Shaping Surgical Ablation.

Cardioblate®
CryoFlex™
Surgical Ablation System

Unique Cardioblate® malleability delivers Argon-powered cryoablation for reproducible, transmural lesions with a single probe.
Cardioblate® Surgical Ablation Systems have been designed with maneuverability, placement and visualization in mind. Uniquely malleable devices put surgeons in control of every procedure with superior energy sources that give greater confidence of lesion transmurality.
The Cardioblate® CryoFlex™ Argon-Powered Surgical Ablation System provides the capability of creating deep, extensive lesions to treat cardiac arrhythmias through sternotomy and minimally invasive approaches. Compared with dry radiofrequency, cryoablation provides added safety around vulnerable tissue structures.1, 2 Probe tips can be reshaped by hand to achieve good tissue apposition in varying surgical situations and approaches. A single probe can be used for all procedures.

Advantage Argon.

Argon gas is the coldest ablation source commercially available for the surgical treatment of cardiac arrhythmias. The CryoFlex Probe reaches temperatures of approximately -150°C in test freezes.3 During in vitro testing, Argon cryoablation achieved deeper lesions than Nitrous Oxide cryoablation.4 This provides greater confidence that lesions are transmural.

---

**Argon vs. Nitrous Oxide**

Argon Freezes to Lethal Cell Temperatures Deeper and Faster4

Bench test comparison between Cardioblate® CryoFlex™ probe and AtriCure Cryo 1™ probe on 7 mm thick porcine tissue. Simultaneous freezes with both devices were performed upon tissue, while recording temperatures on the tissue surface opposite of the probes.

**Levels of Cell Death**5,6,7,8

Effective Cryoablation Achieves Necrotic Cell Temperatures Through Targeted Tissue

- **Necrosis** (≈ -20°C – -40°C and colder) Cell destruction is immediate and irreversible.
- **Apoptosis** (≈ 0°C – -20°C) Cells are damaged and may recover; some cells destroyed.
- **Hypothermia** (≈ 32°C – 0°C) Cells temporarily stop functioning.

---

NB. Results may not be indicative of clinical performance.

*Source: [Cardioblate® CryoFlex™](https://www.cardioblate.com) [Clinical Studies](https://www.cardioblate.com/cardioblate-cryoflex-manual) [Clinical Trials](https://www.cardioblate.com/cardioblate-cryoflex-manual) [Surgical Techniques](https://www.cardioblate.com/cardioblate-cryoflex-manual) [Surgical Outcomes](https://www.cardioblate.com/cardioblate-cryoflex-manual)*
Cardioblate® CryoFlex™ Surgical Ablation Probes

**Distinctly malleable.**

Hand Malleable. 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.

Adjustable Insulation Sheath. The length of the ablation probe tip can be adjusted using a sliding insulation sheath, helping to shield non-targeted tissue.

**Cardioblate® CryoFlex™ Surgical Ablation Probes**

Malleable probes that shape to any anatomy.

Cardioblate® CryoFlex™ Surgical Ablation Probes are distinctly malleable, allowing them to be easily shaped and reshaped by hand to address varying tortuous anatomical situations from various surgical approaches. CryoFlex probes are great choices for right thoracotomy procedures. The probes are available in 7 cm and 10 cm lengths.

10-S for increased rigidity.

The Cardioblate® CryoFlex™ 10-S Surgical Ablation Probe optimizes malleability and shape retention to provide secure tissue apposition and produce linear lesions. With added rigidity compared with the standard CryoFlex probes, the 10-S probe is firm enough to secure tissue contact, yet easy to reshape by hand multiple times.
The Cardioblate® CryoFlex™ Surgical Ablation Clamp and Probe combine the utility of the CryoFlex probe with the familiar and useful delivery of a clamp. The only two-in-one cryoablation device, the clamp houses a 10 cm malleable probe that can be ejected and used separately to create lesions. The clamp and probe are a great choice for surgical ablation procedures through a sternotomy.

**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.

**Wide-opening Jaws.** Aid in placement and clamp positioning. Distal jaw has a hole for tying umbilical tape facilitating clamp placement.

**2-in-1 Device.** The probe can be removed from the clamp to complete extensive ablations with a single device.

**The convenience of a clamp and probe in a single device.**

The Cardioblate® CryoFlex™ Surgical Ablation Console is quick and easy to set up for use and has intuitive, one-touch, push-button controls.
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 Cardioblate® 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. For more information, call 877-526-7890 or 763-526-7890.

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>- North American Standard</td>
<td>671PCE</td>
<td>1 each</td>
<td>Reusable</td>
</tr>
<tr>
<td>- European Standard</td>
<td>671PCY</td>
<td>1 each</td>
<td>Reusable</td>
</tr>
<tr>
<td>- Italian Standard</td>
<td>671PCUK</td>
<td>1 each</td>
<td>Reusable</td>
</tr>
<tr>
<td>- United Kingdom Standard</td>
<td>671PCUK</td>
<td>1 each</td>
<td>Reusable</td>
</tr>
<tr>
<td>CryoFlex™ Regulator (with pressure sensor cable)*</td>
<td>67RXA</td>
<td>1 each</td>
<td>Reusable</td>
</tr>
<tr>
<td>- North American Standard</td>
<td>67RAXA</td>
<td>1 each</td>
<td>Reusable</td>
</tr>
<tr>
<td>- European Standard</td>
<td>67RAX</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>

* Order one per local standard.

References

5. Baust JG, Gage AA. The molecular basis of cryosurgery. Institute of Biomedical Technology, State University of New York, Binghamton, and School of Medicine and Biomedical Sciences, State University of New York at Buffalo, Buffalo, New York, NY, USA, pp. 1187-91.

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

Adverse Events or Complications: Potential adverse events with this device are similar to other cardiac surgery procedures and may include the following: bleeding, re-operation, extension of extracorporeal bypass, heart rhythm disturbances (atrial and/or ventricular), effusion, pericarditis, cardiac tamponade, pleural effusions, mediastinal constriction, pericardial effusion and/or tamponade, myocardial ischemia, and myocardial event; thrombus formation; low cardiac output; stroke; renal, gastrointestinal or respiratory complications; sepsis; adjacent structural damage; and death.

Avoid contact between the cryoablation probe and the phrenic nerve to avoid injury. Perioperative heart rhythm disturbances (atrial and/or ventricular); sepsis; adjacent structural damage; and death.

In general, cryoablation should be limited to areas of the heart that are not directly involved with the target lesion.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician for a complete listing of all indications, contraindications, precautions and warnings, please refer to the instructions for Use which accompany each product.

www.medtronic.com

World Headquarters
Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: (763) 514-4000
Fax: (763) 514-4879

Medtronic USA, Inc.
Toll-free: 1 (800) 328-2518
(24-hour technical support for physicians and medical professionals)

Europe
Medtronic International Trading
Sàrl
Route du Mouillau 31
Case postale 84
CH-1131 Tolochenaz
Switzerland
Tel: 41.21.802.7000
Fax: 41.21.802.7900

Canada
Medtronic of Canada Ltd.
99 Hereford Street
Brampton, Ontario L6Y 0R3
Canada
Tel: (905) 460-3800
Fax: (905) 826-6620
Toll-free: 1 (800) 268-5346

Asia Pacific
Medtronic International, Ltd.
Suite 1602 16/F Manulife Plaza
The Lee Gardens, 33 Hysan Avenue
Causeway Bay
Hong Kong
Tel: (852) 2891 4068
Fax: (852) 2591 0313
enquiryap@medtronic.com

Latin America
Medtronic USA, Inc.
Doral Corporate Center II
3750 NW 87th Avenue Suite 700
Miami, FL 33178
USA
Tel: (305) 500-9328
Fax: (786) 709-4244

LifeLine
CardioVascular Technical Support
Tel: (877) 526-7890
Tel: (763) 526-7890
Fax: (763) 526-7888
E-mail: rs.cstechsupport@medtronic.com

UCM100527 EN © Medtronic, Inc. 2011. All Rights Reserved and Printed in USA