BioGlue®
Surgical Adhesive

BioGlue Syringe Delivery System

Catalogue Number	Product	Contains
BG3510-5-US	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
BG3515-5-US	Syringe 5mL 5-Pack Kit	Five single packs – Each contains one 5mL syringe and syringe plunger, and four standard syringe 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

[1] Fehrenbacher JW, Siderys H. Use of BioGlue in Aortic Surgery: Proper Application Techniques and Results in 92 Patients. Heart Surg Forum 2006; 9(5):E794-9.

[2] Zehr KJ. Use of Bovine Albumin-Glutaraldehyde Glue in Cardiovascular Surgery. Ann Thorac Surg 2007;84:1048-52.

[3] BioGlue Surgical Adhesive Instructions for Use.

INDICATIONS FOR USE BioGlue® Surgical Adhesive is indicated for use as an adjunct to standard methods of achieving hemostasis (such as sutures and staples) in adult patients in open surgical repair of large vessels (such as aorta, femoral, and carotid arteries). Rx Only.

CONTRAINDICATIONS Not for patients with a known sensitivity to materials of bovine origin. Not for intravascular use. Not for cerebrovascular repair. BioGlue for use in neurosurgery, including use as a dural sealant, is not an approved indication. FDA has not evaluated the safety and effectiveness in support of a neurosurgical indication; however, serious adverse events such as stroke, infection, meningitis, and cerebrospinal fluid leaks have been reported.

WARNINGS

Warning: Polymerized BioGlue has space occupying properties. When used improperly, or applied incorrectly, serious adverse events have been reported relating to compression of adjacent anatomic structures. BioGlue should be used only when complete visualization of the target application location is possible, when it is properly primed to achieve optimal viscosity, and a minimal amount is used. Please see the Indications for Use and Directions for Use sections of this label.

Warning: Animal studies have shown that direct application of BioGlue to the exposed phrenic nerve can cause acute nerve injury. BioGlue application to the surface of the heart can cause coagulation necrosis that extends into the myocardium, which could reach underlying conduction tissue and may cause acute, focal sinoatrial node degeneration.

Use of BioGlue in pediatric patients has not been studied. BioGlue should not be applied circumferentially to tissue that needs to grow, as it bonds with the tissue and may not allow that tissue to grow or expand. Do not use BioGlue as a substitute for sutures or staples. Do not expose valve leaflets or intracardiac structures to BioGlue. Do not allow BioGlue in either the uncured or polymerized form to contact circulating blood. BioGlue entering the circulation can result in local or embolic vascular obstruction. Avoid exposing nerves to BioGlue. Avoid contact with skin or other tissue not intended for application. Minimize use of BioGlue in patients with abnormal calcium metabolism (e.g., chronic renal failure, hyperparathyroidism). Glutaraldehyde-treated tissue has an enhanced propensity for mineralization. Laboratory experiments indicate that unreacted glutaraldehyde may have mutagenic effects. Do not use BioGlue if staff are not adequately protected (e.g., wearing gloves, mask, protective clothing, and safety glasses). Unreacted glutaraldehyde may cause irritation to eye, nose, throat, or skin, induce respiratory distress, and cause local tissue necrosis. Prolonged exposure to unreacted glutaraldehyde may cause a central nervous system or cardiac pathology. If contact occurs, flush affected areas immediately with water and seek medical attention. Do not use BioGlue in the presence of infection and use with caution in contaminated areas of the body. Avoid repeat exposure of BioGlue in the same patient. Hypersensitivity reactions are possible upon exposure to BioGlue. Sensitization has been observed in animals. BioGlue contains a material of animal origin, which may be capable of transmitting infectious agents. BioGlue, which degrades via proteolysis, can be slow to resorb dependent on the quantity of adhesive applied. The slow resorption of excessive amounts of BioGlue has been associated with sterile inflammatory response requiring explant of the material. BioGlue should be applied as a thin layer, as an adjunct to sutures or staples, and in amounts sufficient to seal the area. BioGlue should not be applied in excess.

PRECAUTIONS Safety and effectiveness of BioGlue in minimally invasive procedures have not been established. Safety and effectiveness of BioGlue in coronary artery bypass grafting (CABG) and other use on small diameter vessels has not been established. Do not use blood saving devices when suctioning excess BioGlue from the surgical field. Clamp and depressurize vessels prior to applying BioGlue to targeted anastomoses. To prevent the entrance of BioGlue into the cardiovascular system, avoid any negative pressure during application and polymerization of BioGlue. For example, left ventricular vents should be turned off prior to the application of BioGlue. There have been reports of BioGlue being suctioned into the aorta and impeding heart valve function when used in conjunction with an active left ventricular vent. It is recommended that surgical gloves, sterile gauze pads/towels, and surgical instruments be maintained moist to minimize the potential for BioGlue inadvertently adhering to these surfaces. BioGlue solutions cartridges, applicator tips, and applicator tip extenders are for single patient use only. Do not re-sterilize. Do not use if packages have been opened or damaged. Take care not to spill contents of the solutions cartridge. Do not compress the main delivery unit trigger mechanism while attaching the solutions cartridge to the delivery device. Do not apply BioGlue in a surgical field that is too wet. This may result in poor adherence. Avoid tissue contact with material expelled from applicator during priming. BioGlue polymerizes rapidly. Priming must occur quickly, followed immediately by the application of BioGlue. Pausing between priming and application can cause polymerization within the applicator tip. Do not peel away BioGlue from an unintended site, as this could result in tissue damage.

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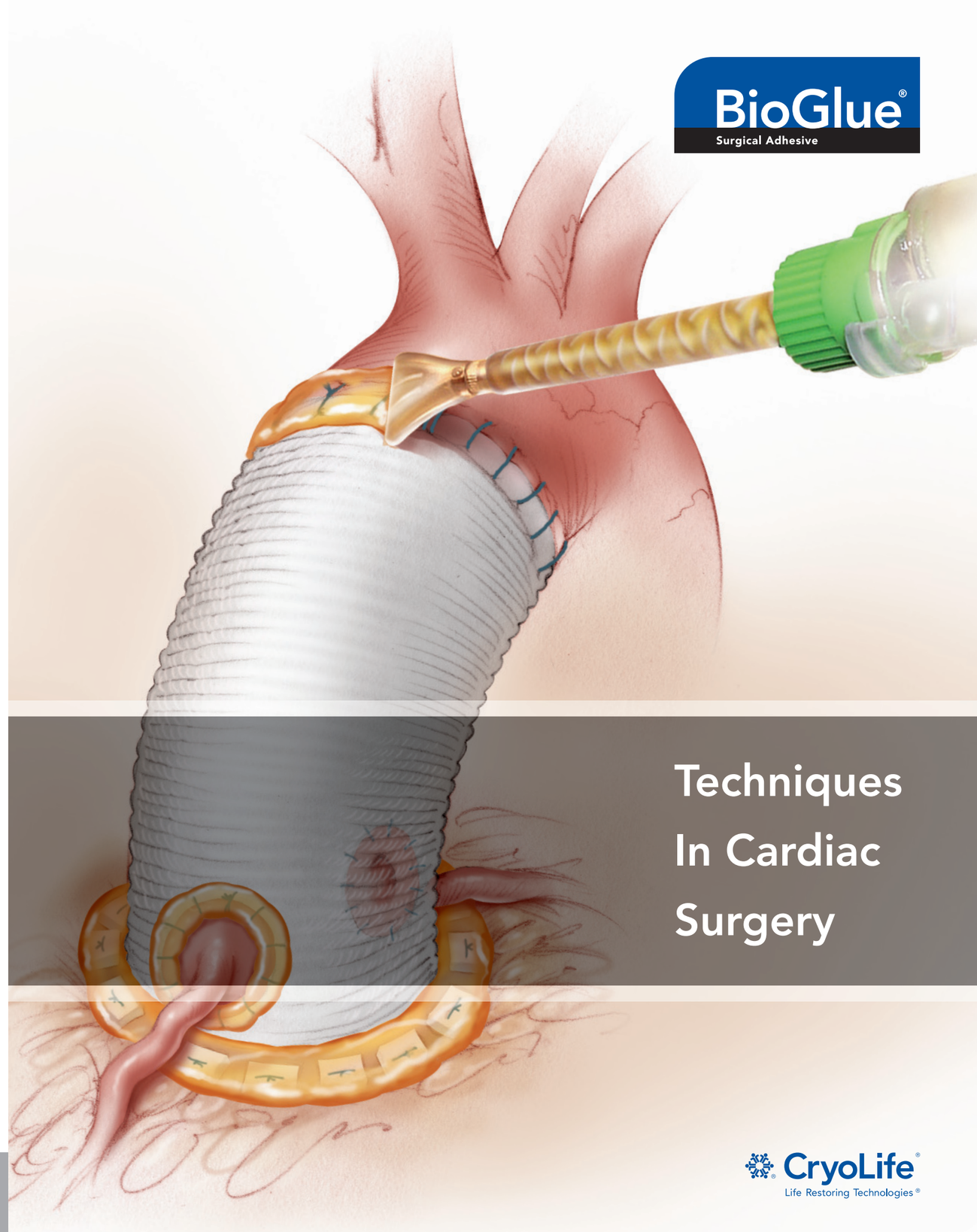
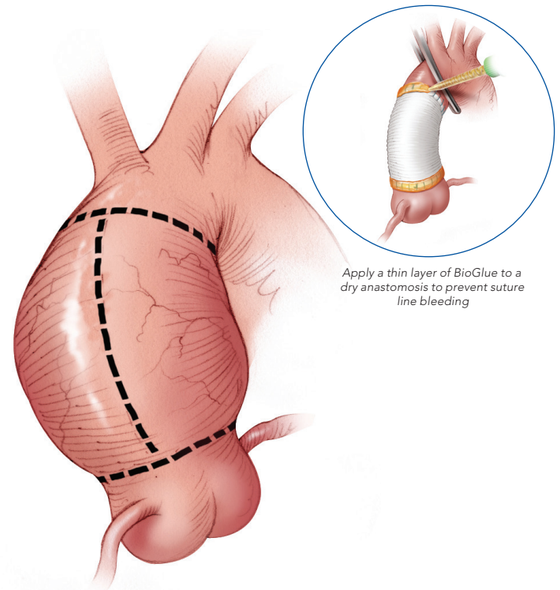


BioGlue®
Surgical Adhesive

Techniques In Cardiac Surgery

CryoLife®
Life Restoring Technologies®

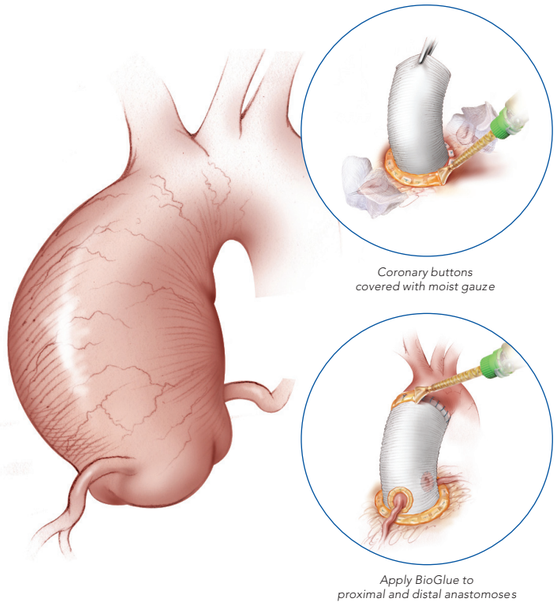
Application Techniques in Cardiac Surgery



Apply a thin layer of BioGlue to a dry anastomosis to prevent suture line bleeding

Aortic Aneurysm[1,2]

- Clamp and depressurize vessel prior to BioGlue application
- Dry the target site to ensure optimal adherence of BioGlue to the target tissue
- Prime the applicator tip and apply a thin layer of BioGlue that extends 1cm in either direction of the suture line
- Wait 2 minutes for BioGlue to completely polymerize before pressurizing the anastomosis
- Complete the final anastomosis, and again apply a thin layer of BioGlue to prevent suture line bleeding
- Wait 2 minutes before re-establishing systemic blood flow

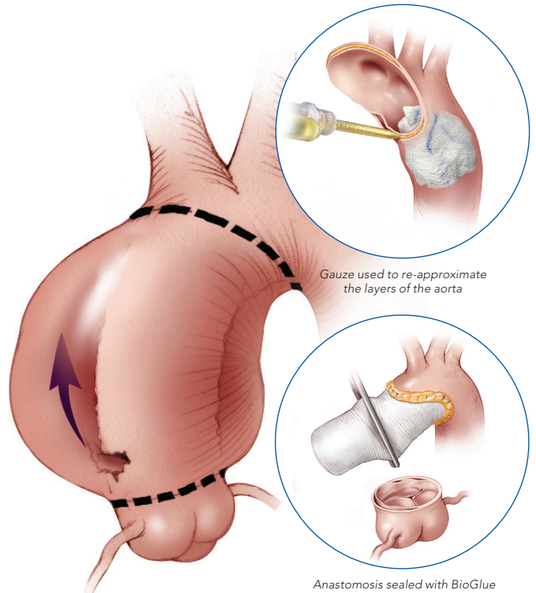


Coronary buttons covered with moist gauze

Apply BioGlue to proximal and distal anastomoses

Aortic Valve Replacement[1,2]

- Cover the coronary buttons with moist gauze prior to the application of BioGlue
- Prime the applicator tip and apply a thin layer of BioGlue to a dry, depressurized vessel
- Apply slight tension to the graft during BioGlue application to mimic the position of the graft once systemic flow has been re-established
- Do not allow excess BioGlue to pool around the base of the valve
- Always allow 2 minutes for the full polymerization of BioGlue before manipulating the anastomosis



Gauze used to re-approximate the layers of the aorta

Anastomosis sealed with BioGlue

Type A Aortic Dissection[1,2]

Distal Repair

- Insert gauze into the true lumen to re-approximate layers of the aorta
- Obliterate false lumen by applying a 2mm thick and 2cm deep layer of BioGlue
- Use caution to avoid over-filling the false lumen
- After 2 minutes inspect lumen and carefully remove any excess BioGlue
- Repaired aorta may be further reinforced with felt strips if desired
- Once graft has been sewn in place, seal anastomosis with a thin layer of BioGlue to prevent suture line bleeding

Apply BioGlue in a "spiralling-out" motion

Proximal Repair

- Cover aortic valve leaflets with moist gauze prior to BioGlue application
- Obliterate false lumen by applying a 2mm thick and 2cm deep layer of BioGlue
- Use caution to avoid overfilling the false lumen
- After 2 minutes inspect lumen and carefully remove any excess BioGlue
- Repaired aorta can be further reinforced with felt strips if preferred

Key Application Techniques[3]

1. Dry the target site to ensure optimal adherence of BioGlue to target tissue
2. Clamp and depressurize vessels prior to applying BioGlue to targeted anastomoses
3. Prime the applicator tip to ensure proper mixing of the components
4. Switch from Cell Saver® to wall suction to prevent BioGlue from entering the pump system
5. Apply a thin layer of BioGlue directly onto the suture line to prevent suture line bleeding
6. Wait 2 minutes before pressurizing the anastomoses to allow for full BioGlue polymerization