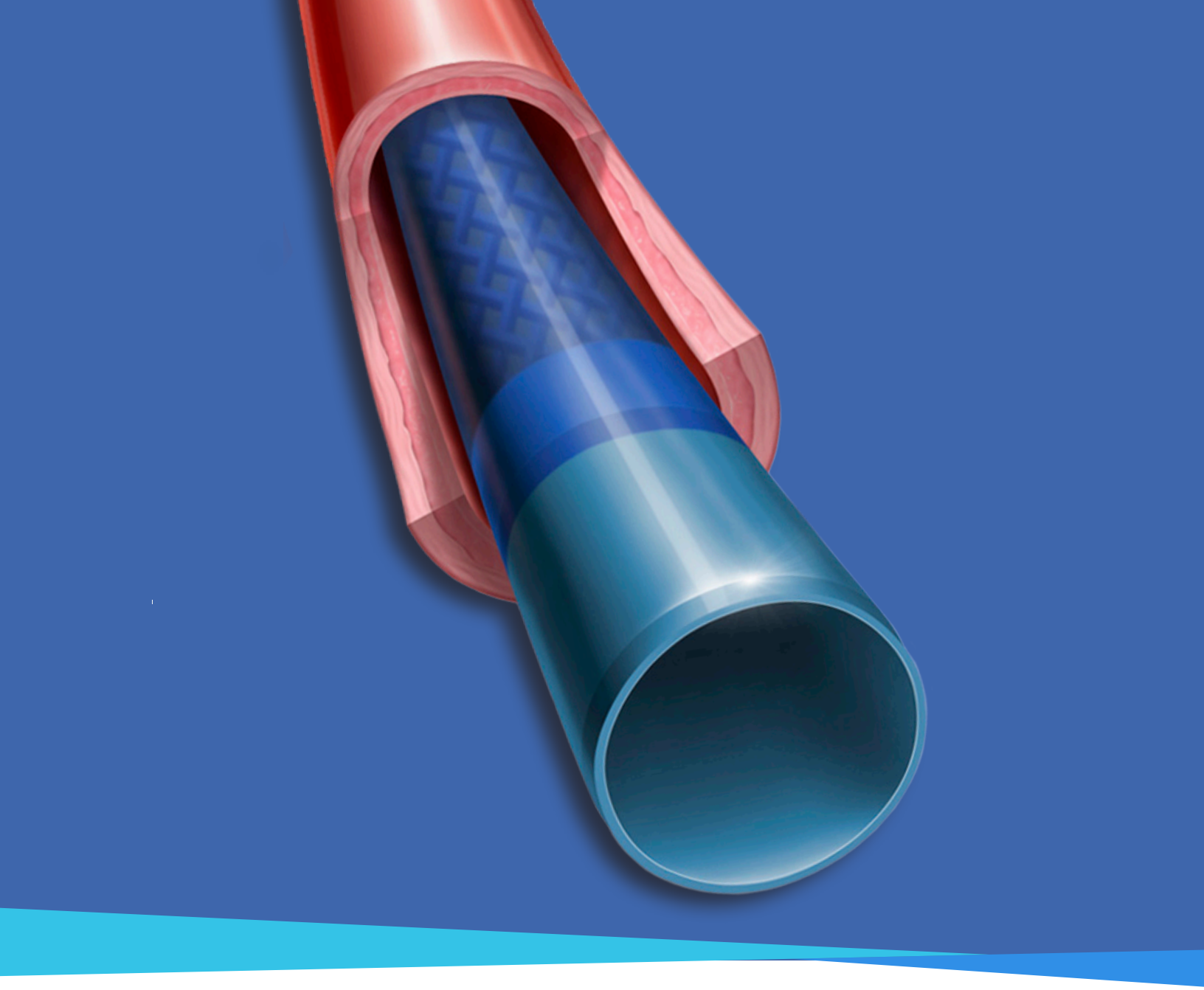


The Evolution of Thin-Walled Sheaths Has Arrived

A Comparison of 5F Halo One™ Thin-Walled Guiding Sheath versus 5F Terumo GlideSheath Slender®

Halo One™

Thin-Walled Guiding Sheath

BD

The Benefits of Thin-Walled Technology
Engineered for Performance

Halo One™ Thin-Walled Guiding Sheath outperformed Terumo GlideSheath Slender® across several key performance attributes[1]:

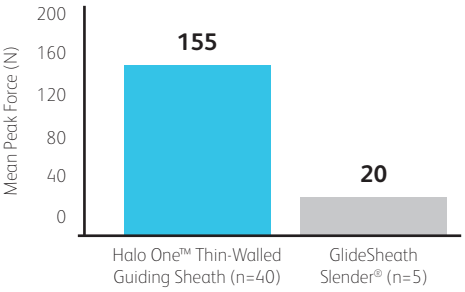
- Tensile Strength
- Compression Resistance
- Tip Transition
- Kink Resistance
- Tip Visibility

Benchtop Testing Results

Tensile Strength[2]

Test protocol: This test measured the force required to cause separation of the sheath shaft.

Higher tensile strength means more support in challenging anatomies by reducing the risk of separation to the sheath shaft.

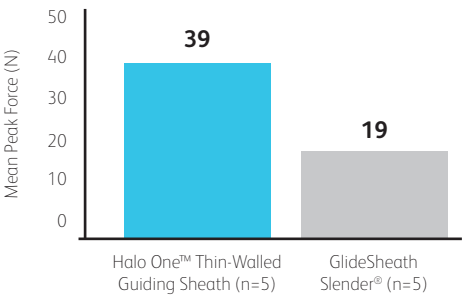


7x MORE TENSILE STRENGTH

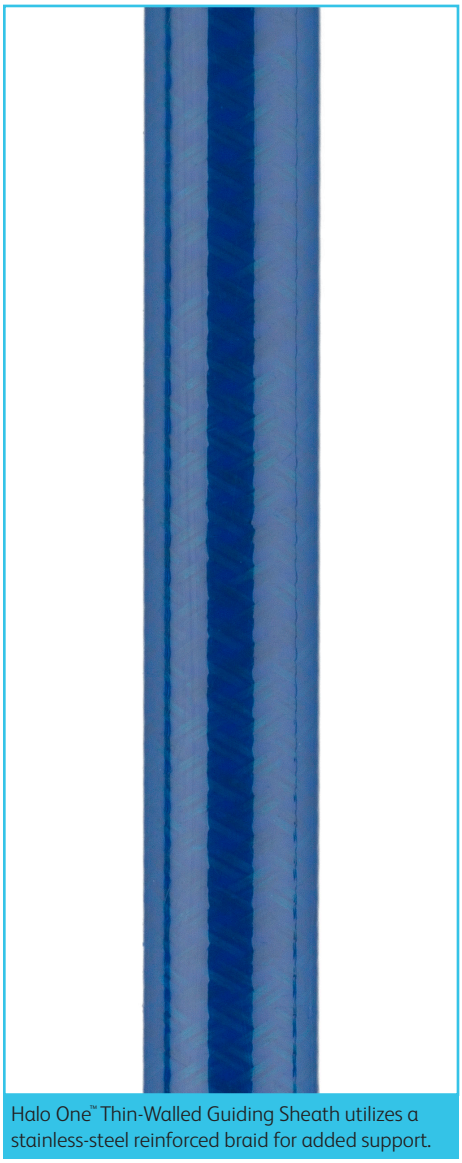
Compression Resistance[2]

Test protocol: This test measured the maximum force that the sheath shaft could sustain when compressed by 15mm.

Higher compression resistance helps maintain sheath lumen integrity when advancing or exchanging procedural devices.



107% MORE COMPRESSION RESISTANCE

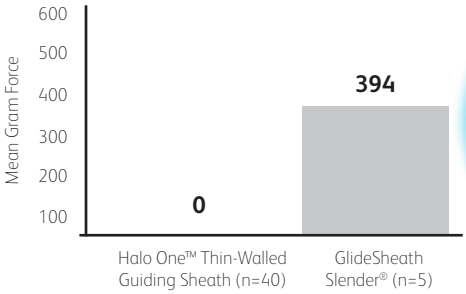


Halo One™ Thin-Walled Guiding Sheath utilizes a stainless-steel reinforced braid for added support.

Tip Transitions[2]

Test protocol: This test measured the peak penetration force between the sheath and dilator.

A smooth dilator to sheath transition is designed to improve the ease of vessel insertion and reduce the risk of tip roll back.



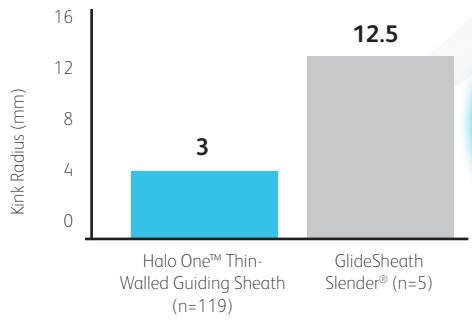
100%
SMOOTHER TIP TRANSITIONS

Halo One™ Thin-Walled Guiding Sheath has a formed atraumatic tip to provide a seamless transition.

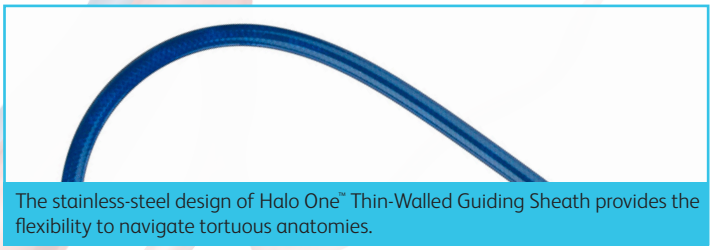
Kink Resistance[2]

Test protocol: This test evaluated the resistance to kinking by measuring the smallest radius that the sheath could bend around before a kink occurred.

Lower kink radius means the sheath can withstand more acute bends without kinking which is helpful when navigating tortuous anatomy.



4x
MORE KINK RESISTANCE



The stainless-steel design of Halo One™ Thin-Walled Guiding Sheath provides the flexibility to navigate tortuous anatomies.

Tip Visibility

Halo One™ Thin-Walled Guiding Sheath has a platinum iridium marker band at the distal tip for increased visibility under fluoroscopy. GlideSheath Slender® does not have a distal marker band.

The platinum iridium marker band is designed to make it easier to find your sheath tip location under fluoroscopy.

Halo One™ Thin-Walled Guiding Sheath Offers a Robust Size Matrix

- Only thin-walled guiding sheath with lengths suitable for distal peripheral intervention[3]
- Enables alternative approaches such as pedal and radial access sites

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

Halo One™

Thin-Walled Guiding Sheath

[1] The products discussed herein may not have the exact same indications for use. Please consult respective product labels and instructions for use for indications, contraindications, hazards, warnings, and precautions.

[2] Data on File. BD. Tempe, AZ. Halo One™ 5F 90cm and Terumo GlideSheath Slender 5F 10 cm tested. Bench test results may not necessarily be indicative of clinical performance. Different tests may yield different results. Data on File.

[3] Shaft lengths of 45, 70, and 90 cm are available in 4F and 5F sizes only. As of April 2020.

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 packaging inserts for more detailed safety information and instructions for use.