START CONFIDENT.
FINISH STRONG.

A complete toolkit of the most extensively proven and world-leading Access and Closure solutions supports your success from start to finish, and every step in between.

START YOUR CASES WITH CONFIDENCE

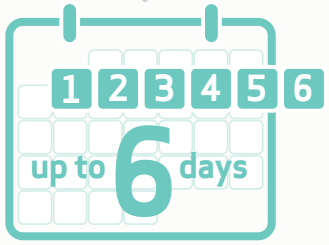
DELIVER PROVEN OUTCOMES YOUR PATIENTS DESERVE

TERUMO
INTERVENTIONAL SYSTEMS

RECOGNIZE THE RATE OF **VASCULAR ACCESS COMPLICATIONS**

patients will have a vascular bleeding complication[1]

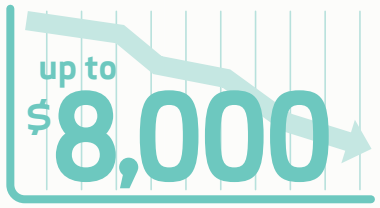
Leading to significant consequences



increased length of stay

Average increase in patient length of stay (LOS) associated with complications is 4 to 6 days[1]

Marso S, *JAMA*. 2010



in reduced profitability

Average increase in facility costs per patient associated with complications and longer LOS[1]

Marso S, *JAMA*. 2010

The amount reported in this brochure refers to the U.S. market only.

REDUCE COMPLICATIONS WITH RADIAL AND FEMORAL SOLUTIONS

PATIENT SELECTION
Choose the most appropriate approach

Radial Approach

Good Access

Ultrasound
Increase first-pass success rate[2]

Hydrophilic Sheath
Reduce radial artery spasm disruptions[4]

Sheath-to-Artery Ratio
Reduce the risk of radial artery occlusions[6]

Femoral Approach

Good Access

Ultrasound
Reduce vascular access complications[3]

Micropuncture
Reduce bleeding complications[5]

Seamless Sheath Transitions
Minimize or eliminate vascular access trauma[7]

Good Access techniques are important factors in achieving Good Closure results

Good Closure

Patent Hemostasis
Minimize vascular access complications[8]

Good Closure

Active Closure
Rapid and reliable hemostasis[9]

Reduced Access Site Complications

- Opportunity for same-day discharge
  - Cost savings up to $3,500[10]
- Improved patient satisfaction[9,11,12]

The amount reported in this brochure refers to the U.S. market only.

TERUMO INTERVENTIONAL SYSTEMS

RADIAL SOLUTIONS

Proven to reduce bleeding rates, in-hospital mortality and related hospital costs[13,14]*

Increase first-pass success rate

(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† with a significantly higher first-pass success rate.[2]

†Difficult procedures defined as requiring ≥5 attempts

Reduce radial artery spasm with hydrophilic coated sheaths

(n=790) Rathore S. *JACC*. 2010

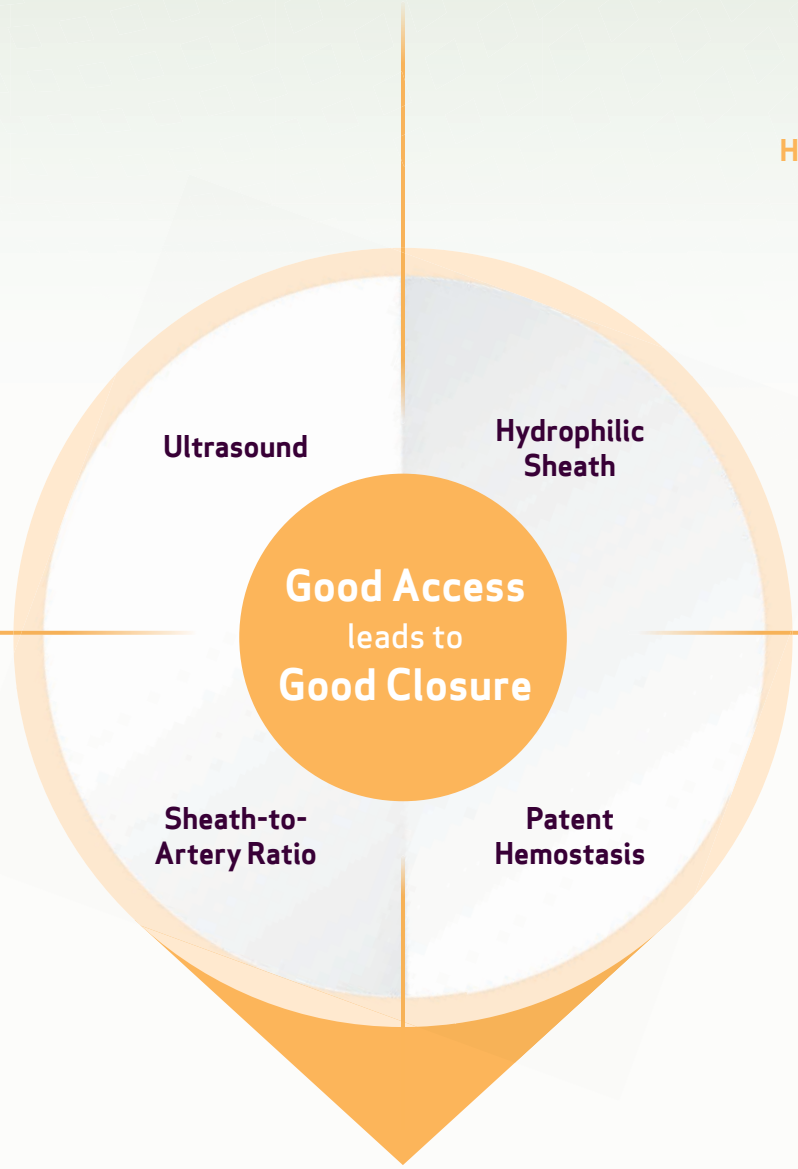
Hydrophilic coated sheaths vs. Uncoated sheaths

81% Success rate

61.1% Success rate

Radial artery spasm avoidance

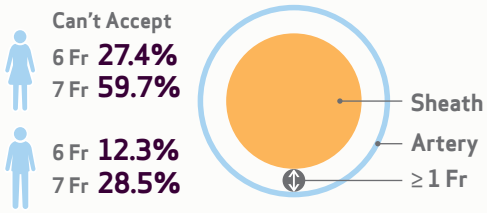
Compared to uncoated sheaths, hydrophilic coated sheaths reduce the incidence of radial artery spasm which may lead to procedural disruption, patient discomfort and procedural failure.[4]



Reduce the risk of radial artery occlusions (RAO) with the right-sized sheath

(n=250) Saito S. *Cathet Cardiovasc Intervent*. 1999

Optimal Sheath-to-Artery Ratio



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.[6]

Reduce radial artery occlusion (RAO) with patent hemostasis technique

(n=480) Pancholy S. PROPHET Study. *Cathet Cardiovasc Intervent*. 2008

Patent hemostasis vs. Traditional compression technique

1.8% Patent hemostasis

7% Traditional compression technique

30 DAY FOLLOW UP

% of patients developed evidence of RAO

Compared to traditional compression techniques, patent hemostasis minimizes evidence of radial artery occlusion and vascular access complications.[8]

Reduced Access Site Complications

- Opportunity for same-day discharge
- Improved patient satisfaction[11,12]

*Compared to femoral access

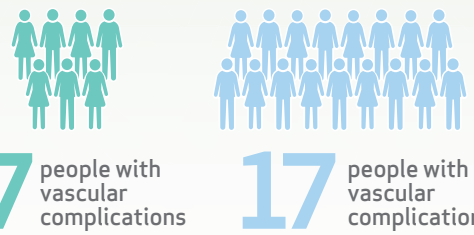
FEMORAL SOLUTIONS

Proven to reduce complications that may enable same-day discharge

Reduce vascular complications with ultrasound technology

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

Ultrasound vs. Fluoroscopy

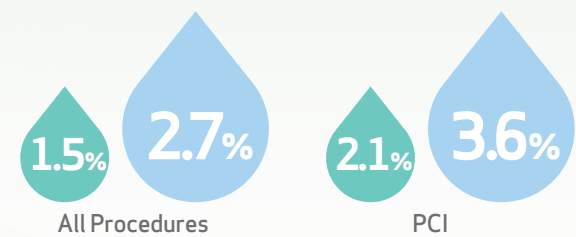


Compared to fluoroscopy, real-time ultrasound guidance reduces number of attempts, time to access, and improved first-pass success—leading to reduced vascular complications.[3]

Reduce bleeding complications with micropuncture needle technology

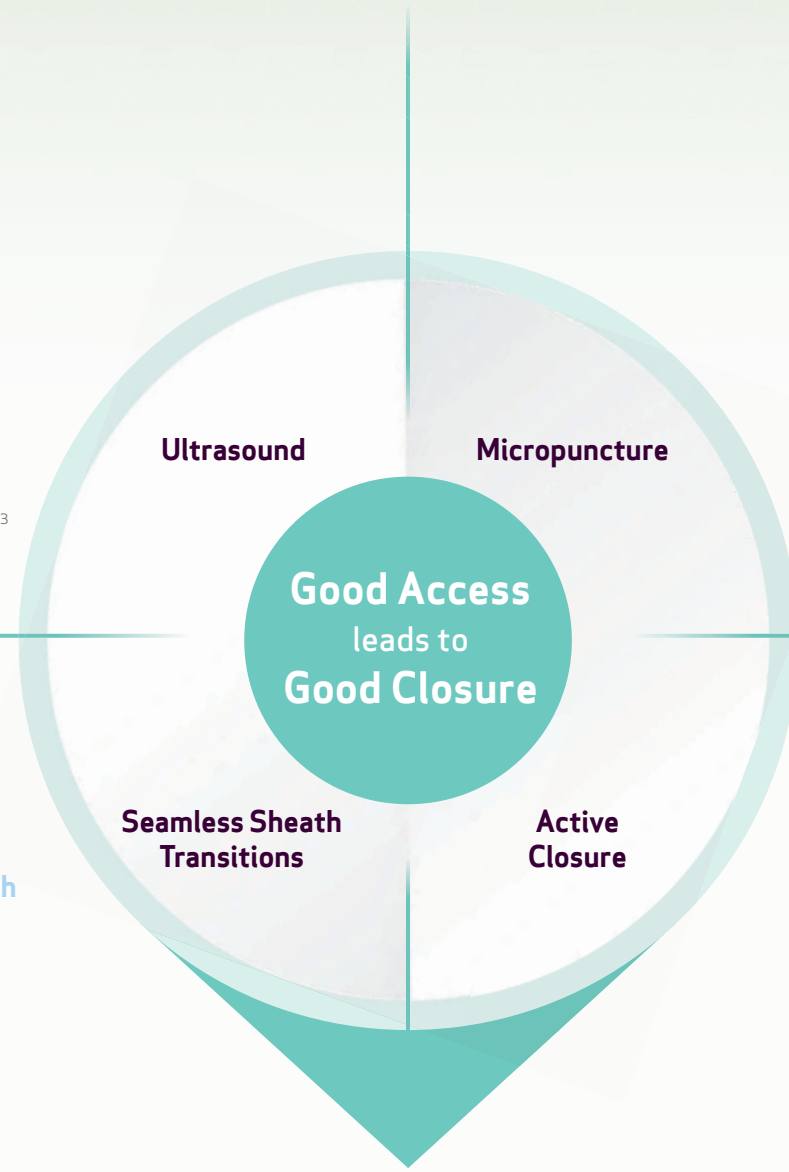
(n=1,475) Daggubati RB. FAMOUS. *JACC*. 2011

Micropuncture vs. Tactile



Bleeding events within 72 hours

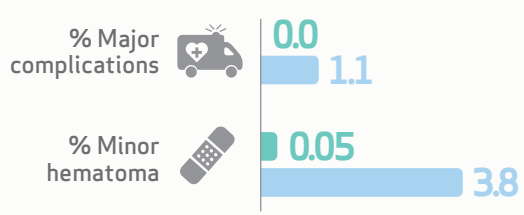
Compared to tactile access, using a micropuncture needle for femoral access during cardiac catheterization reduces complications, such as bleeding or the need for transfusion.[5]



Reduce complications with seamless sheath transitions

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

Seamless sheath transition vs. Conventional sheath

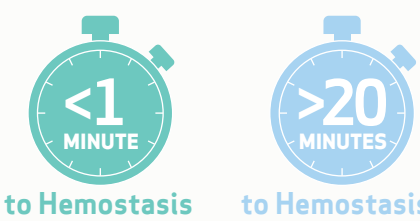


Compared to conventional sheaths, seamless sheath-to-dilator transitions may minimize or even eliminate vascular access trauma.[7]

Achieve rapid & reliable hemostasis and reduce time to ambulation

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

Active closure vs. Other hemostasis methods



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.[15]

Reduced Access Site Complications

- Opportunity for same-day discharge
- Improved patient satisfaction[9]

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PUSHING BOUNDARIES

Terumo Interventional Systems is **committed to your success** with innovative procedural solutions and ongoing support for your most challenging cases.

We are relentlessly seeking new ways to help you apply effective solutions and achieve **better outcomes for more patients.**

Learn more about how Terumo Learning EDGE™ programs can support the advancement of your practice and patient care—from large group to individual proctorships in dynamic clinical settings. For more information, contact us at **LearningEdge@terumomedical.com**

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References:

1. Marso S, et al. Association between use of bleeding avoidance strategies and risk of periprocedural bleeding among patients undergoing percutaneous coronary intervention. *JAMA*. 2010;303(210):2156-64. **2.** Seto A, et al. Real-time ultrasound guidance facilitates transradial access RAUST (Radial Artery Access with ultrasound trial). *JACC Cardiovasc Interv*. 2015;8(2):283-91. **3.** Seto AH, et al. Real-time ultrasound guidance facilitates femoral arterial access and reduces vascular complications: FAUST (Femoral Arterial Access with Ultrasound Trial). *JACC Cardiovasc Interv*. 2010;3(7):751-8. doi: 10.1016/j.jcin.2010.04.015. **4.** Rathore S. Impact of Length and Hydrophilic Coating of the Introducer Sheath on Radial Artery Spasm During Transradial Coronary Intervention A Randomized Study. *JACC Cardiovasc Interv*. 2010;3(5):475-83. **5.** Daggubati RB, Brantley H, Adusumalli S, et al. Femoral access methods and outcomes: understanding the strategy (FAMOUS) trial. *JACC*. 2011;57(14):E1288. doi:10.1016/S0735-1097(11)61288-6. **6.** Saito S, et al. Influence of the ratio between radial artery inner diameter and sheath outer diameter on radial artery flow after transradial coronary intervention. *Cath Cardio Interv*. 1999;46:173-178. **7.** Allie D. Optimizing Vascular Access Management—Focus on the introducer sheath and entry arteriotomy. Cath Lab Digest website. 2009; www.cathlabdigest.com/articles/Optimizing-Vascular-Access-Management-%E2%80%94-Focus-Introducer-Sheath-and-Entry-Arteriotomy. Accessed January 11, 2018. **8.** Pancholy S. Prevention of radial artery occlusion—patent hemostasis evaluation trial (PROPHET Study): A randomized comparison of traditional versus patency documented hemostasis after transradial catheterization. *Cath Cardio Interv*. 2008;72:335-340. **9.** Kapadia SR, Raymond R, Knopf W, et al. The 6Fr Angio-Seal arterial closure device: Results from a multimember prospective registry. *Am J Cardiol*. 2001;87:789-791. **10.** Amin A, et al. Costs associated with access site and same-day discharge among Medicare beneficiaries undergoing percutaneous coronary intervention. *JACC Cardiovasc Interv*. 2017;10(4):342-51. **11.** Schussler JM. Effectiveness and safety of transradial artery access for cardiac catheterization. *Proc (Bayl Univ Med Cent)*. 2011; 24(3):205-209. **12.** Duffin DC, Muhlestein JB, Allisson SB, et al. Femoral arterial puncture management after percutaneous coronary procedures: a comparison of clinical outcomes and patient satisfaction between manual compression and two different vascular closure devices. *J Invasive Cardiol*. 2001;13(5):354-362. **13.** Valgimigli M, et al. MATRIX Trial. Radial versus femoral access in patients with acute coronary syndromes undergoing invasive management: a randomized multicenter trial. *Lancet*. 2015;385:2465-76. **14.** Data on File. Terumo Medical Corporation. Premiere Perspective Database. **15.** Manolis S, et al. Simplified swift and safe vascular closure device deployment without a local arteriogram: Single center experience in 2074 consecutive patients. *Indian Heart Journal*. 2016;68:529-38.

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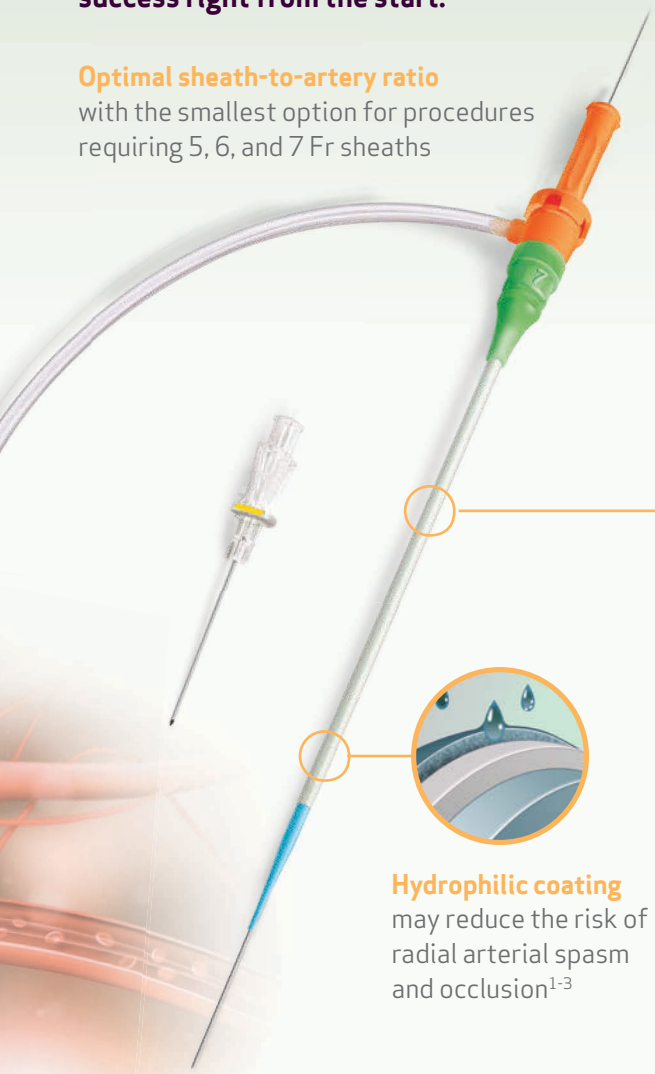
TERUMO INTERVENTIONAL SYSTEMS

Glidesheath Slender®

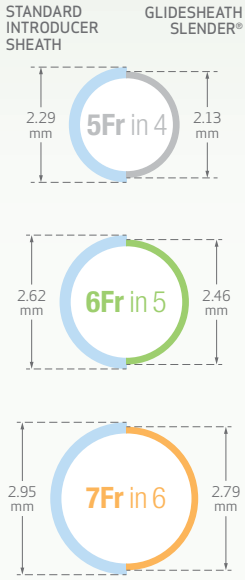
Hydrophilic Coated Introducer Sheath

Unique thin-wall sheath design with best-in-class hydrophilic coating proven to address the majority of complication risks associated with radial access, setting you up for procedural success right from the start.

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[1-3]



The outer diameter of the introducer sheath is reduced by one Fr size with thin-wall technology to maintain larger inner-diameter equivalent.

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

RADIAL SOLUTIONS | START YOUR CASES **WITH CONFIDENCE.**

*Data on file.

References:
1. Rao S, Bernat I, Bertrand O. *Euro Heart J.* 2012;33(20):2521-2526. When compared to the existing thin wall sheaths on the market: Merit Prelude IDeal and Cordis RAIN Sheath. Data on file. The third-party trademarks used herein are trademarks of their respective owners. **2.** Saito S, Tanaka S, Hiroe Y, et al. *Cath Cardio Inter.* 2002;56(3):328-332. Data on file. **3.** Rathore S. *JACC. Cardiovascular Interventions.* 2010;3(5):475-83.

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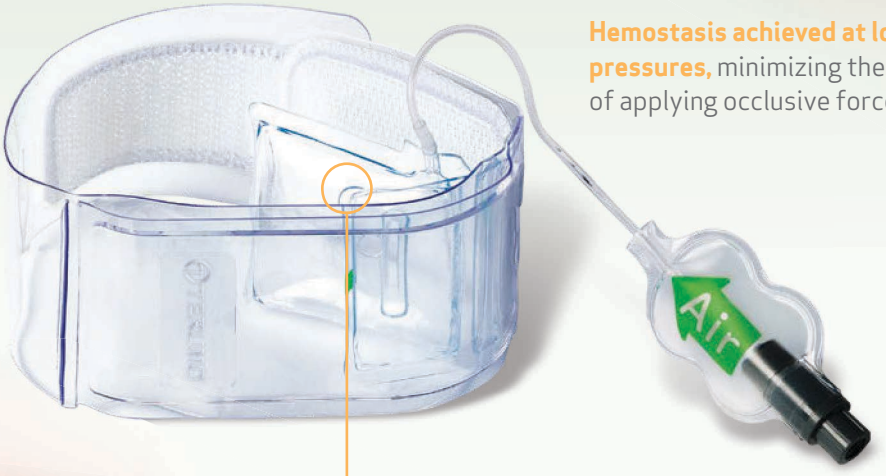
TR Band®

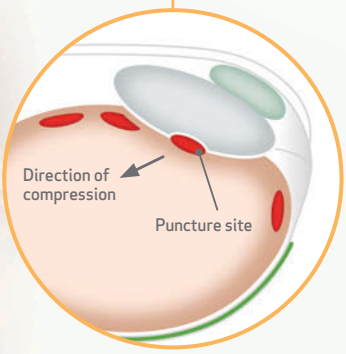
Radial Compression Device

Precise compression with an innovative design that delivers the benefits of patent hemostasis with consistent, controlled performance.



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*

RADIAL SOLUTIONS | FINISH STRONG.

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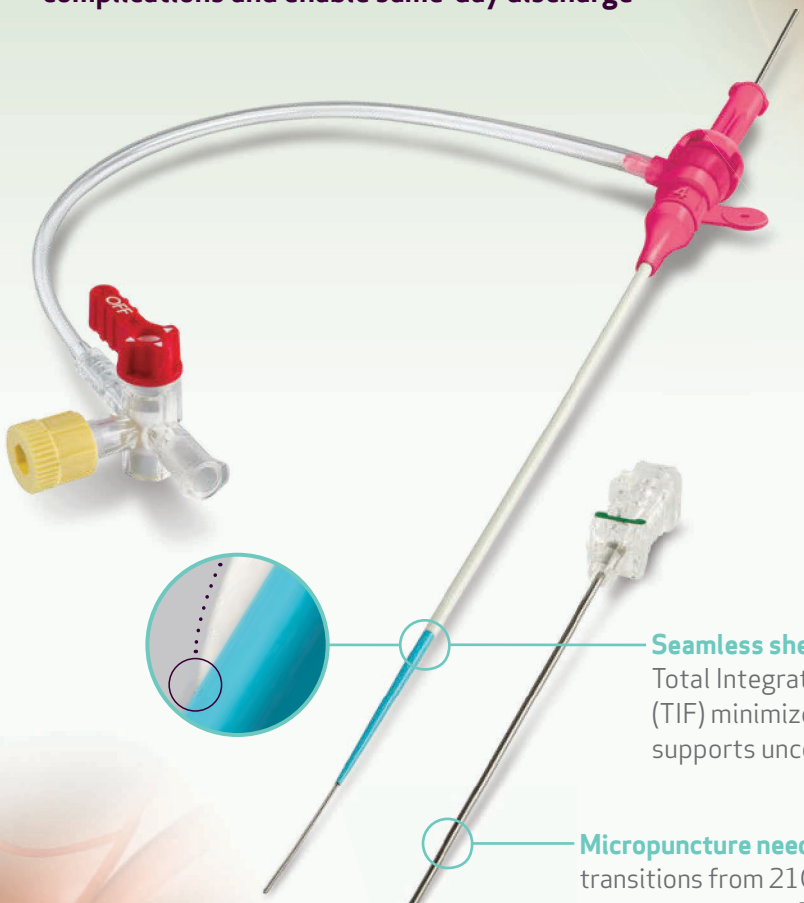
Pinnacle® Precision

Access System

Smooth atraumatic access proven to help reduce complications and enable same-day discharge[1]



Seamless sheath transition with Total Integrated Fit Technology (TIF) minimizes trauma and supports uncomplicated closing[2]

Micropuncture needle features tapered transitions from 21G tip to 19G shaft for better blood return[2]

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 entry[2]

The #1 vascular access sheaths on the global market*

FEMORAL SOLUTIONS | START YOUR CASES **WITH CONFIDENCE.**

*Data on file.

References:
1. Data on File. Terumo Medical Corporation. TIF Engineering Evaluation and Test Production Results #20070045. **2.** Data on File. Terumo Medical Corporation. Pinnacle Precision Access System Competitor Evaluation Report #20170018.

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Angio-Seal®

Vascular Closure Device

Angio-Seal is the only femoral closure device indicated for early ambulation, empowering clinicians like you to deliver the proven outcomes your patients deserve.[1]

Patients undergoing diagnostic angiography with Angio-Seal can **ambulate safely as soon as possible** after sheath removal and device placement.[1]

Lower bleeding complication rates compared to other hemostasis strategies[2]

The bioabsorbable anchor and collagen provides **dual security reinforcement for hemostasis without compromising blood flow**[3-5]

Active closure using bioabsorbable anchor and collagen with 99.7% deployment success[6]

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

The #1 vascular closure device on the global market[7]

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*Reprinted from *EuroIntervention*. Vol 5. Tellez A, Cheng Y, Yi G, et al. *In vivo* intravascular ultrasound analysis of the absorption rate of the Angio-Seal™ vascular closure device in the porcine femoral artery:731-736. ©2010, with permission from Europa Digital & Publishing.

Indications:
The Angio-Seal Vascular Closure Device 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 8F Angio-Seal device and a 6 French or smaller procedural sheath for the 6F Angio-Seal device. Angio-Seal is 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 physicians with training qualifying them to perform arterial access and closure for endovascular procedures through the common femoral artery and have participated in a Terumo Medical Corporation Angio-Seal physician instruction program.

Exception (applicable to US and China only):
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:
1. ANGIO-SEAL VIP Instructions for Use. ASIN0004. 2018-09-01. **2.** Tavris D. *J Invasive Cardiol.* 2012;24(7):2-8. **3.** Nash JE, Evans DG. Herz. 1999;24(8):597-606. http://dx.doi.org/10.1007/bf03044483 **4.** Tellez A, et al. *EuroIntervention.* 2010 Jan;5(6):731-6. **5.** Aker UT, et al. *Cathet Cardiovasc Diagn.* 1994;31(3):228-32. **6.** Applegate RJ, Turi Z, Sachdev N, et al. *J Invasive Cardiol.* 2010;22(9):420-6. **7.** Data on file.

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