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
2. Cross fibrotic septum while reducing mechanical force
3. Cross the septum at precise locations
4. Rounded atraumatic tip reduces risk of skiving and embolism
5. Reduce transseptal procedure and fluoroscopy time 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™ Pigtaiw Wire
- RFX-BAY-TS or RFX-SU-N Connector Cable
- Grounding Pad
NRG™ Transseptal Needle

SPECIFICATIONS

<table>
<thead>
<tr>
<th>Model</th>
<th>Product Number</th>
<th>Needle Length</th>
<th>Compatible Transseptal Sheaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Curve C0</td>
<td>NRG-E-HF-98-C0</td>
<td>98 cm</td>
<td>Steerable sheath with 72 cm usable length</td>
</tr>
<tr>
<td></td>
<td>NRG-E-HF-71-C0</td>
<td>71 cm</td>
<td>Fixed Curve sheath with 63 cm usable length</td>
</tr>
<tr>
<td></td>
<td>NRG-E-HF-89-C0</td>
<td>89 cm</td>
<td>Fixed Curve sheath with 81 cm usable length</td>
</tr>
<tr>
<td></td>
<td>NRG-E-HF-71-C1</td>
<td>71 cm</td>
<td>Steerable sheath with 63 cm usable length</td>
</tr>
<tr>
<td>Curve C1</td>
<td>NRG-E-HF-89-C1</td>
<td>89 cm</td>
<td>Steerable sheath with 63 cm usable length</td>
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</tr>
</tbody>
</table>

ACCESSORIES

- **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.
  - 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 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 arrhythmia, Atrial Flutter, Hemoptysis, Vascular thrombosis, Perforation of the myocardium, Hematoma, Allergic reaction to contrast medium, Ventricular Tachycardia, Pain and Tenderness, Thermal damage to tissue, Anterograde fistula, Percardial Effusion.

- **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.

- **SUREX-SU-N Connector Cable**
  - A specifically designed push-lock system allows for a quick and secure connection between the NRG™ Transseptal Needle and Generator.

- **SUREX-SU-N Connector Cable**
  - A disposable grounding pad acts as a return for the RF energy.

- **SUREX-SU-N Connector Cable**
  - EP-1557409-AA

- **SUREX-SU-N Connector Cable**
  - Baylis Medical Company Inc.

- **SUREX-SU-N Connector Cable**
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- **SUREX-SU-N Connector Cable**
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- **SUREX-SU-N Connector Cable**
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