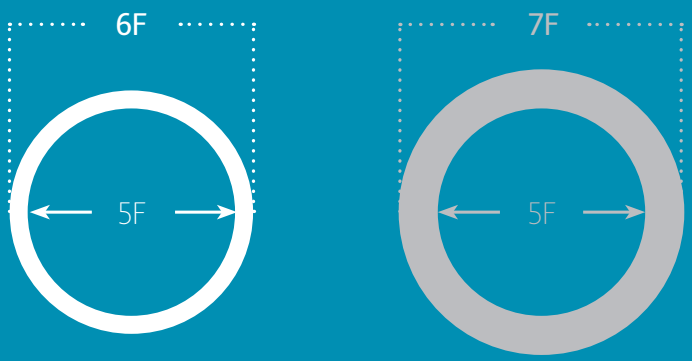
Downsize Your Access Site Profile

5F Profile Size Comparison



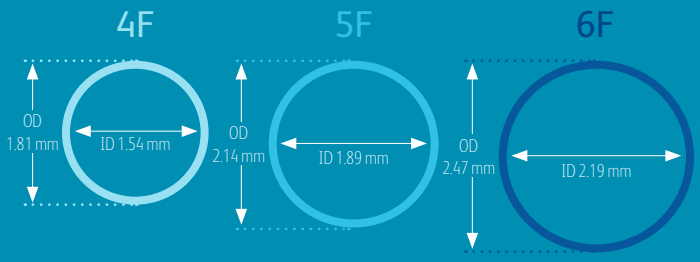
Halo One™
Thin-Walled Guiding Sheath

Standard 5F
Guiding Sheath

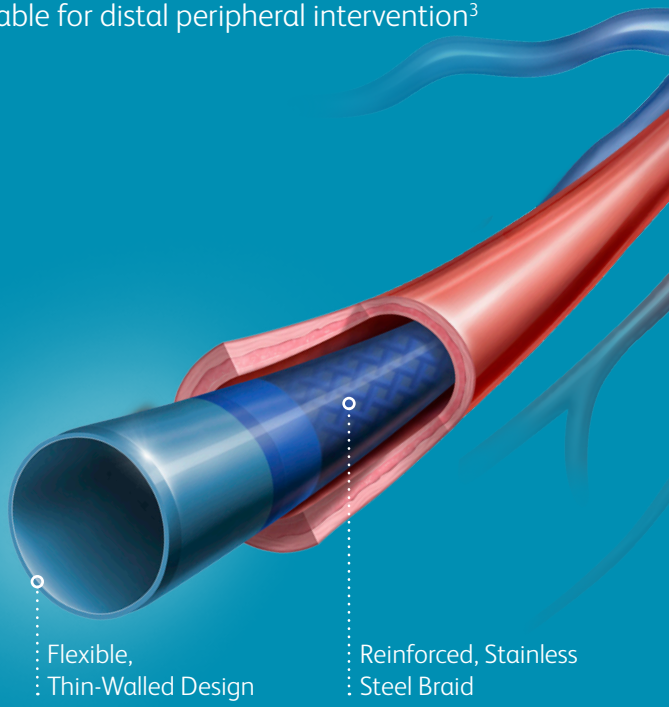
Not drawn to scale. For illustrative purposes only.

- Thin-walled design reduces arteriotomy size which can help minimize access site complications[1,2]
- Halo One™ Thin-Walled Guiding Sheath is the only thin-walled guiding sheath with lengths suitable for distal peripheral intervention[3]

Thin-Walled Design To Reduce Arteriotomy Size [4]



Not drawn to scale



Halo One™

Thin-Walled Guiding Sheath

BD

Halo One™

Thin-Walled Guiding Sheath

French Size	Sheath Length (cm)	Recommended Guidewire	Product Codes	Hydrophilic Coating
4	10	0.018"	HLO41018FH	Yes
	10	0.035"	HLO41035F	No
	10	0.035"	HLO41035FH	Yes
	25	0.035"	HLO42535	No
	25	0.035"	HLO42535H	Yes
	45	0.035"	HLO44535	Yes
	70	0.035"	HLO47035	Yes
	90	0.035"	HLO49035	Yes
5	10	0.018"	HLO51018FH	Yes
	10	0.035"	HLO51035F	No
	10	0.035"	HLO51035FH	Yes
	25	0.035"	HLO52535	No
	25	0.035"	HLO52535H	Yes
	45	0.035"	HLO54535	Yes
	70	0.035"	HLO57035	Yes
	90	0.035"	HLO59035	Yes
6	10	0.035"	HLO61035F	No
	10	0.035"	HLO61035FH	Yes
	25	0.035"	HLO62535H	Yes
	25	0.035"	HLO62535	No
	New 45	0.035"	HLO64535	Yes
	New 70	0.035"	HLO67035	Yes
	New 90	0.035"	HLO69035	Yes

Robust Size Offering

Halo One™ Thin-Walled Guiding Sheath offers a broad size matrix to fit your everyday needs

	10cm		25cm	45cm	70cm	90cm
Dilator size	0.018"	0.035"	0.035"	0.035"	0.035"	0.035"
4F	✓	✓	✓	✓	✓	✓
5F	✓	✓	✓	✓	✓	✓
6F		✓	✓	✓	✓	✓

✓ Indicates New Size

REPRESENTATIVE'S NAME

CONTACT PHONE NO.

PHYSICIAN'S SIGNATURE

1 Ortiz, Daniel, et al. "Access site complications after peripheral vascular interventions: incidence, predictors, and outcomes." Circulation: Cardiovascular Interventions 7.6 (2014): 821-828.

2 Compared to standard guiding sheaths of the same French size.

3 Shaft lengths of 45, 70, and 90cm are available in 4F,5F and 6F sizes.

4 Data on File. Halo One data are provided for non-hydrophilically coated product. Specifications for hydrophilically-coated devices are as follows: 4F OD = 1.84mm, ID = 1.54mm; 5F OD = 2.17mm, ID = 1.89mm; 6F OD = 2.50mm, ID =2.19mm

Halo One™ Thin-Walled Guiding Sheath

Indications for Use: The Halo One™ Thin-Walled Guiding Sheath is indicated for use in peripheral arterial and venous procedures requiring percutaneous introduction of intravascular devices. The Halo One™ Thin-Walled Guiding Sheath is NOT indicated for use in the neurovasculature or the coronary vasculature.

Contraindications: There are no known contraindications for the Halo One™ Thin-Walled Guiding Sheath.

Warnings: 1) Contents supplied STERILE using ethylene oxide (EtO). Non-pyrogenic. Do not re-use, reprocess or re-sterilize. This device is intended for single use only. 2) Do not resterilize. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing and/or resterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes. 3) This device has been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints, and/or crevices between components – are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications. 4) Visually inspect the packaging to verify that the sterile barrier is intact. Do not use if the sterile barrier is opened or damaged. 5) Use the sheath prior to the "Use By" date specified on the package. 6) Do not advance the guidewire, sheath/dilator, procedural device, or any component if resistance is met, without first determining the cause and taking remedial action. 7) Do not use a power injector through the sideport or the three-way stopcock. 8) The Halo One™ Thin-Walled Guiding Sheath has not been evaluated for use in the neurovasculature or the coronary vasculature. 9) After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices and applicable local, state and federal laws and regulations. 10) Only advance or retract the sheath with the dilator inserted and only advance or retract the sheath and dilator while placed over a properly sized guidewire. 11) Failure to deactivate the procedural device prior to removal through the sheath may cause damage to the sheath and may result in patient injury.

Precautions: 1) The Halo One™ Thin-Walled Guiding Sheath shall only be used by trained physicians. Access procedures should be conducted under fluoroscopic guidance with appropriate x-ray equipment and / or ultrasound. 2) Prior to beginning radial artery access, an assessment such as the Allen or Barbeau test should be performed to assess the presence/adequacy of dual arterial circulation to the hand. Radial artery access is not recommended for patients with abnormal Allen or Barbeau test results or radial pulse, or insufficient dual arterial supply. 3) Prior to beginning pedal access, physicians should assess the vascular anatomy to assure there is adequate antegrade flow at the level of the ankle. 4) The minimum acceptable sheath French size is printed on the package label. Do not attempt to pass devices through a smaller size sheath introducer than indicated on the device label. 5) The pouch should be inspected prior to opening to ensure the sterile barrier is not compromised. The device should be carefully removed and placed in the sterile field. The entire procedure from skin puncture or incision to sheath withdrawal must be carried out aseptically. 6) Carefully inspect the sheath prior to use to verify that the sheath has not been damaged during shipment and that its size, shape and condition are suitable for the procedure for which it is to be used. Do not use if product damage is evident. 7) Careful attention must be paid to the maintenance of tight valve connections for duration of procedure to avoid blood leakage or the introduction of air into the system. Take remedial action if any excessive blood leakage is observed. 8) Insert dilator into the center of the sheath valve. Forced insertion of the dilator which misses the center of the valve may cause damage and result in blood leakage. 9) Advance or withdraw the sheath slowly. If resistance is met do not advance or withdraw until the cause of resistance is determined. 10) When inserting, manipulating or withdrawing a device through the introducer always maintain the introducer position. 11) Remove the dilator from the sheath slowly to avoid incomplete closing of the valve resulting in blood leakage. 12) When using procedural devices close to the tip of the sheath care must be taken to ensure the active mechanism portion of the procedural device (e.g., balloon, stent zone, material removal section of atherectomy device) is not within the tip of the sheath. The radiopaque marker is located within 5 mm of the end of the tip but does not mark the true distal tip of the sheath. 13) Before removing or inserting the interventional/diagnostic device through the sheath, aspirate blood from the 3-way stopcock to remove any fibrin deposition which may have accumulated in or on the tip of the sheath. 14) Ensure to deactivate the procedural device prior to removal through the sheath. 15) Take care when back loading the tip of the dilator over the guidewire to avoid damage to the dilator. 16) Ensure the dilator is securely connected with the sheath prior to advancing otherwise only the sheath may advance into the vessel and the sheath tip may cause damage to the vessel. 17) Ensure the dilator is in place within the sheath before advancing the sheath as otherwise damage may be caused to the vessel. 18) Do not place sutures on the sheath tubing since this may restrict access/flow through the sheath. When puncturing, suturing or incising near the sheath be careful not to damage the sheath. Proper functioning of the sheath depends on its integrity. Care should be used when handling the sheath. 19) If using fluid injection through the 3 way stopcock, ensure the dilator or procedural device is not in place at the same time. 20) If resistance is felt during post-procedure withdrawal of the procedural device, it is recommended to remove the procedural device, guidewire, and sheath as a single unit. 21) In order to activate the hydrophilic coating, it is recommended to wet the Halo One™ Thin-Walled Guiding Sheath with heparinized saline solution immediately prior to its insertion in the body. Failure to activate the coating may lead to sub-optimal trackability of the sheath. To maintain lubricity this surface must be kept completely wet. 22) Proper functioning of the Halo One™ Thin-Walled Sheath depends on its integrity. Care should be used when handling the sheath. Damage may result from kinking, stretching, or forceful wiping of the Halo One™ Thin-Walled Guiding Sheath. Do not continue to use the sheath if the shaft has been bent or kinked.

Potential Adverse Effects: Potential adverse effects that may result from a percutaneous vascular procedure (directly or indirectly associated with the device) may include, but are not limited to: • Air embolism • Aneurysm or pseudoaneurysm • Arteriovenous fistula • Compartment Syndrome • Death • Embolism • Endocarditis • Hematoma • Hemorrhage, including bleeding at the puncture site • Intimal tear • Radial artery occlusion/spasm • Sepsis/infection/inflammation • Tissue necrosis • Thrombus formation • Vessel spasm, perforation or dissection • Potential systemic indirect/inherent adverse effects related to general endovascular procedures may include, but are not limited to: • Arrhythmias • Drug reactions, allergic reaction to contrast media • Hypotension/hypertension • Pain and tenderness

Please consult product labels and instruction for use for indications, contraindications, hazards, warnings, and precautions.

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