Scepter Mini™

Occlusion Balloon Catheter

INSTRUCTIONS FOR USE

MicroVention™
TERUMO

Scepter Mini™ Occlusion Balloon Catheter

Instructions for Use

DEVICE DESCRIPTION

The Scepter Mini Occlusion Balloon Catheter is a dual lumen catheter with an external hydrophilic coating applied to the distal 100 cm of the device. The guidewire lumen is provided for guidewire introduction and delivery of agents. The inflation lumen is used exclusively for the inflation and deflation of the balloon. The guidewire lumen of the balloon catheter is compatible with 0.008 inch or smaller guidewire and the balloon can be inflated and deflated independently with or without the presence of a guidewire. The balloon catheter incorporates two radiopaque marker bands to facilitate fluoroscopic visualization and indication of the balloon position. The balloon incorporates a distal air-purge hole to purge air from the inflation lumen prior to use.

The Scepter Mini Occlusion Balloon Catheter is intended for single use only. Do not resterilize or reuse the balloon catheter. After use, dispose of the catheter in accordance with hospital, administrative and/or local government policy. Do not use the balloon catheter if the sterile package is breached or damaged.

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One Occlusion Balloon Catheter
One Introducer Sheath
One Catheter Stylet
One Compliance Card

INDICATIONS FOR USE/ INTENDED PURPOSE

The Scepter Mini Occlusion Balloon Catheter is intended:

For use in the peripheral and neuro vasculature where temporary occlusion is desired. The balloon catheter provides temporary vascular occlusion which is useful in selectively stopping or controlling blood flow. The balloon catheter also offers balloon assisted embolization of intracranial aneurysms.

For use in the peripheral vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents such as embolization materials.

For neurovascular use for the infusion of diagnostic agents such as contrast media, and therapeutic agents, such as embolization materials, that have been approved or cleared for use in the neurovasculature and are compatible with the inner lumen of the Scepter Mini Occlusion Balloon Catheter.

CONTRAINDICATIONS

Not intended for embolectomy or angioplasty procedures

Not intended for use in coronary vessels

Not intended for pediatric or neonatal use

CAUTIONS

Rx Only: Federal (USA) law restricts this device to sale by or on the order of a physician.

Do not use if pouch is opened or damaged.

This device is intended for single use only. Do not resterilize or reuse. 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.

After use, dispose in accordance with hospital, administrative and/or local government policy.

WARNINGS

Verify the size of the vessel under fluoroscopy. Ensure that the balloon catheter is appropriate for the size of the vessel.

Do not exceed the maximum recommended inflation volume as balloon rupture may occur.

The balloon catheter has been tested for compatibility or use with Onyx™ liquid embolic System and DMSO. For all other liquid embolics, refer to their Instructions For Use.

The balloon catheter is provided sterile and non-pyrogenic. Do not use if the packaging is breached or damaged.

Viscosity and concentration of contrast will affect balloon inflation and deflation times.

During preparation, do not deflate the balloon unless the distal tip is submerged in saline or contrast to prevent air from entering balloon.

Do not attach any high-pressure devices to the balloon inflation port as this may rupture the balloon.

Do not inflate the balloon with air or any other gas while in the body.

Improper preparation may introduce air into the system. The presence of air may inhibit proper fluoroscopic visualization.

Excessive pressure higher than 700 PSI (4826kPa, 47.6atm) may cause leakage or rupture of the balloon catheter guidewire lumen.

When air-purging the balloon catheter, inject fluid slowly otherwise balloon rupture may occur.

Do not over-tighten the RHV around the balloon catheter. Over-tightening could delay balloon inflation and deflation.

Do not advance the balloon catheter or guidewire against resistance. If resistance is felt, assess the source of resistance using fluoroscopic means.

Always inflate and deflate the balloon while visualizing under fluoroscopy to ensure patient safety.

n-BCA (n-butyl cyanoacrylate) and solutions containing ethyl esters of iodized fatty acids of poppy seed oil are not compatible with the balloon.

PRECAUTIONS

Immediately prior to use visually inspect all the sterile barrier systems, that are labeled as sterile. Do not use if breaches in sterile barrier system integrity are evident such as a damaged pouch.

After balloon preparation for use and prior to use, re-inflate to nominal volume and inspect for any irregularities or damage. Do not use if any inconsistencies are observed.

Verify balloon catheter compatibility when using other ancillary devices commonly used in intravascular procedures. Physician must be familiar with percutaneous, intravascular techniques and possible complications associated with the procedure.

The balloon catheter has a lubricious surface and should be hydrated for at least 30 seconds prior to use. Once the balloon catheter is hydrated, do not allow it to dry.

Exercise care in handling the balloon catheter to reduce the chance of accidental damage.

With the exception of dimethyl sulfoxide (DMSO), use of other organic solvents may damage the balloon catheter and/or coating on the surface.

DMSO-based embolization materials should only be used in accordance with their neurovascular approved intended use.

Verify that the diameter of any guidewire or accessory device used is compatible with the inner diameter of the balloon catheter prior to use.

Take precaution when manipulating the balloon catheter in tortuous vasculature to avoid damage. Avoid advancement or withdrawal against resistance until the cause of resistance is determined.

Presence of calcifications, irregularities or existing devices may damage the balloon catheter and potentially affect its insertion or removal.

Always verify proper balloon vessel occlusion prior to and during embolic material delivery.

Excessive torque applied to the syringe might result in damage to the Scepter hub assembly.

Exercise necessary precautions to limit X-radiation doses to patients and operators by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors where possible.

POTENTIAL COMPLICATIONS

Potential complications include, but are not limited to vessel or aneurysm perforation, vasospasm, hematoma at the site of entry, embolism, ischemia, intracerebral/intracranial hemorrhage, pseudoaneurysm, seizure, stroke, infection, vessel dissection, thrombus formation, and death.

Exposure to angiographic and fluoroscopic X-radiation presents potential risks of alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia that increase in probability as procedure time and number of procedures increase.

COMPATIBILITY

Scepter Mini balloon catheter is compatible with .008” (0.20mm) or smaller guidewire.
Note: Guidewire not required for inflation of balloon

Choose appropriate guiding catheter with minimum inner diameter larger than or equal to 0.053” (1.35mm)
Note: The maximum outer diameter of the balloon catheter is 0.037” (0.94mm)
Scepter Mini balloon catheter is compatible for use with dimethyl sulfoxide (DMSO).
Scepter Mini balloon catheter has been verified to be compatible for use with diagnostic agents (such as contrast media) and DMSO based liquid embolic agents (Onyx™ Liquid Embolic System).
For all other liquid embolic, refer to their Instructions For Use.

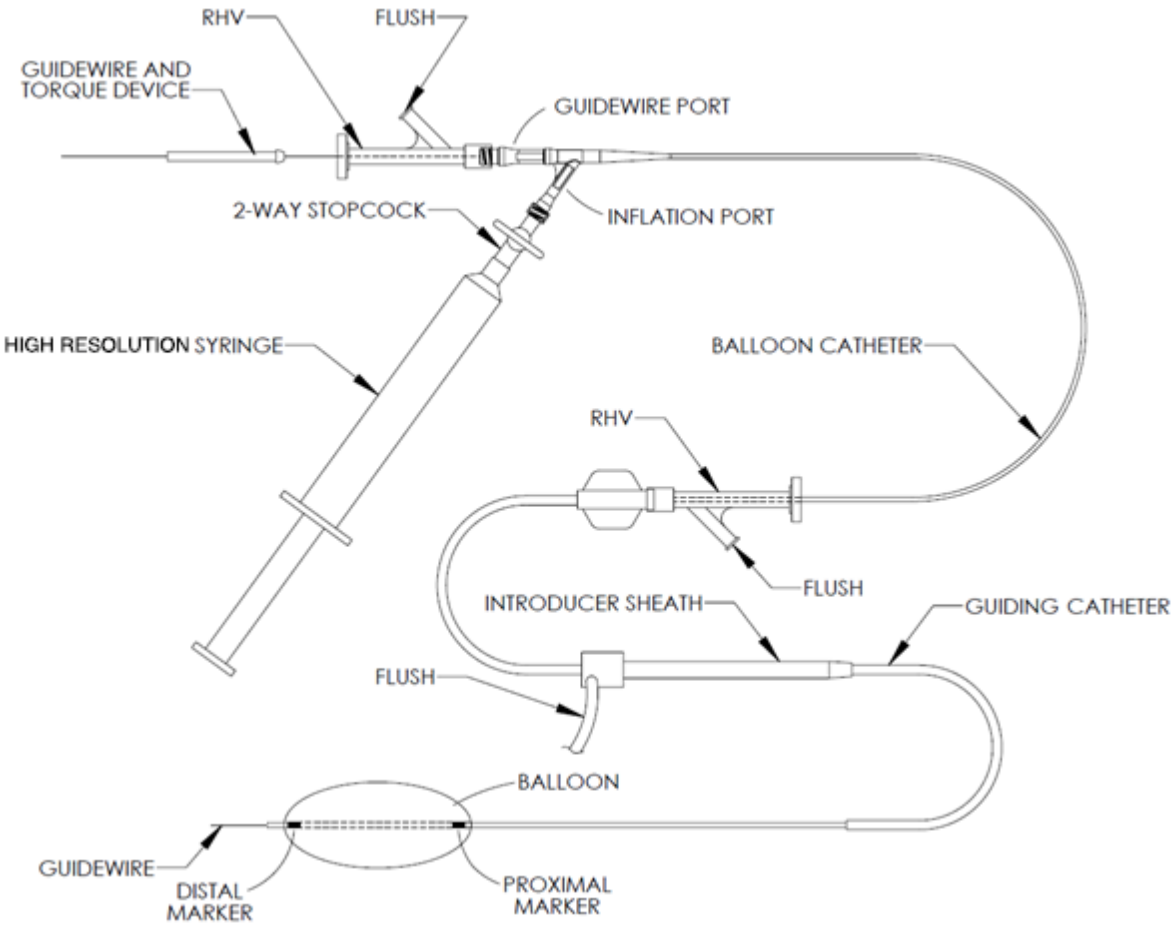

DIAGRAM OF BALLOON CATHETER SETUP

HYDRATION FLUSH

1. Choose a balloon catheter that is appropriate for the size of the vessel.

2. Before removing the balloon catheter from the dispenser tube, fully hydrate the hydrophilic segment of the device by flushing heparinized saline through the dispenser tube using a syringe attached to the flush port. Allow 30 seconds of hydration time.

Table 1: Approximate Balloon Deflation Time			
Contrast Name	Viscosity @ 37˚C (cps)	Contrast:Saline	**Scepter Mini (seconds)**
			2.2x9mm
Omnipaque 300	6.3	100:0	≤ 15

Table 2:	
Approximate Prime Volume of the Entire Inflation Lumen	**Approximate Prime Volume of the Entire Guidewire Lumen**
Volume of Inflation Lumen + Inflation Hub	Volume of Guidewire Lumen + Guidewire Hub
0.53cc	**0.44cc**

BALLOON PREPARATION

1. Remove the balloon catheter by pulling it from the dispenser tube. If resistance is observed, repeat the flushing procedure in preparation for use until the balloon catheter is well hydrated and can be easily removed from the dispenser tube. Inspect the balloon catheter thoroughly to ensure it is not damaged. Do not allow balloon catheter to dry prior to introduction into the guiding catheter. Do not reinsert a hydrated balloon catheter into its packaging.

2. Remove the stylet wire from the guidewire lumen. **Do not use the stylet in a balloon catheter and advance in a guide catheter.** Stylet is used for additional support during removal from dispenser hoop only

3. Use a syringe with heparinized saline to flush the guidewire lumen. Remove the syringe. Carefully introduce a hydrated guidewire into the guidewire lumen of the balloon catheter.

   WARNING: Excessive pressure higher than 700 PSI (4826kPa, 47.6atm) may cause leakage or rupture of the balloon catheter

4. Prepare a 100% contrast solution using Table 1 as a guide.

   WARNING: Viscosity and concentration of contrast will affect balloon inflation and deflation times.

5. Fill a 1cc syringe with contrast solution and carefully attach directly to inflation port without injecting contrast into hub. Ensure there are no bubble(s) in syringe prior to attaching

6. Hold balloon proximal to inflation plug and point balloon upright with one hand.

7. Hold the attached syringe upright (pointing up) with the other hand and apply pressure on syringe plunger using thumb.

8. If the balloon is initially inflated with air, then maintain constant syringe pressure.

9. Maintain pressure and DO NOT TILT the balloon until the contrast reaches the distal purge hole and the contrast has completely filled the balloon.

10. Once the balloon has been fully inflated with contrast, inspect balloon for any damages and bubbles. Then place tip in saline bowl, deflate balloon.

11. Remove the 1cc syringe and attach a stopcock to a high-resolution syringe filled with contrast solution.

12. Prime the high resolution syringe and stopcock with contrast solution, attach to the hub of the primed inflation port and proceed to step A.

A. BALLOON FINAL INSPECTION
   1. Re-inflate the balloon to nominal volume to inspect the balloon catheter prior to use for any irregularities or damage. Do not use if any inconsistencies are observed.
   2. Inspect the balloon catheter distal tip for any contrast leakage from air purge hole. If contrast leakage is observed then discard of unit.
   3. Deflate once more while distal tip is submerged in saline and let the pressure within the catheter equalize. With the catheter and balloon completely primed, the balloon catheter is ready for use.
      WARNING: Do not attach any high pressure devices to the balloon inflation port as this may rupture the balloon.
      WARNING: Do not inflate the balloon with air or any other gas while in the body.

WARNING: Improper preparation may introduce air into the system. This may inhibit proper fluoroscopic visualization.

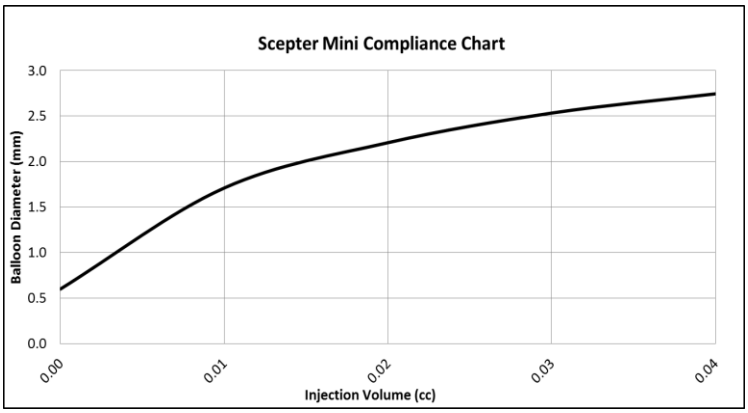

Table 3 **Balloon Inflation Compliance**

Inflation Volume* (cc)	Scepter Mini Dia., (mm)
0.01	1.7
0.02	2.2
0.03	2.5
0.04**	2.7

*After Priming Catheter **Maximum Injection Volume

Table 4	Approximate Nominal Flow Rates at 100 and 300 psi Infusion Pressure							
	Saline		50/50% Contrast (300mgI/ml)		100% Contrast (300mgI/ml)		100% Contrast (350mgI/ml)	
Scepter Mini	100 psi	300 psi	100 psi	300 psi	100 psi	300 psi	100 psi	300 psi
	0.7 cc/sec	1.1 cc/sec	0.3 cc/sec	0.5 cc/sec	0.1 cc/sec	0.4 cc/sec	0.1 cc/sec	0.2 cc/sec

DIRECTIONS FOR USE (Refer to diagram for reference)

1. Attach a rotating hemostatic valve (RHV) to the guidewire lumen of the balloon catheter. Set up a continuous saline flush line and connect it to the sidearm of the RHV.

2. Choose appropriate guiding or diagnostic catheter. Attach a RHV to the proximal hub of the guiding or diagnostic catheter. To prevent backflow of blood into the lumen of the catheter, connect the continuous saline flush line to the sidearm of the RHV.

3. Open the RHV on the hub of the guiding or diagnostic catheter and introduce the balloon catheter/guidewire into the guiding catheter using the introducer sheath. Carefully advance the balloon catheter/guidewire to the guiding catheter distal tip. After the balloon catheter/guidewire reaches the tip of the guiding catheter, remove the introducer from the balloon catheter shaft by retracting the introducer from the RHV and peeling off the introducer. Advance the balloon catheter through the RHV.
4. Advance the balloon catheter and guidewire to the desired location in the vasculature using fluoroscopic visualization. Carefully tighten the valve of the RHV around the balloon catheter to prevent leakage from the RHV. The RHV should still allow for balloon catheter advancement after tightening.
   WARNING: Do not over-tighten the RHV around the balloon catheter. Over-tightening could delay balloon inflation and deflation.
   WARNING: Do not advance the balloon catheter or guidewire against resistance. If resistance is felt, assess the source of resistance using fluoroscopic means.
5. Attach a 2-way stopcock to a high-resolution syringe filled with appropriate contrast solution. Prime the 2-way stopcock so that no air is present. Slowly inflate the balloon to the recommended volume to achieve the desired diameter as described in Table 3.
   WARNING: Do not exceed the maximum recommended inflation volume as balloon rupture may occur.
   WARNING: Always inflate and deflate the balloon while visualizing under fluoroscopy to ensure patient safety.
6. After inflation, lock the stopcock if desired.
7. If desired, remove the guidewire from the balloon catheter and prepare per the respective diagnostic or therapeutic agent IFU(s) for delivery through the guidewire lumen.
   WARNING: Excessive pressure higher than 700 PSI (4826kPa, 47.6atm) may cause leakage or rupture of the guidewire lumen.
8. When deflating balloon, use fluoroscopy to ensure complete deflation prior to removal. See Table 1 for respective deflation times. After procedure is complete, slowly remove the balloon catheter and guidewire.

STORAGE

Avoid exposure to water, sunlight, extreme temperatures and high humidity during storage. Store the balloon catheter under controlled room temperature. See the product label for the device shelf life. Do not use the device beyond the labeled shelf life.

MATERIALS

The balloon catheter does not contain latex or PVC materials.

SYMBOLS

	Lot Number		Caution
	Catalog Number		Use-by Date
	Contents		Date of Manufacture
	Sterilized Using Ethylene Oxide		Manufacturer
	Do Not Reuse		Non-pyrogenic
	Consult Instructions for Use		Authorized European Representative
	CE Mark		For Prescription Use Only
	Single Sterile barrier system with protective packaging inside		Medical Device
	Do not use if package is damaged		Country of manufacture
	Keep Dry		Keep Away from Sunlight
	Do Not Resterilize		Importer

WARRANTY

MicroVention, Inc. 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. Handling, storage, cleaning and sterilization of the device as well as factors relating to the patient, diagnosis, treatment, surgical procedure and other matters beyond MicroVention's control directly affect the device and the results obtained from its use. MicroVention's obligation under this warranty is limited to the repair or replacement of this device and MicroVention shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this device. MicroVention neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. MicroVention assumes no liability with respect to devices reused, reprocessed or resterilized and makes no warranties, expressed or implied, including, but not limited to, merchantability or fitness for intended use, with respect to such device.

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eIFU website: www.microvention/eIFU-MicroVention.c

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