Solus Gold™ Embolization Device

Instructions for Use

RELEASED

Solus Gold Embolization Device

Device Description

The Solus Gold™ Embolization Device is a vessel occlusion device expanded by saline injection. The Solus Gold Embolization Device is comprised of an implant assembly and a delivery system assembly. The delivery system assembly is comprised of a microcatheter for atraumatic delivery of the implant to the target vessel segment and a hydrophilic coated delivery catheter with a rotating hemostatic valve (RHV) and a 3-way stopcock for injecting fluid to facilitate expansion of the implant. The delivery system detaches from the implant by mechanical means. The Solus Gold Embolization Device is placed in a packaging hoop, sealed in a Tyvek pouch, and packaged in a shelf carton. The Solus Gold Embolization Device is provided sterile, non-pyrogenic, and is intended for single use only.

Figure 1 – The Solus Gold Embolization Device

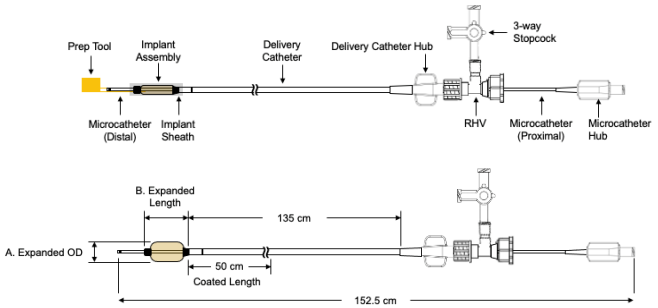

Table 1 – Solus Gold Implant Dimensions

Device	A. Expanded Implant OD	B. Expanded Implant Length	Target Vessel Diameter
3 mm Device	3.0 mm	6.7 mm	2.0 – 2.5 mm
3.5 mm Device	3.5 mm	7.6 mm	2.3 – 2.9 mm
4 mm Device	4.0 mm	8.4 mm	2.6 – 3.3 mm
4.5 mm Device	4.5 mm	9.3 mm	2.9 – 3.7 mm
5 mm Device	5.0 mm	10.2 mm	3.3 – 4.1 mm
5.5 mm Device	5.5 mm	11.1 mm	3.6 – 4.6 mm
6 mm Device	6.0 mm	11.9 mm	3.9 – 5.0 mm

Table 2 – Solus Gold Delivery System Dimensions

Device	ID	OD	Working Length	Overall Length	Coated Length
Microcatheter	0.017”	0.026”	-	152.5 cm	-
Delivery Catheter	0.034”	0.044”	135 cm	-	50 cm

Indications for Use

The Solus Gold Embolization Device is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature.

Contraindications

The Solus Gold Embolization Device is not indicated for use in blood vessels where crush or bend forces are anticipated (*e.g.,* joint areas, superficial vasculature).

Compatibility

The Solus Gold Embolization Device is compatible with access devices labeled with an ID of 0.070” or larger. Refer to Table 2 for Solus Gold Delivery System dimensions. Refer to labeling provided with other medical devices to determine compatibility.

Warnings

- The Solus Gold Embolization Device is provided sterile and non-pyrogenic, unless the unit package is opened, breached or damaged. Do not use if the packaging is opened, breached or damaged.
- The Solus Gold Embolization Device is intended for single use only. After use, dispose of the Solus Gold Embolization Device and its component parts in accordance with hospital, administrative, and local government policy. The Solus Gold Embolization Device should not be cleaned, re-processed, re-sterilized, or reused as these processes may damage the components or surface of the Solus Gold Embolization Device and compromise performance. In addition, the risk of infection of a reprocessed Solus Gold Embolization Device has not been established. Structural integrity or function may be impaired by cleaning, re-processing, re-sterilization, or reuse.
- The distal segment (50 cm) of the delivery catheter includes lubricious coating. Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.
- Use prior to the expiration date printed on the product packaging label.
- Physicians must be prepared to deal with urgent situations that may arise during use of the Solus Gold Embolization Device, such as inadvertent device migration or embolization, which may require removal of the implant portion of the Solus Gold Embolization Device. This includes confirming the availability of an on-site surgeon prior to use of the Solus Gold Embolization Device.
- The safety and effectiveness of the Solus Gold Embolization Device has not been established for cardiac uses (*e.g.*, cardiac septal occlusion, patent ductus arteriosus, and paravalvular leak closure) or neurologic uses (*e.g.*, occlusion of neurovascular vessels, aneurysms, and arteriovenous malformations).
- The Solus Gold Embolization Device should be used only by physicians who are trained in standard endovascular techniques. Physicians should determine which patients are candidates for procedures that use the Solus Gold Embolization Device. It is important to read the instructions for use prior to using the Solus Gold Embolization Device.
- A Quantitative Vascular Analysis (QVA) must be performed and the Solus Gold Embolization Device sized to the target vessel using dimensions from Table 1.
- The Solus Gold Embolization Device should be advanced or manipulated only under fluoroscopic guidance.
- Do not advance or retract the Solus Gold Embolization Device when excessive resistance is met until the cause of resistance is determined.
- Do not use a power injector to inject contrast solution into or through the Solus Gold Embolization Device.
- Do not twist or rotate the Solus Gold Embolization Device as this may damage the device.

Precautions

- The Solus Gold Embolization Device includes an implant made of gold metal that is generally considered to be safe. However, patients who are allergic to gold may have an allergic reaction to the device, especially patients with a history of metal allergies. Certain allergic reactions can be serious. Patients should be instructed to notify their physicians immediately if they suspect they are experiencing an allergic reaction such as hives, swelling of the face or throat, or difficulty breathing.
- The component of the detachment mechanism that is joined to the delivery catheter of the Solus Gold Delivery System contains a nickel-titanium alloy that is generally considered to be safe. This component is not part of the permanent implant and is removed with the delivery catheter. However, physicians should exercise clinical judgement when using the Solus Gold Embolization Device with patients known to have nickel allergies.
- Physicians should exercise clinical judgement in situations that involve use of anticoagulants or antiplatelet drugs before, during or after use of the Solus Gold Embolization Device.
- Please note special care that may be indicated in pregnant and nursing patients:
    - care should be taken to minimize radiation exposure to the mother and fetus, and nursing mothers;
    - there has been no quantitative assessment of the presence of leachables in breast milk.
- Physicians and medical staff should exercise care in handling the Solus Gold Embolization Device to reduce the chance of accidental device damage.
- Prior to use, physicians should verify that the diameter of any device that is used with the Solus Gold Embolization Device is compatible with the Solus Gold Embolization Device.
- Potential adverse events that may occur during or after a procedure or surgery where the Solus Gold Embolization Device is used include, but are not limited to:
    - Air embolus
    - Allergic reaction
    - Toxic effects
    - Bleeding
    - Death
    - Device migration
    - Embolism of foreign material
    - Fever
    - Hemolysis
    - Infection
    - Occlusion of an unintended vessel
    - Thromboembolism
    - Recanalization of a treated vessel
    - Residual flow in a treated vessel
    - Stroke or transient ischemic attack
    - Surgical intervention
    - Vascular access site complication
    - Vessel trauma, including dissection, perforation, or rupture

MRI Information

MR Conditional

Non-clinical testing demonstrated that the Solus Gold Embolization Device is MR Conditional. A patient with the implant portion of the Solus Gold Embolization Device can be scanned safely in an MR system under the following conditions:

- static magnetic field of 1.5-Tesla or 3-Tesla, only;
- maximum spatial gradient magnetic field of 3,000-Gauss/cm (30-T/m); and
- maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.

Under the scan conditions defined, the Solus Gold Embolization Device is expected to produce a maximum temperature rise of 1.5℃ after 15-minutes of continuous scanning (e.g., per pulse sequence).

In non-clinical testing, the image artifact caused by the Solus Gold Embolization Device extends approximately 5-mm from the implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

Accessories Devices and Materials

The following devices and materials are required for use with the Solus Gold Embolization Device:

- Heparinized saline solution
- Compatible access sheath and/or guide catheter
- Compatible 0.014” guidewire
- 10 cc syringe
- Contrast agent
- Inflation device

Preparation for Use

1) Access the vessel and perform an angiogram using standard technique to measure the vessel diameter at the desired occlusion site. Select a Solus Gold Embolization Device that is appropriately sized in diameter to the corresponding vessel diameter. Ensure the targeted vessel meets the recommended diameter (see Table 1).
2) Ensure that the occlusion site is long enough to accommodate the Solus Gold Embolization Device implant without obstructing unintended vessels or branches.
3) Remove the Solus Gold Embolization Device from the packaging hoop ensuring the microcatheter and delivery catheter components are removed simultaneously.

> **WARNING!** Inspect the Solus Gold Embolization Device prior to use for any irregularities or damage and discard if any inconsistencies are observed.

4) Connect a 10cc syringe containing sterile saline to the delivery catheter 3-way stop-cock. Flush the 3-way stop-cock, hub, and RHV. Tighten the delivery catheter RHV. Elevate the distal tip of the device and flush the delivery catheter. Saline drip should be seen exiting the distal end of the implant around the de-airing prep tool.
5) Remove de-airing prep tool by holding the flag and pulling on the prep tool.
6) Connect a 10cc syringe containing sterile saline to the microcatheter hub. Flush the microcatheter lumen. Saline drip should be seen exiting the distal end of the microcatheter.
7) Remove the Solus Gold Embolization Device implant sheath.
8) Insert a 0.014” guidewire through the proximal microcatheter hub and advance until distal tip of the guidewire exits the distal tip of the microcatheter.

Directions for Use

9) Insert the guidewire and Solus Gold Embolization Device into the patient through the RHV of the guide catheter or guide sheath. Tighten the RHV enough to prevent retrograde blood flow but not so tight as to pinch any portion of the Solus Gold

Embolization Device as that could damage the device or inhibit forward or backward movement.

WARNING! Do not retract microcatheter until ready to detach the Solus Gold Embolization Device implant as this may cause premature detachment.

10) Advance the guidewire and Solus Gold Embolization Device until the implant is positioned optimally in the target vessel segment. Verify position of the Solus Gold Embolization Device and implant using fluoroscopy and angiography (if appropriate) and confirm that the implant remains joined to the delivery catheter.
11) Attach an inflation device containing a heparinized saline solution or saline / contrast mixture to the 3-way stop-cock of the Solus Gold Embolization Device delivery catheter. Expand the Solus Gold Embolization Device implant using the inflation device.

WARNING! Do not exceed 18 atmospheres of pressure when expanding the Solus Gold Embolization Device as this may cause device or vessel damage.

12) Verify the implant portion of the Solus Gold Embolization Device is appropriately expanded and the rate of blood flow in the target vessel segment has been reduced by injecting contrast through the guide sheath or guide catheter. If needed, inject additional saline or saline / contrast mixture into the implant until fully expanded. If the Solus Gold Embolization Device implant does not expand appropriately, remove the Solus Gold Embolization Device, including the implant portion.

WARNING! Do not detach a Solus Gold Embolization Device implant that is not appropriately expanded as this may cause vessel damage or implant migration.

13) Once ready to detach the expanded Solus Gold Embolization Device implant, retract the microcatheter until the radiopaque marker band on microcatheter is proximal to the implant and delivery catheter marker band.
14) Retract the delivery catheter until the expanded Solus Gold Embolization Device implant is separated from the delivery catheter. Detachment of the Solus Gold Embolization Device implant from the delivery catheter and microcatheter can be confirmed by confirming the radiopaque marker bands on the delivery catheter and microcatheter move away from the expanded implant while the expanded implant remains in place.
15) Retract the guidewire into the microcatheter. Remove the guidewire and delivery catheter and microcatheter assembly as a unit from the patient and complete the procedure following standard techniques.

WARNING! Do not attempt to remove the Solus Gold Embolization Device delivery catheter with the implant attached, as this could result in vessel damage or implant migration.

Device Storage & Disposal

- Avoid exposure to water, sunlight, extreme temperatures and high humidity during storage.
- Store the Solus Gold Embolization Device under controlled room temperature.
- See the product label for the shelf life of the Solus Gold Embolization Device. Do not use the Solus Gold Embolization Device beyond the labeled shelf life.
- After use, dispose of all of the components of the Solus Gold Embolization Device that remain outside the patient and the Solus Gold Embolization Device packaging in accordance with hospital, administrative and local government policy.

Materials

The Solus Gold Embolization Device does not contain any latex or PVC materials.

Warranty

Artio Medical, Inc. (Artio Medical) warrants that reasonable care has been used in the design and manufacture of this device. **This warranty is in lieu of, and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular use.** Handling, storage, cleaning, and sterilization of this device, as well as other factors relating to the patient, diagnosis, treatment, interventional procedures, surgical procedures, and other matters beyond Artio Medical's control directly affect this device, and the results obtained from its use. Artio Medical's obligation under this warranty is limited to the repair or replacement of this device, and Artio Medical shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. Artio Medical neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. **Artio Medical assumes no liability with respect to reuse, re-processing, or re-sterilization of this device and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for intended use, with respect to such device**.

Solus Gold is a trademark of Artio Medical, Inc.

Glossary

The following symbols are used in Artio Medical labeling:

	Catalogue number
	Lot number
	Medical device
	Unique device identifier
	Use-by date
	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician
	Keep dry
	Sterilized using ethylene oxide

	Do not use if package is damaged
	Do not re-use
	MR Conditional
	Caution
	Consult Instructions for Use
	Contents of Package = 1
	Manufacturer

Manufacturer

The Solus Gold Embolization Device is manufactured and packaged at:

Artio Medical, Inc.
127 Independence Dr.
Menlo Park, CA 94025
Phone: +1-833-322-7846