

Cardioblate® iRF

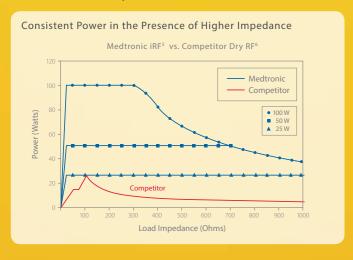
Irrigated Radiofrequency Surgical Ablation System

- Quick lesions that consistently achieve conduction block¹
- Bipolar algorithm customizes energy and confirms transmurality²
- One system for both beating and arrested heart procedures
- Options for both sternotomy and MICS procedures

iRF vs. Dry RF



RF From a More Capable Generator



With **One** Comprehensive Surgical Ablation Source, Your Choice is Clear.

Cardioblate is the innovative and comprehensive surgical ablation portfolio powered by superior energy sources offering devices that put surgeons in control of every procedure with malleability that conforms to any anatomy.

To learn more about Cardioblate surgical ablation solutions, please contact your Medtronic representative.



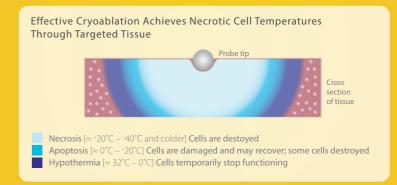


Cardioblate® CryoFlex™

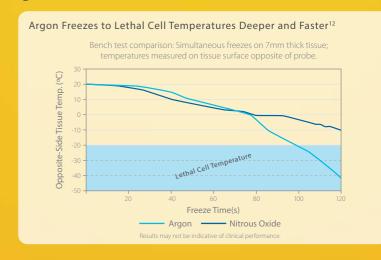
Argon-powered Surgical Ablation System

- Added safety on vulnerable tissue structures⁷
- Reproducibility of transmural lesions
- Facilitates single, right thoracotomy procedures
- Single malleable probe for all procedures

Levels of Cell Death^{8,9,10,11}



Argon vs. Nitrous Oxide





References

- 1. Premarket Notification (510(k)), K080509, Section 20.6.8, May 5, 2008. Food and Drug Administration (FDA) Center for Devices and Radiological Health.
- 2. Medtronic Animal Study on File RSCH0077: Medtronic Cardioblate BP Surgical Ablation Device Chronic Ovine Model Summary.
- 3. Erdogan A, Grumbrecht S, Neumann T, Neuzner J, Pitschner H. Microwave, irrigated, pulsed, or conventional radio frequency energy source: which energy source for which catheter ablation? PACE 2003. 26:(Pt. II):504–06.
- 4. Demazumder D, Mirotznik M, Schwartzman D. Biophysics of radiofrequency ablation using an irrigated electrode. Journal of Interventional Cardiac Electrophysiology 2001. (5): 377–89.
- 5. Cardioblate® 68000 Surgical Ablation System Technical Manual. A12265001 Rev. D. © Medtronic, Inc. 2006.
- 6. AtriCure Ablation and Sensing Unit (ASU) User's Manual. Model ASU2-115, Model ASU3-230. P000010 Rev. G. p. 23.
- 7. FrostByte Chronic Dosing Study Summary Report. Data on file. MO61 Rev-0 August 2005. CryoCath Technologies Inc. Montreal, Canada.
- 8. Baust, John G. Cryotherapeutic Intervention in Cardiovascular Disease. © Institute of Biomedical Technology, SUNY, 2002.
- 9. Gage A, Baust JM, Baust JG. Experimental cryosurgery investigations in vivo. Journal of Society for Cryobiology 2009. Vol 59: 3; 229–43.
- 10. Aoyama H, Nakagawa H, Pitha J, et al. Comparison of cryothermia and readiofrequency current in safety and efficacy of catheter ablation within the canine coronary sinus close to the left circumflex coronary artery. J Cardiovasc Electrophysiol 2005. Vol. 16:1218-26.
- 11. Gage AA, Baust J. Review Mechanisms of Tissue Injury in Cryosurgery. Cryobiology Vol. 37; pp. 171-86. State University of New York, Binghamtom, NY. @1998 Academic Press.
- 12. Medtronic in vitro test data on file. Bench test comparison between Cardioblate® CryoFlex™ probe to AtriCure Cryo 1™ probe on 7mm thick porcine tissue. Both devices performed simultaneous freeze upon tissue, while recording temperatures on the surface opposite of probes.

LP and BP2 (Bipolar Clamp)

Indications for Use: is intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.

- Contraindications: The Cardioblate LP and BP2 Surgical Ablation Device should not be used for:
- Patients that have active endocarditis at the 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.

Gemin

Indications for Use: is intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.

- Contraindications: The Cardioblate Gemini Surgical Ablation Device should not be used for:
- Patients that have active endocarditis at the time of surgery
- $\bullet \, \text{Ablation in a pool of blood (e.g., through a purse string suture on a beating heart).} \, \text{Effects of this type of ablation are unknown.}$

en/XL Pen

Indications for Use: 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 the time of surgery.

MAPS

Europe

Indications for Use: The Cardioblate® MAPS Surgical Mapping, Ablation, Pacing, and Sensing Device is a sterile, single use electrosurgery device intended to ablate cardiac tissue using radiofrequency energy when connected to the Cardioblate® 68000 Generator or for temporary cardiac pacing, sensing, recording, and stimulation during the evaluation of cardiac arrhythmias during surgery when connected to an external temporary cardiac pacemaker. Contraindications: The Cardioblate MAPS Mapping, Ablation, Pacing and Sensing Device should not be used for patients that have active endocarditis at the time of surgery.

Cardioblate® 68000 iRF Generator

www.medtronic.com

Medtronic International Trading

Route du Molliau 31

CH-1131 Tolochenaz

www.medtronic.eu

Tel: +41 (0)21 802 70 00

Fax: +41 (0)21 802 79 00

Case postale

The Cardioblate® Surgical Ablation System is intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy. To avoid the risk of electrical shock and/or burns to the patient, do not touch the patient while touching the outer housing or connections on the Cardioblate generator. Do not allow the patient to come into contact with the grounded metal surfaces during RF energy delivery. 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.

Potential Complications: Possible complications related to the ablation of cardiac tissue in combination with open heart surgery are: tissue perforation, extension of extracorporeal bypass, perioperative heart rhythm disturbances (atrial and/or ventricular), postoperative embolic complications, pericardial effusion or tamponade, injury to the great vessels, valve leaflet damage, conduction disturbances (SA/AV node), acute ischemic myocardial event, thrombus formation. Refer to Instructions for Use which accompany each product.

United Kingdom/Ireland

Croxley Green Business Park

Medtronic Limited Building 9

Hatters Lane

Herts WD18 8WW

www.medtronic.co.uk

Tel: +44 (0)1923 212213 Fax: +44 (0)1923 241004

Watford

The Cardioblate CryoFlex Surgical Ablation System

Indications for Use: is intended for minimally invasive cardiac surgical procedures, including the treatment of cardiac arrhythmias. 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 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.

- Avoid contact between the cryoablation probe and the phrenic nerve to avoid injury. Perioperative heart rhythm disturbances (atrial and/or ventricular)
- Cryosaltation involving coronary vessels has been associated with subsequent clinically significant arterial stenosis. It is unknown
 whether Cryosaltation with the Cardioblate 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 Cryosaltation.

For a complete listing of all indications, contraindications, precautions and warnings, please refer to the Instructions for Use which accompany each product.

Cardioblate is a registered trademark of Medtronic, Inc.

Gemini and CryoFlex are trademarks of Medtronic, Inc.



Medtronic Cardioblate

cardiobiat

SURGICAL ABLATION SYSTEMS

