BioGlue Syringe Delivery System

<table>
<thead>
<tr>
<th>Catalogue Number</th>
<th>Product</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td>BGST-16</td>
<td>Syringe 16mm Spreader Tip</td>
<td>Ten single packs – Each contains three 16mm spreader tips</td>
</tr>
<tr>
<td>BGST-12</td>
<td>Syringe 12mm Spreader Tip</td>
<td>Ten single packs – Each contains three 12mm spreader tips</td>
</tr>
<tr>
<td>BGAT-27-SY</td>
<td>Syringe 27cm Applicator Tip</td>
<td>Ten single packs – Each contains four 27cm syringe tips</td>
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<tr>
<td>BGAT-SY</td>
<td>Syringe Applicator Tip</td>
<td>Ten single packs – Each contains four standard syringe tips</td>
</tr>
<tr>
<td>BG3500N</td>
<td>Syringe Delivery Device</td>
<td>One single pack – Contains one non-sterile reusable syringe delivery device</td>
</tr>
<tr>
<td>BGDTE-10</td>
<td>10cm Delivery Tip Extension 20 pack kit</td>
<td>10 double packs – Each pack contains two 10cm Delivery Tip Extensions</td>
</tr>
<tr>
<td>BGDTE-27</td>
<td>27cm Delivery Tip Extension 20 pack kit</td>
<td>10 double packs – Each pack contains two 27cm Delivery Tip Extensions</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>
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<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>
</tbody>
</table>

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.

BioGlue should not be used circumferentially to tissue that needs to grow, as it bonds with the tissue and may not allow tissue to grow or repair. Do not use BioGlue as a substitute for sutures or staples. Do not expose when bulleted or intricate structures to BioGlue. Do not allow BioGlue to either the unused or polymerized form to contact circulating blood. BioGlue entering the circulation can result in local or embolic vascular destruction. Avoid exposure to BioGlue. Avoid contact with skin or other tissue that is not intended for application. Microscopic use of BioGlue is in patients with advanced vascular applications (e.g., chronic renal failure, hepatic/portal hypertension). Gastrointestinal treated lesions has an enhanced propensity for migration. Laboratory experiments indicate that untreated glutaraldehyde has inordinate effects. Do not use BioGlue if staff are not adequately protected (e.g., wearing gloves, masks, protective clothing, and safety glasses). Untreated glutaraldehyde may cause irritation to eyes, nose, throat, or skin, induce respiratory distress, and cause local tissue necrosis. Moistened exposure to untreated glutaraldehyde may cause a central nervous system or cardiac pathology. Contact causes fluid afferent arcs 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 repeated exposure of BioGlue in the same patient. Hypersensitive reactions are possible upon reexposure to BioGlue. Sensitization has been observed in animals. BioGlue contains a material of animal origin, which may be capable of transmitting infectious agents. BioGlue, which degrades on proteases, can be stored at room temperature, dependent on the quantity of adhesive applied. The slow absorption 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.

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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. 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.