BIOGLUE Competitive Primer

BIOGLUE is a two-component surgical adhesive composed of purified bovine serum albumin (BSA) and glutaraldehyde solutions.

- Completely synthetic and contains no human or animal proteins
- Elastic and flexible
- Gels in 5 seconds with complete polymerization in one minute to reduce migration potential
- Does not produce a potential adverse tissue response
- Remains at the treated graft site for approximately 7 days, and is then completely eliminated from the body in 30 days
- Contains glutaraldehyde, known to cause tissue necrosis
- Clinically proven to reduce the severity of post-operative adhesion formation
- Can be sprayed, allowing easy application to larger areas
- Independent of the coagulation cascade
- May be used in the vicinity of nerves without injury
- Shown to restrict dilatation in an aortic model
- Broad labeling for a variety of surgical settings

FOR INTERNAL USE ONLY


**References**


**Probing Questions for Surgeons**

Have you ever used BIOGLUE only to realize that you have to reaccess the surgical site? BIOGLUE can be removed should you need to reaccess the site, and then be easily reapplied. Further, sutures can be placed through COSEAL if reinforcement is required.

• Attempting to peel away BIOGLUE may result in tissue damage, and tissue dissection may be required.

Do you ever find that BIOGLUE does not cover an area in which you need to achieve hemostasis or need sealed? Because COSEAL can be applied by using spray devices designed for both open and minimally-invasive procedures, or through a manual applicator, it is far more versatile for a wide variety of procedures than BIOGLUE.

Are you aware of the studies showing the toxicity and carcinogenicity associated with products containing glutaraldehyde? Multiple studies have found that glutaraldehyde causes significant tissue and nerve injury.6,16 Case reports indicate that BIOGLUE is believed to have caused coronary embolism, acute ischemia, superior vena cava stenosis, and pseudoneuromas formation.6,9,10 The BIOGLUE IFU itself warns that unreacted glutaraldehyde may cause everything from eye irritation, respiratory issues, and tissue necrosis to central nervous system or cardiac pathology. COSEAL is nontoxic and has a proven record of safety.

What do you do for your pediatric patients? A recent study found a strong association between the use of BIOGLUE and postoperative wound complications in pediatric patients.7 COSEAL is safe-to-use in pediatric patients, and has been clinically proven to reduce the severity of postoperative cardiac adhesions.8 This is an important consideration in patients who will undergo staged cardiac procedures.

**Handling Objections**

I use BIOGLUE because I can use it to glue the layers of the aorta in the case of aortic dissection. Although it can be useful for this application, there are reports indicating BIOGLUE may weaken local tissue by causing an ongoing inflammatory response, thus predisposing patients to pseudoneuromas formation.9 Alternative methods to glue dissected layers should be explored. Although COSEAL is not indicated for gluing dissected aortic tissue, it is noteworthy to state it does not produce an adverse tissue response and absorbs fully in 30 days,6,18

I use BIOGLUE because it’s a stronger adhesive than COSEAL. While this may be true, in aortic surgery sealants with greater stiffness than aortic tissue and aortic root replacement graft material may restrict normal physiological dilation and cause anastomotic strictures.6 BIOGLUE is much less compliant than COSEAL when used for sealing in aortic root replacement.6

**Product Attributes and Effectiveness**

**COSEAL**

- Gels in 5 seconds with complete polymerization within one minute
- 20–30 seconds, reaches full strength in 2 minutes
- High reproducibility
- Can be used to glue tissue together in aortic dissection repair
- Glutaraldehyde covalently bonds BSA molecules to each other and other tissue surface

**BIOGLUE**

- Reusable delivery device with disposable syringe
- Disposable syringe with various applicator tips:
  - 12 mm and 16 mm spreader tips
  - 10 mm and 27 cm extension tips
- Syringe box contains an additional three 12 mm spreader tips