INSTRUCTIONS FOR USE

SIEGE™

VASCULAR PLUG

MERITMEDICAL®

SIEGE™ VASCULAR PLUG

INSTRUCTIONS FOR USE - ENGLISH

PRODUCT DESCRIPTION

The Siege™ Vascular Plug ("Device") is a self- expanding braided nitinol vascular embolization implant (Figure 1) that is supplied with components used for implantation (Figure 2). The Device has radiopaque marker bands attached to each end and a screw attachment for connection to a Delivery Wire. The Device is packaged collapsed within a Loader and attached to a 225 cm Delivery Wire that is provided within a hoop dispenser. The Delivery Wire has a lubricious, hydrophilic coating at its distal end (approximately 26.5cm long). A Tuohy Borst Valve is provided for flushing and maintaining hemostasis; a Torque Device is provided for releasing the Device; a non-vented luer cap is provided for device preparation. Device implant sizing and dimensions are specified in Table 1. The Device, based on its size, is designed to be used with most 0.021" and 0.027" inner diameter commercial microcatheters (Table 2) under fluoroscopy for delivery and implantation in the peripheral vasculature.

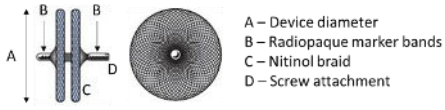
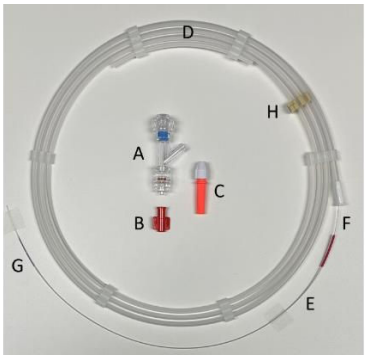


Figure 1: Siege Vascular Plug – Implant Components

Catalog Number	Minimum artery diameter (mm)	Maximum artery diameter (mm)	Approximate length* in minimum artery diameter (mm)	Approximate length* in maximum artery diameter (mm)
SVP2.5-0.021	1.5	2.5	15	13
SVP4-0.021	2.5	4.0	23	19
SVP6-0.027	4.0	6.0	28	22

*Plug lengths are approximate based on bench testing

Table 1: Siege Vascular Plug – Sizing & Dimensions



A. Tuohy Borst Valve
B. Non-vented luer cap
C. Torque device
D. Hoop dispenser
E. Loader
F. Delivery wire (in hoop dispenser)
G. Plug (in loader)
H. Retention clip

Note: Loader shown removed from hoop dispenser for clarity

Figure 2: Siege Vascular Plug

COMPATIBILITY INFORMATION

Description	Catalog Number	Minimum Inner Diameter (in / mm)	Maximum Length (cm)
Boston Scientific Renegade™ STC 18 (2.4F/3.0F)	SVP2.5-0.021 SVP4-0.021	0.021 / 0.533	175
Medtronic Rebar™ (2.4F/2.7F)			
Merit Medical SwiftNinja® (2.4F/2.6-2.9F)			
Stryker Trevo® Pro 18 (2.4F/2.7F)			
Terumo Progreat® (2.4F/2.9F)			
Boston Scientific Renegade™ Hi-Flo™ (2.8F/3.0F)	SVP6-0.027	0.027 / 0.686	175
Medtronic Rebar™ (2.8F/2.8F)			
Stryker Excelsior® XT-27® (2.7F/2.9F)			
Terumo Progreat® (2.8F/3.0F)			

All trademarks are the property of their respective owners

Table 2: Compatible Microcatheters

- Compatibility with the microcatheters listed in Table 2 has been established. Physicians should exercise their clinical judgement for the selection and use of microcatheters. Refer to the instructions for use for each product listed. Manufacturers may make changes to their microcatheters without notice, which may impact the suitability for use with Siege Vascular Plugs. Merit Medical provides no warranty, express or implied, on third party microcatheters used with Merit Medical products.

  WARNING: Compatibility with microcatheters not listed in Table 2 has not been established. The use of other microcatheters may result in an inability to deliver, deploy, or recapture the Device.
- The Tuohy Borst Valve is compatible with standard luer fittings.

HOW SUPPLIED

The Device is supplied sterile (ethylene oxide gas) and intended for single use only.

CONTENTS

Contents of one (1) Siege Vascular Plug package:
- One (1) Siege Vascular Plug
- One (1) Patient Implant Card
- One (1) Instructions for Use

SPECIAL STORAGE AND/OR HANDLING

Store in a cool, dry place.

INTENDED USE

The Siege Vascular Plug is intended for therapeutic embolization to reduce or obstruct blood flow.

INDICATIONS FOR USE

The Siege Vascular Plug is indicated for arterial embolization in the peripheral vasculature.

CONTRAINDICATIONS

None known.

PATIENT POPULATION

The Siege Vascular Plug is for use in patients requiring a peripheral arterial embolization procedure. The physician should determine which patients are candidates for procedures that use the Device.

USER(S)

For use by physicians who are trained in standard endovascular techniques.

CLINICAL BENEFITS

The intended clinical benefit of the Siege Vascular Plug is rapid and stable single device peripheral arterial embolization in patients requiring a permanent peripheral embolization procedure.

POTENTIAL COMPLICATIONS

Include, but are not limited to:
- Air or thrombus embolism
- Allergic reaction
- Bleeding
- Blood vessel spasm
- Death
- Occlusion of unintended vessels
- Recanalization
- Residual flow
- Device migration
- Foreign material embolization
- Hematoma at the entry site
- Infection
- Stroke / Transient Ischemic Attack
- Surgical intervention
- Vessel dissection or perforation

PRECAUTIONS
- Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if the sterile package is open or damaged.
- Use before the expiration date printed on the packaging label.
- For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Rx only. Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- The physician should exercise clinical judgment in situations that involve the use of anticoagulants or antiplatelet drugs before, during and after use of the Device.
- When flushing the Loader ensure that all fittings are secure to prevent air introduction.
- When the Device is being delivered though the microcatheter, manipulate only under fluoroscopic guidance.
- Care should be taken to minimize radiation exposure to pregnant women and their fetus.
- Consideration should be given before implanting the Device in nursing mothers because of the potential presence of leachables in breast milk.

- Do not rotate the Delivery Wire during Device advancement, deployment and recapture. Doing so may cause premature detachment.
- The Device has not been tested with microcatheters other than those listed as compatible microcatheters in Table 2.

MAGNETIC RESONANCE IMAGING SAFETY INFORMATION

Non-clinical testing has demonstrated the Siege Vascular Plug is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 3.0 Tesla or less
- Maximum spatial field gradient of 3,000-Gauss/cm (30-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Operating Mode) for 60 minutes of continuous RF (a sequence or back to back series/scans without breaks)

Under the scan conditions defined above, the Siege Vascular Plug is expected to produce a maximum temperature rise of less than 3.5 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the Siege Vascular Plug extends approximately 6 mm from the Device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

The health state of the patient or the presence of other implants may require reduction of the MR limits.

WARNINGS

- The safety and effectiveness of the Device has not been established for cardiovascular (e.g. septal occlusion, patent ductus arteriosus, paravalvular leaks) or neurovascular uses.
- The safety and effectiveness of the Delivery Wire has not been established for cardiovascular or neurovascular uses.
- The safety and effectiveness of the Siege Vascular Plug has not been established in veins.
- Physicians must be prepared to deal with urgent situations, such as device embolization, which may require removal of the Device. This includes the availability of an on-site surgeon.
- The Device is constructed from a nickel-titanium alloy (nitinol). Patients who are allergic to nickel may have an allergic reaction to the Device, especially those with a history of metal allergies. Prior to implantation, patients should be counseled on the materials contained in the device, as well as potential for allergy/hypersensitivity to these materials. Certain allergic reactions can be serious; patients should notify their physicians immediately if they suspect they are experiencing an allergic reaction such as difficulty breathing or inflammation of the face or throat. Some patients may also develop an allergy to nickel if the Device is implanted.
- Failure to abide by the information provided in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.
- Following detachment from the Delivery Wire, the Device cannot be recaptured using supplied components.
- Do not perform the procedure if air bubbles are present.

INSTRUCTIONS FOR USE

a. Ensure the sterile packaging is intact prior to use. Do not use the Device if the sterile package is open or damaged.

b. Using standard interventional techniques, access and measure the blood vessel diameter at the intended embolization site.

c. Select a Device per the sizing recommendations in Table 1. Depending on the degree of oversizing and the elasticity of the blood vessel, the Device will elongate when deployed.

d. Select appropriate compatible microcatheter from Table 2 and prepare per manufacturer's instructions.

e. Using the provided accessories, attach the non-vented luer cap (B) to the Tuohy Borst Valve (A). Insert the distal tip of the loader (E) with collapsed Plug (G) into the Tuohy Borst Valve and close. Gently flush the loader with approximately 3 ml of sterile saline just prior to use to hydrate the hydrophilic coating on the delivery wire (F). Saline will exit the loader at the proximal end near the red band during flushing (Figure 3).

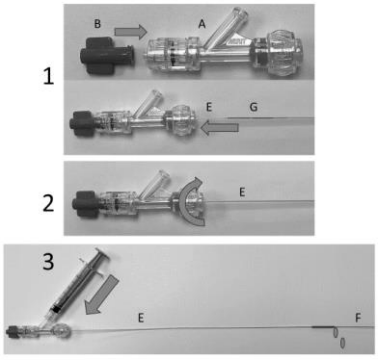


Figure 3: Accessory Assembly and Flushing Loader

CAUTION: Do not perform procedure if air bubbles are present.

f. Introduce a microcatheter (Table 2) into the patient over a guidewire. Position the distal tip of the microcatheter at the intended embolization site.

g. Remove the Loader from the Tuohy Borst Valve.

CAUTION: Do not perform procedure if air bubbles are present.

h. Open the Tuohy Borst Valve attached to the proximal end of the microcatheter to allow passage of the Loader. Insert the Loader until it comes into contact with the hub of the microcatheter. Tighten the Tuohy Borst Valve onto the Loader.

i. Check the secure attachment of the Device by gently rotating the Delivery Wire clockwise.

Advance the Delivery Wire forward to transfer the Device from the loader into the microcatheter.

CAUTION: Do not advance the Device if you experience excessive force.

j. Remove the loader after advancing the plug approximately 30 cm into the microcatheter. Continue to advance the Device under fluoroscopic control to the target embolization site.

CAUTION: Do not twist or rotate the Delivery Wire during Device advancement.

k. To deploy the Device at the embolization site, hold the Delivery Wire in place and slowly retract the microcatheter. The device will elongate during deployment when sized correctly (reference Table 1).

l. If the Device position is unsatisfactory, recapture it. To recapture, advance the microcatheter until it is in contact with the Device. Fix the microcatheter with one hand and pull the Device into the microcatheter using the Delivery Wire.

m. To release the Device (G), slide the Torque Device (C) onto the Delivery Wire (F) and tighten. Detach the Device by rotating the Torque Device in a counter-clockwise direction (Figure 4).

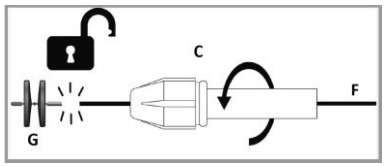


Figure 4: Device Detachment

CAUTION: Do not advance the Delivery Wire after detaching it from the Device.

n. Retract the Delivery Wire into the microcatheter and remove the Delivery Wire from the patient. Complete the procedure following standard technique.

o. Use solid biohazard waste procedures to discard components.

p. Dispose of all packaging materials as appropriate. The box and instructions for use are recyclable.

PATIENT IMPLANT INFORMATION CARD

A Patient Implant Information Card is provided with this device. The Patient Data, Implant data and Hospital Data should be carefully recorded on the card and given to the patient.

Apply one of the peel-off stickers found on the product label on the pouch to the indicated area on the Patient Implant Information Card. This peel-off sticker contains important information about the patient's embolic implant. The patient should carry this card with them and provide to any medical personnel caring for the patient in the future.

SYMBOLS

The following symbols may appear on the device labeling and packaging:

SYMBOL	DESIGNATION
	Single Use
	Do Not Re-sterilize
STERILE EO	Sterilized Using Ethylene Oxide
	Do Not Use if Package is Damaged or Opened and Consult Instruction for Use
	Consult Instructions for Use For electronic copy scan QR code, or go to www.merit.com/ifu and enter IFU ID. For printed copy, call U.S.A or EU Customer Service
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Non-Pyrogenic
MD	Medical Device
	Manufacturer
REF	Catalog Number
	Date of Manufacture YYYY-MM-DD
LOT	Lot Number
	Single Sterile Barrier System
	Use-By Date YYYY-MM-DD
UDI	Unique Device Identifier
	MR Conditional
	Minimum Inner Diameter
	Vessel Diameter
	Keep Dry

www.merit.com

Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, Utah 84095
U.S.A. 1-801-253-1600
U.S.A. Customer Service 1-800-356-3748

69007 Rev D 09-2024