COLDER MATTERS.

Deliver argon-powered colder temperatures to reliably create transmural lesions with a single CryoFlex™ probe.
DESIGNED FOR EASY ACCESS

Convenient choice for standard or minimally invasive procedures.

CryoFlex™ surgical ablation systems are designed with maneuverability, placement, and visualization in mind.

Adjustable Insulation Sheath.
The length of the ablation probe segment can be adjusted using a sliding insulation sheath.

Malleable by Hand.
The tip of the probe can be custom-shaped quickly, by hand, to meet the specific needs of the surgical case. A shaping tool is not required.

Clamp and Probe in One Device.
The clamp may be used in conjunction with probe option; Model 60CM1.
VERSATILE CONFIGURATIONS

Choose a style that meets your procedural preference.

The CryoFlex™ surgical ablation probes are easily shaped and reshaped by hand to address patient anatomies and surgical approaches.

Configuration Choices.
- Single probe
- Clamp-and-probe device
- 7 cm and 10 cm lengths

Procedural Flexibility.
The CryoFlex™ 10-S probe offers increased stiffness, yet is still shapeable by hand.

Visual Confirmation.
A unique viewing window in the proximal jaw of the clamp allows visualization of frost coming completely through the tissue.

THE ONLY 2-IN-1 DEVICE

The probe can be removed from the clamp to complete extensive ablations with a single device.

Deliver Cold Temperatures.
One-touch push-button controls and the gas monitoring system facilitate the delivery of cold, argon-powered cryoablation.

Configuration Choices.
- Single probe
- Clamp-and-probe device
- 7 cm and 10 cm lengths

Procedural Flexibility.
The CryoFlex™ 10-S probe offers increased stiffness, yet is still shapeable by hand.

Visual Confirmation.
A unique viewing window in the proximal jaw of the clamp allows visualization of frost coming completely through the tissue.

Single-trigger Mechanism.
Enables easy clamp and release.
CREATE DEEP, EXTENSIVE LESIONS.

Transmural lesions made with cryo technology require a temperature low enough to induce irreversible cell destruction.

Cryoablation is characterized by distinct necrotic temperature zones and preserved cellular integrity.

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**Levels of Cell Death**

Effective cryoablation requires exposure to lethal temperatures.

<table>
<thead>
<tr>
<th>Tissue Temperature (°C)</th>
<th>Temperature Target</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>-100</strong></td>
<td>Argon-based Probe Temperature -150°C</td>
</tr>
<tr>
<td><strong>-40</strong></td>
<td>Lethal when held frozen or over repeated freeze-thaw cycles. Temperature is sufficiently low to destroy tissue in a single cycle.</td>
</tr>
<tr>
<td><strong>0°C to -20°C</strong></td>
<td>Tissue temperatures of 0°C to -20°C are not completely lethal and cells may survive.</td>
</tr>
<tr>
<td><strong>-20°C to -40°C</strong></td>
<td>Tissue temperatures of -20°C to -40°C are lethal when held frozen for an extended period or repeated.</td>
</tr>
<tr>
<td><strong>Below -40°C</strong></td>
<td>Tissue temperatures below -40°C are lethal.</td>
</tr>
</tbody>
</table>

-40°C AND COLDER

Temperatures below -40°C are in the lethal target temperature range.
The CryoFlex™ system is the only cardiac surgical ablation system powered by argon gas. During in vitro test freezes, the CryoFlex™ probe reached temperatures of approximately -150° C and achieved deeper lesions than nitrous oxide-powered cryoablation.5

In all of the tissue thicknesses tested, on average, the argon-based surgical ablation system probe achieved the lethal temperature (-40° C) faster than the nitrous oxide-based probe. On average, the nitrous oxide surgical ablation system probes reached the potentially necrotic temperature zone (-20° to -40° C) and apoptotic temperature zone (0° to -20°) in a 2-minute freeze. Argon-based surgical ablation system probes reach lethal temperatures in all tested tissue thicknesses in under 2 minutes.

ACHIEVE LETHAL TEMPERATURES WITH ARGON.

Surgical ablation systems powered by argon gas freeze tissues to temperatures colder than -40° C in under two minutes in 4, 6, and 8 mm tissue thicknesses.5
## CryoFlex™ Single-use Probes

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>CATALOG CODE</th>
<th>NO.</th>
<th>USE</th>
</tr>
</thead>
<tbody>
<tr>
<td>CryoFlex™ probe, 7 cm</td>
<td>60SF7</td>
<td>1 each</td>
<td>single</td>
</tr>
<tr>
<td>CryoFlex™ probe, 10 cm</td>
<td>60SF2</td>
<td>1 each</td>
<td>single</td>
</tr>
<tr>
<td>CryoFlex™ 10-S probe, 10 cm</td>
<td>60SF3</td>
<td>1 each</td>
<td>single</td>
</tr>
<tr>
<td>CryoFlex™ clamp and probe, 10 cm</td>
<td>60CM1</td>
<td>1 each</td>
<td>single</td>
</tr>
</tbody>
</table>

Note: The CryoFlex™ argon-powered surgical ablation system uses argon refrigerant for rapid ablation. Argon gas tanks are obtained and refilled by local gas suppliers of the hospital’s choice.

## CryoFlex™ Console Components

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>CATALOG CODE</th>
<th>NO.</th>
<th>USE</th>
</tr>
</thead>
<tbody>
<tr>
<td>CryoFlex™ control panel</td>
<td>65CS1</td>
<td>1 each</td>
<td>reusable</td>
</tr>
<tr>
<td>Power cord; CryoFlex™ control panel</td>
<td>671PCNA</td>
<td>1 each</td>
<td>reusable</td>
</tr>
<tr>
<td>CryoFlex™ regulator (with pressure sensor cable)</td>
<td>67RAXNA</td>
<td>1 each</td>
<td>reusable</td>
</tr>
<tr>
<td>Gas hose; CryoFlex™ system</td>
<td>67H08</td>
<td>1 each</td>
<td>reusable</td>
</tr>
<tr>
<td>Pressure sensor cable; CryoFlex™ system (replacement only)</td>
<td>67PS6</td>
<td>1 each</td>
<td>reusable</td>
</tr>
<tr>
<td>CryoFlex™ tank carrier</td>
<td>65TC1</td>
<td>1 each</td>
<td>reusable</td>
</tr>
</tbody>
</table>
CryoFlex™ Surgical Ablation System

Indications for Use
The Cardioblate™ CryoFlex Surgical Ablation System is intended for minimally invasive cardiac surgical procedures, including the treatment of cardiac arrhythmias. The Cardioblate CryoFlex 7 cm, 10 cm, and 10-S probes plus the Cardioblate CryoFlex Clamp and Cardioblate CryoFlex Surgical Ablation Console freeze target tissue and block the electrical conduction pathways by creating an inflammatory response and cryonecrosis.

Contraindications
The CryoFlex Surgical Ablation Probe is not designed for use inside a beating heart.

Adverse Effects
Potential adverse effects with this device are similar to other cardiac surgery procedures and may include the following: bleeding; reoperation; extension of extracorporeal bypass; heart rhythm disturbances (atrial and/or ventricular); pericardial effusion; pericarditis; cardiac tamponade; pleural effusion; mediastinitis; conduction disturbances (SA/AV node); acute ischemic myocardial event; thrombus formation; low cardiac output; stroke; renal, gastrointestinal, or respiratory complications; sepsis; adjacent structural damage; and death.

Cryoaulation involving coronary vessels has been associated with subsequent clinically significant arterial stenosis. It is unknown whether cryoaulation with the CryoFlex Surgical Ablation Probe will have such an effect, but as in all such procedures, care should be taken to minimize unnecessary contact with coronary vessels during cryoaulation.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Important Safety Information
For a listing of indications, contraindications, precautions, warnings, and potential adverse effects, please refer to the Instructions for Use.