RFP-100A
RF Puncture Generator

CONTROLLED TISSUE PUNCTURE USING RADIOFREQUENCY ENERGY
RF Puncture vs. RF Ablation

High impedance conditions are key to create a precise puncture in tissue with minimal surrounding damage. The RFP Generator is designed to function at high impedance, whereas a typical RFA Generator is not.

RF Puncture
- Objective: To create a small opening in tissue
- Occurs under these conditions: Low power (5-25 W), Short duration (<3 s), High voltage (2/70-400 V)
- Impedance range: 2000-6000 Ω
- Minimal collateral damage to surrounding tissue

RF Ablation
- Objective: To create a lesion to destroy electrically conductive tissue
- Occurs under these conditions: High power (30-50 W), Long duration (60-90 s), Low voltage (35-50 V)
- Impedance range: 150-300 Ω
- Thermal destruction of surrounding tissue

Features
- AC power indicator
- Right soft-touch keys for parameter adjustments
- Large LCD message window
- Return electrode fault indicator
- USB port (side) for up to 20 treatment data recordings
- Return electrode connector
- Luminous RF ON/OFF button and indicator
- Connector cable connection

Custom RF Settings
Use Constant Mode or Pulse Mode, and customize settings to your preference. Improved cutting ability enables shorter RF activation time.

Intelligent Interface

1. STANDBY
Connect grounding pad and connector cable. Generator automatically recognizes devices and makes available only appropriate modes.

2. READY
With all components connected, select desired Time and Cut settings. Using footswitch or RF ON button, initiate RF.

3. RF ON
Once RF ON button is pressed, generator enters “RF-ON” state. Flashed time is displayed during RF delivery. Screen will maintain until RF delivery concludes.
**RFP-100A RF Puncture Generator**

**SPECIFICATIONS**

<table>
<thead>
<tr>
<th>Product Code</th>
<th>RFP-100A</th>
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</thead>
<tbody>
<tr>
<td>RF Energy</td>
<td>468 kHz, Sinusoidal</td>
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<tr>
<td></td>
<td>Maximum output power of 50 W</td>
</tr>
<tr>
<td>Duty Cycle</td>
<td>Durations from 300 or 1000 ms ± 5 ms</td>
</tr>
<tr>
<td>Count-up Timer</td>
<td>Settable from 1-10 s (Device dependent) Display resolution: 1 s</td>
</tr>
<tr>
<td>Dimensions</td>
<td>Width: 11.25 in (28.5 cm) Length: 15.6 in (39.6 cm) Height: 7 in (18.7 cm)</td>
</tr>
<tr>
<td>Weight</td>
<td>20 lb (9.1 kg)</td>
</tr>
<tr>
<td>Input Voltage</td>
<td>100-240 VAC</td>
</tr>
<tr>
<td>Current Rating</td>
<td>5.0 A, 50-60 Hz</td>
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<tr>
<td>Power Cord Length</td>
<td>10 ft</td>
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**WARNING:** The RFP-100A RF Puncture Generator is designed and intended for use with RF transeptal solutions from Boston Scientific.

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**MULTI-PLATFORM DESIGN FOR MAXIMAL HOSPITAL VALUE**

**VersaCross™ RF Transseptal Solution**

The VersaCross™ RF Transseptal Solution offers all-in-one versatility for transeptal and beyond in a single device.

**NRG™ Transseptal Needle**

The NRG™ Transseptal Needle is uniquely designed to assist the physician in gaining access to the left atrium.

**SupraCross™ RF Solution**

When the conventional solution may not be optimal, use SupraCross™ RF Solution to gain alternate access into the left atrium.

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Baylis Medical Company Radiofrequency Puncture Generator RFP-100A

**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 Baylis Medical Company Radiofrequency Puncture Generator & Footswitch (optional accessory) is to be used with separately approved radiofrequency devices in general surgical procedures to cut soft tissues.

**CONTRAINDICATIONS:** The RFC Radiofrequency Puncture Generator is not recommended for use in the following:

1. Patients undergoing cardiac ablation procedures.
2. Patients with metallic implants or medical devices.
3. Patients with pacemakers or defibrillators.
4. Patients with arrhythmias that are not well controlled.
5. Patients with a history of allergies to radiation or radiofrequency energy.

**PRECAUTIONS:**

1. The generator should be used in conjunction with a properly functioning radiofrequency ablation system.
2. The generator should be used in a manner that is consistent with the manufacturer’s instructions.
3. The generator should not be used in conjunction with any other medical device.
4. The generator should not be used in a manner that is inconsistent with the manufacturer’s instructions.
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