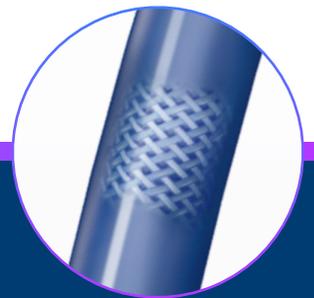




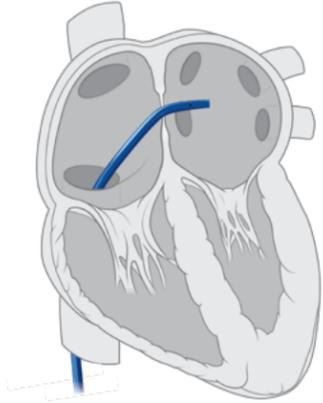
**TorFlex™**  
Transseptal Guiding Sheath



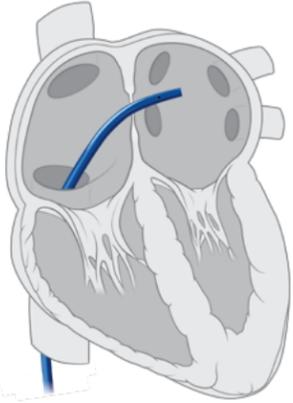
SMOOTH AND CONTROLLED CROSSING.™

# TorFlex™ Transseptal Guiding Sheath

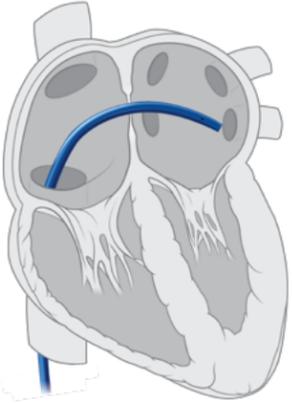
Boston Scientific is committed to innovations in transseptal punctures. Our transseptal products are designed to provide a smooth and controlled transseptal puncture.



45° Curve  
Left atrium – Posterior

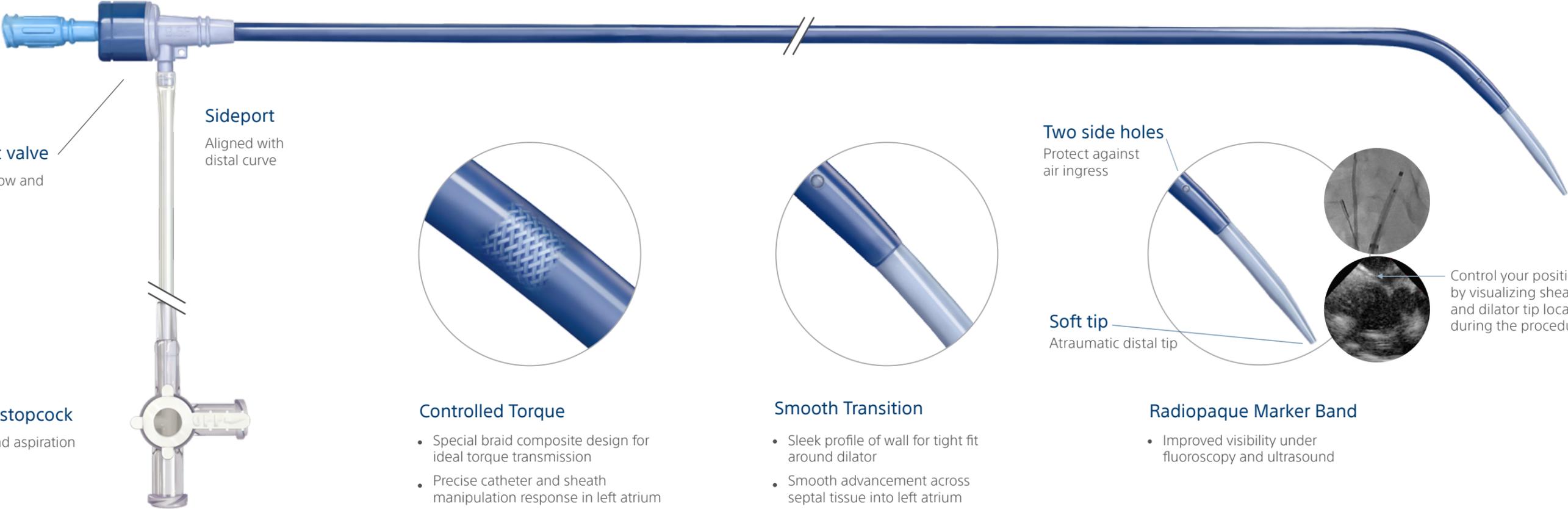


55° Curve  
Left atrium – Posterior



90° Curve  
Left atrium – Inferior

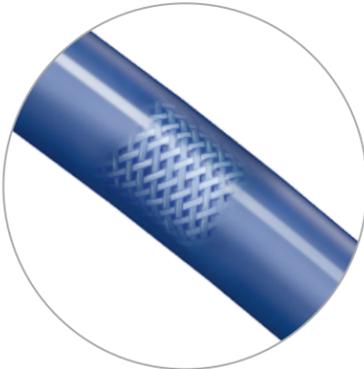
Reliable and consistent hub-snap mechanism



**Hemostatic valve**  
Prevent backflow and air ingress

**Sideport**  
Aligned with distal curve

**Three-way stopcock**  
For flushing and aspiration



**Controlled Torque**

- Special braid composite design for ideal torque transmission
- Precise catheter and sheath manipulation response in left atrium

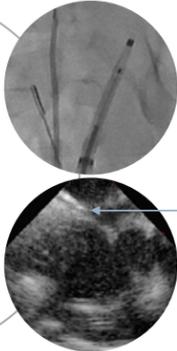


**Smooth Transition**

- Sleek profile of wall for tight fit around dilator
- Smooth advancement across septal tissue into left atrium

**Two side holes**  
Protect against air ingress

**Soft tip**  
Atraumatic distal tip



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

**Radiopaque Marker Band**

- Improved visibility under fluoroscopy and ultrasound

# TorFlex™ Transseptal Guiding Sheath

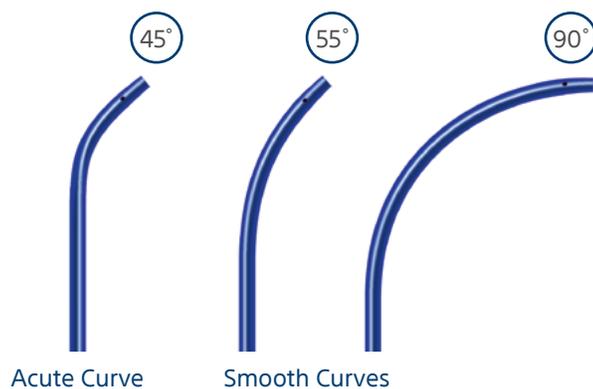
## SPECIFICATIONS

| Feature                      | Specification         |
|------------------------------|-----------------------|
| French size compatibility    | 8.5F (2.84 mm)        |
| Sheath usable length         | 63 cm, 81 cm          |
| Sheath radiopaque marker     | Platinum/iridium band |
| Sheath curves                | 45°, 55°, 90°         |
| Dilator usable length        | 67 cm, 85 cm          |
| Dilator inner diameter       | 0.033" (0.83 mm)      |
| Guidewire max outer diameter | 0.032" (0.81 mm)      |
| Guidewire length             | 180 cm                |

## ORDERING INFORMATION

| French size compatibility | Guidewire max outer diameter | Sheath usable length | Sheath curve |
|---------------------------|------------------------------|----------------------|--------------|
| TF85                      | - 32                         | - 63                 | - 45         |
| TF85                      | - 32                         | - 63                 | - 55         |
| TF85                      | - 32                         | - 63                 | - 90         |
| TF85                      | - 32                         | - 81                 | - 45         |

## CURVES



### TorFlex™ Transseptal 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 TorFlex™ Transseptal Guiding Sheath kit is used for the percutaneous introduction of various types of cardiovascular catheters and guidewires to all heart chambers, including the left atrium via transseptal perforation / puncture.

**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 TorFlex™ Transseptal Guiding Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the TorFlex™ Transseptal Guiding Sheath kit. Reuse can cause 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. • Careful manipulation must be performed to avoid cardiac damage or tamponade. Sheath advancement should be done under fluoroscopic guidance. Echocardiographic guidance is also recommended.

**PRECAUTIONS:** • Careful manipulation must be performed to avoid cardiac damage, or tamponade. Sheath, dilator and guidewire advancement should be done under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device.

**ADVERSE EVENTS:** Adverse events that may occur while using the TorFlex™ Transseptal Guiding Sheath kit include: • Infection • Air embolus • Local nerve damage • Hemorrhage • Embolic events • Vessel spasm • AV fistula formation • Atrial septal defect • Pseudoaneurysm • Perforation and/or tamponade • Arrhythmias • Pericardial/pleural effusion • Hematoma • Vessel trauma • Valve damage • Catheter entrapment

EP-1515406-AA

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