Optimize transseptal location to save time and deliver therapy on target\textsuperscript{1,2}

Mitral Valve Repair
Left Atrial Appendage Closure
Pulmonary Vein Isolation

NRG\textsuperscript{TM} Transseptal Needle

Blunt Tip
Fine tune your position on the septum before crossing

Radiopaque Tip
Control your positioning by visualizing needle tip location

TorFlex\textsuperscript{TM} Transseptal Guiding Sheath

Controlled Torque
Special braid composite design for ideal torque transmission

Optimize transseptal location to save time and deliver therapy on target\textsuperscript{1,2}
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

- Radiopaque Band: Visualize distal sheath location
- Radiopaque Wire: Visualize wire location
- Radiopaque Tip: Control your crossing through:
  - Reduced excessive tenting
  - Reduced mechanical forces
  - Reduced needle jumping
- Controlled Torque: Special braid composite design for ideal torque transmission

ProTrack™ Pigtail Wire

- Instant Anchor: Save time: Simply deploy the pigtail wire, with no need to probe and insert guidewire in a pulmonary vein
- Soft Tip: Reduce risk of perforation
- Radiopaque Wire: Visualize wire location

Target

- Fine tune your position on the septum before crossing
- Radiopaque Tip: Control your positioning by visualizing needle tip location

Cross

- Proven RF Puncture Technology: Reliably cross normal, aneurysmal, and fibrotic septa using a short, focused RF energy pulse
- Re lysed RF Puncture Technology: Reduced excessive tenting
- Reduced mechanical forces
- Reduced needle jumping
- Smooth Transition: Facilitate advancement across septum with a sleek dilator-to-sheath profile

Access

- Stiff Body: Facilitate exchange of large sheaths
- Soft Tip: Cushion against left atrial wall
- Radiopaque Wire: Visualize wire location
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 RFF-100A*

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

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 device that does 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 electrical shock to the patient or operator.

PRECAUTIONS: • Placement of the dispensing 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 lining 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 • Abdominal Aneurysm • Hemorrhage • Vascular thrombosis • Perforation of the myocardium • Hypertension • Allergic reaction to contrast medium • Ventricular Tachycardia • Pain and Tenderness • Thermal damage to tissue • Atherosclerotic plaques • Percutaneous Emissary

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 puncture / perforation.

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 debride and reuse the TorFlex™ Transseptal Guiding Sheath. 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 introducing through the site 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 • All fistula formation • Atrial septal defect • Pseudoaneurysm • Perforation and/or tamponade • Atrial Septal Defect • Percutaneous/effective Robertsorium • Hemorrhage • Vessel trauma • Valve damage • Catheter entrapment

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/orifice. • 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 implantation, dissection, or perforation. • Impact 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 vascular 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. 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.

ADVERSE EVENTS: Potential complications associated with the use of the pigtail wire include, but are not limited to: • Vessel Perforation/Dilation/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 • Percutaneous/effective Robertsorium • Sepsis/Infection/Inflammation • Foreign Body/Wire/Fracture • Hemolysis • Hypereosinophilia • Myocardial ischemia and/or infarction • Stroke/Transient ischemic Attack • Vessel Occlusion • Wire Entrapment/Entanglement • Valve Complication

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