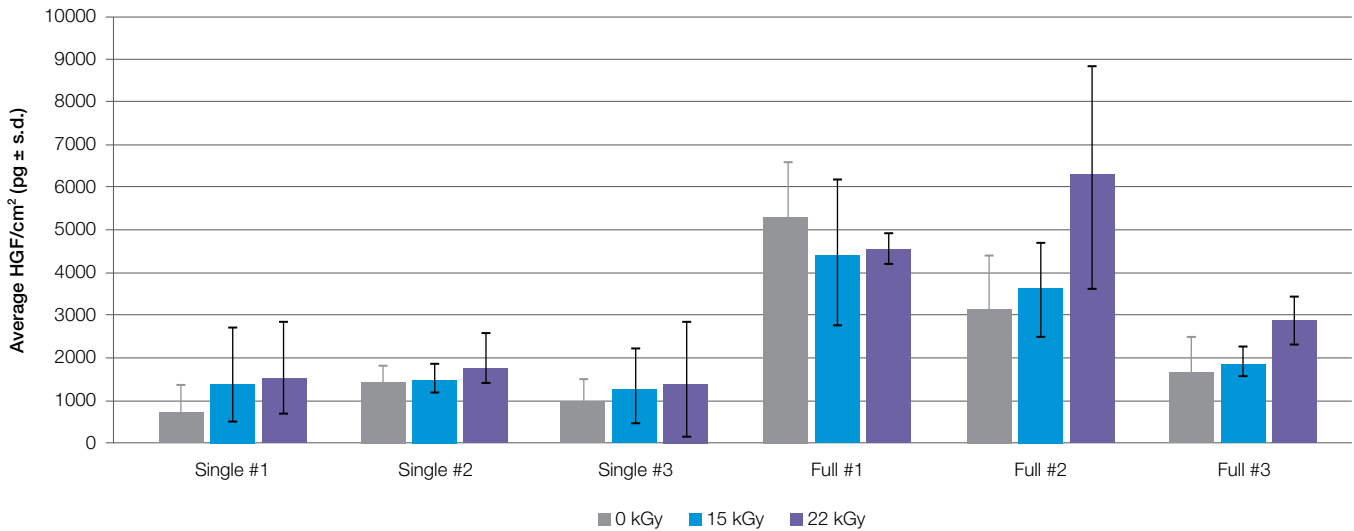
Amniotic Membrane Elution of Growth Factors

Amnion Membrane GF Assay



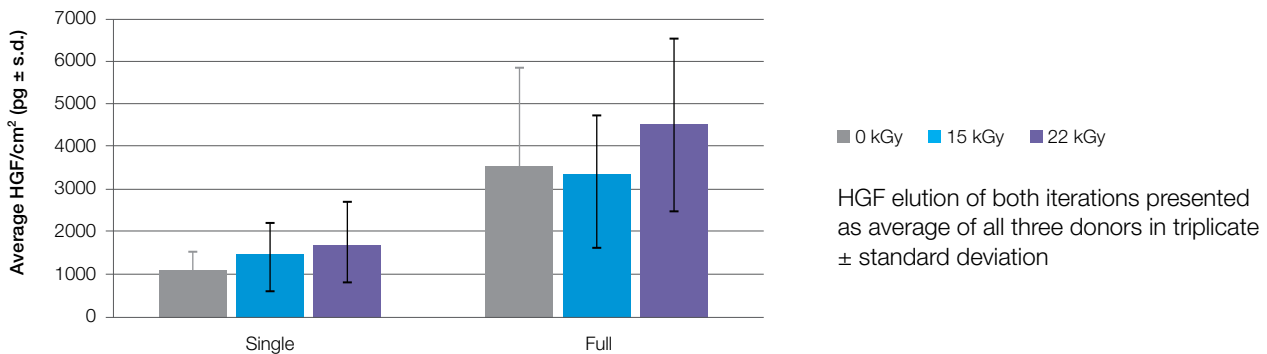
Comparison of Membrane Tissue Iterations

HGF per cm²



The HGF eluted from single layer and full thickness amniotic membrane were compared in triplicate for three separate donors.

Amnion GF's per cm² after E-beam



HGF elution of both iterations presented as average of all three donors in triplicate ± standard deviation

Conclusion

- Multiplex magnetic immunoassays revealed no significant reduction in growth factor elution following up to 22 kGy of E-beam exposure.
- Reported data from E-beam sterilization effectiveness concluded that the Sterility Assurance Level (SAL) of 10⁻⁶ was achieved based on VDMax 15 method.
- Evaluation of the growth factor content revealed that the E-beam exposure had no significant negative effect on HGF, SDF-1 α or GRO- α across exposure levels.

Significance

This study reveals that E-beam exposure can be safely and effectively used for sterilization of amniotic tissues while exhibiting no significant negative effects or reduction in growth factors across exposure levels.

1. Gajiwala K and Gajiwala A.L. (2004). Evaluation of lyophilized, gamma-irradiated amnion as a biological dressing. *Cell and Tissue Banking*, 5, 73-80.
2. Hanumanthappa M.B. et al. (2012). Amniotic membrane dressing versus normal saline dressing in non-healing lower limb ulcers: A prospective comparative study at a teaching hospital. *Journal of Clinical & Diagnostic Research*, May Suppl-1, 6(3). 423-427.
3. Mostaque, A.K. and Rahman, K.B.M.A. (2001). Comparisons of the effects of biological membrane (amnion) and silver sulfadiazine in the management of burn wounds in children. *Journal of Burn Care & Research*, 32(2), 200-209.



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