THE PROVEN CHOICE



THE **ONLY** PRODUCT APPROVED FOR SEALING, GLUING AND TISSUE REINFORCEMENT BioGlue **BioGlue**® **USED IN OVER** WORLDWIDE

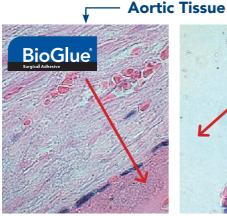


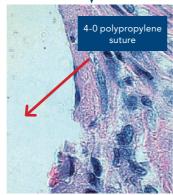


BioGlue is a protein hydrogel that covalently bonds with tissue and mechanically binds with synthetic materials for optimal strength and adherence.

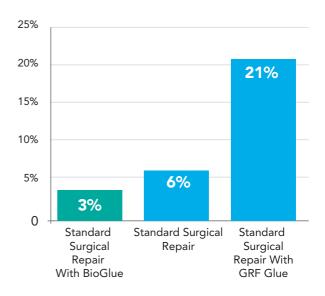
Safe

- Histopathological observations with BioGlue are consistent with a normal foreign body reaction¹
- Tissue, on the contrary, in contact with polypropylene suture material exhibits a marked increase in inflammatory response, consisting of macrophage formation and tissue fibrosis





Published Rates of Pseudoaneurysms

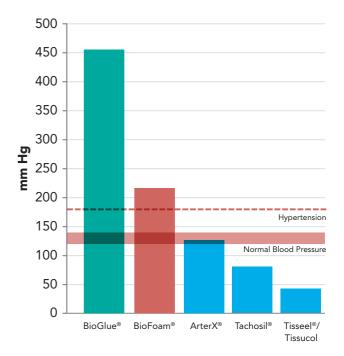


<3% pseudo-aneurysm rate Elefteriades et al.²

Effective

- 99% complete haemostasis in aortic surgery* (*Passage J. et al.*)⁴
- 6-7% mortality rate in aortic dissection repair (Westaby S. et al.)⁵, (Bavaria et al.)⁶
- CSF leak rates between 0.6% and 1.2% in neurosurgery (*Kumar A. et al.*)⁷, (*Esposito F. et al.*)⁸

Burst Strength³



^{*}BioGlue used as adjunct to standard method

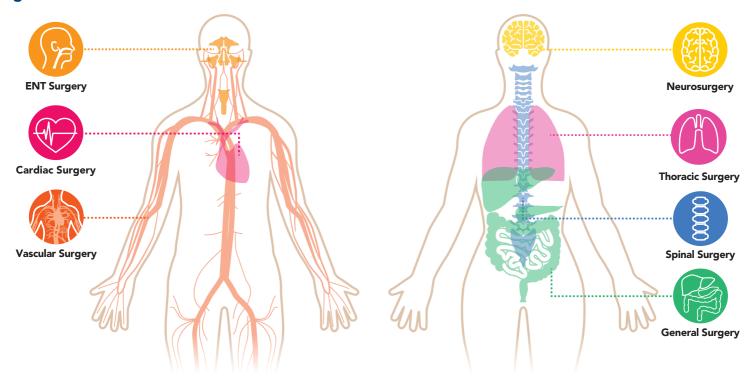
Bovine Serum Albumin (BSA) (45%) and glutaraldehyde (10%) components are combined to form BioGlue, a protein hydrogel consisting of BSA and 65% water.

There is no risk of tissue necrosis from BioGlue because glutaraldehyde is fully consumed during the polymerisation step.

Clinically Proven

BioGlue has been used in over one million procedures since 1998. Over 500 scientific articles have been published discussing the safety and efficacy of BioGlue as an adjunct to standard methods of repair in many types of surgical procedures.

Surgical Indications



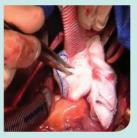




Application Technique



1. De-air remove all air from the syringe



2. Dry
the target site
(by suction and/
or gauze)



3. Prime the syringe



4. Apply
a thin layer in
a slow and
steady manner



5. Wait 2 minutes for full strength

For full application technique please see IFU.

BioGlue Syringe Delivery System

Catalogue Number	Product	Contains
BG3502-5-G	Syringe 2mL 5-Pack Kit	Five single packs – Each contains one 2mL syringe and syringe plunger, and four standard syringe tips
BG3515-5-G	Syringe 5mL 5-Pack Kit	Five single packs – Each contains one 5mL syringe and syringe plunger, and four standard syringe tips
BG3510-5-G	Syringe 10mL 5-Pack Kit	Five single packs – Each contains one 10mL syringe and syringe plunger, four standard syringe tips, and three 12mm spreader tips
BG3500N	Syringe Delivery Device	One single pack – Contains one non-sterile reusable syringe delivery device
BGAT-SY	Syringe Applicator Tip	Ten single packs – Each contains four standard syringe tips
BGAT-10-SY	Syringe 10cm Applicator Tip	Ten single packs – Each contains four 10cm syringe tips
BGAT-27-SY	Syringe 27cm Applicator Tip	Ten single packs – Each contains four 27cm syringe tips
BGST-12	Syringe 12mm Spreader Tip	Ten single packs – Each contains three 12mm spreader tips
BGST-16	Syringe 16mm Spreader Tip	Ten single packs – Each contains three 16mm spreader tips

Indications For Use:

BioGlue Surgical Adhesive is indicated for use as an adjunct to standard methods of surgical repair (such as sutures, staples, electrocautery, and/or patches) to bond, seal, and/or reinforce soft tissue. BioGlue may also be applied alone to seal and/or reinforce damaged parenchyma when other ligature or conventional procedures are ineffective or impractical. Indicated soft tissues are cardiac, vascular, pulmonary, genitourinary, dural, alimentary (oesophageal, gastrointestinal and colorectal), and other abdominal (pancreatic, splenic, hepatic and biliary). Additionally, BioGlue is used in the fixation of surgical meshes in hernia repair.

- ¹ Summary of Safety and Effectiveness, CryoLife. BioGlue Surgical Adhesive.
- ² Elefteriades, J. et al. Role of Bovine Serum Albumin-Glutaraldehyde Glue in the Formation of Anastomatic Pseudoaneurysms J Card Surg 2011;26:76-81.
- ³ Data on file, test conducted on femoral artery Test # RD0118. Lab Notebook # CSW01.
- ⁴ Passage J. et al. BioGlue surgical adhesive an appraisal of its indications in cardiac surgery Ann Thorac Surg 2002; 74: 432-437.
- Westaby S. et al. Acute Type A Dissection: Conservative Methods Provide Consistently Low Mortality. Ann Thorac Surg 2002;73:707-13.
- ⁶ Bavaria J.E. et al. Advances in the Treatment of Acute Type A Dissection: An Integrated Approach. Ann Thorac Surg 2002;74:S1848 –52.
- ⁷ Kumar A. et al. Evaluation of use of a protein-based bioadhesive in neurosurgical procedures. Journal of Clinical Neuroscience (2003) 10(6), 661–664.
- ⁸ Esposito F. et al. Graded repair of cranial base defects and cerebrospinal fluid leaks in transsphenoidal surgery. Neurosurgery 2007;60(ONS Supple 2):ONS-295—ONS-304.



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