Device Description
The AMPLATZER™ TorqVue™ 2 Delivery Sheath is designed to provide a pathway through which a device may be delivered. The delivery sheath consists of 2 components.
A. The single lumen sheath is radiopaque for visibility under fluoroscopy.
B. The dilator, which advances through the sheath, eases penetration of tissue and facilitates passage of the sheath through the vessel to the intended site.

![Diagram of AMPLATZER™ TorqVue™ 2 Delivery Sheath components]

Figure 1. AMPLATZER™ TorqVue™ 2 Delivery Sheath components

Table 1. Sheath dimensions

<table>
<thead>
<tr>
<th>REF</th>
<th>Fr</th>
<th>mm (in)</th>
<th>mm (in)</th>
<th>cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-TV2-05F120</td>
<td>5</td>
<td>1.82 (0.072)</td>
<td>2.51 (0.099)</td>
<td>120</td>
</tr>
<tr>
<td>9-TV2-06F120</td>
<td>6</td>
<td>2.11 (0.083)</td>
<td>2.79 (0.110)</td>
<td>120</td>
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<tr>
<td>9-TV2-07F120</td>
<td>7</td>
<td>2.44 (0.096)</td>
<td>3.17 (0.125)</td>
<td>120</td>
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</tbody>
</table>

Indications and Usage
The AMPLATZER™ TorqVue™ 2 Delivery Sheath is intended to provide a pathway through which devices are introduced within the peripheral vasculature.

Contraindications
None known.
Warnings
• Do not use this device if the sterile package is open or damaged.
• Use on or before the last day of the expiration month that is printed on the product packaging label.
• Do not use a power injection syringe to inject contrast solution through the sheath.
• The device was sterilized with ethylene oxide and is for single use only. Do not reuse or resterilize this device. Attempts to resterilize this device can cause a malfunction, insufficient sterilization, or harm to the patient.
• Remove the dilator and sheath from the patient slowly to prevent an ingress of air.

Precautions
• This device should be used only by physicians who are trained in standard transcatheter techniques. The physician should determine which patients are candidates for procedures that use this device.
• The physician should exercise clinical judgment in situations that involve the use of anticoagulants or antiplatelet drugs before, during, and/or after the use of this delivery sheath.
• Use caution when advancing the dilator and sheath to avoid damaging tissue and vessels or interfering with previously implanted medical devices.
• Prolonged procedures may result in increased exposure to anesthesia, contrast media, and/or radiation.
• Store in a dry place.

Potential Adverse Events
Potential adverse events that may occur during or after a procedure using this sheath include, but are not limited to:

- Air embolism
- Bleeding
- Death
- Fever
- Foreign material embolic event
- Infection
- Peripheral embolism
- Peripheral pulse loss
- Stroke
- Thrombus formation
- Tissue trauma/damage
- Transient ischemic attack
- Vascular access site complications
- Vessel trauma/damage

Device Compatibility
Refer to the instructions for use provided with the device to determine delivery sheath compatibility.

Directions for Use
Materials recommended for use with the delivery sheath:
• 0.035-inch guidewire
• Hemostasis valve

Procedure
CAUTION: When placing a device using an AMPLATZER™ TorqVue™ 2 Delivery Sheath, refer to the instructions for use provided with the device.

1. Select the appropriate size delivery sheath for the device that will be introduced through the sheath. See Table 1. to determine the appropriate size.
2. Place a 0.035-inch guidewire according the device’s instructions for use.
3. Prepare the components for use:
   - Inspect the sterile pouch and verify that it is unopened and undamaged. Do not use the components if the sterile barrier has been compromised.
   - Gently open the sterile pouch and inspect the components for damage. Do not use damaged or kinked components.
   - Flush the components with sterile saline.
   - Wipe the dilator and sheath with sterile gauze dampened with sterile saline to remove any foreign material.
4. Insert the dilator into the sheath. You may encounter resistance as the dilator reaches the distal end of the sheath because the tip of the sheath is tapered.
5. Turn the rotating luer on the dilator clockwise to lock the components together.
6. Advance the dilator and sheath over the guidewire.
7. Turn the rotating luer on the dilator counterclockwise to unlock the components. Remove the dilator from the sheath.
   WARNING: Remove the dilator slowly to prevent an ingress of air.
8. Remove the guidewire.
9. Connect a hemostasis valve to the sheath to prevent excessive bleeding or air embolism.
10. Deliver the device according to the device’s instructions for use.

11. When the procedure is complete, remove the sheath.
    
    WARNING: Remove the sheath slowly to prevent an ingress of air.

Disposal

• The instructions for use are recyclable. Dispose of all packaging materials appropriately.

• Dispose of delivery systems and accessories following standard solid biohazard waste procedures.

Warranty

AGA Medical Corporation warrants to buyer that, for a period equal to the validated shelf life of the product, this product shall meet the product specifications established by the manufacturer when used in accordance with the manufacturer's instructions for use and shall be free from defects in materials and workmanship. AGA Medical Corporation's obligation under this warranty is limited to replacing or repairing at its option, at its factory, this product if returned within the warranty period to AGA Medical Corporation and after confirmed to be defective by the manufacturer.

EXCEPT AS EXPRESSLY PROVIDED IN THIS WARRANTY, AGA MEDICAL CORPORATION DISCLAIMS ANY REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY AS TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

See the Terms and Conditions of Sale for further information.

State of California (USA) Only:

WARNING: This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.
Symbol Definitions
The following symbols may appear on the device packaging.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
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</thead>
<tbody>
<tr>
<td><img src="image" alt="Manufacturer" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="image" alt="EUauthorizedrepresentative" /></td>
<td>EU authorized representative</td>
</tr>
<tr>
<td><img src="image" alt="ReferenceNumber" /></td>
<td>Reference number</td>
</tr>
<tr>
<td><img src="image" alt="ProductSerialNumber" /></td>
<td>Product serial number</td>
</tr>
<tr>
<td><img src="image" alt="ProductLotNumber" /></td>
<td>Product lot number</td>
</tr>
</tbody>
</table>
| ![UseByDate](image) | Use by date  
(Use on or before the last day of the expiration month noted on the product packaging.) |
<p>| <img src="image" alt="DoNotReuse" /> | Do not reuse |
| <img src="image" alt="SterilizedUsingEthyleneOxide" /> | Sterilized using ethylene oxide |
| <img src="image" alt="ConsultInstructionsForUse" /> | Consult instructions for use |
| <img src="image" alt="KeepDry" /> | Keep dry |
| <img src="image" alt="DoNotUseIfPackageIsDamaged" /> | Do not use if package is damaged |
| <img src="image" alt="DoesNotContainNaturalRubberLatexComponents" /> | Does not contain natural rubber latex components |
| <img src="image" alt="InnerDiameter" /> | Inner diameter |
| <img src="image" alt="OuterDiameter" /> | Outer diameter |
| <img src="image" alt="Length" /> | Length |
| <img src="image" alt="UsableLength" /> | Usable length |
| <img src="image" alt="RecommendedDeliverySheathCatheterDimensions" /> | Recommended delivery sheath/catheter dimensions |
| <img src="image" alt="IndicationOfConformityWithTheEssentialHealthAndSafetyRequirementsSetOutInEuropeanDirectives" /> | Indication of conformity with the essential health and safety requirements set out in European Directives |
| <img src="image" alt="FederalLawUSARestrictsThisDeviceToSaleByOrOnTheOrderOfAPhysicianOrProperlyLicensedPractitioner" /> | Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner). |</p>
<table>
<thead>
<tr>
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<th>Detail</th>
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<td><img src="image" alt="Image" /></td>
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<tr>
<td><img src="image" alt="Image" /></td>
<td>Delivery Sheath</td>
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<tr>
<td><img src="image" alt="Image" /></td>
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