Transmural lesions made with cryo technology require a temperature low enough to induce irreversible cell destruction.¹⁻³
CREATE DEEP, EXTENSIVE LESIONS.

Tissue that is frozen to temperatures below -40° C is destroyed by direct damage in a single ablation. 4

<table>
<thead>
<tr>
<th>Tissue Temperature (° C)</th>
<th>Levels of Cell Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>-10</td>
<td>Incomplete destruction and cell survival. 4,5</td>
</tr>
<tr>
<td>-20</td>
<td>Lethal when held frozen or over repeated freeze-thaw cycles.</td>
</tr>
<tr>
<td>-30</td>
<td>Temperature is sufficiently low to destroy tissue in a single cycle. 4</td>
</tr>
<tr>
<td>-40</td>
<td>Tissue temperatures of -20° C to -40° C are lethal when ablation is repeated 4 or held frozen for an extended period. 5</td>
</tr>
<tr>
<td>-50</td>
<td>Tissue temperatures below -40° C are lethal. 5-7</td>
</tr>
<tr>
<td>-60</td>
<td></td>
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<tr>
<td>-70</td>
<td></td>
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<tr>
<td>-80</td>
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<tr>
<td>-90</td>
<td></td>
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<tr>
<td>-100</td>
<td></td>
</tr>
</tbody>
</table>

Argon-based Probe Temperature -150° C
Argon-based Surgical Ablation System vs. Nitrous Oxide-based Surgical Ablation System Comparison†

![Graph showing temperature changes over time for different tissue thicknesses and gas types.]

- **Lethal temperature** (< -40°C)‡‡
- **Lethal in repeated or extended cycles** (-20°C to -40°C)‡‡
- **Incomplete destruction and cell survival** (0°C to -20°C)‡}

1In vitro comparison of argon-based and nitrous oxide-based surgical ablation systems by thermocouple embedded in porcine tissue of 4-8 mm thickness, over two minutes total time.‡ Medtronic data on file. Results may not be indicative of clinical performance.

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.
REFERENCES

IMPORTANT SAFETY INFORMATION

**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 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.

Cryoablation involving coronary vessels has been associated with subsequent clinically significant arterial stenosis. It is unknown whether cryoablation 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 cryoablation.

**Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician. For a listing of indications, contraindications, precautions, and warnings, please refer to the Instructions for Use.

For more information, contact your local Medtronic Surgical Ablation Representative.

**U.S. Customer Service 1-800-328-1357.**

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