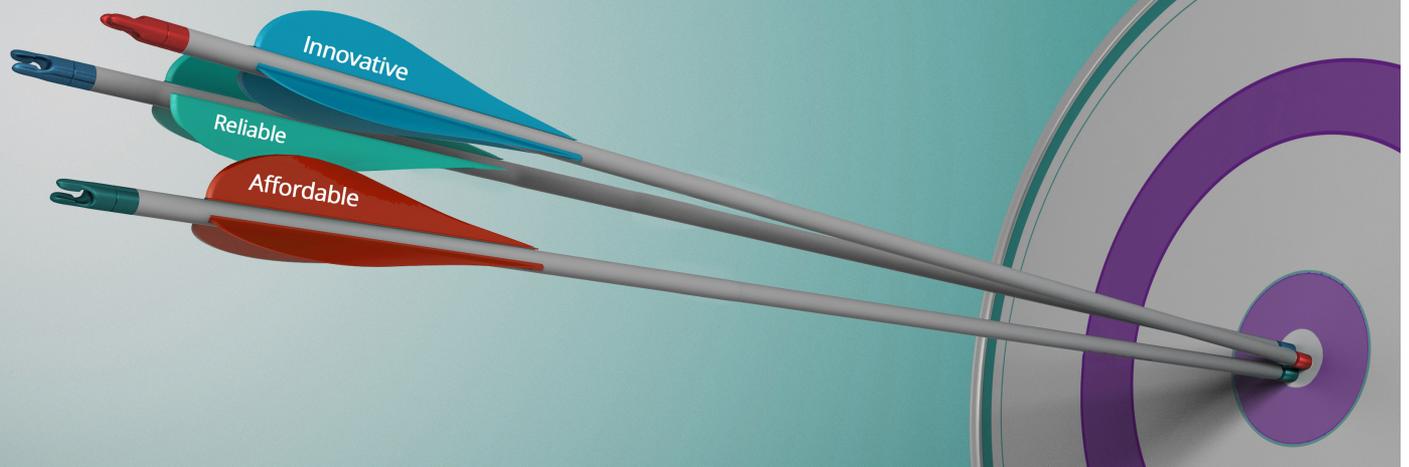


InnovaMatrix™

Platform Technology



A Targeted Approach to Material Selection

Triad Life Sciences® unique placenta source is an ideal material for extracellular matrix medical devices due to its high content of collagen, hyaluronic acid, and for its naturally embedded functional proteins.



A New Category of Advanced Biologic Wound Dressings

Until recently, wound care clinicians who have wanted to utilize ECMs to treat their patients have been limited to choosing products from two categories: placental allografts (Human Cellular Tissue/Products) or xenograft-derived medical devices.

Graft inconsistency has long been an issue for ECMs due to:

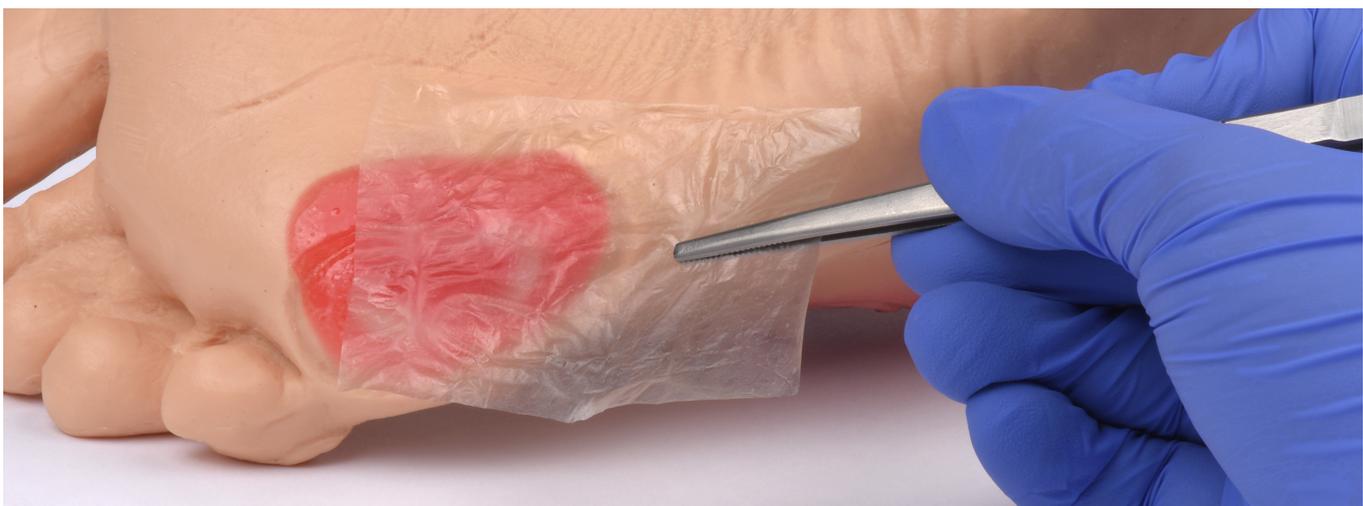
- Variability of human donated placentas
- Limitations to processing of the membrane
- Cellular remnants and debris remain in the ECM
- Age of the source tissue

Triad's porcine placenta source is an ideal material for ECMs because it supports fetal growth and development, it is a relatively young organ in which its age corresponds to the gestation period, and over 10,000 pre-clinical and clinical studies support its use as a wound dressing.

The placenta contains a unique and high component combination of functional ECM molecules such as:

- Elastin
- Hyaluronic Acid
- Sulfated GAGS
- Laminin and Fibronectin

Clinicians now have a new, next generation option for treating their complex surgical, burn, and chronic wounds with the introduction of InnovaMatrix™ AC Placental ECM by Triad Life Sciences®. InnovaMatrix™ AC is the first and only placental-derived medical device that addresses the inherent limitations of human placental grafts.



Processing Matters

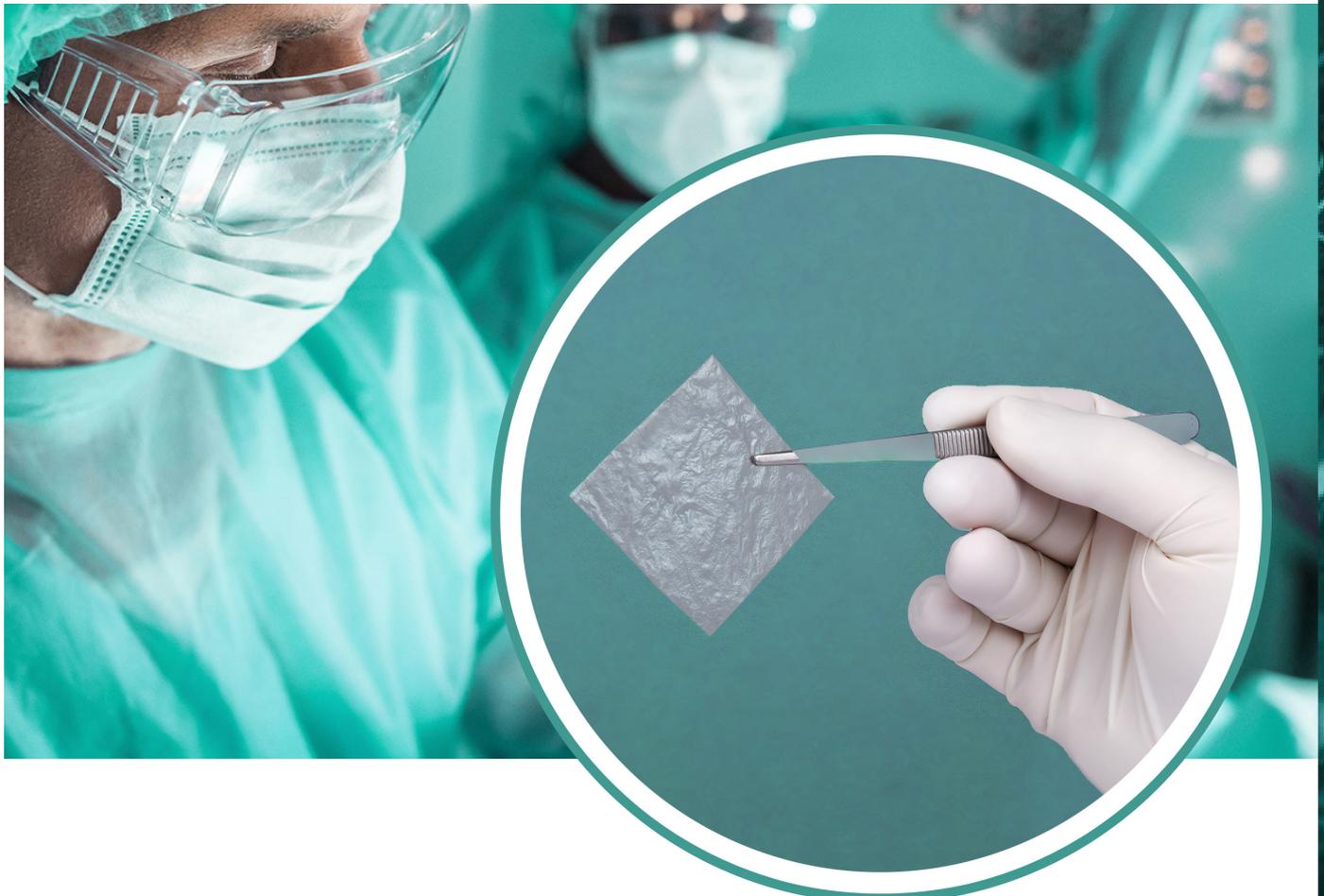
Triad Life Sciences® has developed the state-of-the-art TriCleanse™ Process that has been validated to disinfect tissue, deactivate viruses, and thoroughly decellularize the ECM while maintaining the structural components of the ECM. The combination of the inherent advantages of the placenta and thorough decellularization via the TriCleanse™ Process yields the first-ever placental-derived medical device for wound management.

Processing for ECM membranes has evolved over time and is performed by numerous processors, it is essential to understand that not all processes are similar.

Process variables can include:

- Heated drying
- Antibiotics
- Fixation chemicals
- Oxidizing agents

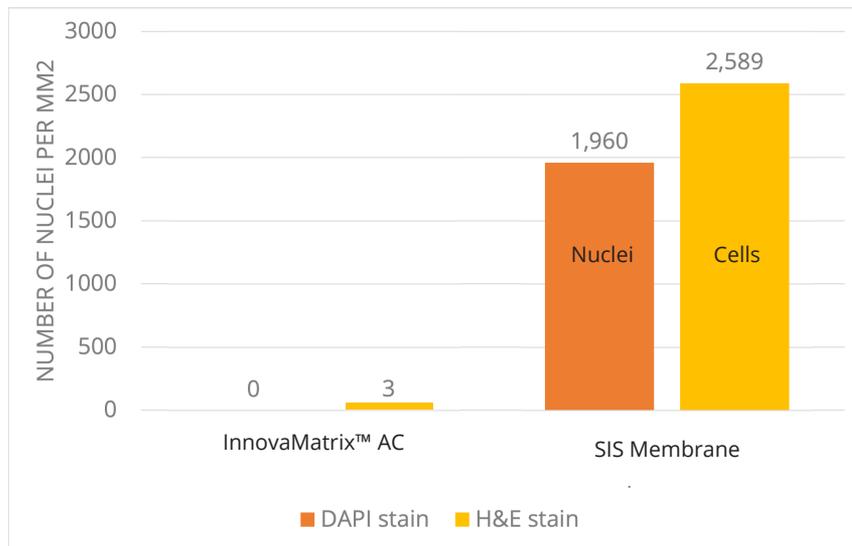
These variables may affect the processed tissue in multiple ways, including residuals from the processing chemicals, presence of antibiotics, and moisture content. Those variations can impact performance and safety of the device.



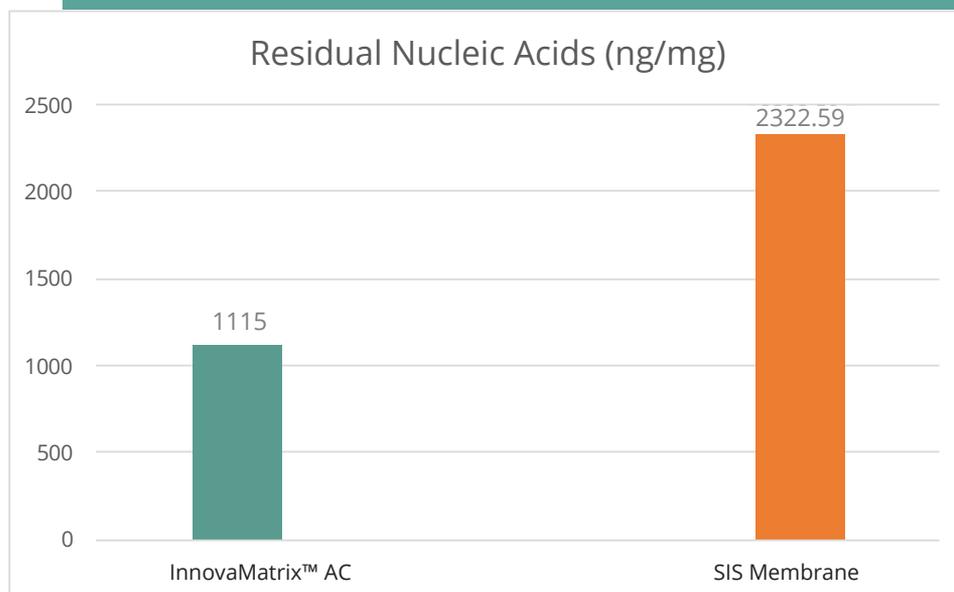
Balancing Decellularization Efficiency and the Denaturing of ECM Proteins

As a placental medical device processed with the proprietary TriCleanse™ Process, InnovaMatrix™ AC was biochemically characterized extensively to identify and quantify the different structural and functional proteins. These results were then compared to a SIS membrane device as a base line for comparison.

Cellular Debris Comparison

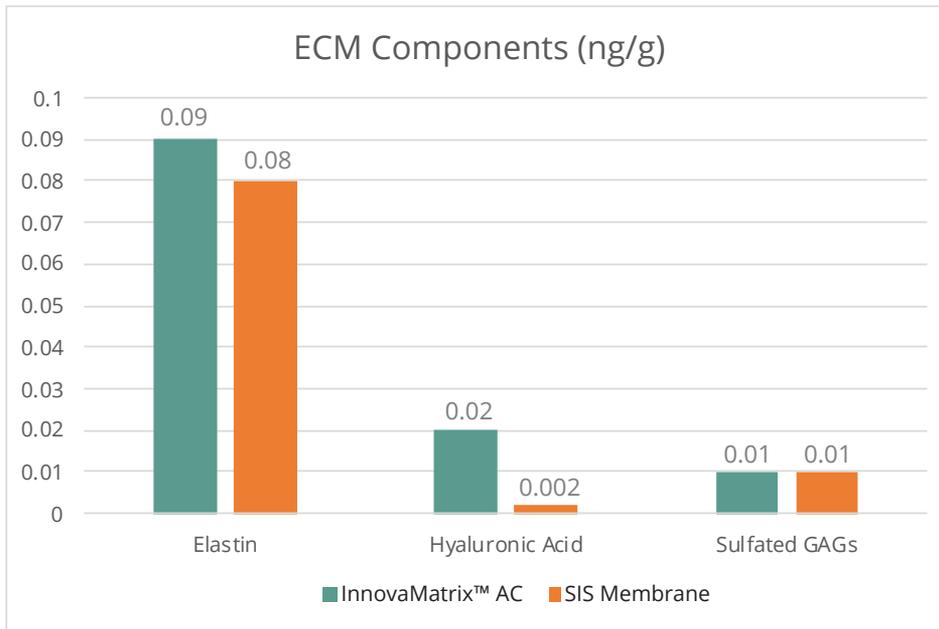


The presence of intact cells and nuclei creates an immunogenic response as cellular antigens are recognized as foreign by the host's immune system.

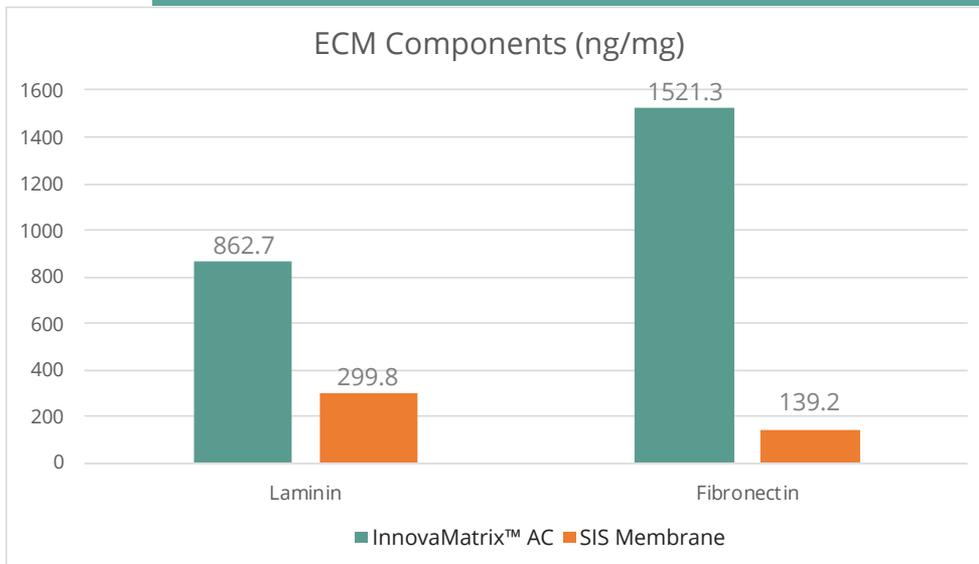


The immune system has the innate capability to recognize nucleic acids not contained within the nucleus via pattern recognition receptors and mount an inflammatory response to their presence.

Naturally Occurring Proteins Content



Functional ECM molecules have an active role in wound healing. Hyaluronic Acid has been demonstrated to play an important role in all stages of wound healing¹.

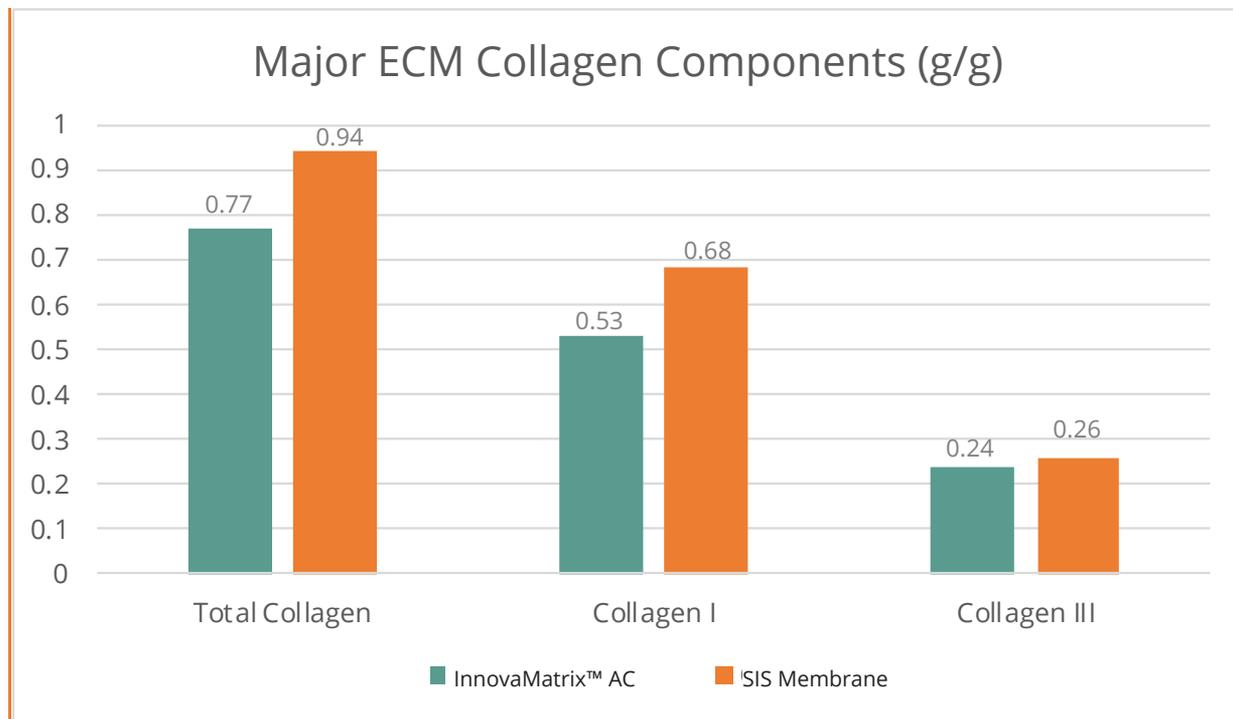


Laminin, a basement membrane protein, plays a critical role in the regulation of cell adhesion, motility, survival, and differentiation and is therefore critical for wound healing².

Fibronectin, an adhesive glycoprotein, plays a crucial role in wound healing, particularly during ECM formation and re-epithelialization³.

1. Litwiniuk M, Krejner A, Speyrer MS, Gauto AR, Grzela T. Hyaluronic Acid in Inflammation and Tissue Regeneration. *Wounds*. 2016 Mar;28(3):78-88.
2. Malinda KM, Wysocki AB, Koblinski JE, Kleinman HK, Ponce ML. Angiogenic laminin-derived peptides stimulate wound healing. *Int J Biochem Cell Biol*. 2008;40(12):2771-80
3. Grinnell F, Billingham RE, Burgess L. Distribution of fibronectin during wound healing in vivo. *J Invest Dermatol*. 1981 Mar;76(3):181-9.

Collagen Content



Collagen, while an important structural protein, has limited regenerative properties when compared to non-collagenous proteins.⁴

Conclusion:

This comparison demonstrates that InnovaMatrix™ AC and the SIS membrane device have similar biochemical constituents, but the quantities of those constituents vary between the two products. While the SIS membrane contains slightly greater quantities of Collagen I, it also contains a slightly more denatured collagen than the InnovaMatrix™ AC device. In addition, InnovaMatrix™ AC has 10 times the amount of Hyaluronic Acid, approximately three times the amount of Laminin, and 11 times the amount of Fibronectin than that of the SIS membrane.

In addition to these varying quantities of proteins, the amount of cellular debris and nucleic acid found in the two ECMs also vary greatly. The SIS-based device, despite claiming decellularization, has 2 times the amount of nucleic acid debris and over 1,000 times more cells and cellular debris than that found in InnovaMatrix™ AC. The comparison found that InnovaMatrix™ AC contains virtually no intact cells or cellular debris and very little remaining nucleic acid, which demonstrates the decellularization efficiency of Triad's proprietary TriCleanse™ Process.

Based on this comparison InnovaMatrix™ AC device has slightly less denatured collagen, a more thoroughly decellularized scaffold, and contains higher amounts of functional proteins. Making InnovaMatrix™ AC an excellent biologic wound dressing that allows the host to heal the wound with little inflammatory response.

4. Cassel JM., Kanagy JR. Studies on the purification of Collagen. U.S. Department of Commerce National Bureau of Standards. Research Paper RP1992 Volume 42, June 1949

Process Flow Chart

Material Source

Production begins with a carefully selected tissue that is sourced from a highly controlled, monitored, and exclusive facility. The site is certified to ISO 13485:2016 and ISO 9001:2015 standards and compliant with the FDA's Good Manufacturing Practices in 21 CFR 820. In addition, the raw placental tissues are compliant with ISO 22442-2 standards.

Physical Processing

The placental tissue undergoes thorough bulk washing, which removes surface contaminants, residual blood, and amniotic fluid.

Final Processing

The dried tissue is processed to its final configuration.

Preservation

The tissue is dried.

TriCleanse™ Process

The placental tissue is subjected to a series of chemical baths and washes that disinfect and decellularize the tissue.

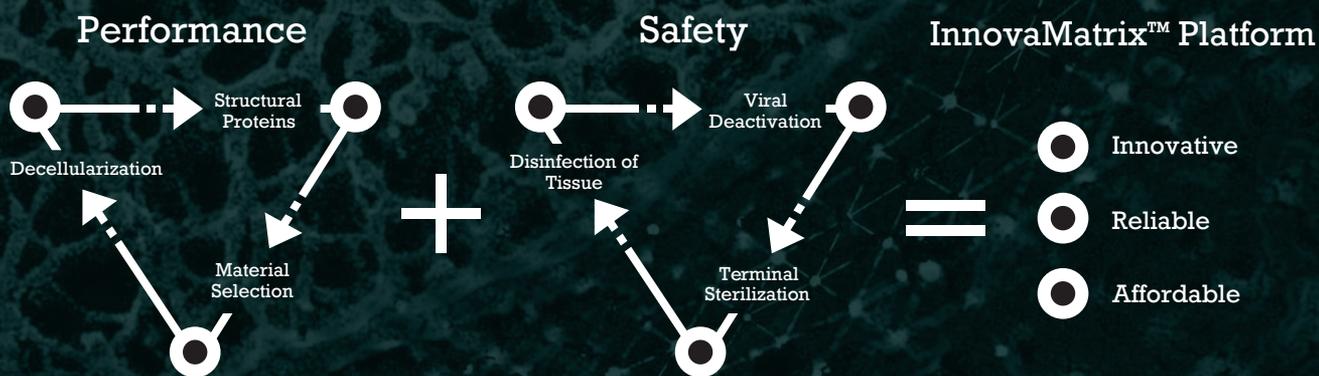
Sterilization

Terminal irradiation to a SAL 10^{-6} .

Triad Life Sciences® is a biotech company dedicated to increasing patient access to innovative, reliable and affordable technologies that address acute, traumatic, and chronic wounds, surgical applications, soft tissue injuries, and other regenerative applications.

The Triad Equation

First placental-derived medical device for surgical and chronic wounds.



Engineered by Nature, Powered by Science®

1770 Moriah Woods Blvd. • Suite 18 • Memphis, TN 38117 • www.triadls.com

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