BioGlue Syringe Delivery System

<table>
<thead>
<tr>
<th>Catalogue Number</th>
<th>Product</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td>BG5005-US</td>
<td>Syringe 16mm Spr</td>
<td>Five single packs – Each contains one 16mm syringe and syringe plunger, one 12mm spreader tip, and one 10cm delivery tip</td>
</tr>
<tr>
<td>BG5005-US</td>
<td>Syringe 12mm Spr</td>
<td>Five single packs – Each contains one 12mm syringe and syringe plunger, one 12mm spreader tip, and one 10cm delivery tip</td>
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<tr>
<td>BG5005-US</td>
<td>Syringe 27cm Applicator T</td>
<td>Five single packs – Contains one 27cm syringe tip and one flexible applicator tip</td>
</tr>
<tr>
<td>BG2177-SD</td>
<td>Syringe 10mL 5 Pack Kit</td>
<td>One single pack – Contains one 10mL syringe and syringe plunger, and four standard syringe tips</td>
</tr>
<tr>
<td>BG3502-5-US</td>
<td>Syringe 2mL 5 Pack Kit</td>
<td>Five single packs – Each contains one 2mL syringe and syringe plunger, and four standard syringe tips</td>
</tr>
<tr>
<td>BG3515-5-US</td>
<td>Syringe 5mL 5 Pack Kit</td>
<td>Five single packs – Each contains one 5mL syringe and syringe plunger, and four standard syringe tips</td>
</tr>
<tr>
<td>BG3510-5-US</td>
<td>Syringe 10mL 5 Pack Kit</td>
<td>Five single packs – Each contains one 10mL syringe and syringe plunger, and four standard syringe tips</td>
</tr>
</tbody>
</table>

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 techniques of large vessels (such as artery, vein, and arterial procedures). In Only.

WARNING: Polymeric BioGlue has space occupying properties. When used improperly or applied incorrectly, severe adverse events have been reported including compression of adjacent anatomic structures. BioGlue should be used only when complete vascular control cannot be achieved. Under some circumstances, BioGlue may form, grow, and remain on the underlying contact tissue and may cause acute, local, and/or systemic side effects.

CONTRAINdications: Not for patients with a known sensitivity to materials of bovine origin. Not for intravascular use. Do not use in the presence of infection or under conditions where the extrusion of BioGlue could result in the transmission of infectious agents. BioGlue, which degrades over a period of time, 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) surgery has been established. Safety and effectiveness of BioGlue in coronary artery bypass grafting (CABG) surgery has not been tested.

Use of BioGlue in pediatric patients has not been studied. BioGlue should not be applied in an area that extends too far from the tissue to be sealed. Do not use BioGlue on an area where there is a possibility of tissue necrosis. BioGlue should not be applied in regions where there is a possibility of tissue necrosis. BioGlue should not be applied in areas where there is a possibility of tissue necrosis.

BioGlue provides the following for informational purposes only. Surgical technique at the discretion of the surgeon. Variations in technique and practices will inevitably and appropriately occur when clinicians take into account the needs of individual patients, available resources, and limitations unique to an institution or type of practice.
**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 1 cm 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. Clamp and depressurize vessels prior to applying BioGlue to targeted anastomoses
2. Dry the target site to ensure optimal adherence of BioGlue to target tissue
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
- Clinically Proven in more than 750,000 procedures worldwide
- BioGlue’s mode of action allows it to seal the anastomosis regardless of the patient’s coagulopathic state.