Controlled heat matters.

Cardioblate™ IRF BP2 Surgical Ablation Device

Medtronic is committed to cardiac surgery and providing you with technologically advanced surgical ablation devices designed with temperature control and ease of use in mind.
Designed for easy access

Uniquely shapeable devices facilitate access to create lesions.

Cardioblate™ irrigated radiofrequency (RF) systems have been designed with maneuverability, placement, and visualization in mind, for cardiac surgery procedures on an arrested or beating heart. Our devices put you in control of your procedures by creating transmural lesions.

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.

Our bipolar clamps offer you versatility for easy access.

Cardioblate IRF BP2 and LP Bipolar Clamps

Cardioblate bipolar clamps feature rotatable jaws and flexible necks. Rotate the head of BP2 or LP devices up to 300° to facilitate placement in varying anatomies.
**Shape and ablate**

Cardioblate BP2
Irrigated RF Bipolar Clamp

**One-of-a-kind malleable jaws conform to varying cardiac anatomies.**
The Cardioblate BP2 bipolar clamp features jaws that can be shaped by hand for device placement on cardiac anatomies.

**Ergonomic handle.**
The BP2 and LP devices fit comfortably in your hands and help provide a clear line of sight.

**Malleable neck.**
Enhances maneuverability, placement, and visualization.

Cardioblate LP
Irrigated RF Bipolar Clamp

**Rigid, low-profile jaws allow access to varying anatomies.**
The Cardioblate LP bipolar clamp combines curved, low-profile jaws and an extended neck to offer navigation in tight spaces.

Cardioblate Monopolar Surgical Ablation Pens

**Linear ablation**
Our irrigated RF monopolar surgical ablation pens reach areas of the heart that are difficult to ablate with a bipolar clamp.
We offer the Cardioblate monopolar XL pens as a solution based on your procedural needs.
Controlled heat matters.

Irrigation and controlled heat make the difference.

Temperature matters. Too hot, and the tissue can be damaged and create ineffective lesions; too cool, and you can’t attain conduction block. Controlling temperatures is key to achieving conduction block.1-5

The Cardioblate™ irrigated RF surgical ablation system has features that can prevent overheating, which helps create transmural lesions. Our smart energy algorithm detects changes in the tissue and responds by increasing or decreasing power to maintain tissue in the effective heating range (Figure 1).

Irrigation cools the surface of the targeted tissue and facilitates deep energy penetration.6-8 Cardioblate iRF is the only surgical ablation system that combines a smart energy algorithm with irrigation to consistently create deep, wide lesions.
Overheating impacts lesions.

Heating tissue above 100 C may produce microbubbles and char\(^5,9\):

- Microbubbles and char are barriers to energy flow, which inhibits lesion creation.
- Overheating cardiac tissue is counterproductive – and may lead to suboptimal lesions.

50–100 C

Optimal heating range for creating transmural lesions

The optimal lesion is created in tissue temperatures of 50 to 100 C.\(^1\text{-}^5\) Only the Cardioblate™ iRF surgical ablation system has irrigation and automatic power adjustments that help maintain temperatures in this ideal range.

A mean high temperature of 70 C between the jaws of the Cardioblate bipolar device was observed during in vitro testing. Temperatures were recorded when the system indicated transmurality at an average of 16 seconds over a sample size of 90 ablations.\(^10\) Additional testing demonstrates no discernable evidence of char.\(^10\)

Test results discussed in this section may not be indicative of clinical performance.
Smart energy delivery matters.

The Cardioblate irrigated RF surgical ablation system uses a smart energy algorithm that detects changes in the tissue and responds by increasing or decreasing power. This helps prevent overheating and keeps the temperature in the optimal heating range — so you can efficiently create transmural lesions.

**Power and impedance work together.**

The Valleylab™ FT10 energy platform is now designed to operate with your Cardioblate™ surgical ablation devices. Easily connect a Cardioblate iRF bipolar clamp or a Cardioblate monopolar device to the generator for an all-in-one RF energy solution.
Ordering information

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<th>Product</th>
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<td>Cardioblate surgical ablation XL pen‡</td>
<td>49314</td>
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</tbody>
</table>

† If foot pedal operation is desired, the Ligasure LS0300 purple pedal foot switch is required for ValleyLab FT10 operation with Cardioblate devices.

‡ 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, tubing, and normal saline is required for use with all Cardioblate devices.

References

The 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 that have active endocarditis at the time of surgery. Ablation in a pool of blood is contraindicated (for example, through a purse string suture).

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.

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 (e.g., 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, electrical shock, infection, ischemia, organ dysfunction (cardiac), perforation, and tissue damage. The following are possible adverse effects related to the ablation of cardiac tissue in combination with open heart surgery: Atrial lead dislodgement, atrioesophageal fistula, bleeding, cardiac perforation/tamponade, conduction disturbances (SA or AV node), esophageal injury, 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, vagal nerve injury, and valve leaflet damage.

CAUTION: Federal law (USA) restricts these devices 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 (e.g., 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, electrical shock, infection, ischemia, organ dysfunction (cardiac), perforation, and tissue damage. The following are possible adverse effects related to the ablation of cardiac tissue in combination with open heart surgery: Atrial lead dislodgement, atrioesophageal fistula, bleeding, cardiac perforation/tamponade, conduction disturbances (SA or AV node), esophageal injury, 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, vagal nerve injury, and valve leaflet damage.

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

Cardioblate™ XL Surgical Ablation Pen
Indications for Use
The Cardioblate XL Surgical Ablation Pen is intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.

Contraindications
The Cardioblate XL 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, electrical shock, infection, ischemia, organ dysfunction (cardiac), perforation, and tissue damage. The following are possible adverse effects related to the creation of spot or linear lesions in cardiac tissue in combination with open heart surgery: Atrial lead dislodgement, atrioesophageal fistula, bleeding, cardiac perforation/tamponade, conduction disturbances (SA or AV node), esophageal injury, 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, vagal nerve injury, and valve leaflet damage.

CAUTION: Federal law (USA) restricts these devices 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, electrical shock, infection, ischemia, organ dysfunction (cardiac), perforation, and tissue damage. The following are possible adverse effects related to the creation of spot or linear lesions in cardiac tissue in combination with open heart surgery: Atrial lead dislodgement, atrioesophageal fistula, bleeding, cardiac perforation/tamponade, conduction disturbances (SA or AV node), esophageal injury, 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, vagal nerve injury, and valve leaflet damage.

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

For more information, contact your local Medtronic Surgical Ablation Representative. U.S. Customer Service 1-800-328-1357.