Temperature matters. Controlling temperatures is key to achieving conduction block.
Why does temperature matter?

**Temperature matters** because surgical ablation procedures rely on specific temperatures to induce irreversible cell death. Delivery of too much RF energy may overheat and char tissue; and temperatures that aren’t cold enough may not completely freeze tissue.

**RF Ablation**
- Controlled heat matters ............................................. 3
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- Algorithm matters ..................................................... 5

**Cryoablation**
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Key risks of cardiac ablation include arrhythmia, perforation, tissue burn, and organ dysfunction. For a listing of Valleylab™ FT10 and Cardioblate™ precautions, warnings, and potential adverse effects, please refer to the Instructions for Use.
Controlled heat matters

The optimal transmural lesion is created in tissue temperatures of 50°-100° C.\textsuperscript{1-5}

- **OVERHEATING**: High temperature at the tissue site may result in coagulum formation, endocardial disruption, steam popping, or perforation.\textsuperscript{5}
- **OPTIMAL HEATING**: Critical temperature range for irreversible myocardial injury.\textsuperscript{1}
- **INSUFFICIENT HEATING**: Irreversible loss of cellular excitability requires temperatures greater than 50° C.\textsuperscript{4}
Irrigation matters

**Dry RF**
Heating tissue above 100° C may produce microbubbles and char, which are barriers to energy flow, and inhibits lesion creation.\(^3,7\)

**Irrigated RF**
Irrigated RF cools the surface temperature of tissue and increases RF energy delivery, reducing the likelihood of charring.\(^6,8,9\)

\(^\dagger\)All lesion dimensions are in millimeters. Results may not be indicative of clinical performance.
A dose response algorithm is embedded into the software that powers Cardioblate™ technology. This algorithm was designed to adjust the power output of the devices based on changes in tissue impedance during an ablation, allowing for maximum power delivery.

Impedance and power work together:
• An increase in impedance decreases power.
• An impedance plateau increases power.
Levels of cell death
Effective cryoablation requires exposure to lethal temperatures.

Colder matters

Tissue temperatures of 0° C to -20° C are not completely lethal and cells may survive.\textsuperscript{10,11}

Tissue temperatures of -20° C to -40° C are lethal when ablation is repeated\textsuperscript{10} or held frozen for an extended period.\textsuperscript{11}

Tissue temperatures below -40° C are lethal.\textsuperscript{10-13}

Temperature is sufficiently low to destroy tissue in a single cycle.\textsuperscript{10}

Tissue that is frozen to temperatures below -40° C is destroyed by direct damage in a single ablation.\textsuperscript{10}

Argon-based probe temperature -150° C

Incomplete destruction and cell survival.\textsuperscript{10,11}

Lethal when held frozen\textsuperscript{11} or repeated\textsuperscript{10} freeze-thaw cycles.

Temperature is sufficiently low to destroy tissue in a single cycle.\textsuperscript{10}
Gas choice matters

**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.

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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.
Temperature does matter

Heat controlled. Transmural lesions created.
Only the Cardioblate™ irrigated RF surgical ablation system has irrigation and automatic power adjustments to maintain temperatures in the effective heating ranges.
Argon-powered energy delivered. The CryoFlex™ system – the only cardiac surgical ablation system powered by argon gas – reached temperatures of approximately -150° C during in vitro test freezes and achieved deeper lesions than nitrous oxide cryoablation.\textsuperscript{14}
### Cardioblate™ Surgical Ablation System

<table>
<thead>
<tr>
<th>Product</th>
<th>Catalog code</th>
<th>Quantity</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valleylab™ FT10 energy platform†</td>
<td>VLFT10GEN</td>
<td>1 each</td>
<td>reusable</td>
</tr>
<tr>
<td>Valleylab FT10 cart</td>
<td>VLFTCRT</td>
<td>1 each</td>
<td>reusable</td>
</tr>
<tr>
<td>†LigaSure™ purple pedal footswitch (If foot pedal operation is desired, the Ligasure LS0300 purple pedal foot switch is required for ValleyLab FT10 operation with Cardioblate devices)</td>
<td>LS0300</td>
<td>1 each</td>
<td>reusable</td>
</tr>
<tr>
<td>Cardioblate BP2 surgical ablation device</td>
<td>49321</td>
<td>1 each</td>
<td>single</td>
</tr>
<tr>
<td>Cardioblate Gemini™-s surgical ablation device</td>
<td>49351</td>
<td>1 each</td>
<td>single</td>
</tr>
<tr>
<td>Cardioblate LP surgical ablation device</td>
<td>49341</td>
<td>1 each</td>
<td>single</td>
</tr>
<tr>
<td>Cardioblate surgical ablation pen</td>
<td>49313</td>
<td>1 each</td>
<td>single</td>
</tr>
<tr>
<td>Cardioblate surgical ablation XL pen</td>
<td>49314</td>
<td>1 each</td>
<td>single</td>
</tr>
</tbody>
</table>

Additional requirements: An adult REM electrode, Model E7507 (9-foot) cord or E7507DB (15-foot) cord is required for use with the Cardioblate surgical ablation pen, Model 49313; and XL pen, Model 49314. A commercially available pressure bag, IV tubing set, and normal saline solution is required for use with all Cardioblate devices.

### CryoFlex™ Surgical Ablation System

<table>
<thead>
<tr>
<th>Single-use probes</th>
<th>Catalog code</th>
<th>Quantity</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.

<table>
<thead>
<tr>
<th>Console components</th>
<th>Catalog code</th>
<th>Quantity</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>

Order one per local standard.
References


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. 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.

Cardioblate™ Pen

Indications for use: The Cardioblate surgical ablation pen is intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.

Contraindications: The Cardioblate surgical ablation pen should not be used for patients that have active endocarditis at time of surgery.

Adverse effects: The following known adverse effects are associated with the use of the product:
- Abrasion
- Arrhythmia or EKG/ECG changes
- Burn
- Atrial lead dislodgement
- Atrioesophageal fistula
- Bleeding
- Cardiac perforation/tamponade
- Conduction disturbances (SA or AV node)
- Esophageal injury
- Pericarditis
- Electrical shock
- Infection
- Ischemia
- Organ dysfunction (cardiac)
- Extension of extracorporeal bypass
- Major complication (death)
- Mediastinitis
- Myocardial infarction in the context of cardiac ablation
- Pericarditis
- Phrenic nerve paralysis
- Perirectal
- Pleural effusion
- Pulmonary vein stenosis
- Stroke or transient ischemic attack (TIA) post-ablation
- Valgus nerve injury
- Valve leaflet damage

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

Cardioblate™ Gemini-s

Indications for use: The Cardioblate Gemini-s surgical ablation device is intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy. The system is indicated for use, under direct or endoscopic visualization, in surgical procedures, including minimally invasive surgical procedures.

Contraindications: The Cardioblate Gemini-s surgical ablation device should not be used for:
- Patients that have active endocarditis at time of surgery
- Ablation in a pool of blood (for example, through a purse string suture on a beating heart)

(Effects of this type of ablation are unknown.)

Adverse effects: The following known adverse effects are associated with the use of the product:
- Abrasion
- Arrhythmia or EKG/ECG changes
- Burn
- Atrial lead dislodgement
- Atrioesophageal fistula
- Bleeding
- Cardiac perforation/tamponade
- Conduction disturbances (SA or AV node)
- Esophageal injury
- Pericarditis
- Electrical shock
- Infection
- Ischemia
- Organ dysfunction (cardiac)
- Extension of extracorporeal bypass
- Major complication (death)
- Mediastinitis
- Myocardial infarction in the context of cardiac ablation
- Pericarditis
- Phrenic nerve paralysis

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

Cardioblate™ LP

Indications for use: The Cardioblate LP surgical ablation device is intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.

Contraindications: The Cardioblate LP surgical ablation device should not be used for:
- Patients that have active endocarditis at time of surgery
- Ablation in a pool of blood (for example, through a purse string suture on a beating heart)

(Effects of this type of ablation are unknown.)

Adverse effects: The following known adverse effects are associated with the use of the product:
- Abrasion
- Arrhythmia or EKG/ECG changes
- Burn
- Atrial lead dislodgement
- Atrioesophageal fistula
- Bleeding
- Cardiac perforation/tamponade
- Conduction disturbances (SA or AV node)
- Esophageal injury
- Pericarditis
- Electrical shock
- Infection
- Ischemia
- Organ dysfunction (cardiac)
- Extension of extracorporeal bypass
- Major complication (death)
- Mediastinitis
- Myocardial infarction in the context of cardiac ablation
- Pericarditis
- Phrenic nerve paralysis
- Pleural effusion
- Pulmonary vein stenosis
- Stroke or transient ischemic attack (TIA) post-ablation
- Valgus nerve injury
- Valve leaflet damage

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
Cardioblate ™ BP2
Indications for use: The Cardioblate BP2 surgical ablation device is intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.

Contraindications: The Cardioblate BP2 surgical ablation device should not be used for:
• Patients that have active endocarditis at time of surgery
• Ablation in a pool of blood (for example, through a purse string suture on a beating heart)
(Effects of this type of ablation are unknown.)

Adverse effects: The following known adverse effects are associated with the use of the product:
• Abrasion
• Arrhythmia or EKG/ECG changes
• Burn
• Infection
• Ischemia
• Organ dysfunction (cardiac)
• Perforation
• Tissue damage

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

ValleyLab™ FT10 Energy Platform
Indications for use: The Valleylab FT10 Energy Platform is a high frequency electrosurgical generator intended for use with monopolar and bipolar accessories for cutting and coagulating tissue. When used with compatible sealing devices, it is indicated for sealing vessels up to and including 7 mm, tissue bundles, and lymphatics. When used with compatible ablation devices it is indicated for cardiac tissue ablation. The generator can also be used with compatible resectoscopes for endoscopically controlled removal or coagulation of tissue using 0.9% NaCl solution as the irrigation medium. The tissue fusion function has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this function for these procedures.

Contraindications: The cardiac tissue ablation feature is contraindicated for patients with active endocarditis at the time of surgery. Ablation in a pool of blood is contraindicated (for example, through a purse string suture on a beating heart).

Adverse effects: The potential adverse events related to the use of ablation systems include, but are not limited to, the following risks:
• Abrasion
• Arrhythmia
• Burn
• Infection
• Ischemia
• Organ dysfunction
• Perforation
• Tingling
• Tissue damage

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

Important Safety Information
Key risks of cardiac ablation include arrhythmia, perforation, tissue burn, and organ dysfunction. For a listing of Valleylab FT10 and Cardioblate precautions, warnings, and potential adverse effects, please refer to the Instructions for Use.
For more information, contact your local Medtronic Surgical Ablation Representative.
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