



**NRG™**  
Transseptal Needle

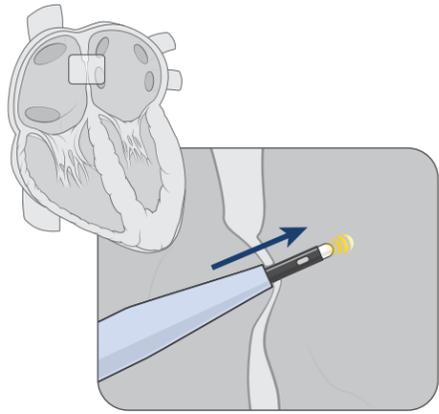


**BE PRECISE. SAVE TIME.™**

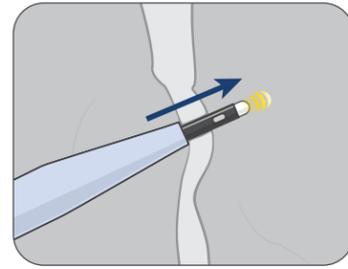
# NRG™ Transseptal Needle

The NRG™ Transseptal Needle delivers a short and highly focused radiofrequency (RF) energy pulse, allowing a transseptal puncture that is smooth and controlled. This unique RF feature enables a variety of benefits to the transseptal procedure.

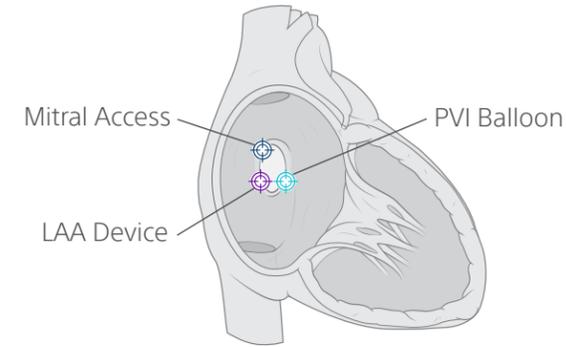
## 7 Reasons to use the NRG™ Transseptal Needle



**1** Cross thin aneurysmal septum while reducing excessive tenting<sup>1</sup>



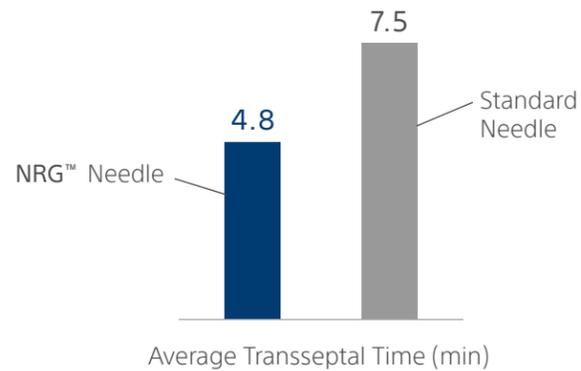
**2** Cross fibrotic septum while reducing mechanical force<sup>2</sup>



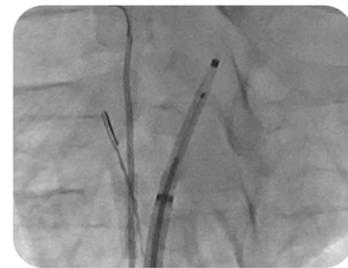
**3** Cross the septum at precise locations



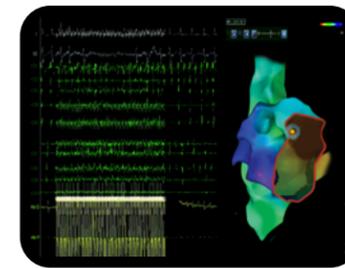
**4** Rounded atraumatic tip reduces risk of skiving and embolism<sup>4</sup>



**5** Reduce transseptal procedure and fluoroscopy time<sup>1,3</sup> vs. mechanical needle



**6** Visualize needle tip exact location with radiopaque marker



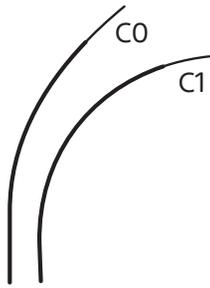
**7** Visualize the NRG™ Transseptal Needle on your mapping system

### ACCESSORIES

- RFP-100A RF Puncture Generator\*
- TorFlex™ Transseptal Guiding Sheath
- SureFlex™ Steerable Guiding Sheath
- ProTrack™ Pigtail Wire
- RFX-BAY-TS Connector Cable
- Grounding Pad

# NRG™ Transseptal Needle

## SPECIFICATIONS



Model	Product Number	Needle Length	Compatible Transseptal Sheaths
Curve C0	NRG-E-56-32-C0	56 cm*	Small Anatomy Fixed Curve sheath with 48 cm usable length
	NRG-E-HF-71-C0	71 cm	Fixed Curve sheath with 63 cm usable length
	NRG-E-HF-89-C0	89 cm	Fixed Curve sheath with 81 cm usable length
			Steerable sheath with 63 cm usable length
NRG-E-HF-98-C0	98 cm	Steerable sheath with 72 cm usable length	
Curve C1	NRG-E-HF-71-C1	71 cm	Fixed Curve sheath with 63 cm usable length
	NRG-E-HF-98-C1	98 cm	Steerable sheath with 72 cm usable length

Compatible with 0.032" dilator systems; \*proximal gauge 19 ga, distal gauge 22 ga.

## ACCESSORIES



### RFP-100A RF Puncture Generator

Designed specifically to make a controlled puncture in tissue while causing little to no damage to surrounding tissue.



### TorFlex™ Transseptal Guiding Sheath

The TorFlex™ Transseptal Guiding Sheath provides controlled movements in the left atrium due to its high torquability.



### SureFlex™ Steerable Guiding Sheath

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



### ProTrack™ Pigtail Wire

The ProTrack™ Pigtail Wire is designed to reduce the risk of perforation and prevent the loss of the left atrium access.



### RFX-BAY-TS Connector Cable

A specifically designed push-lock system allows for a quick and secure connection between the NRG™ Transseptal Needle and Generator.



### Grounding Pad

A disposable grounding pad acts as a return for the RF energy.

## 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

\*Baylis Medical Company Radiofrequency Puncture Generator RFP-100A. Baylis Medical Company is a wholly owned subsidiary of Boston Scientific Corporation.

<sup>1</sup>Fromentin S, et al. J Interv Card Electrophysiol. doi: 10.1007/s10840-011-9564-2

<sup>2</sup>Smelley MP, et al. J Cardiovasc Electrophysiol. doi: 10.1111/j.1540-8167.2009.01656.x

<sup>3</sup>Winkle RA, et al. Heart Rhythm. doi: 10.1016/j.hrthm.2011.04.032

<sup>4</sup>Feld GK, et al. J Interv Card Electrophysiol. doi: 10.1007/s10840-010-9531-3

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