Hemostasis Management and Vascular Closure Options
RAPID HEMOSTASIS WITH PROVEN SAFETY AND EFFICACY

St. Jude Medical vascular closure products offer rapid hemostasis with proven safety and efficacy following interventional and diagnostic procedures.

**Angio-Seal**
- Interventional and diagnostic procedures
- Patients at higher risk of bleeding complications
- Antegrade and retrograde access procedures
- Peripheral vascular disease
- Immediate repuncture and rapid bioabsorption
- Patient comfort and early ambulation
- Cost effectiveness and increased efficiency

**FemoStop**
- Arterial and venous femoral closures, including > 8 F punctures
- Pseudoaneurysm repair

**RadiStop**
- Radial access closure after interventional and diagnostic procedures
ANGIO-SEAL
IMMEDIATE HEMOSTASIS FOR INTERVENTIONAL AND DIAGNOSTIC PATIENTS

For femoral access site closure following interventional and diagnostic procedures:

- Angio-Seal provides instant, safe and reliable hemostasis of the puncture site, with no need for manual pressure. *
- Angio-Seal has high device deployment and hemostasis success rates. **

** Angio-Seal Evolution vascular closure device demonstrated high rates of success in a 1,004 patient multicenter registry. 

*** Deployment success and immediate hemostasis were defined separately in each clinical trial. Martin et al. reported rates of arterial closure deployment success, but did not report hemostasis or procedure success rates.

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High device success rates with low complication rates

3. Evolution Registry and Subset Data (white paper).
5. The CAP Registry Report (St. Jude Medical white paper).
   * Angio-Seal Instructions for Use.
   ** Device success was recorded as successful completion of device deployment.
   *** Deployment success and immediate hemostasis were defined separately in each clinical trial. Martin et al. reported rates of arterial closure deployment success, but did not report hemostasis or procedure success rates.
Angio-Seal reduces complications vs. manual compression, and compared to other closure devices.\textsuperscript{2}

Vascular closure devices reduce bleeding events for interventional patients.\textsuperscript{1}

Use in interventional patients with reduced complications compared to manual compression
ANTEGRADE AND RETROGRADE ACCESS PROCEDURES

Angio-Seal has proven **clinical performance** in both retrograde and antegrade access procedures.¹

- Certain patients present unique challenges in terms of peripheral vascular disease.
- Angio-Seal is appropriate for vascular closure in a variety of peripheral procedures, including limb ischemia, limb salvage and superficial femoral artery (SFA) stenting.¹⁻⁵

PVD and use in antegrade punctures

Safe repuncture and rapid bioabsorption

1. Angio-Seal Instructions for Use.*

*If repuncture at the same location of the previous Angio-Seal device is necessary, immediately or in less than 90 days, re-entry 1 cm proximal to the previous access site can be performed safely based on published medical literature.

IMMEDIATE REPUNCTURE AND RAPID BIOABSORPTION

Angio-Seal can be safely used for immediate repuncture,1-2 with its secure seal.3

- Angio-Seal components rapidly bioabsorb. The anchor is 95% absorbed in 42 days.4
- The suture and collagen are absorbed within 60-90 days.5
- There is no blood flow impairment, residual stenosis, chronic scar tissue or inflammation.4,6,7
INCREASED PATIENT COMFORT AND RAPID AMBULATION

Angio-Seal provides a solution that increases patient comfort vs. manual compression and other closure devices.¹,²

- Angio-Seal also facilitates early ambulation and discharge.¹-⁴
- For diagnostic patients, clinical data supports 20-minute ambulation and discharge one-hour post-ambulation.⁴*

Patient satisfaction and early ambulation

4. Angio-Seal Instructions for Use.

*Results of a clinical study demonstrate that patients who have undergone diagnostic angiography and have received a 6 F Angio-Seal vascular closure device can safely and effectively ambulate in less than 20 minutes and be discharged one-hour post-ambulation.
Angio-Seal provides a cost-effective alternative to manual compression, and can increase hospital productivity and efficiency.\(^1\)\(^{-3}\)

- Angio-Seal can help reduce the burden of bleeding complications and their associated costs.\(^1\)^4,5
- It can also improve staff efficiency, ergonomics and cath lab throughput by enabling earlier discharge.\(^2\)\(^{\text{3-6}}\)\(^\text{8}\)
**HANDS-FREE, EFFICIENT HEMOSTASIS**

For femoral artery and venous access sites, including larger puncture sizes than 8 F:

- FemoStop compression assist device offers precise, hands-free, efficient hemostasis following interventional and diagnostic procedures, vs. manual compression.\(^1,^2\)
- FemoStop achieves hemostasis faster and is shown to reduce vascular complications.\(^1,^2\)
- It can also facilitate ambulation in 90 minutes.\(^2\)

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Reduced complications and rapid ambulation

OPTION FOR CLOSURE IN NON-STANDARD SITUATIONS

FemoStop can also be used if the patient has an access puncture in these non-standard locations:*  
- Where a vascular closure device is not indicated  
- That requires an IABP sheath removal  
- In a venous access site

FemoStop provides an option to be used:*  
- For compression repair of femoral pseudoaneurysm  
- To obtain hemostasis in patients who may not respond well to routine hemostasis management, including urgent and unexpected cases

* FemoStop Instructions for Use. FemoStop is indicated for use in the compression of the femoral artery or vein after vessel cannulation and in ultrasound-guided compression repair of a femoral artery pseudoaneurysm.
Hands-free compression time example, and rapid ambulation after diagnostic procedure.\textsuperscript{1,2}

<table>
<thead>
<tr>
<th>Compression time example</th>
<th>Diagnostic: 90 minutes to ambulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1</td>
<td>2 minutes, Systolic BP+20 mmHg</td>
</tr>
<tr>
<td>1–3**</td>
<td>8 minutes, M.A.P *</td>
</tr>
<tr>
<td>15</td>
<td>5 minutes, 40 mmHg</td>
</tr>
<tr>
<td>2</td>
<td>Bed rest with FemoStop 0 mmHg</td>
</tr>
<tr>
<td>2</td>
<td>15 minutes, 0 mmHg</td>
</tr>
<tr>
<td>60–180***</td>
<td>Bed rest</td>
</tr>
<tr>
<td>≥10</td>
<td>Total: 90 minutes</td>
</tr>
</tbody>
</table>

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2. FemoStop Instructions for Use.

\* Mean Arterial Pressure

\** After max three minutes: lower to mean arterial pressure. Check pedal pulse.

\*** The length of compression depends on factors that vary, such as sheath size and anticoagulation status.

Note: If there is a venous sheath, inflate the dome to 20–30 mmHg and remove.

To minimize the risk of AV-fistula formation, venous hemostasis should be achieved prior to removal of the arterial sheath.
For radial access closure following interventional and diagnostic procedures:

- RadiStop compression assist device provides reliable and efficient hemostasis. With its unique support plate, it also provides comfortable positioning of the hand, wrist and arm.
- RadiStop demonstrated a reduced incidence of major and minor bleeding, compared to those treated with a competitive device.¹

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**2008 SCAAR data**

**Major Bleeding after PCI**

<table>
<thead>
<tr>
<th>Device</th>
<th>n</th>
<th>Bleeding</th>
</tr>
</thead>
<tbody>
<tr>
<td>TR Band</td>
<td>4264</td>
<td>0.75%</td>
</tr>
<tr>
<td>RadiStop</td>
<td>465</td>
<td>0.43%</td>
</tr>
</tbody>
</table>

**Major and Minor Bleeding after PCI**

<table>
<thead>
<tr>
<th>Device</th>
<th>n</th>
<th>Bleeding</th>
</tr>
</thead>
<tbody>
<tr>
<td>TR Band</td>
<td>4264</td>
<td>1.41%</td>
</tr>
<tr>
<td>RadiStop</td>
<td>465</td>
<td>0.86%</td>
</tr>
</tbody>
</table>

Bleeding that results in more treatment than compression, longer hospital stay or Hb drop > 20 g/L.

Bleeding around the insertion site.

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Reduced minor bleeding complications

Brief Summary: Please review the Instructions for Use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications: St. Jude Medical 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 at 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 proce-
dural sheath for the 6 F Angio-Seal device. The Angio-Seal STS Plus, 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 interventional procedure to safely ambulate after sheath removal and device placement. 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.

FemoStop, RadiStop are designed, developed and manufactured by St. Jude Medical Systems AB.

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