AMPLATZ® Vascular Plug

Instructions for Use
220089-001 (01)

Caution
Federal law (USA) restricts this device to sale by or on the order of a veterinarian.

Device Descriptions
The AMPLATZ Vascular Plug is indicated for arterial and venous embolizations in the peripheral vasculature. The device is sold for animal use only and its sale is restricted to veterinarians only. It may not be used in humans.

The AMPLATZ Vascular Plug is a self-expandable, cylindrical device made from a Nitinol wire mesh. The device is secured on both ends with platinum marker bands. A stainless steel micro screw is welded to one of the platinum marker bands, which allows attachment to the 135 cm long pusher wire (Fig. 1).

The AMPLATZ Vascular Plug is sterile and preloaded in a loader, and is attached to a 135 cm long pusher wire that is placed within a hoop dispenser (Fig. 2). Refer to Table 1 for recommended catheter size.

![Fig 1.](image1.png) ![Fig 2.](image2.png)

Table 1

<table>
<thead>
<tr>
<th>AMPLATZ Vascular Plug</th>
<th>Device Length</th>
<th>Minimum ID</th>
<th>Maximum Length</th>
<th>Delivery Sheath**</th>
<th>Guiding Catheter Minimum Size**</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-PLUG-004</td>
<td>4 mm</td>
<td>7 mm</td>
<td>.056&quot;</td>
<td>100 cm</td>
<td>5 Fr</td>
</tr>
<tr>
<td>9-PLUG-006</td>
<td>6 mm</td>
<td>7 mm</td>
<td>.056&quot;</td>
<td>100 cm</td>
<td>5 Fr</td>
</tr>
<tr>
<td>9-PLUG-008</td>
<td>8 mm</td>
<td>7 mm</td>
<td>.056&quot;</td>
<td>100 cm</td>
<td>5 Fr</td>
</tr>
<tr>
<td>9-PLUG-010</td>
<td>10 mm</td>
<td>7 mm</td>
<td>.067&quot;</td>
<td>100 cm</td>
<td>5 Fr</td>
</tr>
<tr>
<td>9-PLUG-012</td>
<td>12 mm</td>
<td>8 mm</td>
<td>.067&quot;</td>
<td>100 cm</td>
<td>5 Fr</td>
</tr>
<tr>
<td>9-PLUG-014</td>
<td>14 mm</td>
<td>8 mm</td>
<td>.088&quot;</td>
<td>100 cm</td>
<td>6 Fr</td>
</tr>
<tr>
<td>9-PLUG-016</td>
<td>16 mm</td>
<td>8 mm</td>
<td>.088&quot;</td>
<td>100 cm</td>
<td>6 Fr</td>
</tr>
</tbody>
</table>

* For use with standard guiding catheters meeting minimum internal diameter requirements.

** Please note that a guiding catheter is sized by the Outer diameter (OD) whereas a sheath is sized by the inner diameter (ID). This terminology accounts for the apparent difference in sizes between the guiding catheter and sheath required for a given size device.

Contraindications
Warnings
The safety and effectiveness of this device for cardiac uses (for example, patent ductus arteriosus or paravalvular leak closures) and neurological uses have not been established.

Potential Adverse Events
Potential complications include, but are not limited to: hematoma at the site of entry, vessel perforation, or embolization of the device.

Precautions
Handling
• Patients allergic to nickel may suffer an allergic reaction to this device.
• The AMPLATZER Vascular Plug is for single use only. Do not reuse or resterilize.
• Use before the Expiration Date noted on the packaging.
• Do not use open or damaged packages.
• Store in a cool, dry place.
• Do not use if the sterile barrier is compromised in any way.

Directions for Use
Note: A Single Y-Connector Kit (B. Braun Medical, Order No. 610400) is recommended for use with the AMPLATZ Vascular Plug.

• Perform an angiogram and measure the diameter of the vessel.
• Select a device approximately 30-50% larger than the vessel diameter.
• Flush the loader through its hoop to purge air from the loader.
• Remove the white hub clip and pull the pusher wire with the preloaded AMPLATZ Vascular Plug from the hoop.
• Insert and advance the selected guiding catheter to the target vessel.
• Insert the loader through the Single Y-Connector and advance until it contacts the hub of the guide catheter and flush with saline through the sidearm which purges the air from the loader.
• Advance the AMPLATZ Vascular Plug from the loader into the catheter to the target vessel.
• Remove the loader if desired.
• Verify correct position of the AMPLATZ Vascular Plug with a test injection through the catheter. If device position is unsatisfactory, the device can be repositioned or removed together with the catheter.
• If device position is satisfactory, release the device by rotating the pusher wire in a counterclockwise fashion.
• More than one AMPLATZ Vascular Plug may be required to achieve occlusion of a vessel.
• If detachment is difficult, a torque device or surgical clamp may be used to assist with the release of the device by rotating the pusher wire in a counterclockwise fashion.

MR Safe
Through non-clinical testing, the AMPLATZER Vascular Plug has been shown to be MR safe at field strengths of 3.0 Tesla or less with a maximum whole body averaged specific absorption rate (SAR) of 3.83 W/kg at 1.5 Tesla and 5.57 W/kg at 5.0 Tesla for a 20 minute exposure to a B1 of 118 μT.

The AMPLATZER Vascular Plug should not migrate in this MR environment. Non-clinical testing has not been performed to rule out the possibility of migration at field strengths higher than 3.0 Tesla.

In this testing, the device produced a temperature rise of 1.1°C at 1.5 Tesla and 1.6°C at 5.0 Tesla.
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the device.