Micro Plug Set

Instructions for Use

Micro Plug Set

Instructions for Use - English

RX ONLY
Caution:
Federal (USA) law restricts this device to sale by or on the order of a licensed physician.

Device Description:
The Micro Plug Set includes the Micro Plug Device ("Device") which is a self-expanding braided nitinol vascular occlusion device that is supplied with components used for implantation. 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 180 cm Delivery Wire that is provided within a hoop dispenser. A 125 cm Delivery Catheter is provided within a hoop dispenser for delivery and implantation of the Device; the Delivery Catheter contains a standard luer hub adapter at the proximal end and a single radiopaque marker band at the distal end. The Delivery Catheter is hydrophilic coated. Tuohy Borst Valves are provided for flushing; a Torque Device is provided for releasing the Device. The Micro Plug Set is designed to be used under fluoroscopy for delivery and implantation in the peripheral vasculature.

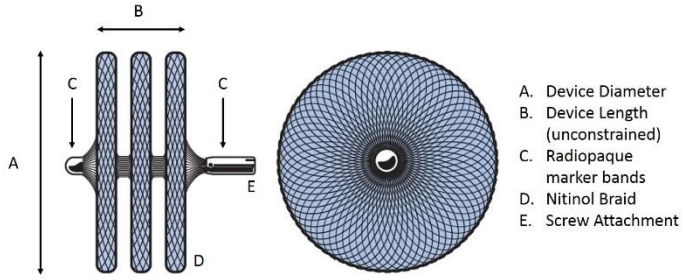

Figure 1: Micro Plug Device

Order Number	Device Diameter (Unconstrained) - A	Device Length (Unconstrained) - B
90000	3 mm	2.5 mm
90001	4 mm	2.5 mm
90002	5 mm	2.5 mm
90003	6 mm	2.5 mm

Table 1: Micro Plug Device Dimensions

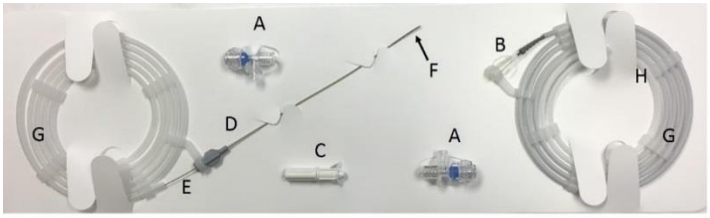

Figure 2: Micro Plug Set

Compatible Materials:

- Introduction of the Delivery Catheter can be performed co-axially through a 5F, 0.038 (0.97 mm) inch guidewire compatible diagnostic catheter up to 100 cm in length.
- The Delivery Catheter and Loader hubs as well as the Tuohy Borst Valves are compatible with standard luer fittings.

Note: Physicians should exercise their clinical judgment in the selection and use of commercial catheters.

Indications for Use:
The Micro Plug Set is indicated for arterial embolization in the peripheral vasculature.

Infusion Pressure Setting (psi)	Catheter Length (cm)	Dead Space Volume (cc)	Flow Rate Setting	Actual Flow Rate
300	125	.57	6.0 ml/sec	1.5 ml/sec
450	125	.57	6.0 ml/sec	2.2 ml/sec
600	125	.57	6.0 ml/sec	2.7 ml/sec

Table 2: Delivery Catheter Flow Rates (ISOVUE®- 300 at 37°C)

Contraindications:
None known.

Warnings:

- The safety and effectiveness of the Device for cardiac uses (e.g. septal occlusion, patent ductus arteriosis, paravalvular leaks) and neurologic uses have not been established.
- The Delivery Catheter is not intended for use in the coronary vasculature or neuro vasculature.
- Infusion pressure through the Delivery Catheter should not exceed 600 psi; static pressure should not exceed 750 psi.
- 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. 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.
- Following detachment from the Delivery Wire, the Device cannot be recaptured using supplied components.
- Do not perform the procedure if air bubbles are present.
- If flow through the Delivery Catheter becomes restricted, do not attempt to clear the catheter by infusion.

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.
- The Device is for single use only. Do not reuse or resterilize the Device as it may cause harm to the patient.
- The hydrophilic coating on the Delivery Catheter must be kept hydrated in order to be lubricious.
- 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.
- The Device should only be used by physicians who are trained in standard endovascular techniques. The physician should determine which patients are candidates for procedures that use the Device.
- When the Delivery Catheter is in the patient, manipulate only under fluoroscopic guidance and only over a guide wire.
- When flushing the Delivery Catheter and Loader ensure that all fittings are secure to prevent air introduction.
- 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 for compatibility with commercially available microcatheters.

MRI Safety Information

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

- Static magnetic field of 1.5 Tesla or 3.0 Tesla
- 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)

Under the scan conditions defined above, the Micro Plug Device is expected to produce a maximum temperature rise of less than 3°C after 15 minutes of continuous scanning.

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

Potential complications include, but are not limited to:

- Air or thrombus embolism
- Allergic reaction
- Bleeding
- Death
- Occlusion of unintended vessels
- Recanalization
- Residual flow
- Device migration
- Foreign material embolization
- Hematoma at the entry site
- Infection
- Stroke / TIA
- Surgical intervention
- Vessel dissection or perforation

Storage:

Store the Micro Plug Set in a cool, dry area.

Procedure:

1.) Ensure the sterile packaging is intact prior to use. Do not use the Device if the sterile package is open or damaged.
2.) Using standard interventional techniques, access and measure the blood vessel diameter at the intended occlusion site.
3.) Select a Device approximately 50-100 % larger than the blood vessel to be occluded. Depending on the degree of oversizing and the elasticity of the blood vessel the Device will undergo some elongation.
4.) Flush the Delivery Catheter hoop dispenser with sterile heparinized saline using the provided flush port and carefully remove the Delivery Catheter from the hoop dispenser. Attach the provided Tuohy Borst Valve and flush with sterile heparinized saline solution. Do not perform the procedure if air bubbles are present.
5.) Introduce the Delivery Catheter into the patient over a guidewire. Position the distal tip at the intended occlusion site.
6.) Remove the Loader with collapsed Device and attached Delivery Wire from the hoop dispenser. Attach the provided Tuohy Borst Valve and flush with sterile saline solution. Do not perform the procedure if air bubbles are present.
7.) Open the Tuohy Borst Valve attached to the Delivery Catheter to allow passage of the loader. Insert the loader until it comes into contact with the hub of the catheter. Tighten the Tuohy Borst Valve onto the loader.
8.) Check the secure attachment of the Device by rotating the Delivery Wire clockwise.
9.) Advance the Delivery Wire forward to transfer the Device from the loader into the Delivery Catheter.
CAUTION: Do not advance the Device if you experience excessive force.
10.) Continue to advance the Device under fluoroscopic control to the occlusion site.
CAUTION: Do not twist or rotate the Delivery Wire during Device advancement.
11.) To deploy the Device at the occlusion site, hold the Delivery Wire in place and slowly retract the Delivery Catheter.
12.) If the Device position is unsatisfactory, recapture it. To recapture, advance the Delivery Catheter until it is in contact with the Device. Fix the Delivery Catheter with one hand and pull the Device into the Delivery Catheter using the Delivery Wire.
13.) To release the Device, slide the Torque Device onto the Delivery Wire and tighten. Detach the Device by rotating the Torque Device in a counter-clockwise direction.

Disposal:

- The box and instructions for use are recyclable. Dispose of all packaging materials as appropriate.
- Use solid biohazard waste procedures to discard components.

Warranty:

- KA Medical, LLC, warrants to the buyer that, for a period equal to the validated shelf life of the product, this product shall meet the product specifications established by the manufacturer when used in accordance with the manufacturer's instructions for use and shall be free from defects in materials and workmanship. KA Medical's obligation under this warranty is limited to replacing or repairing at its option, at its factory, this product if returned within the warranty period to KA Medical and after confirmed to be defective by the manufacturer.

Symbol Definitions:

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

Symbol	Definition
	Manufacturer
	Authorized Representative in the European Community
	Catalogue number
	Batch code
	Use by date
	Do not re-use
	Do not resterilize
	Sterilized using ethylene oxide
	Consult instructions for use
	Keep dry
	Do not use if package is damaged
	Caution
	MR Conditional
Rx Only	Device to sale by or on the order of a licensed physician

KA Medical
1265 Grey Fox Road, Suite 550
Arden Hills, MN 55112
USA
1-801-253-1600
U.S.A. Customer Service 1-800-356-3748
www.merit.com

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