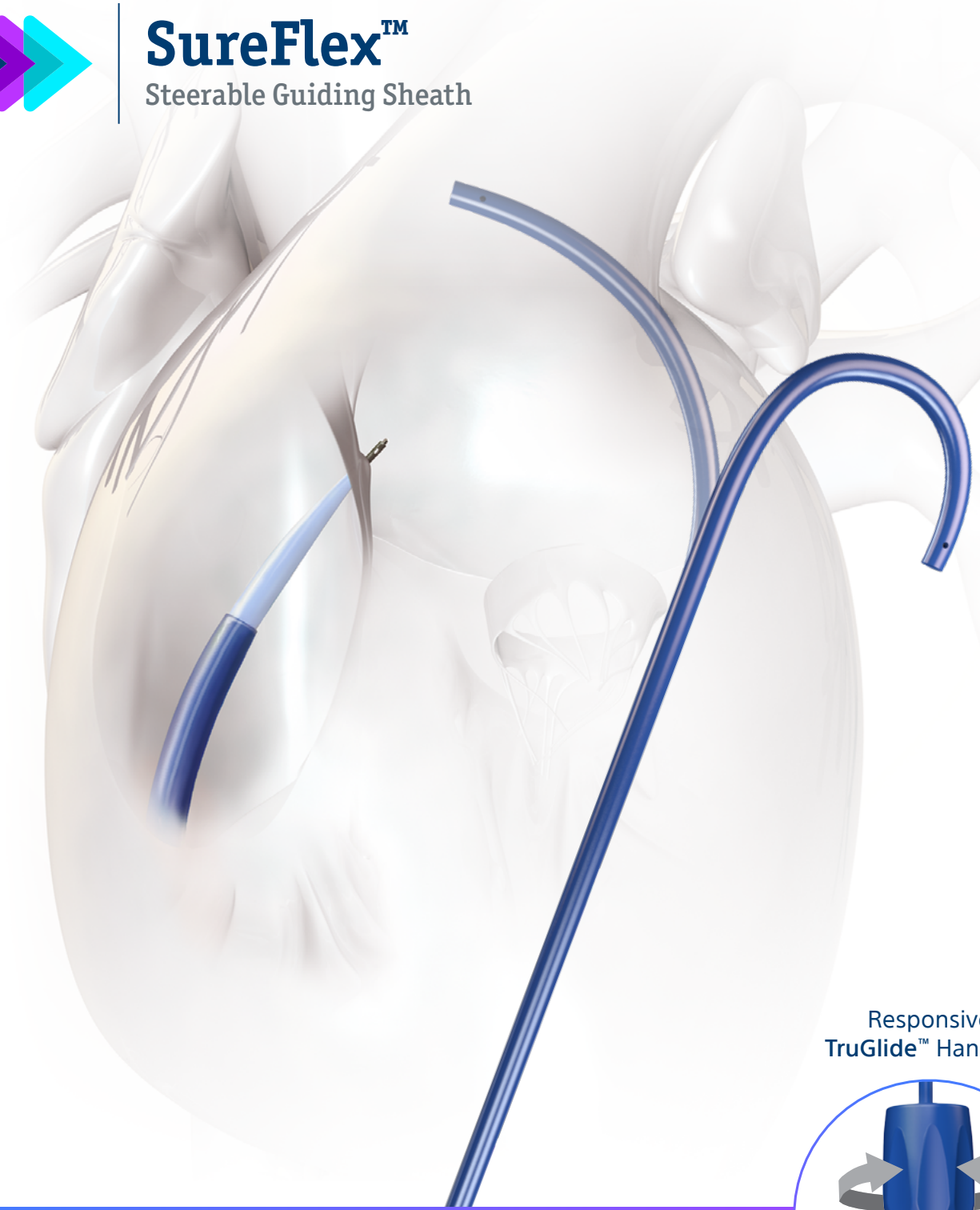




SureFlex™
Steerable Guiding Sheath



Responsive
TruGlide™ Handling



FEEL CONTROL. SEE RESULTS.™

FEEL CONTROL. SEE RESULTS.™

The SureFlex™ Steerable Sheath has been engineered to provide maximum control throughout your entire procedure.

Schedule a case with one of our clinical specialists to experience the control for yourself.



Reliable and consistent hub-snap mechanism



Controlled Crossing[†]

The advanced sheath-dilator design enables smooth and consistent access, providing you with a more predictable crossing experience.*



Precise Steering[†]

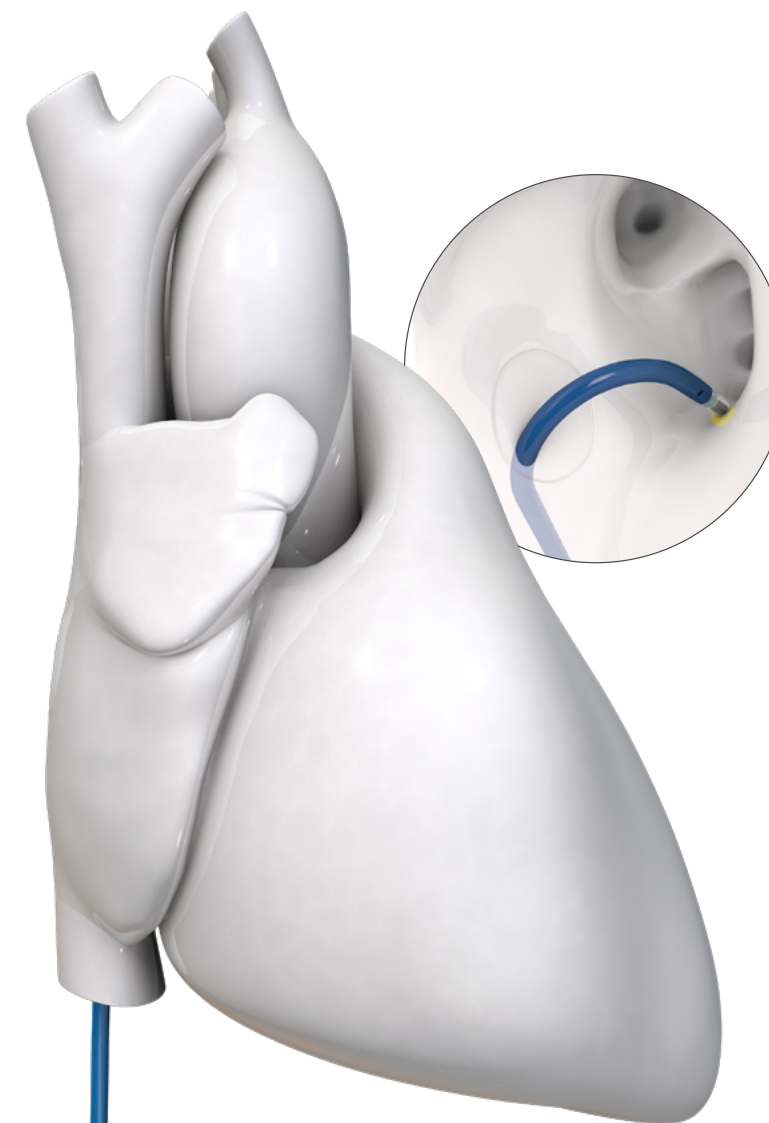
Feel your curve, know your position. Achieve maximum precision and control* with TruGlide™ Handling and intuitive tactile feedback.



Reliable Performance[§]

Engineered to support consistent contact of cardiovascular catheters, while providing premium strength and durability.*

DELIVER



Consistent Contact Force[§]

Support the consistent contact force of catheters.^{1*} Consistent contact force of ablation catheters provides better therapeutic results.²

Strength and Durability[§]

High performance; greater durability than the leading competitor.*

Engineered to retain your curve throughout the procedure.



Self-locking Dial

Maintain your position - deliver therapy on target as the dial retains your curve.

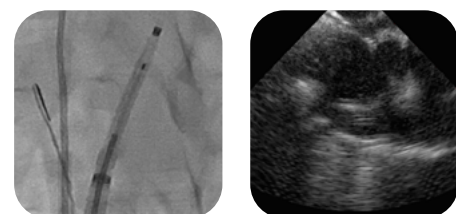
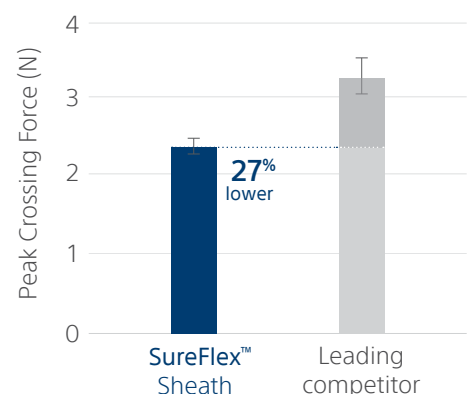
EVERY TIME.

CROSS

Confidence in Crossing[†]

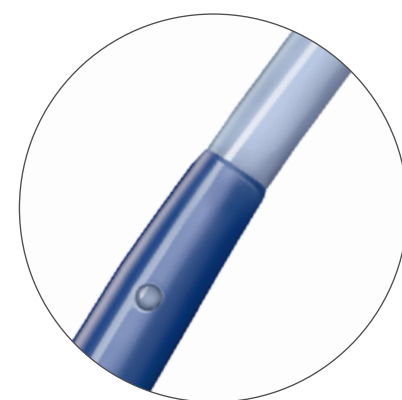
Gain access with confidence:

- A 27% lower peak crossing force, with a smoother profile.*



Radiopaque Tips

Control your position by visualizing sheath and dilator tip locations during the procedure.



Smooth Transition[†]

A 40% smoother dilator-to-sheath transition than the leading competitor,* to facilitate a smoother crossing.

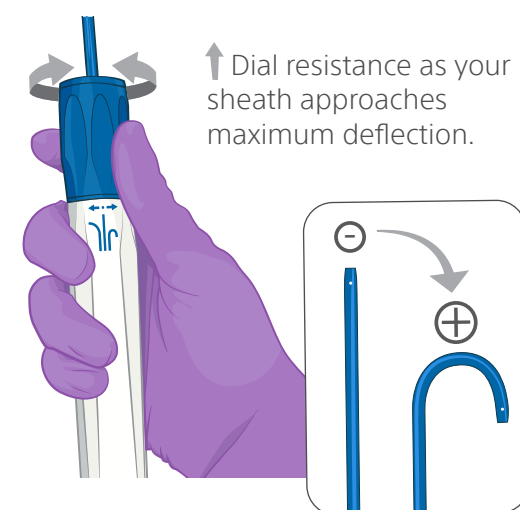
TARGET

Responsive TruGlide™ Handling

Smooth, high-precision steering to confidently position your curve.

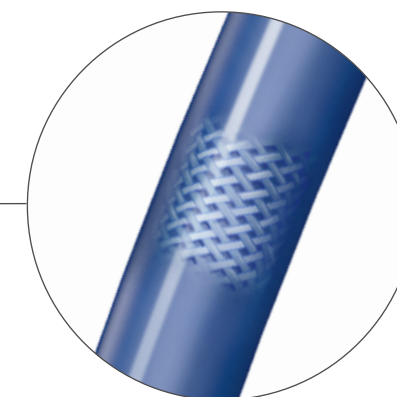
Tactile Feedback

Feel the extent of your curve deflection with intuitive tactile feedback.



Controlled Torque[†]

Position yourself accurately with a 1:1 torque response,* enabled by a composite braid design.



DELIVER



Consistent Contact Force[§]

Support the consistent contact force of catheters.^{1*} Consistent contact force of ablation catheters provides better therapeutic results.²

Strength and Durability[§]

High performance; greater durability than the leading competitor.*

Engineered to retain your curve throughout the procedure.



Self-locking Dial

Maintain your position - deliver therapy on target as the dial retains your curve.

SureFlex™ Steerable Guiding Sheath

SPECIFICATIONS

Feature	Specification
French size compatibility	8.5F (2.8 mm)
Sheath usable length	72 cm, 63 cm
Sheath overall length	93 cm, 84 cm
Sheath radiopaque marker	Platinum/iridium band
Dilator usable length	95 cm, 85 cm
Guidewire length	180 cm
Compatible guidewire	0.032" (0.81 mm)
Bidirectional curve angles	90° CCW, 180° CW

ORDERING INFORMATION

Sheath Usable Length	Product Number	Distal Curve Diameter
72 cm	TSK85-32-BD-71S	Small (17 mm)
72 cm	TSK85-32-BD-71M	Medium (22 mm)
72 cm	TSK85-32-BD-71L	Large (50 mm)
63 cm	TSK0005	Medium (22 mm)
63 cm	TSK0006	Large (50 mm)

SureFlex™ Steerable Guiding Sheath

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INDICATIONS FOR USE: The SureFlex™ Steerable Guiding Sheath kit is indicated for introducing various cardiovascular catheters to the heart, including the left side of the heart through the interatrial septum.

CONTRAINDICATIONS: There are no known contraindications for this device.

WARNINGS: • Laboratory staff and patients can undergo significant x-ray exposure during interventional procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. The use of echocardiography is recommended. • The SureFlex™ Steerable Guiding Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the SureFlex™ Steerable Guiding Sheath kit. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. • Care should be taken to ensure that all air is removed from the sheath before infusing through the side port. • Do not attempt direct percutaneous insertion of the sheath without the dilator as this may cause vessel injury. • Maintain continuous hemodynamic monitoring throughout procedure. • Provide continuous heparinized saline infusion while the introducer remains in vessel. • DO NOT attempt to insert or retract the guidewire through a metal cannula or a percutaneous needle, which may damage the guidewire and may cause patient injury.

PRECAUTIONS: • Careful manipulation must be performed to avoid cardiac damage, or tamponade. Sheath, dilator and guidewire advancement should be done under fluoroscopic guidance. Echocardiographic guidance is also recommended. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device. • Avoid deflecting distal end of sheath during delivery and removal, otherwise damage to vessels may occur. • Do not attempt to use the guidewire with electrocautery tools. • Do not reshape distal tip or curve of the guidewire. Excessive bending or kinking of the distal curve may damage the integrity of the wire or coating and lead to patient injury.

ADVERSE EVENTS: Adverse events that may occur while using the SureFlex™ Steerable Guiding Sheath include: • Infection • Air embolus • Local nerve damage • Vasovagal reaction • Dissection • Vessel spasm • AV fistula formation • Atrial septal defect • Pseudoaneurysm • Aortic puncture • Arrhythmias • Perforation and/or tamponade • Hematoma • Hemorrhage • Catheter entrapment • Embolic events • Stroke • Valve damage • Myocardial infarction • Pericardial/pleural effusion • Pacemaker/defibrillator lead displacement • Pulmonary edema • Coronary artery spasm and/or damage • Vessel trauma

EP-1556511-AA

*Bench testing or pre-clinical study results may not necessarily be indicative of clinical performance. The testing was performed by or on behalf of Boston Scientific. Data on file.

†Assessed by laser micrometry measurements along the length of the sheath-dilator transition (p<0.001, 5 SureFlex™ compared to 5 competitor sheaths) and by force gauge measurements during simulated transeptal crossing (p<0.001, 10 SureFlex™ compared to 8 competitor sheaths).

‡Assessed by handle rotation to a full 360° to test axial torque transfer and the maximum rotational capabilities of each sheath (5 SureFlex™ compared to 3 competitor sheaths).

§Assessed by full bidirectional articulation to maximal extension up to 10 times to achieve mechanical fatigue (p=0.007, 5 SureFlex™ compared to 3 competitor sheaths) and by repeated unidirectional articulation until failure or up to 300 cycles (5 SureFlex™ compared to 6 competitor sheaths).

¹Brunelli M, et al. Europace. doi: 10.1093/europace/eur333

²Piorkowski C, et al. Circ Arrhythm Electrophysiol. doi: 10.1161/CIRCEP.110.957761

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Advancing science for life™

Baylis Medical Company Inc.
5959 Trans-Canada Highway
Montreal, QC Canada H4T 1A1
www.baylismedical.com
info@baylismedical.com

General Inquiries
(514) 488-9801

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