

Patient Information for BioGlue Surgical Adhesive

Product General Description

BioGlue is a surgical glue that comes in a syringe with 2 chambers. One chamber contains 4 parts of bovine serum albumin (BSA). The other chamber contains 1 part of glutaraldehyde. The 2 solutions mix inside the applicator tip which is an accessory that comes with the BioGlue and is attached to the end of the syringe. BioGlue stays in the body long-term (more than 30 days).

BioGlue Surgical Adhesive is used to seal, adhere, or reinforce soft tissue in adults. It should be used along with the usual surgical ways to seal tissues, which can include sutures, staples, and/or patches. It can be used for soft tissues of the cardiac, vascular, lung, and outside layer of the brain and spinal cord.

Information on Materials and Substances

BioGlue syringes are available in 3 configurations - 2mL, 5mL, and 10mL. Each syringe is composed of bovine serum albumin (BSA) and glutaraldehyde solutions in a 4:1 ratio, respectively. The BSA solution is amber in color and free-flowing. The glutaraldehyde solution is clear and also free-flowing.

The specification for the BSA solution is a 45% (weight/volume ratio) solution. The maximum 45% BSA solution target weights for each size are: 2.71 grams (2mL syringe), 4.75 grams (5mL syringe), and 9.50 grams (10mL syringe). Based on these targets, the maximum quantity of animal origin material coming into contact with the patient when using a single device is 1.22 grams (2mL syringe), 2.14 grams (5mL syringe), and 4.23 grams (10mL syringe) for each configuration.

The specification for the glutaraldehyde solution is a 10% (weight/volume ratio) solution. The maximum 10% glutaraldehyde solution target weights for each size are: 0.63 grams (2mL syringe), 1.10 grams (5mL syringe), and 2.16 grams (10mL syringe). Based on these targets, the maximum quantity of glutaraldehyde coming into contact with the patient when using a single device is 0.06 grams (2mL syringe), 0.11 grams (5mL syringe), and 0.22 grams (10mL syringe) for each configuration.

Warning, Precaution, or Measures to be taken by the Patient with regard to use of BioGlue with other Medical Devices

The warnings and precautions in the Instructions for Use (IFU), located at www.cryolife.com/eifu/biogluce, instruct the doctor or health care provider how to use the BioGlue safely and correctly during surgery. BioGlue is not for patients with known sensitivity to materials of bovine origin. There are no patient-related operating instructions. BioGlue requires no monitoring or maintenance post-surgery. The IFU does not contain warnings and precautions for patients. There are no residuals from manufacturing that pose a risk.

MRI Compatibility

BioGlue is safe for diagnostic procedures and imaging using Magnetic Resonance (MR) technology (i.e., an item that poses no hazard in all MR environments).

Expected Lifetime of BioGlue

BioGlue Surgical Adhesive is a long-term implant meaning it will be in your body greater than 30-days.

BioGlue is degraded via proteolysis (breakdown of proteins in the body). The rate of degradation of BioGlue will depend on the location and the amount of BioGlue applied. BioGlue degrades more quickly in areas with more blood vessels and less quickly in areas where there are less blood vessels. Thin applications of BioGlue will degrade more quickly than thick applications.

Please report any serious device related incident to the manufacturer at www.cryolife.com or 800-438-8285, and the competent authority of the Member State or Territory in which the patient is established. For patients in Australia, report any serious adverse events to the Therapeutic Goods Administration, <https://www.tga.gov.au>, click on the "Report a problem" link.