CryoLife, Inc.
Biotechnologies for Medicine™

BioGlue® Surgical Adhesive
Instructions for Use

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Biotechnologies for Medicine℠

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Instructions for Use

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Read Instructions for Use prior to using this product.

DEVICE DESCRIPTION

BioGlue® Surgical Adhesive (BioGlue) is a two-component surgical adhesive composed of purified bovine serum albumin (BSA) and glutaraldehyde. The BSA is obtained from cattle exclusively from bovine spongiform encephalopathy (BSE) free countries and undergoes processing that reduces or inactivates viruses. The solutions are dispensed by a controlled delivery system, composed of a reusable delivery device, applicator tips, and applicator tip extenders. Once dispensed, the adhesive solutions (in a predefined ratio) are mixed in the applicator tip where cross-linking begins. The glutaraldehyde molecules covalently bond (cross-link) the BSA molecules to each other and, upon application, to the tissue proteins at the repair site, creating a flexible mechanical seal independently of the body's clotting mechanism. The delivery device-mediated application is designed to provide reproducible mixing of the components *in vitro*. BioGlue begins to polymerize within 20 to 30 seconds and reaches its bonding strength within 2 minutes. BioGlue also adheres to synthetic graft materials via mechanical interlocks within the interstices of the graft matrix. The BioGlue component has a shelf life of 3 years if stored at 25 °C.

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).

CONTRAINDICATIONS

- Not for patients with a known sensitivity to materials of bovine origin
- Not for intravascular use
- Not for cerebrovascular repair

WARNINGS

Warning: Animal studies have shown that direct application of BioGlue to the exposedphrenic 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.

- 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.

PRECAUTIONS

- Safety and effectiveness of the BioGlue in minimally invasive procedures have not been established.
- Safety and effectiveness of the 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.
- 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.

ADVERSE EVENTS – OBSERVED AND POTENTIAL

Observed Adverse Events

Adverse events observed during the clinical studies included the following (see Table 3 for more detail):

- BioGlue applied to non-targeted tissue
- Failure of BioGlue to adhere
- Death
- Hemorrhage
- Infection
- Inflammatory, immune systemic allergic reaction
- Irreversible morbidity
- Ischemia
- Myocardial infarction
- Neurological deficit
- Organ system failure
- Paraplegia
- Pleural effusion
- Renal dysfunction/failure
- Respiratory dysfunction/failure
- Stroke or cerebral infarction
- Thromboembolism
- Thrombosis

Potential Adverse Events That May Occur From the Use of BioGlue

- A hypersensitivity reaction such as swelling or edema at the application site
- Application of adhesive to tissue not targeted for procedure
- Failure of BioGlue to adhere to tissue
- Local tissue necrosis
- Mineralization of tissue
- Possible transmission of infectious agents from material of animal origin
- Thrombosis and thromboembolism

Potential Adverse Events Related to Cardiac and Vascular Procedures

Adverse events associated with cardiac and vascular repair procedures may include but are not limited to:

- Adhesions
- Anastomotic pseudoaneurysm
- Aortic insufficiency
- Cardiac tamponade
- Cerebral emboli
- Death or irreversible morbidity
- Dissection
- Hemorrhage
- Infection
- Injury to normal vessels or tissue
- Ischemia
- Myocardial infarction
- Neurological deficits
- Organ system dysfunction/failure
- Paraplegia
- Pleural effusion
- Pulmonary emboli
- Renal dysfunction/failure
- Respiratory dysfunction/failure
- Stroke or cerebral infarction
- Thrombosis
- Vasospasm
- Vessel rupture and hemorrhage

CLINICAL STUDIES

In June 1998, CryoLife, Inc. began a clinical trial investigating the use of BioGlue as an adjunct in the surgical repair of acute, Stanford Type A aortic dissections. A total of 175 patients were enrolled in this study. This included 54 non-randomized (lead-in) patients, 60 patients randomized to standard surgery plus BioGlue, and 61 patients randomized to standard surgery only. An interim analysis was performed after the 100th patient was enrolled into the randomized portion of the trial and had completed the 30-day follow-up period. There was no statistically significant difference in early mortality (primary endpoint) between the two groups; however, BioGlue-treated patients required fewer pledgets, hemostatic agents, and make-up stitches than the patients in the control group. There were no confirmed unanticipated adverse device effects, and no differences in adverse events between the two groups.

Based on data from the lead-in patients, CryoLife filed a Humanitarian Device Exemption (HDE) for the use of BioGlue in the surgical repair of acute thoracic aortic dissections, which was approved by FDA in December 1999 (H990007). CryoLife gained approval in May 2000 to investigate the use of BioGlue for sealing anastomotic sites in cardiac and vascular repairs.

The following information is from the cardiac and vascular repair investigation:

Study Design

The BioGlue Effectiveness and Safety Trial as a Surgical Adjunct in Cardiac and Vascular Surgical Repairs was a prospective, multi-center, randomized, controlled trial. Patients were randomized to receive standard surgical repair with BioGlue applied to the anastomotic site prior to clamp removal (BioGlue group, n = 76) or standard surgical anastomotic repair alone (control group, n = 75). One patient crossed over from the control group to the BioGlue group due to uncontrolled bleeding. Data from this patient are included in the safety table, but omitted in the effectiveness table below. The overall objective was to collect clinical data concerning the safety and effectiveness of BioGlue used as an anastomotic sealant to provide hemostasis. The hypothesis was that hemostasis would be achieved in a higher percentage of the Bioglue treated patients than in the control patients.

Patient Assessment

Safety and Effectiveness Evaluations

The BioGlue group and the control group were compared to evaluate the following endpoints:

Primary Evaluation

- Anastomotic hemostasis (yes or no) of each of the repaired sites
  Anastomotic hemostasis was defined as an anastomosis that did not require additional agents (pledgets, sutures, hemostatic devices, antifibrinolytic agents, thrombin glues, fibrin glues) at the treated site(s) to control bleeding at any point during the course of the original operation.
- Anastomotic hemostasis (yes or no) on a per patient basis
  Patients with hemostasis at all anastomotic sites were considered successful.

Secondary Evaluations

- Quantity, type, and number of donor exposures of blood replacement products administered
- Type of additional agents used (pledgets, sutures, hemostatic devices, antifibrinolytic agents, thrombin glues, fibrin glues)
- Re-operation due to anastomotic site bleeding
- Major complications/adverse events through final follow-up
- Minor complications/adverse events through final follow-up
- Early hospital discharge mortality and mortality through last follow-up

Safety Evaluations

- Unanticipated Adverse Device Effects (UADE)
- Device complications
- Surgical procedure complications

Demographic Data

A total of 151 patients (76 in the BioGlue test group, and 75 in the control group) were treated at 6 investigational sites in the cardiac and vascular repair arm of the U.S. IDE clinical trial. Surgical procedures performed are shown in Table 1.

Table 1 – Cardiac and Vascular Procedures Included (*All Randomized*)

	Treatment Group			
System	Surgical Repair with BioGlue	Conventional Surgical Repair	Crossover	Total
Cardiac Procedures**	24	25	0	49
Aortic Procedures†	57	47	1	105
Peripheral Vascular Procedures***	25	23	0	48
Total	106	95	1	202

***Cardiac repairs include: aortic root replacement (4), aortoplasty (1), aortic valve annuloplasty (5), aortic valve resuspension (1), aortic valve replacement (23), Bentall procedure (2), composite valved conduit procedure (8), mitral valve replacement (2), Ross procedure (2), coronary artery bypass grafting (1).*

†Aortic aneurysm repairs include: abdominal aortic aneurysm (21), ascending aortic aneurysm (21), ascending/ transverse aortic arch aneurysm (9), ascending/ transverse arch/ descending aortic aneurysm (1), descending aortic aneurysm (8), thoracoabdominal aortic aneurysm (32), transverse aortic arch aneurysm (12), Type B aortic dissection (1).

****Peripheral vascular repairs include: aorto-femoral bypass (5), aorto-iliac bypass (2), aorto-innominate bypass (1), carotid bypass (1), carotid endarterectomy (19), femoral-distal bypass (3), femoral-femoral bypass (2), femoral-popliteal bypass (5), hepatic-renal bypass (1), popliteal-dorsalis pedis bypass (1), profunda endarterectomy (1), renal bypass (6), renal endarterectomy (1).*

Data Analysis and Results

The tables and figures in this section present information from the cardiac and vascular repair arm of the U.S. IDE clinical trial.

Efficacy Data

Table 2 – Effectiveness Endpoints

Parameter of Interest	BioGlue Group (n = 76)	Control Group (n = 74)	Comments/p value
Hemostasis success per patient[1]	61% (46/76)	39% (29/74)	0.014
Hemostasis success per repair site[2]	81% (164/202)	57% (105/184)	<0.003
RBC used 0 units 1-5 units >5 units	2.3 ± 3.6 37 29 10	1.9 ± 2.4 33 34 7	NS[4]
Platelets used 0 units 1-10 units >10 units	5.1 ± 10.1 47 21 8	5.2 ± 10.0 42 27 5	NS
Fresh Frozen Plasma used 0 units 1-10 units >10 units	3.8 ± 6.6 43 24 8	3.3 ± 5.0 41 23 9	NS
Cryoprecipitate used 0 units 1-10 units >10 units	4.3 ± 11.9 63 3 9	2.0 ± 8.3 67 1 4	NS
Donor Exposures 0 donors 1-20 donors >20 donors	 26 11 11	 23 15 13	NS
Pledgets used on Primary Repair	26% (53/202)	36% (66/184)	0.047
Make up stitches used	82% (31/38)[3]	81% (64/79)[3]	1.00
Hemostatic agent used	8% (3/38)[3]	10% (8/79)[3]	1.00
Additional BioGlue	55% (21/38)[3]	N/A	N/A
Other	8% (3/38)[3]	19% (15/79)[3]	0.17
Re-operation for bleeding	0	1 (1.4%)	One-sided 95% CI - -, 0.9
Bypass time (min)	168.1 ± 67.6 (54 - 358) n =34	144.2 ± 60.6 (54 – 387) n = 35	NS
Cross-clamp time (min)	74.0 ± 46.1 (10 – 196) n = 54	69.1 ± 41.3 (19 – 196) n = 55	NS
Total Operative time (min)	237.7 ± 125.1 (85 – 650) n = 75	228.7 + 100.8 (60 – 515) n = 73	NS
ICU Time (days)	3.9 ± 5.6 (0 – 32) n = 70	4.8 ± 7.1 (0 – 36) n = 72	NS
Hospitalization time (days)	9.5 ± 10.6 (1 - 81) n = 72	10.9 ± 9.7 (1 – 55) n = 73	NS

[1] *Defined as hemostasis of 100% of the anastomotic repair sites*
[2] *The average number of sites (anastomoses) per patient were 2.6 (range 1 to 8)*
[3] *Denominator reflects number of patients in whom immediate hemostasis was not achieved*
[4] *Not statistically significant*

Table 3 - Safety Endpoints

Adverse Event Description	BioGlue Group N = 77			Control Group N = 74			*p* value
	n	%	#events	n	%	#events	
Pleural Effusion	20	26.0%	25	21	28.4%	22	0.855
Respiratory Dysfunction/Failure	13	16.9%	18	12	16.2%	15	1.000
Infection	13	16.9%	15	10	13.5%	13	0.653
Renal Dysfunction/Failure	13	16.9%	13	9	12.2%	10	0.492
Neurological Deficits	5	6.5%	6	16	21.6%	18	0.009
Death	5	6.5%	5	5	6.8%	5	0.999
Hemorrhage	3	3.9%	3	3	4.1%	3	1.000
Ischemia	3	3.9%	3	2	2.7%	2	1.000
Organ System Dysfunction/Failure	3	3.9%	4	2	2.7%	2	1.000
Myocardial Infarction	3	3.9%	3	1	1.4%	1	0.620
Inflammatory, Immune Systemic Allergic Reaction[1]	2	2.6%	2	0	0%	0	0.497
Stroke or Cerebral Infarction	1	1.3%	1	3	4.1%	5	0.360
Paraplegia	1	1.3%	3	2	2.7%	3	0.615
Thromboembolism	1	1.3%	1	1	1.4%	4	1.000
Application of Adhesive to Non-Targeted Tissue[2]	1	1.3%	1	0	0%	0	1.000
Failure of Products to Adhere to Tissue[2]	1	1.3%	1	0	0%	0	1.000
Irreversible Morbidity	0	0%	0	1	1.4%	1	0.490
Thrombosis	0	0%	0	1	1.4%	1	0.490
Other[3,4]	46	59.7%	108	40	54.1%	100	0.514

[1] *These adverse events were not device related. One patient had an allergic reaction to a preoperative antibiotic and the other patient had an allergic reaction to protamine sulfate.*

[2] *These adverse events were device related, see Warnings and Precautions Sections of this Instructions for Use.*

[3] *Other adverse events observed in the BioGlue group were as follows: acidosis (1%), acute shortness of breath (1%), altered mental status (3%), anemia (5%), atelectasis (8%), cardiac arrhythmia (22%), cerebral hemorrhage (1%), colecystitis (1%), coagulopathy (1%), congestive heart failure (4%), decreased femoral pulse (1%), deep vein thrombosis (1%), depression (4%), diarrhea (3%), dysphagia (5%), edema (3%), fever (3%), heart enlargement (4%), hematuria (1%), hemoptysis (1%), hernia (4%), hoarseness (1%), hypotension (1%), ileus (4%), incisional pain (3%), lymphatic fistula (1%), malnutrition (5%), nausea (3%), perforated viscus (1%), pericardial effusion (1%), pneumothorax (3%), rectal bleeding (1%), seizure (1%), thigh and back pain (3%), thrombocytopenia (1%), urinary retention (4%), vocal cord paralysis (3%).*

[4] *Other adverse events observed in the control group were as follows: abdominal pain (1%), abnormal lab value (5%), acidosis (1%), altered mental status (3%), anemia (3%), angina (1%), aphasia (1%), atelectasis (4%), back pain (1%), cardiac arrhythmia (19%), cerebral hemorrhage (3%), congestive heart failure (1%), diarrhea (3%), dizziness (1%), duodenal ulcer (1%), dysphagia (1%), edema (1%), emphysema (1%), encephalopathy (1%), failed extubation (1%), fever (3%), heart block (2%), hematuria (1%), hemothorax (1%), hernia (1%), hoarseness (4%), hypotension (4%), ileus (3%), incisional pain (5%), lower extremity weakness (1%), nausea (4%), near syncope (1%), neck deformity (1%), pericardial effusion (3%), pneumothorax (3%), post-kidney collection (3%), reintubation (1%), seizure (1%), sexual dysfunction (1%), shortness of breath (1%), thrombocytopenia (4%), thrombophlebitis (1%), transfusion reaction (3%), urinary retention (1%), valve surgery (1%), vocal cord paralysis (3%).*

Adverse events were equal in severity in both the BioGlue group and the standard surgical repair group. There were no unanticipated adverse device effects (UADE) in this investigation.

Conclusion
The BioGlue group was noted to have a statistically significantly higher rate of successful intra-operative hemostasis when compared to the control group on both a "per patient" and a "per anastomotic site" basis. BioGlue-treated patients demonstrated a lower incidence of adjunctive pledgets use on their primary repairs to achieve hemostasis. There were no statistically significant differences in adverse events between BioGlue and control patients.

HOW SUPPLIED

The BioGlue solutions cartridge, applicator tips, and twist rings are supplied sterile for single-patient use only. Discard any unused material from opened or damaged product.

The BioGlue solutions are contained within a capped, double-chambered cartridge. Polymerized BioGlue is non-pyrogenic. Store below 25°C, but do not freeze.

The BioGlue reusable delivery device is supplied sterile. It may be resterilized for reuse nine times. Refer to the Maintaining Delivery Device Effectiveness section of the Instructions for Use supplied with the reusable delivery device for detailed cleaning and resterilization instructions. Retain those Instructions for Use for future reference.

PATIENT COUNSELING INFORMATION

Exposure to BioGlue may cause a hypersensitivity reaction such as swelling or edema at the application site. Development of immune complex disease, with various manifestations, as the device undergoes resorption is also a possibility.

Patients should be counseled to inform surgeons that they have been previously exposed to BioGlue and may be sensitized.

BioGlue contains a material of animal origin, which may be capable of transmitting infectious agents.

DIRECTIONS FOR USE

Apply BioGlue Surgical Adhesive prior to clamp release or after a leak is detected to seal the cardiac or vascular repair site.

Delivery Device Preparation

The BioGlue Surgical Adhesive and its delivery device consist of: main delivery unit, cartridge plunger, solutions cartridge, applicator tip, and twist ring tool.

1. Remove the main delivery unit and cartridge plunger from their packaging. Lift the large latch on the top of the main unit (1a). While pushing upward on the small latch at the back of the main unit (1b), insert the plunger, ribbed side downward, into the front of the main unit (1c).

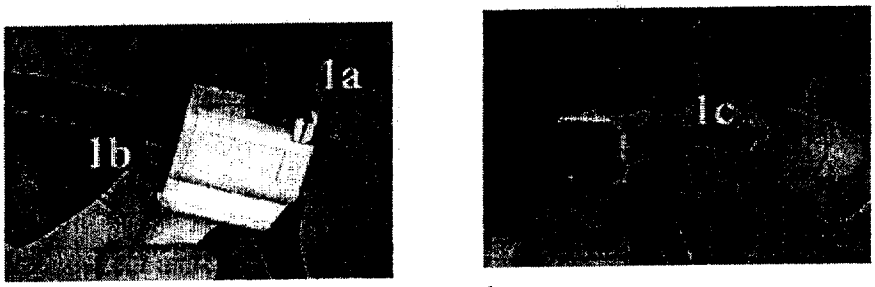


Figure 1

2. Still holding the small latch upward (2a), retract the cartridge plunger completely back (2b).

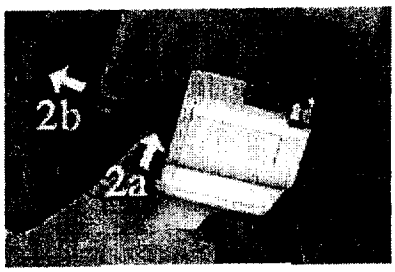


Figure 2

3. Remove a solutions cartridge and an applicator tip from their packaging. While firmly grasping the cartridge, nose upward, turn the cartridge cap 90° counterclockwise and remove the cap by rocking it from side-to-side (3a). Align the tip with the cartridge using the corresponding notches on each and place the tip on the cartridge (3b, 3c).

   CAUTION: Take care not to spill solution from the cartridge during assembly.

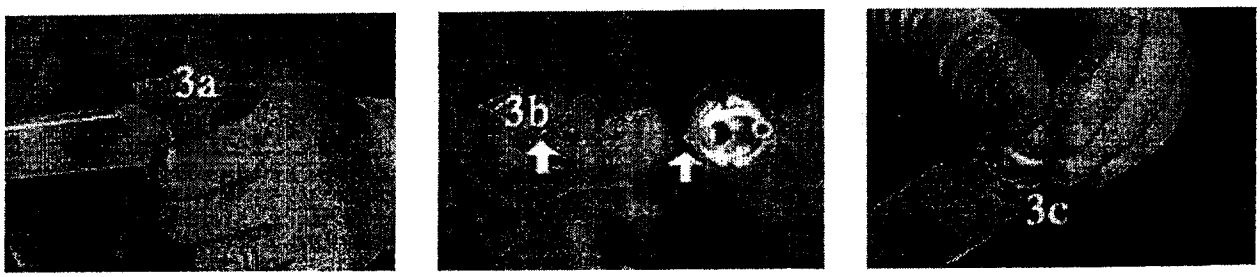


Figure 3

4. Lock the applicator tip in place by pushing the tip firmly toward the solutions cartridge and rotating the tip collar 90° clockwise (4). This may be done either by hand or with the twist ring tool (refer to Step 5).

Figure 4

5. If using the twist ring tool, remove it from its packaging, place the applicator tip through the tool's center hole, seat the tool at the base of the tip, and turn the tool 90° clockwise (5). Remove the tool and save it for aiding tip removal and any additional tip exchanges that may be necessary during the procedure.

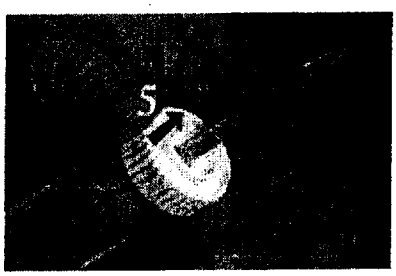
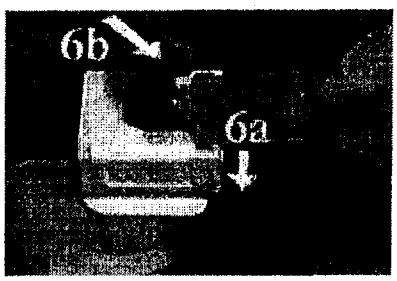


Figure 5

6. Align the small and large barrels of the solutions cartridge above the corresponding cartridge plunger heads in the main delivery unit. Slide the cartridge down into position (6a) and push the large latch down to lock the cartridge in place (6b). Slide the cartridge plunger forward until resistance is felt. The delivery device is now assembled (6c).



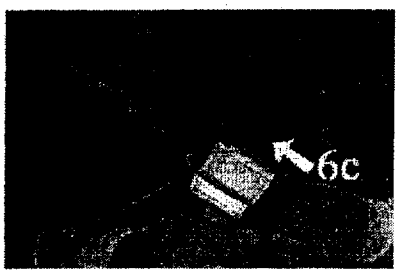


Figure 6

CAUTION: Do not compress the main delivery unit trigger mechanism while attaching the solutions cartridge.

CAUTION: Before using BioGlue in the procedure, the applicator tip must be primed. Refer to Site Preparation and Applicator Tip Priming.

7. If using an applicator tip with a flexible extension, a desired angle may be created by bending the extension at the appropriate location to the desired angle and holding for 3-5 seconds. The angle created should be maintained for up to 5 minutes.
8. To remove occluded applicator tips, grasp the applicator tip collar, rotate the tip collar counterclockwise, and lift the tip off the solutions cartridge by rocking it side to side. The twist ring tool may be used to aid in turning the tip collar.

Site Preparation and Applicator Tip Priming

1. The target surgical field must be properly prepared prior to either priming or applying BioGlue. BioGlue works best when the target surgical field is dry. A dry surgical field can be described as a field that does not restain with blood within 4-5 seconds after wiping dry with a surgical sponge.

   CAUTION: Do not attempt to apply BioGlue to a field that is too wet. Application of BioGlue into a wet field may result in the failure of BioGlue to adhere.

2. Each applicator tip must be primed prior to BioGlue application. Priming removes any air bubbles from BioGlue and ensures a proper mixing ratio. The surgeon should depress the delivery device trigger and expel a narrow ribbon of BioGlue approximately 3 cm long onto a sterile disposable surface (e.g., sponge, gauze, or towel).
3. The surgeon should examine the material expelled during priming and ensure that it is of uniform light yellow to amber color and that it is free from air bubbles. If this material looks colorless or contains bubbles, repeat the prime as outlined in Step 2 until the device delivers a uniform liquid with no bubbles.

   CAUTION: Avoid direct contact with material expelled during priming.

4. When the applicator tip has been properly primed, proceed immediately to application.

   CAUTION: BioGlue polymerizes very quickly. The surgeon must apply BioGlue immediately after priming. Pausing between priming and application can cause polymerization of BioGlue within the applicator tip. Should this occur, replace the obstructed tip with a new tip and repeat the steps for applicator tip priming.

General Techniques for the Use of BioGlue in Surgery

1. BioGlue works best when the target surgical field is dry. A dry surgical field can be described as a field that does not restain with blood within 4-5 seconds after wiping dry with a surgical sponge.
2. Tissues surrounding the target surgical site should be protected from the unintentional application of BioGlue. The most effective method of protection is to cover any non-target tissues with moist sterile gauze pads. These protective pads should be removed before complete polymerization occurs.

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.

3. Apply an even coating of BioGlue to the target area. In general, use an approximately 1 to 3 mm thick coating for vessels that are greater than 2.5 cm in diameter or an approximately ½ to 1 mm thick coating for vessels that are less than 2.5 cm in diameter.

   CAUTION: Avoid contact of the BioGlue with blood-saving devices, such as cell savers and pumps.

4. If BioGlue is inadvertently applied to non-target tissues, allow the adhesive to polymerize completely. Then, using forceps and scissors, carefully dissect the polymerized BioGlue from the unintended area.

   CAUTION: Do not peel BioGlue away from an unintended site, as this could result in tissue damage.

5. Do not compress the area of application or subject it to any extra pressure. BioGlue does not require any clamping or compression in order to polymerize. BioGlue works optimally when it is allowed to polymerize without any manipulation for a full two minutes.

6. When BioGlue has completely polymerized, the surgeon may trim away any excess material or irregular edges with scissors and forceps.

Specific Techniques for the Use of BioGlue in Aortic Dissection Surgery

1. The dissected layers of the aorta should be initially cleared of blood and thrombus material and should be dried, to the extent possible, with surgical sponges.

2. For the distal end of the dissection repair, insert a balloon catheter into the true lumen to define the distal terminus for the application of BioGlue. In addition, the dissected layers of the aorta should be closely approximated by inserting a dilator, sponge, or catheter into the true lumen to preserve the natural architecture of the vessel.

   BioGlue should then be dispensed into the false lumen as far distally as the distal balloon catheter will allow. Filling the false lumen should proceed from distal to proximal with a spiraling out motion for smooth application. Completely fill the false lumen with BioGlue; avoid overfilling the false lumen and spilling BioGlue into the true lumen or surrounding tissue.

3. For the proximal end of the dissection repair, the dissected layers of the aorta should also be closely approximated by using a dilator, sponge, or catheter. If necessary, moist gauze pads should be placed over the aortic valve leaflets to protect them from inadvertent application of BioGlue. BioGlue should then be dispensed to fill the false lumen.

   Graft material may be sutured directly onto the tissues adhered and reinforced with BioGlue at both the proximal and distal aspects of the dissection repair. Allow BioGlue to completely polymerize without any manipulations for a full two minutes prior to suturing through the adhered tissue layers.

PRODUCT INFORMATION DISCLOSURE

Handling and storage of this device by the user as well as factors related to the patient, the patient's diagnosis, treatment, surgical procedures, and other matters beyond manufacturer's control may directly or indirectly affect this device and the results obtained from its use. This device should not be used except on the order of a physician.

DISCLAIMER OF IMPLIED WARRANTIES

CryoLife, Inc. disclaims all implied warranties with respect to BioGlue, including but not limited to, the implied warranty of merchantability and any warranty of fitness for a particular purpose. Prices, specifications, and availability are subject to change without notice.

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