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

**NRG™ Transseptal Needle**
Proven RF Puncture Technology
Reliably cross normal, aneurysmal, and fibrotic septa using a short, focused RF energy pulse

**TorFlex™ Transseptal Guiding Sheath**
Facilitate advancement across septum with a sleek dilator-to-sheath profile

**Pulmonary Vein Isolation**
**Mitral Valve Repair**
**Left Atrial Appendage Closure**

**BE PRECISE. SAVE TIME.™**

**SMOOTH AND CONTROLLED CROSSING.™**
**NRG™ RF Transseptal Kit**

**CUSTOMIZE YOUR KIT**

A Choose your needle curve

B Choose your sheath curve

**NRG™ Transseptal Needle**

**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 electrosurgery of the patient and/or operator.

**PRECAUTIONS:** • Placement of the transseptal catheter into the left or right atrium or ventricle should be done under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device. • 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 • Pulmonary embolism • Thrombotic episodes • Perforation of the myocardium • Hemotoma • Pericardial effusion• Pericardial effusion

**TorFlex™ Transseptal Guiding Sheath**

**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 electrocardiography 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. Electroanatomical 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 • Hemotoma • Vessel spasm • Atrial septal defect • Pseudoaneuryasm • Perforation and/or tamponade • Arrhythmias • Pericardial/pleural effusion • Hemotoma • Vessel trauma • Valve damage • Catheter entrapment

**Kit Model Numbers**

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

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**EP-1506305-AA**

**EP-1515406-AA**

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