PROVEN AT THE POINT OF ACCESS
Global leader in arterial access and closure

REDUCE COMPLICATIONS WITH RADIAL AND FEMORAL SOLUTIONS

RADIAL SOLUTIONS

FEMORAL SOLUTIONS

TERUMO INTERVENTIONAL SYSTEMS
RECOGNIZE THE RATE OF VASCULAR ACCESS COMPLICATIONS

1 out of every 17 patients will have a vascular bleeding complication.

Leading to significant consequences:
- Increased length of stay: up to 6 days
- In reduced profitability: up to $8,000

VASCULAR ACCESS COMPLICATIONS

PATIENT SELECTION
Choose the most appropriate approach

Radial Approach

- Good Access
- Ultrasound
  Increase first-pass success rate
- Hydrophilic Sheath
  Reduce radial artery spasm disruptions
- Sheath-to-Artery Ratio
  Reduce the risk of radial artery occlusions

Femoral Approach

- Good Access
- Ultrasound
  Reduce vascular access complications
- Micropuncture
  Reduce bleeding complications
- Seamless Sheath Transitions
  Minimize or eliminate vascular access trauma

Good Access techniques are important factors in achieving Good Closure results.

Good Closure

- Patent Hemostasis
  Minimize vascular-access complications

Good Closure active closure

Active Closure

- Rapid and reliable hemostasis

Reduced Access Site Complications

- Opportunity for same-day discharge
- Cost savings up to $3,500
- Improved patient satisfaction

The amount reported in this brochure refers to the U.S. market only.
Proven to reduce bleeding rates, in-hospital mortality and related hospital costs\textsuperscript{13,14}\*.

**Increase first-pass success rate**
\textsuperscript{(n=698)} Seto A. RAUST. JACC. 2015

*Ultrasound vs. Palpation*

64.8% with Ultrasound
43.9% with Palpation

Compared to palpation, ultrasound reduces the number of difficult procedures\textsuperscript{1} with a significantly higher first-pass success rate.\textsuperscript{2} \textsuperscript{1}Difficult procedures defined as requiring ≥ 5 attempts

**Reduce the risk of radial artery occlusions (RAO) with the right-sized sheath**
\textsuperscript{(n=250)} Saito S. Catheter Cardiovasc. Intervent. 1999

**Optimal Sheath-to-Artery Ratio**

Can’t Accept
6 Fr: 27.4%
7 Fr: 59.7%
6 Fr: 12.3%
7 Fr: 28.5%

Sheaths with an outer diameter that is equal to or greater than the inner diameter of the patient’s radial artery may cause distal flow reduction and be a factor in radial artery occlusion.\textsuperscript{5}

**Reduce radial artery occlusion (RAO) with hydrophilic coated sheaths**
\textsuperscript{(n=790)} Rathore S. JACC. 2010

**Hydrophilic coated sheaths vs. Uncoated sheaths**

81% Success rate
61.1% Success rate

Radial artery spasm avoidance

Compared to uncoated sheaths, hydrophilic coated sheaths reduce the incidence of radial artery spasm which may lead to procedural disruption, patient discomfort and procedural failure.\textsuperscript{4}

**Reduce radial artery occlusion (RAO) with patent hemostasis technique**

**Patent hemostasis vs. Traditional compression technique**

1.8% Patent hemostasis
7% Traditional compression technique

% of patients developed evidence of RAO

Compared to traditional compression techniques, patent hemostasis minimizes evidence of radial artery occlusion and vascular access complications.\textsuperscript{6}

**Reduced Access Site Complications**

- Opportunity for same-day discharge
- Improved patient satisfaction\textsuperscript{1,11,12}

\textsuperscript{\*Compared to femoral access}
**FEMORAL SOLUTIONS**

Proven to reduce complications that may enable same-day discharge

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**Reduce vascular complications with ultrasound technology**

(n=1,004) Seto AH, FAUST. JACC. 2010

- Ultrasound vs. Fluoroscopy
  - 7 people with vascular complications
  - 17 people with vascular complications

Compared to fluoroscopy, real-time ultrasound guidance reduces number of attempts, time to access, and improved first-pass success—leading to reduced vascular complications.³

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**Reduce complications with seamless sheath transitions**

(n=189) Allie D. Cath Lab Digest. 2009

- Seamless sheath transition vs. Conventional sheath
  - % Major complications
    - Ultrasound: 0.0
    - Conventional: 1.1
  - % Minor hematoma
    - Ultrasound: 0.05
    - Conventional: 3.8

Compared to conventional sheaths, seamless sheath-to-dilator transitions may minimize or even eliminate vascular access trauma.⁷

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**Reduce bleeding complications with micropuncture needle technology**

(n=1,475) Daggubati RB, FAMOUS. JACC. 2011

- Micropuncture vs. Tactile
  - 1.5% All Procedures
  - 2.7% PCI
  - 2.1% Bleeding events within 72 hours

Compared to tactile access, using a micropuncture needle for femoral access during cardiac catheterization reduces complications, such as bleeding or the need for transfusion.⁵

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**Achieve rapid & reliable hemostasis and reduce time to ambulation**

(n=2,074) Manolis S. Indian Heart J. 2016

- Active closure vs. Other hemostasis methods
  - <1 MINUTE to Hemostasis
  - >20 MINUTES to Hemostasis

Compared to manual or mechanical compression, active closure can provide immediate hemostasis, reduce the time to ambulation, and increase the potential for same-day discharge.²⁵

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**Reduced Access Site Complications**

- Opportunity for same-day discharge
- Improved patient satisfaction⁹

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**Ultrasound**

**Micropuncture**

**Good Access**

**Good Closure**

**Seamless Sheath Transitions**

**Active Closure**

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**FEMORAL SOLUTIONS**

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**REDUCE COMPLICATIONS**
Unique thin-wall sheath design combined with hydrophilic coating proven to enable transradial access without compromise

**Optimal sheath-to-artery ratio**
with the smallest option for procedures requiring 5, 6, and 7 Fr sheaths

**Hydrophilic coating**
may reduce the risk of radial arterial spasm and occlusion

**The #1 preferred radial access sheath on the global market***

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*Data on file.

**References:**
Precise compression with innovative design proven to achieve hemostasis

Hemostasis achieved at low pressures, minimizing the chances of applying occlusive force

Air titration provides a more precise way of applying pressure to the radial artery

Dual balloon technology provides precise compression of the radial artery without compromising local nerve structure

The #1 preferred radial access sheath on the global market*

*Data on file.

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Smooth atraumatic access proven to help reduce complications and enable same-day discharge¹

**Seamless sheath transition** with Total Integrated Fit Technology (TIF) minimizes trauma and supports uncomplicated closing²

**Micropuncture needle** features tapered transitions from 21G tip to 19G shaft for better blood return²

**Ultrasound guidance** is facilitated by the enhanced visibility of the spiral echogenic tip. The needle tip also features back bevel cuts which help to ensure a straighter entry²

The #1 vascular access sheaths on the global market*

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*Data on file.

References:
Active closure for rapid and reliable hemostasis proven to accelerate patient mobility and enable same-day discharge

Resorbable components provide immediate closure with uncompromised blood flow

Lower bleeding complication rates compared to other hemostasis strategies

Manual compression not required for reinforcement of the closure

Active closure using bioabsorbable anchor and collagen with 99.7% deployment success

Bioabsorbable ANGIO-SEAL is no longer visible 30 days following implantation

The #1 vascular closure device on the global market


†Data on file.

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 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.

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.

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References:
3. Angio-Seal™ STS Plus, Angio-Seal™ VIP and Angio-Seal™ Evolution Instructions for Use.
References: