Smaller Profile
Bigger Possibilities

Halo One™
Thin-Walled Guiding Sheath
The Halo Effect™

Lowers Your Procedural Profile
Now you can start low profile and stay low profile using the Halo One™ Thin-Walled Guiding Sheath with BD’s innovative portfolio of PAD products. It’s thin-walled design reduces arteriotomy size compared to standard sheaths of the same French size, which can help to minimize access site complications.1,7

Halo One™
Thin-Walled Guiding Sheath

Crosser™
CTA Revascularization Catheter

UltraScore™
Focused Force PTA Balloon

Ultrasound PTA Balloon

Lutonix™
Drug Coated Balloon

LifeStent™ 1.5F
Vascular Stent System

LifeStream™
Balloon Expandable Vascular Covered Stent
Downsize Your Access Site Profile
To Help Minimize Access Site Complications

Why do access site complications matter?

- Access Site Complications have been reported to occur in up to 11% of peripheral vascular interventions.¹
- Access site complications have been associated with increased average hospital stay.¹
- Literature suggests that access site complications may be minimized by reducing sheath size.¹

How does the Halo One™ Thin-Walled Guiding Sheath allow you to downsize your access site profile?

Halo One™ Thin-Walled Guiding Sheath is designed with a stainless-steel reinforced 1 French wall thickness to reduce the size of the arteriotomy compared to standard sheaths of the same French size.

5F Profile Size Comparison

Not drawn to scale. For illustrative purposes only.
What does this thin-walled design mean for your procedure?

Halo One™ Thin-Walled Guiding Sheath is designed to provide the flexibility, trackability, and tensile strength needed to navigate tortuous anatomies while decreasing the access site profile compared to standard sheaths of the same French size.

How is this thin-walled design possible?

The thin-walled design of Halo One™ Thin-Walled Guiding Sheath is made possible through a layering process which creates a matrix of stainless-steel braiding that reinforces a 1 French wall.

*** 0.018” 10cm and 0.035” 45cm, 70cm and 90cm lengths
Performance Delivered
Benchtop Data Comparison of 5F Sheaths

Smooth Trackability
- The low forces needed to track Halo One™ Thin-Walled Guiding Sheath means the device can be easily maneuvered.
- Smooth trackability is helpful when traversing tortuous anatomies.

Unmatched Tensile Strength
- Higher tensile strength means more support in challenging anatomies by reducing the risk of separation to the sheath shaft.
- High tensile strength provides support when accessing challenging treatment locations.

Robust Size Offering
Halo One™ Thin-Walled Guiding Sheath is the only thin-walled guiding sheath with lengths suitable for distal peripheral intervention.

Halo One™ Thin-Walled Guiding Sheath offers lower profile while preserving the size of the inner lumen compared to standard sheaths of the same French size.

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Not drawn to scale. For illustrative purposes only.
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) Do not sterilize. 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 on medical devices—particularly those with long and small lumina, joints, and/or crevices that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes.

4) Visually inspect the packaging to verify that the sterile barrier is intact. Do not use if the sterile barrier has been breached. 7) The minimum acceptable sheath French size is printed on the package label. Do not attempt to pass devices through a smaller sheath than indicated on the device label.

Precautions: 1) The Halo One™ Thin-Walled Guiding Sheath shall only be used by trained physicians. Access procedures shall 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/duration of the procedure (e.g., balloon, stent, material removal section of atherectomy device) may be 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.

4) Data on file. BD, Tempe, AZ. Halo One 90cm (n=40); Terumo GlideSheath Slender 10cm (n=5); Cook Ansul 90cm (n=5); Cordis Brite Tip 45cm (n=5); Terumo Destination 45cm (n=5). Device track performance with use of a Ultravision 0.035 FTA Dilatation Catheter (0.035", 7mm x 400 mm x 130 mm). Bench test results may not necessarily be indicative of clinical performance. Different tests may yield different results.

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

6) Data on File. Halo One data are provided for non-hydraulically coated product. Specifications for hydraulically 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.

7) The minimum acceptable sheath French size is printed on the package label. Do not attempt to pass devices through a smaller sheath than indicated on the device label.

8) Insert dilator into the center of the sheath lumen. Forceful movement of the dilator which causes 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 closure 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, 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 that the true distal tip of the dilator is visible.

15) Take care when backloading 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 valves on the sheath tubing since this may restrict access to flow through the sheath. 19) Before removing or inserting the sheath care must be taken to ensure the active mechanism portion of the procedural device (e.g., balloon, stent, material removal section of atherectomy device) is not within the tip of the sheath. 20) Insert the sheath prior to advancing otherwise only the sheath may advance into the vessel and the sheath tip may cause damage to the vessel. 21) The Halo One™ Thin-Walled Guiding Sheath has been evaluated for use in the neurovasculature or the coronary vasculature. 22) After use, this product may be a potential source of blood leakage. 23) Take care when withdrawing the sheath.

24) Proper functioning of the sheath device must be kept completely wet. 25) Take care when backloading the tip of the dilator over the guidewire to avoid damage to the dilator.

Access 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 • Anemia or preanemia • Arteriovenous fistula • Compartment Syndrome • Death • Embolism • Endocarditis • Hematoma • Hemorrhage, including bleeding at the puncture site • Internal tear • Radial artery occlusion/spasm • Sepsis/infection/inflammation • Tissue necrosis • Thrombosis formation • Vessel spasm, perforation or dissection • Potential systemic indirect/inherent adverse effects related to general endovascular procedures may include, but are not limited to: • Allergic reaction to contrast media • Hypersensitivity reactions • Pain and tenderness.

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

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