Scepter™ Mini

Occlusion Balloon Catheter

US

Skip the Plug. Control the Flow.

Versatile Micro-Balloon

Scepter™ Mini device is the first micro-balloon catheter designed to occlude blood flow and deliver embolization materials. Its small profile and soft balloon is designed to navigate to distal target vessels for embolization. The dual-lumen balloon technology provides instant flow arrest for a controlled liquid embolic injection.[1]

Controlled Liquid Embolic Injection

- In vitro data demonstrates that balloon inflation can minimize the risk of reflux compared to standard microcatheter[2,4,5]
- Self-sealing distal purge hole maintains balloon integrity during liquid embolic injection[3]
- By its design the balloon catheter has less chance of catheter entrapment than standard microcatheters[2]

Instant Flow Arrest

- Selective flow arrest angiography can help better understand malformation angioarchitecture[4]
- Balloon mechanism does not require a plug formation around the microcatheter tip[3,6,7]
- Potential for reduced procedure times and less radiation exposure compared to standard microcatheter embolization[2,6,7]

Designed for Distal Access

- Ability to reach distal target sites due to low profile and proprietary catheter construction[3,4,5]
- Hydrophilic coating reduces friction and improves navigation in tortuous vessels[3,5]

MicroVention™ TERUMO

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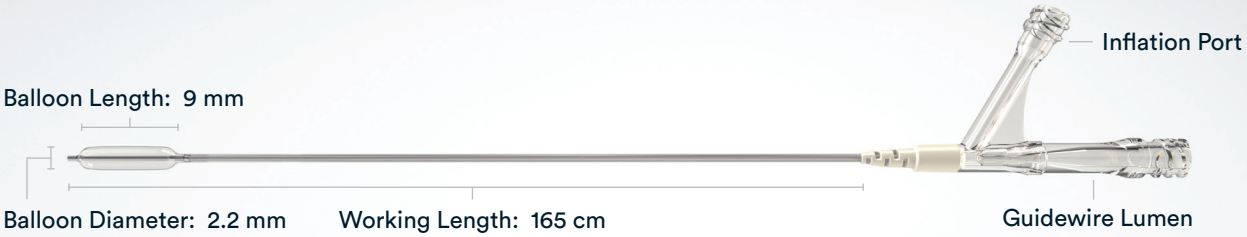

DMSO Compatible

Scepter Mini Occlusion Balloon Catheter

Catalog Number	Nominal Balloon Diameter	Working Balloon Diameter Range	Balloon Length	Tip Length	Distal / Proximal ID	Distal / Proximal OD	Guidewire Lumen Dead Space	Catheter Working Length	Guidewire Lumen Burst Pressure
BC0210M	2.2 mm	1.7–2.7 mm	9 mm	2.5 mm	0.010 in / 0.015 in 0.254 mm / 0.381 mm	1.6 F / 2.8 F 0.02 in / 0.04 in 0.53 mm / 0.94 mm	0.44 mL	165 cm	700 PSI

Must use a compatible ≤0.008˝ (distal OD) guidewire

Balloon Inflation Syringe

Catalog Number	Quantity Per Box	Description
K01-07892	3 syringes	High resolution 0.25 mL syringe for post-preparation balloon inflation

Balloon Diameter Range: 1.7–2.7 mm
Nominal Inflation Volume: 0.02 mL

Balloon Inflation Compliance[2]

Inflation Volume (mL)*	Scepter Mini Diameter (mm)
0.01	1.7
0.02	2.2
0.03	2.5
0.04**	2.7

*After priming catheter **Maximum injection volume

Data and limited clinical references:

1. TR17-124 Onyx and Scepter Compatibility
2. Vollherbst DF, Otto R, Do TD, et al Extra-small dual-lumen micro-balloon catheters can improve endovascular embolization: an experimental in vivo and in vitro study *Journal of NeuroInterventional Surgery* 2018;10:1092-1096.
3. TP17-124, TR17-124: Scepter Mini Design Verification Testing
4. Vohllherbst DF, Chapot R, Wallocha M, et al First clinical multicenter experience with the new Scepter Mini microballoon catheter, *J NeuroIntervent Surg* 2020;01-7.doi:10.1136/neurointsurg-2020-016115
5. Pulli B, et al. Initial experience with the Scepter Mini dual-lumen balloon for transophtalmic artery embolization of anterior cranial fossa dural arteriovenous fistulae; *J NeuroIntervent Surg* 2020;0:1-5. doi:10.1136?neurointsurg-2020-016013
6. Spiotta AM, James RF, Lowe SR, et al. Balloon-augmented onyx embolization of cerebral arteriovenous malformations using a dual-lumen balloon: a multicenter experience. *J Neurointerv Surg* 2015; 7:721-7.
7. Kim JW, Kim BM, Park KY, et al. Onyx embolization for isolated type dural arteriovenous fistula using a dual-lumen balloon catheter. *Neurosurgery* 2016;78:627–36.

INDICATIONS FOR USE

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 delivery of diagnostic agents, such as contrast media, that have been approved or cleared for use in the peripheral vasculature and are compatible with the inner lumen of the Scepter Mini Occlusion Balloon Catheter.

For neurovascular use for the delivery of diagnostic agents, such as contrast media, and liquid embolic agents 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.

RX Only: Federal law restricts this device to sale by or on the order of a physician.

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