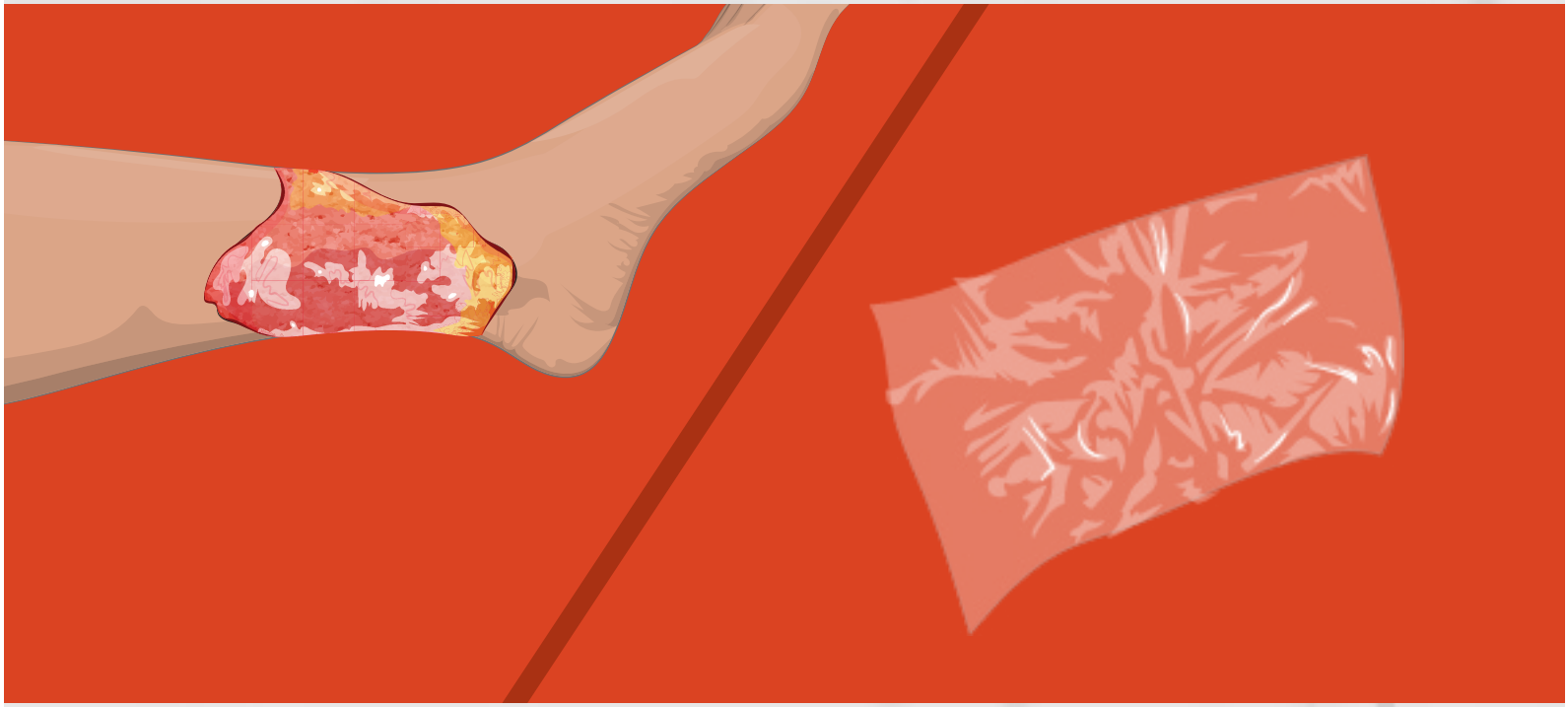
InnovaBurn™

Placental Extracellular Matrix

Application Guide



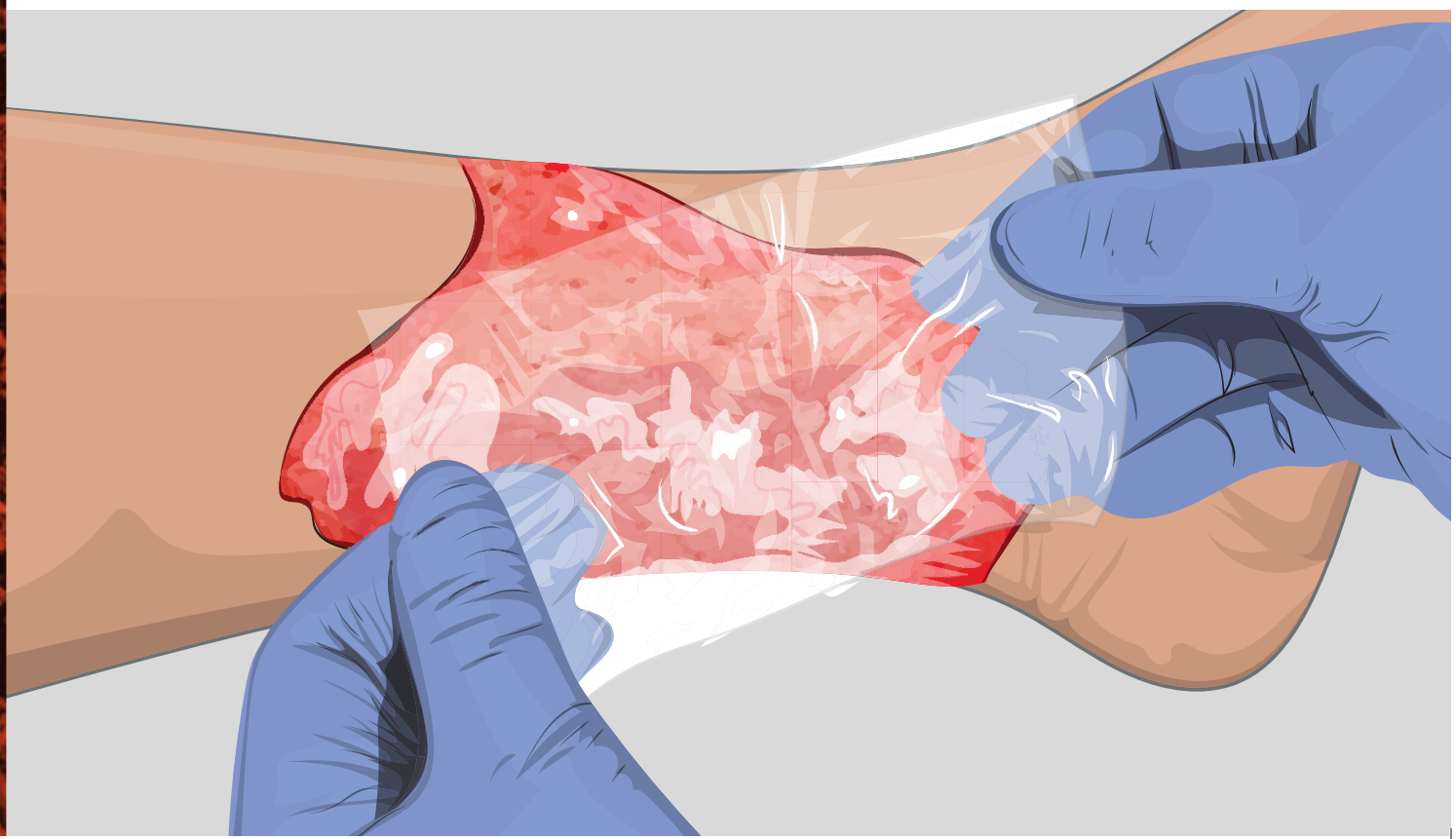
InnovaBurn™

InnovaBurn™ is a significant and innovative advancement in biologic dressings for acute, traumatic, and chronic wound care. Manufactured with Triad's proprietary TriCleanse™ Process, InnovaBurn™ is a new category of placental-derived medical device that preserves the inherent benefits of the placenta while adding the reliability, reproducibility, and safety of a medical device.

Indications for Use

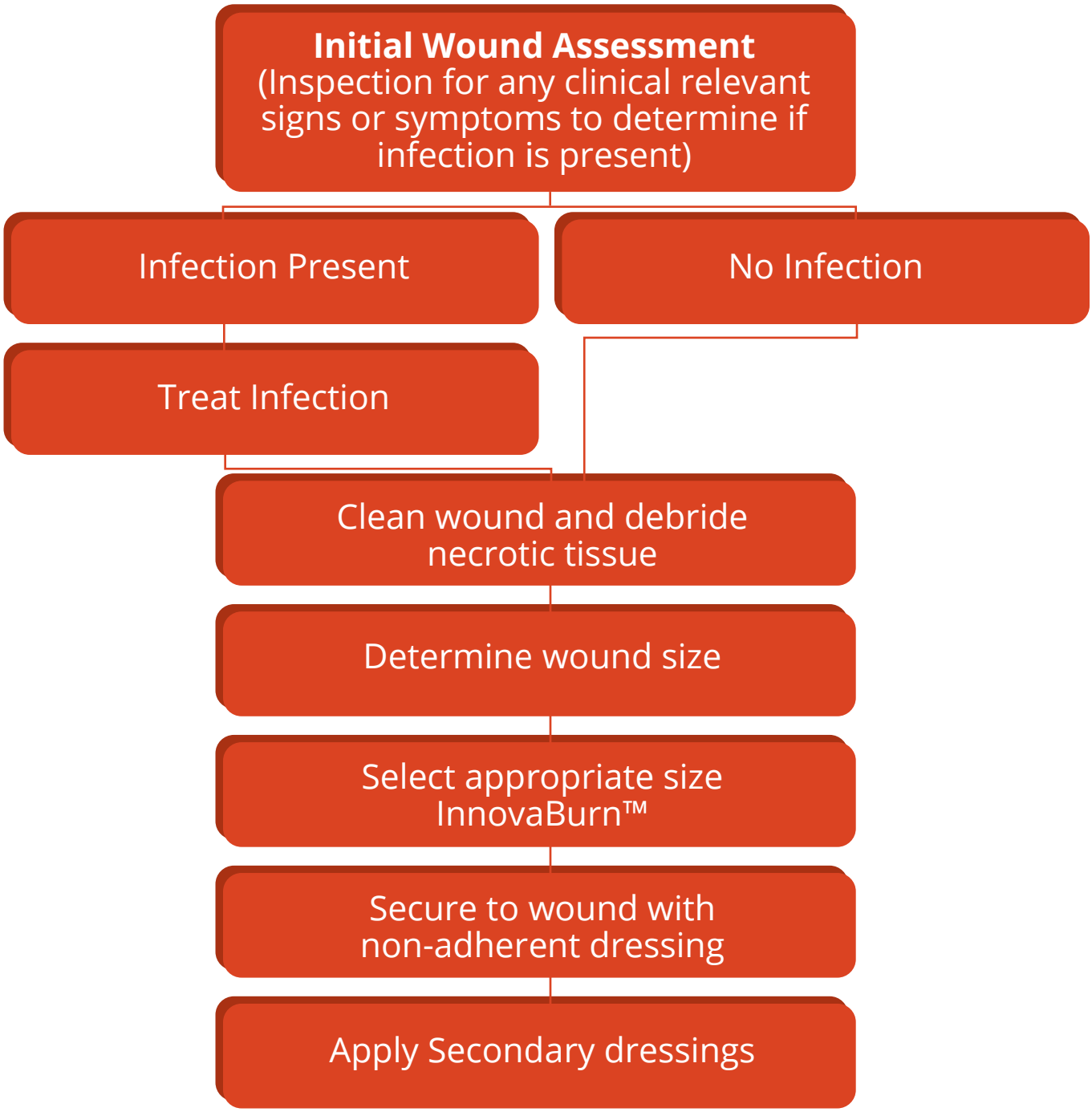
InnovaBurn™ is indicated for the management of wounds including:

- Partial and full-thickness wounds
- Venous ulcers
- Chronic vascular ulcers
- Surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence)
- Trauma wound (abrasions, lacerations, second-degree burns, and skin tears)
- Draining Wounds
- Pressure ulcers
- Diabetic ulcers
- Tunneled/undermined



Wound Management with InnovaBurn™

In order to use InnovaBurn™ effectively, a wound assessment and routine needs to be performed. The following chart briefly mentions the process, starting with the inspection of the wound.



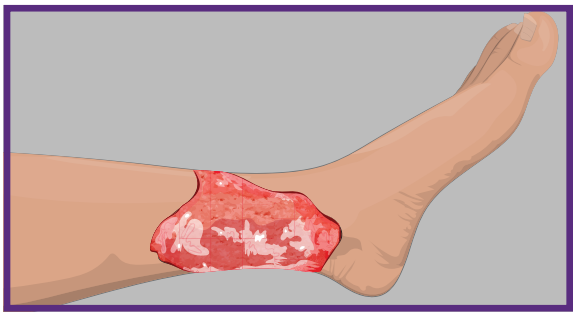
Application Process for InnovaBurn™

1. Wound Bed Preparation

a. Before applying InnovaBurn™, the wound must first be debrided of all non-viable tissue or necrotic tissue. Most importantly, insure there is no active infection.

b. Allow for any bleeding to stop before administering InnovaBurn™.

c. Completely and thoroughly cleanse the wound.

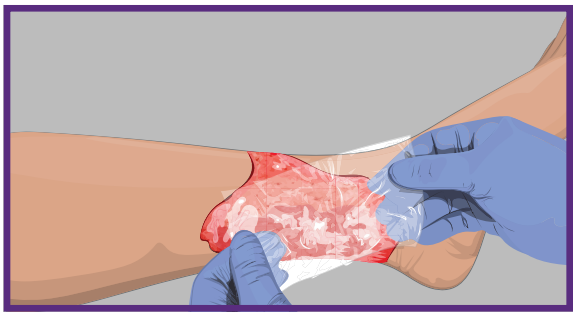


2. Device Size Selection

a. Measure the wound and select the correct size device to cover the entirety of the wound surface.

b. Allow for any bleeding to stop before administering InnovaBurn™.

Note: Cut the sheet to cover the entire wound surface and extend slightly beyond the wound margins.



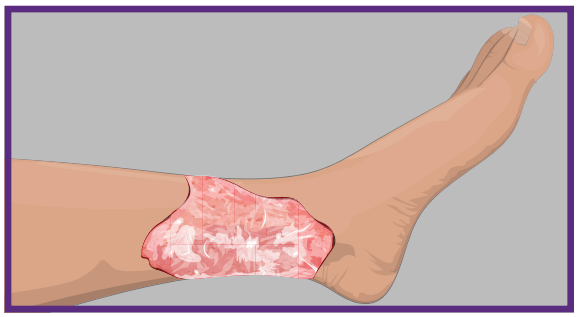
InnovaBurn™	Size	cm^2 coverage
IMB-0507-01	5 cm x 7 cm	35 cm^2 coverage
IMB-0808-01	8 cm x 8 cm	64 cm^2 coverage
IMB-1010-01	10 cm x 10 cm	100 cm^2 coverage
IMB-1020-01	10 cm x 20 cm	200 cm^2 coverage
IMB-1520-01	15 cm x 20 cm	300 cm^2 coverage

3. Device Application

a. Apply the InnovaBurn™ device that is completely dry directly on the wound to ensure ease of handling. Make sure the device is entirely in contact with the wound bed and slightly extends beyond all wound margins. If multiple sheets are needed, slightly overlap the edges of the sheets or mesh with scalpel.

b. Securely anchor InnovaBurn™ with the preferred fixation method (e.g., STERI-STRIP™ tissue sealant, bolsters, dissolvable clips, sutures, staples, or other appropriate fixation method) based on the type, location, and complications of the wound.

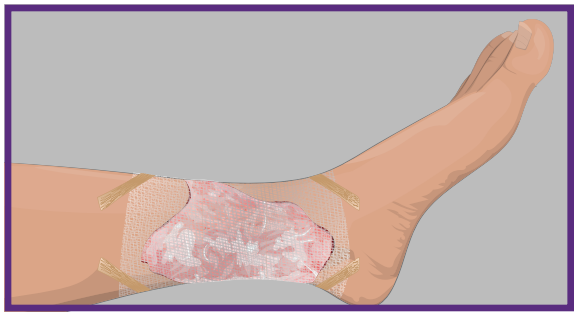
c. Apply sterile saline on the InnovaBurn™ device to rehydrate the sheet.



4. Wound Dressings

a. To protect the device from adhering to secondary dressing apply an appropriate non-adherent primary wound dressing over InnovaBurn™.

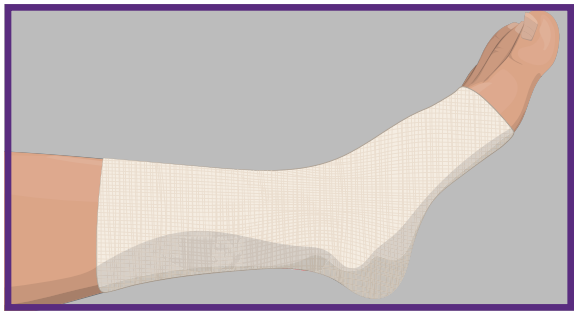
b. Apply appropriate secondary dressing that will manage the wound exudate and keep the InnovaBurn™ moist and securely in place.



5. Dressing Changes

a. To prevent damage to the newly incorporating InnovaBurn™, only change the primary dressing as necessary, typically every 7 days.

b. Change the secondary dressing as appropriate. Take care to avoid dislodging the InnovaBurn™ when secondary dressing is changed.



Management Post Initial Application

1. Wound Assessment and Wound Bed Preparation for Reapplication

a. Change all dressings every 7 days, or as needed.

NOTE: If a gel forms on the wound surface, do not attempt to forcibly remove it. Successful absorption of InnovaBurn™ may form a caramel-colored or off-white gel. Do not remove this gel by debridement. This gel contains ECM, which continues to replace deficient and missing ECM in the wound.

b. As healing occurs, sections of InnovaBurn™ may gradually peel around the edges. Remove any loose product as needed.

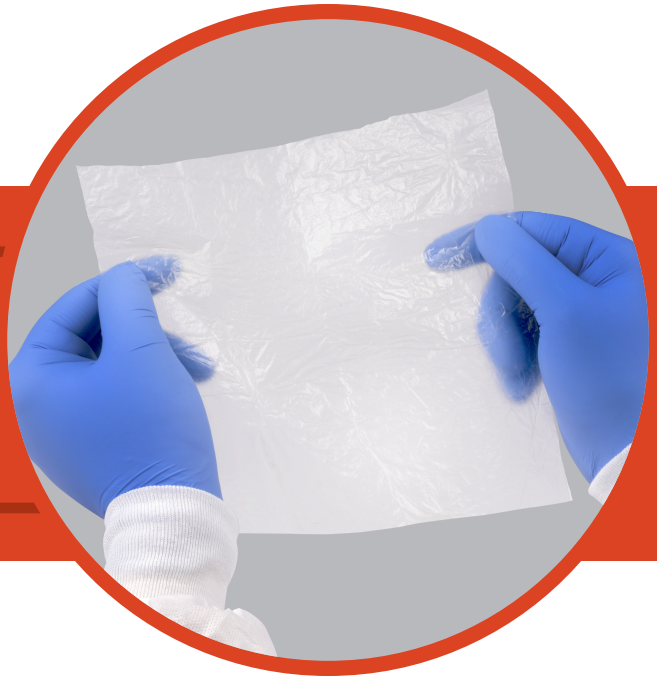
c. Gently cleanse the wound surface with sterile saline; be sure to leave any remaining ECM gel intact.

d. Reassess the wound and record healing progression.

2. Reapplication of InnovaBurn™ and Dressing Changes

a. If the wound is free of infection and necrosis but not fully epithelialized, reapply newly prepared InnovaBurn™ over previously absorbed application. Reapply every 7 days or as needed.

b. Apply new dressings as described earlier in Step 5 – Dressing Changes.



★ Please refer to Instructions for use (IFU) for complete instructions.

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.

TriCleanse™ Process

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

Preservation

The tissue is dried.

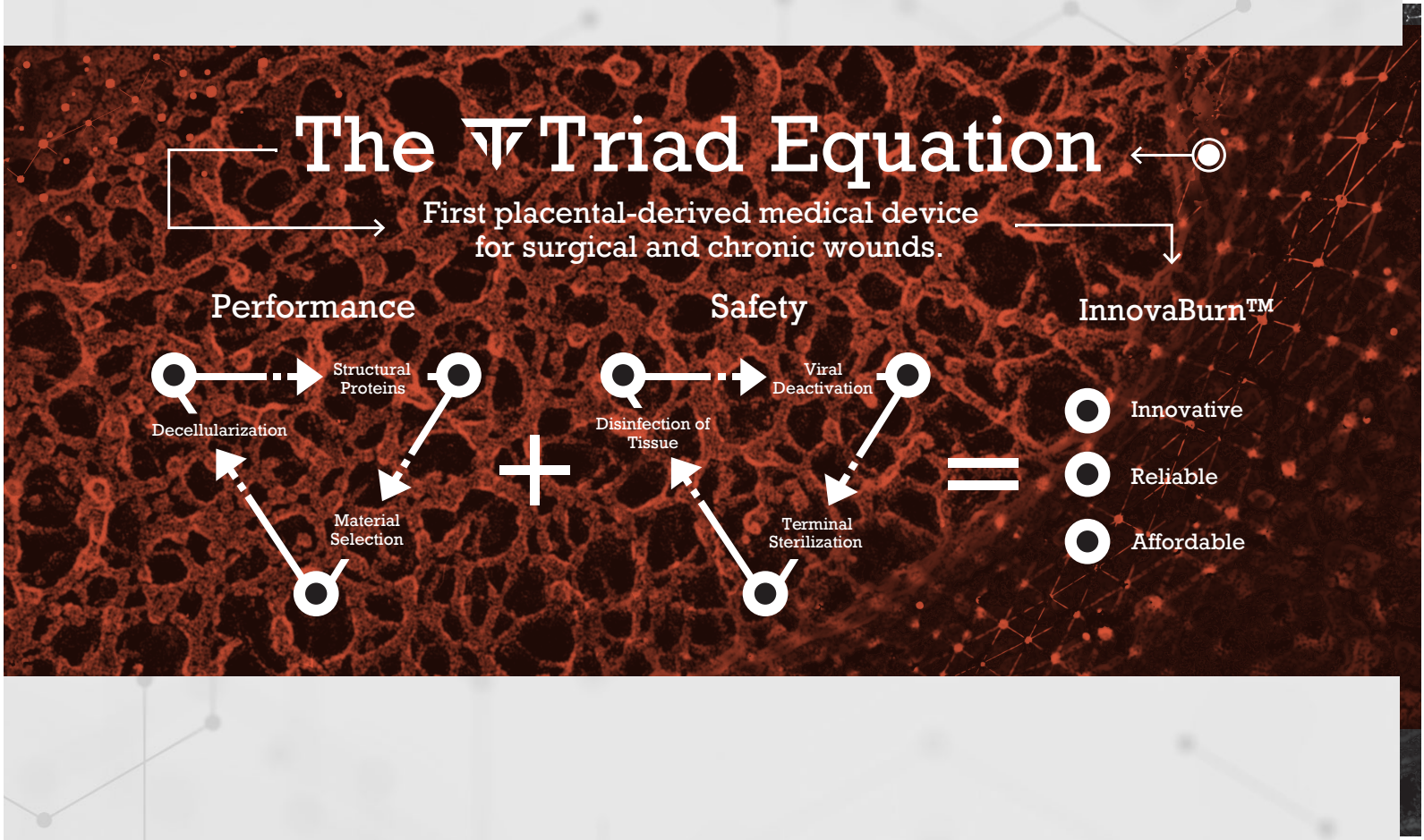
Final Processing

The dried tissue is processed to its final configuration.

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.



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