

# Arstasis<sup>ONE</sup> Access System

INSTRUCTIONS FOR USE

## DESCRIPTION

The Arstasis<sup>ONE</sup> Access System (“System”) is a sterile, single use system intended to provide access for the percutaneous introduction of devices into the peripheral vasculature and to promote hemostasis at the arteriotomy site as an adjunct to manual compression. The System contains the Arstasis<sup>ONE</sup> Access Device (“Device”), which consists of the following components: 1) Device Sheath/Anchor, 2) Shaft, and 3) Handle with control features (see Figure A). A guidewire lumen extends through the handle and shaft. The actuator deploys an anchoring mechanism to position the anchor relative to the artery wall during integrated needle and guidewire introduction.

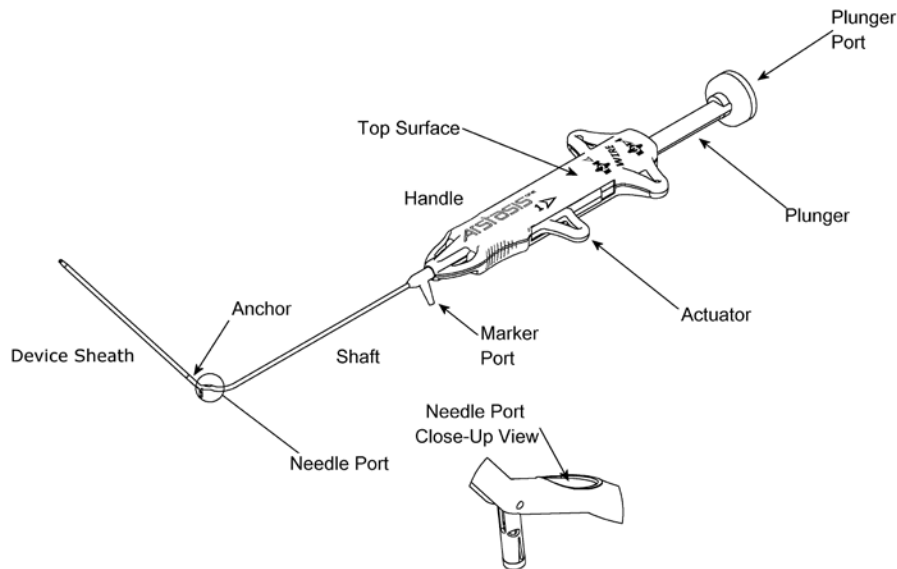


Figure A

The plunger advances the integrated needle. The Device allows the clinician to create a prescribed access pathway for the guidewire from the skin surface through the arterial wall and into the arterial lumen.

## SYSTEM CONTENTS

Pouch 1: One (1) Arstasis<sup>ONE</sup> Access Device  
 Pouch 2: One (1) Guidewire  
 One (1) Access Needle  
 One (1) 5F or 6F Introducer Sheath with Dilator

## INDICATIONS FOR USE

The System is intended to provide access for the percutaneous introduction of devices into the peripheral vasculature and to promote hemostasis at the arteriotomy site as an adjunct to manual compression. The System is indicated for use in patients undergoing diagnostic femoral artery catheterization procedures using 5F or 6F introducer sheaths.

## CONTRAINDICATIONS

The System is not for use in the coronary or cerebral vasculature. The System is not for use with devices or sheaths greater than 6F.

## WARNINGS

- 1) The System is for SINGLE USE only. Do not re-sterilize, autoclave, or reuse. This may result in impaired performance and could cause patient injury and/or the communication of infectious diseases from one patient to another.
- 2) Caution: Federal (USA) law restricts this System to sale in the USA by or on the order of a physician.
- 3) The System should only be used by physicians trained in peripheral percutaneous techniques in a fully equipped catheterization laboratory.
- 4) The System should be used for vascular access only via the femoral artery.
- 5) Although the risks of re-access were surveyed in a small subset of patients, a full understanding of the safety and effectiveness of re-access procedures, including the optimal timing of re-access with either Seldinger technique or the Arstasis<sup>ONE</sup> Vascular Access System, has not been established.

## PRECAUTIONS

- 1) Prior to use, carefully read the instructions packaged with the System. **Note:** Follow the sequence of steps to operate the Arstasis<sup>ONE</sup> device exactly as described in the Instructions for Use. A deviation from the sequence of steps may result in damage to the vessel or surrounding tissue.
- 2) The Device should only be used with the supplied Access Needle, Guidewire and Introducer Sheath.
- 3) Do not use if either package is opened or damaged.
- 4) Do not use after the last day of the month of the “Use By” date on the package.
- 5) Do not pull on the device sheath when removing the Device from the package.
- 6) Inspect the System prior to use to ensure that it is undamaged and suitable for the specific procedure.
- 7) Ensure that the integrated needle is fully retracted within the needle port prior to insertion of the Device.
- 8) Avoid excessive rotation, bending or kinking of the Device during insertion and removal as this may cause damage or affect the performance of the device including obstruction of the needle lumen.
- 9) Avoid kinking the guidewire. Kinking the guidewire may make it difficult to insert, advance, and/or remove the guidewire from the Arstasis device. Should the guidewire become kinked, replace it with a new guidewire. If the guidewire kinks while still inside the Device, carefully attempt to remove the guidewire from the Device and replace with a new one. Stop if excessive resistance is felt when removing the guidewire from Device. If excessive resistance is encountered retract the Device and guidewire together from vasculature.

10) If the guidewire cannot access the vasculature after the plunger is fully depressed, retract the plunger and ensure that the actuator has returned to its disengaged position. Retract the Device until the device sheath's wire exit port is accessible at the skin surface. Insert the guidewire through the device sheath's wire exit port and into the artery. Remove the Device leaving the guidewire in the artery and advance 5F or 6F sheath introducer over the guidewire. Proceed with scheduled procedure.

**ADVERSE EFFECTS**

The System is designed for use by physicians trained in and familiar with peripheral percutaneous diagnostic and/or interventional techniques. Possible complications include, but are not limited to the following:

- Arteriovenous (AV) fistula
- Embolization
- Hematoma
- Infection
- Neural damage
- Pseudoaneurysm
- Vascular hemorrhage requiring transfusion
- Vascular injury including intimal dissection, vessel perforation
- Venous thrombosis

**STORAGE**

Store at room temperature. Avoid storing the System under conditions of excessive heat or humidity.

**CLINICAL STUDIES**

**Studies Summary:** Data presented in this IFU were collected as part of the SECURE-II clinical study to demonstrate the safety and effectiveness of the ITG Vascular Access System. A total of 117 subjects undergoing diagnostic catheterization using a 5 or 6F procedural sheath and targeted for standard manual compression were evaluated as part of this study. 71% of the subjects were male, the mean age of the subjects was 64.6 years, and the subjects' BMI ranged from 19.8 to 41.5. 36 subjects required an intervention as a result of the diagnostic examination.

**Safety:** The primary safety endpoint, defined as a major complication rate through the 30-day follow up visit, where major complications include vascular repair / need for vascular repair, bleeding requiring transfusion, new permanent ipsilateral lower extremity ischemia, permanent nerve injury, infection requiring IV antibiotics, ipsilateral Deep Vein Thrombosis, pseudoaneurysm treated with U/S guided compression or fibrin/thrombin injection, or hematoma > 6cm requiring vascular repair, was compared to a performance goal of 5%. The major complication rate was 0.93% (1/107), and the calculated upper limit of the exact one-sided 95% confidence interval was 4.36%, thus meeting the primary safety endpoint.

**Effectiveness:** The primary effectiveness endpoint of device success, defined as the successful placement of the ITG Device followed by the procedural sheath in the femoral artery, followed by achievement of hemostasis in conjunction with manual or mechanical compression and the absence of major access site-related complications

through the 30-day follow up visit, was compared to a performance goal of 80%. The device success rate was 91.5% (107/117), and the calculated lower limit of the exact one-sided 95% confidence interval was 85.9%, thus meeting the primary effectiveness endpoint.

Secondary Effectiveness Endpoints included: a) Time To Hemostasis and b) Time To Ambulation for the diagnostic cohort only. Subjects requiring an intervention were included in the safety analysis and were treated in accordance with the hospital standard of care. Time to Hemostasis and Time to Ambulation data were not collected for these subjects. The outcomes for these study endpoints were compared to literature control rates of 17 minutes<sup>1,2,3,4,5</sup> for average Time To Hemostasis for standard manual compression and 4.75 hours<sup>3,4,5</sup> for average Time To Ambulation for diagnostic subjects. The mean Time To Hemostasis for Diagnostic subjects of 4.6 ± 2.4 minutes was less than the literature control, and the mean Time To Ambulation for Diagnostic subjects of 2.2 ± 1.3 hours was less than the literature control.

Study Endpoint	Study Results
Device Safety – Major Complication Rate (%)	1/107 (0.93%)
Device effectiveness (%)	107/117 (91.5%)
Time to Hemostasis, Diagnostic (Mean ± Std Dev)	4.6 ± 2.4 minutes (n=73)
Time to Ambulation, Diagnostic (Mean ± Std Dev)	2.2 ± 1.3 hours (n=72)

**Additional Product Performance and Safety Evaluations:** Long term safety (6-12 months post procedure) and ability to safely re-access were also evaluated. One hundred (100) subjects from the SECURE-II study were retrospectively assessed for long term safety and 20 study subjects were determined to have been re-accessed subsequent to the index procedure in the femoral artery for a total of 25 re-access attempts. There were no major complications in either group, and re-access was 100% successful.

Additional Performance and Safety Evaluations	Study Results
Long term Device Safety – Major Complication Rate	0/100 (0%)
Re-access Safety – Major Complication Rate	0/25 (0%)*
Re-access Success	25/25 (100%)

\* In the retrospective re-access study, 4 subjects underwent re-access using the ITG device for a second time. Investigators in 2 of the 4 subjects encountered “moderate” difficulty during the re-access procedure, but these subjects were still defined as a success by the terms of the trial.

**Conclusion:** The results of the clinical studies described above demonstrate the ability to provide access to the arterial lumen and facilitate the introduction and placement of devices into the peripheral vasculature and achievement of hemostasis.

<sup>1</sup> Simon, A., et al. “Manual Versus Mechanical Compression for Femoral Artery Hemostasis After Cardiac Catheterization”. American Journal of Critical Care 7:308-13 (1998).

<sup>2</sup> Ward, S.R., et al. "Efficacy and Safety of a Hemostatic Puncture Closure Device With Early Ambulation After Coronary Angiography". American Journal of Cardiology 81:569-72 (1998).

<sup>3</sup> Schickel, S.I. et al. "Achieving Femoral Artery Hemostasis After Cardiac Catheterization: A Comparison of Methods". American Journal of Critical Care 8(6):406-9 (1999).

<sup>4</sup> Bavry AA, et al "Efficacy of a Novel Procedure Sheath and Closure Device During Diagnostic Catheterization: The Multicenter Randomized Clinical Trial of the FISH Device." J Invasive Cardiology. 2008 April 20(4):152-6.

<sup>5</sup> Hermiller J, et al "Clinical Experience with a Circumferential Clip-Based Vascular Closure Device in Diagnostic Catheterization." J Invasive Cardiology. 2005 October 17(10):504-10.

#### DIRECTIONS FOR USE

- 1) Inspect the packages before opening. Do not use if package is opened or damaged.
- 2) Use sterile technique to carefully remove the System from the packages. Inspect the System to ensure that there are no signs of kinking or other damage.
- 3) Flush the Device with sterile heparinized saline via the plunger port until the solution exits the distal end of the device. Flush the guidewire lumen in the device sheath with heparinized saline.
- 4) SHEATH PREPARATION:
  - a. Identify the insertion site and prepare the site using proper aseptic technique and local anesthesia as required.
  - b. Remove the Sheath Introducer components from the package using proper aseptic technique
  - c. Flush all components with saline or suitable isotonic solution. After flushing side port, turn stopcock to off position to maintain flush in side port and prevent bleed back upon insertion into the vessel.
  - d. Insert vessel dilator into the Sheath Introducer through hemostasis valve and snap into place. Dilator must be securely snapped into place to avoid damage to the vessel.
- 5) Place the access needle into the artery using the modified Seldinger percutaneous technique.
- 6) Place the guidewire through the needle and into the artery, then remove the access needle.
- 7) Advance the device sheath's flexible tip over the guidewire until the guidewire exits the device sheath wire port (Figure B).

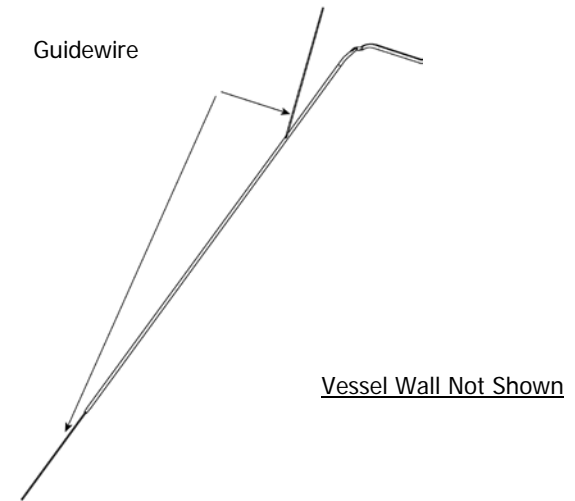


Figure B

- 8) Continue to advance the device sheath into the artery. When the exit point of the guidewire from the device sheath reaches the skin surface, remove the guidewire.
  - a. **Note:** Do not prematurely deploy the heel by retracting the actuator or damage to the vessel or surrounding tissue may result. If the heel is prematurely deployed, do not advance the device. Return actuator to the released position, remove and discard the device, taking care not to remove the guidewire from the femoral artery.
- 9) Continue to advance the Device further into the artery until blood mark / flash is observed coming from the marker port, confirming that the anchor has entered the vessel lumen. Make sure that the top surface of the Device faces upward, away from the skin surface. Maintain this position throughout the remaining procedure.
  - a. **Note:** Avoid excessive twisting or rotation of the device during insertion as this may cause device damage or affect device performance.
  - b. **Note:** Avoid over-manipulation of the device during insertion as this may increase time to hemostasis upon sheath introducer removal due to extension of the primary arteriotomy.
  - c. **Note:** Do not over insert the Device. Observe the marker port during insertion. When blood mark is achieved, stop advancing the device.
- 10) Deploy the heel by pulling back on the actuator until it stops, indicating that the heel has been deployed (Figure C). Do not force the actuator beyond the point where it engages or damage to the device may result.

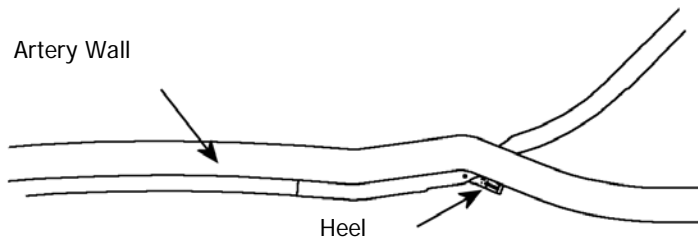


Figure C

- 11) Apply gentle upward traction on the Device to seat the heel against the arterial wall. Confirm that the blood mark from the marker port has stopped or is substantially reduced.
- 12) Advance the integrated needle into the arterial wall by pressing the plunger until it contacts the handle (Figure D).

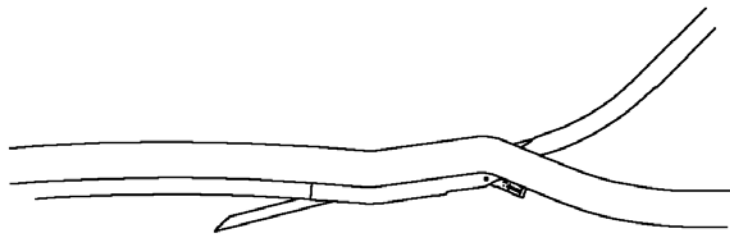


Figure D

- 13) Confirm intra-luminal position by a resumption of blood flow from the marker port.
- 14) Insert and advance the guidewire through the plunger port and into the arterial lumen. The guidewire should be advanced far enough to maintain access while removing the Device (Figure E).
  - a. **Note:** Avoid kinking the guidewire; if the guidewire becomes kinked replace it with a new guidewire. If the guidewire becomes fixed into the device, retract the plunger and remove the device.
  - b. **Note:** If the guidewire is unable to access the vasculature or excessive resistance is felt, abort the Arstasis entry procedure by retracting the plunger and removing the device until the guidewire exit port of the device sheath is visible. Insert the guidewire into the vasculature and insert the procedural sheath in the standard modified Seldinger fashion.

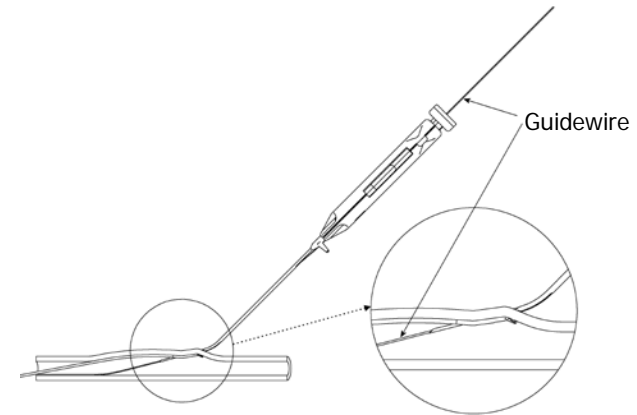


Figure E

- 15) Prior to removing the Device, retract the plunger and verify that the actuator has moved to its disengaged position, releasing the heel. If the actuator did not automatically release, manually move it to the disengaged position.
- 16) Remove the Device, being careful to keep the guidewire in place.
 

Note: If resistance is felt during removal, stop and examine the Device. Verify that the plunger was fully retracted, and the actuator fully disengaged. If resistance is still felt, remove the guidewire and then the Device.
- 17) SHEATH INSERTION:
  - a. Insert the Sheath Introducer/Dilator assembly over the guidewire into the vessel. Using a rotating motion, advance the Sheath Introducer/Dilator assembly through the tissue into the vessel. Grasp the assembly close to the skin as it is being placed into the vessel to avoid buckling.
  - b. After the Sheath Introducer/Dilator assembly has been placed into vessel, detach the Dilator from the Sheath Introducer by bending the Dilator hub down slightly (this will un-snap the Dilator from the Sheath Introducer cap). While holding the Sheath Introducer, carefully remove the Dilator and guidewire together, leaving the Sheath Introducer in the vessel.
  - c. Aspirate from the side port extension to remove any potential air. After the aspiration, flush the side port with a suitable solution. Stopcock should be turned off to maintain flush in the side port.
  - d. Insert selected device (s) (wires, catheters, etc) into the Sheath Introducer. Note: Hold the Sheath Introducer in place when inserting, positioning, or removing the devices. Always exchange or remove devices slowly through the Introducer Sheath.
- 18) SHEATH REMOVAL:
  - a. The Sheath Introducer may be removed when clinically indicated. Compression on the vessel, above the puncture site, should be started as the sheath is slowly removed. Note: Collected fibrin at the tip of the Introducer Sheath may be aspirated via the side arm tubing prior to

removal of the Introducer Sheath. Discard the Introducer Sheath appropriately.

- b. If the Introducer Sheath is to be left in place, an obturator of appropriate size should be placed into the Introducer Sheath. After the Introducer Sheath is flushed, place the obturator through the Introducer Sheath and snap into place. A suitable solution should be flushed through the side arm after the obturator is placed. Note: An obturator that is one French size smaller than the Sheath Introducer should be used to allow flushing, infusion and pressure monitoring. When clinically indicated, the Introducer Sheath and obturator may be removed (see above).

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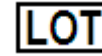
**DEFINITION OF SYMBOLS ON LABEL**



Sterilized using irradiation



Sterilized using EtO



Batch code



Single Use Only



Caution, consult accompanying documents



Manufacturer



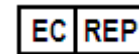
Use By Date



Catalogue Number



Do not use if package is damaged



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