Indications
The Angio-Seal Vascular Closure Device product family, including the 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 VIP and Evolution platform devices are also indicated for use in other patients who have undergone diagnostic angiography angiographically to safely ambulate as soon as possible after sheath removal and device placement, as well as for other patients who have undergone an interventional procedure 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:

©2021 Terumo Medical Corporation. All rights reserved. All brand names are trademarks or registered trademarks of their respective owners. PM-04514

ORDERING INFORMATION

ANGIO-SEAL VIP

<table>
<thead>
<tr>
<th>PRODUCT CODE</th>
<th>FRENCH SIZE</th>
<th>GUIDEWIRE DIAMETER (in)</th>
</tr>
</thead>
<tbody>
<tr>
<td>610130</td>
<td>6</td>
<td>0.035</td>
</tr>
<tr>
<td>610131</td>
<td>8</td>
<td>0.038</td>
</tr>
</tbody>
</table>

ANGIO-SEAL EVOLUTION™

<table>
<thead>
<tr>
<th>PRODUCT CODE</th>
<th>FRENCH SIZE</th>
<th>GUIDEWIRE DIAMETER (in)</th>
</tr>
</thead>
<tbody>
<tr>
<td>810134</td>
<td>6</td>
<td>0.035</td>
</tr>
<tr>
<td>810135</td>
<td>8</td>
<td>0.038</td>
</tr>
</tbody>
</table>

Contents: Vascular Closure Device, Insertion Sheath, Arteriotomy Locator and 70 cm Guidewire with “J” Straightener (10 units per box).
The Angio-Seal Vascular Closure Device product family, including the 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 VIP and Evolution platform devices are also indicated for use in other patients who have undergone diagnostic angiography angiographically to safety ambulate as soon as possible after sheath removal and device placement, as well as for other patients who have undergone an interventional procedure 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:**


©2021 Terumo Medical Corporation. All rights reserved. All brand names are trademarks or registered trademarks of their respective owners. PM-04514
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\(^5,^6\)

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\(^2\)

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; 10 cm)</td>
<td>3</td>
<td>0.0166 – 0.0515</td>
</tr>
<tr>
<td>Vessel Occlusion</td>
<td>0</td>
<td>0 – 0.0259</td>
</tr>
<tr>
<td>Pseudoaneurysm</td>
<td>0</td>
<td>0 – 0.0259</td>
</tr>
<tr>
<td>AV Fistulae</td>
<td>0</td>
<td>0 – 0.0259</td>
</tr>
<tr>
<td>Major Bleeding</td>
<td>0</td>
<td>0 – 0.0259</td>
</tr>
<tr>
<td>Vascular Repair</td>
<td>0</td>
<td>0 – 0.0259</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>0 – 0.0259</td>
</tr>
</tbody>
</table>

A clinical study of 181 patients evaluated safety and efficacy of a restick 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 60 days of the original device placement.
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:
  - 99.7% deployment success
  - 97.8% hemostasis by device

- The anchor and seal are bioabsorbed:
  - Fibrin coats the anchor within hours and becomes totally encapsulated in 7-14 days
  - Anchor begins to hydrate and soften 24-36 hours after deployment
  - Anchor is absorbed 95% at 42 days
  - All components are absorbed within 60-90 days

- Arterial flow is not compromised, no evidence of chronic scar tissue or inflammation

ANGIO-SEAL® Evolution™

RELY ON DUAL SECURITY

The bioabsorbable ANGIO-SEAL anchor + collagen provides dual security, ensuring it is positioned correctly and stays in place:

- Bioabsorbable Anchor
  - Designed to fit closely against the arterial wall, leaving blood flow undisturbed with no residual stenosis

- Bioabsorbable Collagen
  - Designed to conform to the arteriotomy for confident closure

- Bioabsorbable Suture
  - Tethers the anchor and collagen together, providing a secure seal

ANGIO-SEAL® Vascular Closure Device

PERFORM RESTICK WITH CONFIDENCE

Clinical data supports the safety of restick following an initial ANGIO-SEAL deployment:

- 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 – 0.0515</td>
</tr>
<tr>
<td>Vessel Occlusion</td>
<td>0</td>
<td>0 – 0.0259</td>
</tr>
<tr>
<td>Pseudoaneurysm</td>
<td>0</td>
<td>0 – 0.0259</td>
</tr>
<tr>
<td>AV Fistulae</td>
<td>0</td>
<td>0 – 0.0259</td>
</tr>
<tr>
<td>Major Bleeding</td>
<td>0</td>
<td>0 – 0.0259</td>
</tr>
<tr>
<td>Vascular Repair</td>
<td>0</td>
<td>0 – 0.0259</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>0 – 0.0259</td>
</tr>
</tbody>
</table>

A clinical study of 181 patients evaluated safety and efficacy of a restick 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 90 days of the original device placement.
Indications
The Angio-Seal Vascular Closure Device product family, including the 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 vascular puncture sheath or a 6 French vascular puncture sheath for the 8 F Angio-Seal device and a 6 French vascular puncture sheath for the 6 F Angio-Seal device. The Angio-Seal VIP and Evolution platform devices are also indicated for use 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 an intervention 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:

©2021 Terumo Medical Corporation. All rights reserved. All brand names are trademarks or registered trademarks of their respective owners.