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. BioGlue should be applied as a thin layer, as an adjunct to sutures or staples, and in amounts adequate 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 area immediately with water and seek medical attention. Do not use BioGlue in the presence of infection and use with caution in contraindicated areas of the body. Avoid exposure of BioGlue to patients with a history of allergy to animal skin, as there may be a cross-reactivity. Sensitization has been observed in animals. BioGlue contains a mixture of animal origin, which may be capable of transmitting infectious agents. BioGlue, which obviates the need for sutures, can be toxic to rodents. Sensitization 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.

WARNINGS: BioGlue Surgical Adhesive has space occupying properties. When used improperly, or applied to a necrotic or septic area, it can cause acute tissue necrosis. Use of BioGlue in patients with a history of allergy to animal skin, as there may be a cross-reactivity. Sensitization has been observed in animals. BioGlue contains a mixture of animal origin, which may be capable of transmitting infectious agents. BioGlue, which obviates the need for sutures, can be toxic to rodents. Sensitization 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 introducing 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 to adhere to these surfaces. BioGlue is mixed, cartridges, applicator tips, and applicator tip extenders are for single patient use only. Do not re-sterilize. Do not use BioGlue if it appears 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 area immediately with water and seek medical attention. Do not use BioGlue in the presence of infection and use with caution in contraindicated areas of the body. Avoid exposure of BioGlue to patients with a history of allergy to animal skin, as there may be a cross-reactivity. Sensitization has been observed in animals. BioGlue contains a mixture of animal origin, which may be capable of transmitting infectious agents. BioGlue, which obviates the need for sutures, can be toxic to rodents. Sensitization 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.

Use of BioGlue in pediatric patients has not been studied. BioGlue should not be applied to neonates. Avoid contact with skin or other tissue not intended for application. Maintenance 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 it appears 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 area immediately with water and seek medical attention. Do not use BioGlue in the presence of infection and use with caution in contraindicated areas of the body. Avoid exposure of BioGlue to patients with a history of allergy to animal skin, as there may be a cross-reactivity. Sensitization has been observed in animals. BioGlue contains a mixture of animal origin, which may be capable of transmitting infectious agents. BioGlue, which obviates the need for sutures, can be toxic to rodents. Sensitization 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.

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**Application Techniques in Vascular Surgery**

**Abdominal Aortic Aneurysm**
- Clamp and depressurize vessels 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 all remaining anastomoses, and again apply a thin layer of BioGlue to prevent suture line bleeding
- Wait 2 minutes before re-establishing systemic blood flow

**Peripheral Bypass / AV Access**
- Clamp and depressurize vessels 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 directly onto 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

**Carotid Endarterectomy**
- Once the graft has been sewn into place, carefully pack gauze around the target area to prevent BioGlue from running into unwanted areas
- Clamp and depressurize vessels 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 directly onto the suture line around the patch
- Wait 2 minutes for BioGlue to completely polymerize before re-establishing systemic blood flow

**Key Application Techniques**
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

**BioGlue Surgical Adhesive... Ideal for Vascular Surgery**
- Reinforces Friable Tissue
- Seals Needle Holes
- Clinically Proven in more than 580,000 procedures worldwide