Indications
The Angio-Seal Vascular Closure Device product family, including the STS Plus, VIP and Evolution platforms, is indicated for use in closing and reducing time to hemostasis of the femoral arterial puncture site in patients who have undergone diagnostic angiography procedures or interventional procedures using an 8 French or smaller procedural sheath for the 8 F Angio-Seal device and a 6 French or smaller procedural sheath for the 6 F Angio-Seal device. The Angio-Seal STS Plus, VIP and Evolution platforms are also indicated in cases to allow patients who have undergone diagnostic angiography to safely ambulate as soon as possible after sheath removal and device placement, as well as to allow patients who have undergone interventional procedures to safely ambulate after sheath removal and device placement.

Important Safety Information
Possible adverse events for vascular closure devices include, but are not limited to: bleeding or hematoma, AV fistula or pseudoaneurysm, infection, allergic reaction, foreign body reaction, inflammation or edema. This device should only be used by a licensed physician (or other health care professional authorized by or under the direction of such physician) possessing adequate instruction in the use of the device, e.g., participation in an Angio-Seal physician instruction program or equivalent.

RX ONLY. Refer to the product labels and package insert for complete warnings, precautions, potential complications, and instructions for use.

References:
HELP ENSURE SUCCESSFUL HEMOSTASIS

The ANGIO-SEAL active closure anchor gives you the inside advantage. The anchor creates a mechanical seal from the inside out—here’s how:

- The anchor supports proper location for a reliable seal and collagen positioning\(^1,2\):
  - 99.7% deployment success\(^3\)
  - 97.8% hemostasis by device\(^3\)

- The anchor and seal are bioabsorbed:
  - Fibrin coats the anchor within hours and becomes totally encapsulated in 7-14 days\(^4\)
  - Anchor begins to hydrate and soften 24-36 hours after deployment\(^4\)
  - Anchor is absorbed 95% at 42 days\(^5\)
  - All components are absorbed within 60-90 days\(^1,2,6,7\)

- Arterial flow is not compromised, no evidence of chronic scar tissue or inflammation\(^5,6\)

RELY ON DUAL SECURITY

The bioabsorbable ANGIO-SEAL anchor + collagen provides dual security, ensuring it is positioned correctly and stays in place\(^1,2\):

- **Bioabsorbable Anchor**
  - Designed to fit closely against the arterial wall, leaving blood flow undisturbed with no residual stenosis\(^5\)
- **Bioabsorbable Collagen**
  - Designed to conform to the arteriotomy for confident closure\(^2\)
- **Bioabsorbable Suture**
  - Tethers the anchor and collagen together, providing a secure seal\(^2\)

PERFORM RESTICK WITH CONFIDENCE

Clinical data supports the safety of restick following an initial ANGIO-SEAL deployment\(^7\):

- Restick can be performed without device dislodgement or any significant vascular complications
- Arterial closure can be achieved with a second ANGIO-SEAL Vascular Closure Device

Vascular Complications Following Restick

<table>
<thead>
<tr>
<th>COMPLICATIONS</th>
<th>PROPORTION</th>
<th>95% CONFIDENCE INTERVAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large Hematoma (&gt; 10cm)</td>
<td>3</td>
<td>0.0166</td>
</tr>
<tr>
<td>Vessel Occlusion</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Pseudoaneurysm</td>
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<tr>
<td>AV Fistulae</td>
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<tr>
<td>Major Bleeding</td>
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<tr>
<td>Vascular Repair</td>
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<td>0</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

A clinical study of 181 patients evaluated safety and efficacy of resticks of the same artery following an initial ANGIO-SEAL device deployment. Patients were included in the study if they had an ANGIO-SEAL device deployment and subsequently underwent arterial access using the same artery that had previously been closed with an ANGIO-SEAL device within 30 days of the original device placement.