Boston Scientific
Advancing science for life™

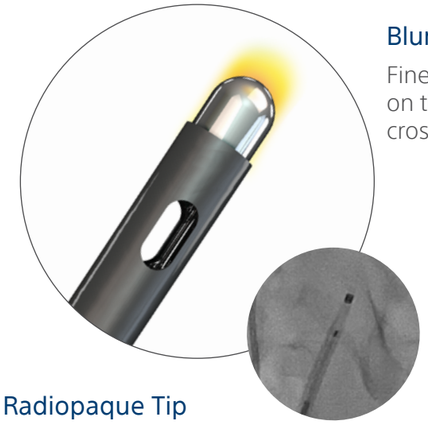
NRG™

RF Transseptal Kit

TAKE CONTROL OF YOUR CROSSING™

TARGET 1 TO SAVE TIME

NRG™ Transseptal Needle



Blunt Tip

Fine tune your position on the septum before crossing

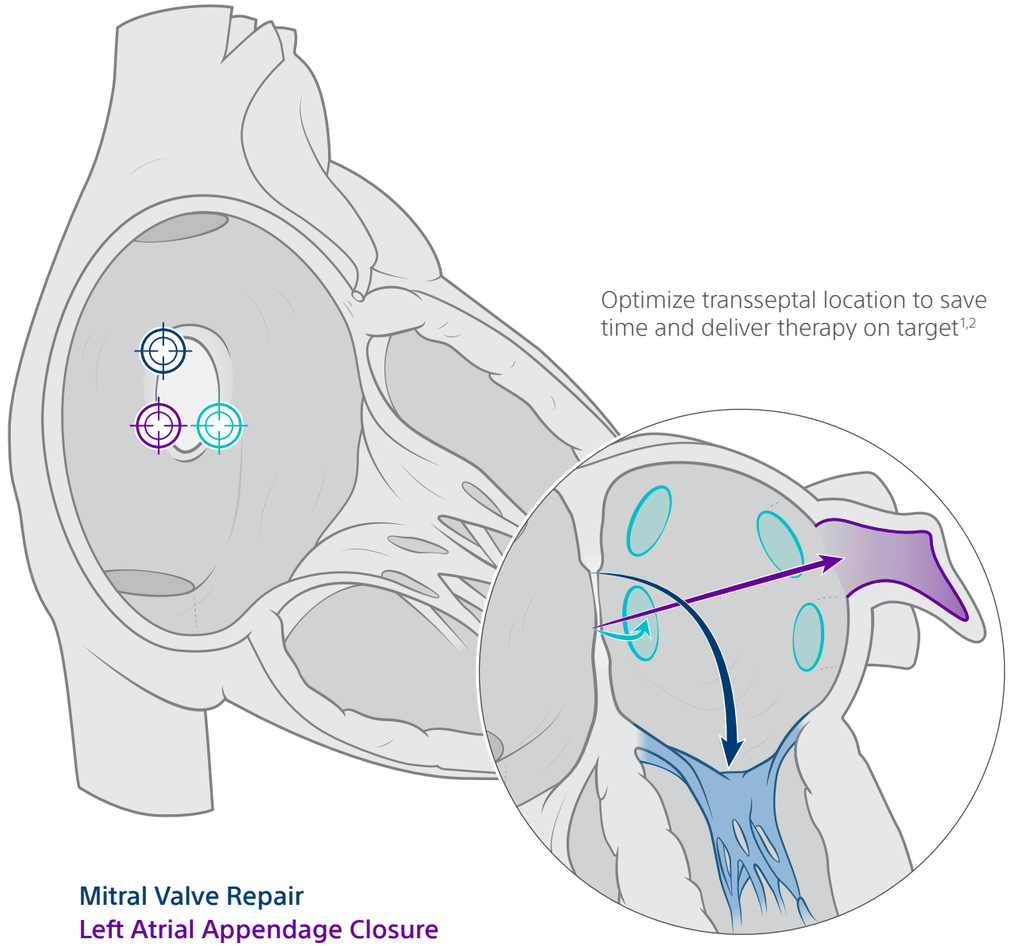
Radiopaque Tip

Control your positioning by visualizing needle tip location

TorFlex™ Transseptal Guiding Sheath

Controlled Torque

Special braid composite design for ideal torque transmission



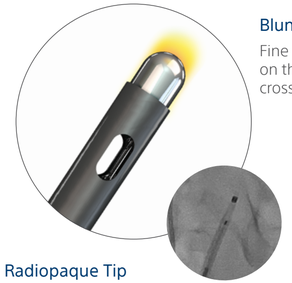
Optimize transseptal location to save time and deliver therapy on target[1,2]

Mitral Valve Repair
Left Atrial Appendage Closure
Pulmonary Vein Isolation

BE PRECISE. SAVE TIME.™

TARGET 1

NRG™ Transseptal Needle



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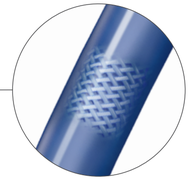


Controlled Torque

Special braid composite design for ideal torque transmission

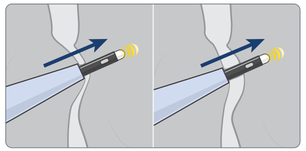
BE PRECISE. SAVE TIME.™

CROSS 2

NRG™ Transseptal Needle

Proven RF Puncture Technology

Reliably cross normal, aneurysmal, and fibrotic septa[3,4] using a short, focused RF energy pulse



Aneurysmal Septum Fibrotic Septum

Control your crossing through:

- Reduced excessive tenting[3]
- Reduced mechanical force[4]
- Reduced needle jumping

TorFlex™ Transseptal Guiding Sheath

Radiopaque Band

Visualize distal sheath location

Smooth Transition

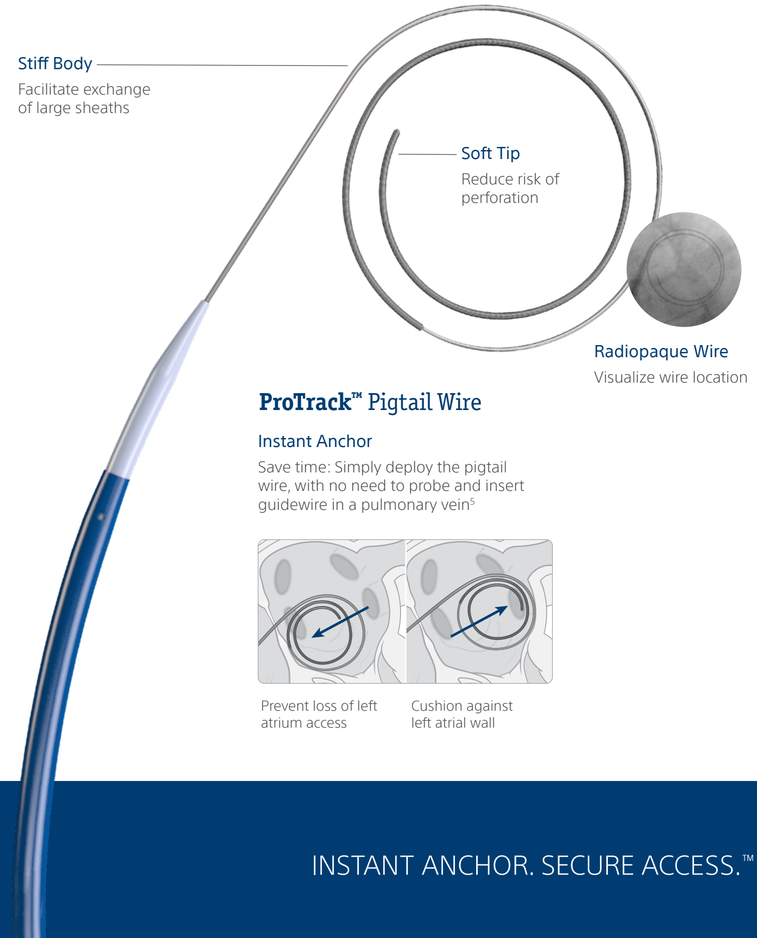
Facilitate advancement across septum with a sleek dilator-to-sheath profile

SMOOTH AND CONTROLLED CROSSING.™

ACCESS 3

Stiff Body

Facilitate exchange of large sheaths



Soft Tip

Reduce risk of perforation

Radiopaque Wire

Visualize wire location

ProTrack™ Pigtail Wire

Instant Anchor

Save time: Simply deploy the pigtail wire, with no need to probe and insert guidewire in a pulmonary vein[5]

Prevent loss of left atrium access Cushion against left atrial wall

INSTANT ANCHOR. SECURE ACCESS.™

NRG™ RF Transseptal Kit

CUSTOMIZE YOUR KIT

A Choose your needle curve

NRG™ Transseptal Needle

Needle length: 71 cm
Proximal gauge: 18 ga
Distal gauge: 21 ga

B Choose your sheath curve

TorFlex™ Transseptal Guiding Sheath

French size compatibility: 8.5F (2.84 mm)
Sheath usable length: 63 cm
Dilator usable length: 67 cm

C Choose your pigtail wire*

ProTrack™ Pigtail Wire

Wire diameter: 0.025″
Overall length: 230 cm or 175 cm

KIT MODEL NUMBERS

For use with Baylis Medical Company Radiofrequency Puncture Generator RFP-100A.*

Ask your sales representative about additional options for the ProTrack™ Pigtail Wire.

	A		B	C	
NTK-71	0	-85	45		230 cm
NTK-71	0	-85	55		
NTK-71	1	-85	45		
NTK-71	1	-85	55		

	A		B	C	
NTK-71	0	-85	45	S	175 cm
NTK-71	0	-85	55	S	
NTK-71	1	-85	45	S	

NRG™ Transseptal Needle

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 NRG™ Transseptal Needle is used to create an atrial septal defect in the heart. Secondary indications include monitoring intracardiac pressures, sampling blood, and infusing solutions.

CONTRAINDICATIONS: The NRG™ Transseptal Needle is not recommended for use with any conditions that do not require cutting or coagulation of soft tissue.

WARNINGS: • Laboratory staff and patients can undergo significant x-ray exposure during radiofrequency puncture 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 NRG™ Transseptal Needle is intended for single patient use only. Do not attempt to sterilize and reuse the needle. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. Failure to do so may result in patient complications. • The NRG™ Transseptal Needle must be used with the BMC Connector Cable. Attempts to use it with other connector cables can result in electrocution of the patient and/or operator.

PRECAUTIONS: • Placement of the dispersive electrode on the thigh or hip could be associated with higher impedance. • In order to prevent the risk of ignition make sure that flammable material is not present in the room during RF power application. • Careful needle manipulation must be performed to avoid cardiac damage, or tamponade. Needle advancement should be done under image guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the needle. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • Thoroughly flush the NRG™ Transseptal Needle with heparinized saline solution prior to use. • If using electroanatomical mapping guidance it is recommended to confirm tip placement on the fossa ovalis and septal tenting before RF puncture with graphic imaging or another imaging modality.

ADVERSE EVENTS: Adverse events that may occur while using the Baylis Medical Radiofrequency Puncture System include: • Tamponade • Sepsis/Infection • Thromboembolic episodes • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Vessel spasm • Sustained arrhythmias • Atrial Flutter • Hemorrhage • Vascular thrombosis • Perforation of the myocardium • Hematoma • Allergic reaction to contrast medium • Ventricular Tachycardia • Pain and Tenderness • Thermal damage to tissue • Arteriovenous fistula • Pericardial Effusion

EP-1506305-AA

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

ProTrack™ Pigtail Wire

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 ProTrack™ Pigtail Wires are intended for use in percutaneous transseptal procedures to introduce and position catheters and other interventional devices within the left heart. The device is not intended for use in the coronary arteries.

CONTRAINDICATIONS: There are no known contraindications for this device.

WARNINGS: • DO NOT push, auger, withdraw or torque a pigtail wire against resistance until the cause of the resistance has been determined. Applying excessive force against unexpected resistance may cause damage to the pigtail wire, interventional device and/or vessel/organ. • When the pigtail wire is exposed to the vascular system, it should be manipulated while under high-resolution imaging guidance including fluoroscopy and/or echocardiography. Improper visualization of the guidewire may lead to misplacement, dissection, or perforation. • Inspect the pigtail wire prior to use for coil separation, kinking, appropriate distal tip flexibility or breakage. If the pigtail wire is damaged or defective, do not use it. Using a damaged or defective pigtail wire may cause vasculature damage and/or compromise pigtail wire performance. • Laboratory staff and patients can undergo significant X-ray exposure during interventional procedures due to the continuous usage of fluoroscopic imaging. The 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.

ADVERSE EVENTS: Potential complications associated with the use of the pigtail wire include, but are not limited to: • Vessel Perforation/Dissection/Trauma or Damage • Vessel Spasm • Hemorrhage • Access Site Complications/Hematoma • Thrombus/Thromboembolism • Allergic reaction • Vascular complication • Cardiac tamponade • Cardiac Perforation/Laceration • Conduction disorder • Embolism • Additional Surgical Procedure • Pericardial/pleural effusion • Sepsis/Infection/Inflammation • Foreign Body/Wire Fracture • Hemolysis • Hypovolemia • Myocardial Ischemia and/or Infarction • Stroke/Transient Ischemic Attack • Vessel Occlusion • Wire Entrapment/Entanglement • Valve Complication

EP-1515204-AA

*Baylis Medical Company is a wholly owned subsidiary of Boston Scientific Corporation.

1 Rich ME, et al. J Vis Exp. doi: 10.3791/52811
2 Rinaldi MJ, et al. Cardiac Interv Today. 2014 Mar-Apr.
3 Sharma G, et al. Catheter Cardio Inte. doi: 10.1002/ccd.26608.
4 Smelley MP, et al. J Cardiovasc Electr. doi: 10.1111/j.1540-8167.2009.01656.x
5 Buchner S, et al. J Interv Cardiol. doi: 10.1111/joic.12224

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