FrostByte® Clamp & SurgiFrost® CryoSurgical Probe

Instructions For Use

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Made in Canada

CAUTION: Federal (USA) law restricts this device to use by or on the order of a physician (or properly licensed practitioner).

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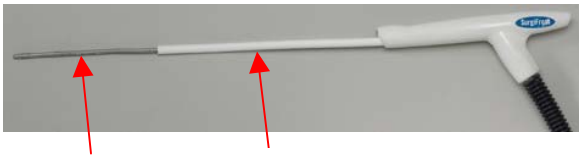
Device Description

The SurgiFrost CryoSurgical Probe (referred to as "the probe" throughout this document) is a single use, disposable cryoprobe that is designed for use with the SurgiFrost Surgical CryoAblation System. The probe has an integrated thermocouple for monitoring temperature at its ablation segment. The probe (shown below) is supplied sterile and cannot be reused or re-sterilized.



Ablation segment is the ribbed portion of the shaft

White insulated sleeve moves up and down the shaft to adjust the length of the freeze zone

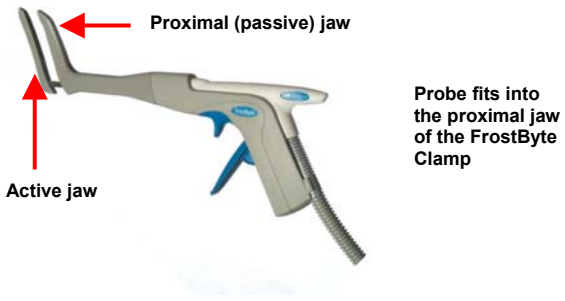
The probe's shaft and ablation segment are made of specially heat-treated stainless steel. The shaft was designed with enough malleability that the surgeon can easily shape it, while still maintaining enough stiffness to ensure its stability in the operating field.

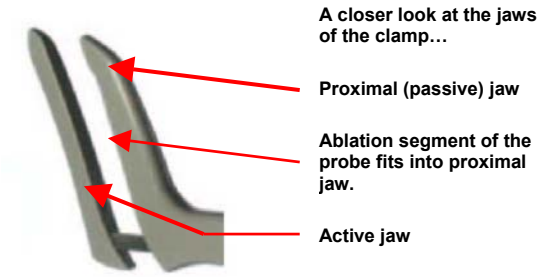
The 70 mm malleable ablation segment has a bellows configuration, which provides superior kink resistance and thermal performance. A movable insulated sleeve on the shaft allows the surgeon to vary the size of the ablation zone up to 70 mm.

The probe has a 3 m (10 ft) connection hose which is to be handed out of the sterile field to an operating room nurse for connection to the control panel. Note that once the probe is connected to the control panel, it should not be disconnected until the end of the procedure because it cannot be reconnected. The probe is disabled once it is disconnected.

The FrostByte Clamp (shown below) is specially designed to work with the SurgiFrost 7 cm probe in order to allow clamping of tissue.

The shaft and ablation segment of the probe is inserted into the FrostByte Clamp so that the probe's ablation segment fits inside the proximal jaw of the clamp.





The FrostByte Clamp has two jaws that can be opened and closed by squeezing and releasing the trigger. The probe fits inside the proximal ("passive") jaw. The other jaw is the "active jaw".

When the FrostByte Clamps is assembled with the probe, the temperature reading on the control panel screen will be the temperature of the probe.

Indications for Use

The SurgiFrost Surgical CryoAblation System is indicated for use in the cryosurgical treatment of cardiac arrhythmias. The probe freezes the target tissue and blocks the electrical conduction pathway by creating an inflammatory response or cryonecrosis.

Contraindications

There are no known contraindications for the use of this device.

Warnings

- Do not insert the SurgiFrost CryoSurgical Probe inside a beating heart. If a breach occurs in the probe inside a beating heart, this may result in severe injury or death to the patient.
- Do not pull on the SurgiFrost CryoSurgical Probe, Clamp or console while its ablation segment is frozen to tissue as this could lead to inadvertent tissue damage.

- Do not use excessive application force when using the SurgiFrost CryoSurgical Probe in order to avoid tissue damage.
- Surgical probe and clamp procedures may mechanically induce arrhythmias
- The SurgiFrost CryoSurgical Probe should be positioned correctly and the placement of the ablation segment confirmed prior to CryoAblation. Ensure that tissue adjacent to the probe or below the targeted zone, that is not intended to be ablated, is protected from freezing. This avoids inadvertent lesion creation.
- The SurgiFrost CryoSurgical Probe contains pressurized refrigerant during operation. Discontinue treatment immediately if a breach in the probe is suspected, as this may result in release of pressurized gas and injury to the patient or the user.
- If an unanticipated event occurs, the injection of refrigerant can be stopped at any time by pushing the Stop Freeze button on the control panel or by pressing the foot switch.
- Do not attempt to disconnect the probe during operation in the freeze mode as the sudden release of pressure may cause the probe to recoil, which may injure the operator. The system must be vented prior to disconnecting the probe.

Cautions

- Only appropriately trained personnel in a fully equipped facility should perform cardiac CryoAblation procedures.
- Do not re-sterilize or re-use the SurgiFrost CryoSurgical Probe or FrostByte Clamp under any circumstances. The SurgiFrost CryoSurgical Probe and FrostByte Clamp are designed for single use only.
- Discard all used SurgiFrost CryoSurgical Probes and FrostByte Clamps in accordance with hospital procedures.
- Prior to removing the SurgiFrost CryoSurgical Probe and FrostByte Clamp from their packaging, inspect the packaging to verify the integrity of the seal. Use sterile techniques when handling the product.
- Ensure that equipment used with the SurgiFrost Surgical CryoAblation System is electrically safe and does not expose the patient to hazards.
- Ensure that all pressure and regulator lines are securely connected.
- Always turn off the main gas cylinder valve prior to venting the inlet pressure line to ensure that excess pressure is safely vented.
- Prior to using the FrostByte Clamp and probe on the patient, test the clamping mechanism to ensure that it is operational.
- Do a test injection before placing the SurgiFrost CryoSurgical Probe on tissue to be ablated.
- CryoAblation involving coronary vessels has been associated with subsequent clinically significant arterial stenosis. It is unknown whether Cryoablation with the SurgiFrost CryoSurgical Probe or FrostByte Clamp will have such an effect, but as in all such procedures, care should be taken to minimize unnecessary contact with coronary vessels during CryoAblation.
- Do not use SurgiFrost CryoSurgical Probes or FrostByte Clamps that are damaged in any way.
- If using the FrostByte Clamp in a procedure, it is highly recommended that you do not disassemble the probe from the clamp until AFTER you have finished using the clamp. It is difficult to reassemble and has not been tested for such an application.
- Do not expose the probe, clamp, accessories, or electrical connectors to cleaning fluids or solvents.
- Follow standard guidelines for the safe handling and storage of high-pressure gas cylinders.
- The SurgiFrost Surgical CryoAblation System meets the requirements of Underwriters Laboratories (UL). It is the user's responsibility after installation to verify and ensure that the system meets the applicable electrical safety requirements with respect to electric shock, fire and mechanical hazards only in accordance with UL 2601-1 & CAN/CSA C22.2 No 601.1.When setting up the foot switch, make sure to place it in a location where it will not be inadvertently activated.
- Do not disconnect the probe from the control panel until the procedure is finished. Once the pin has been pulled out, you cannot reconnect the probe.

How Supplied

The SurgiFrost CryoSurgical Probe and FrostByte Clamp are supplied sterile and packaged assembled.

How to Connect

Refer to the Operator's Manual for the SurgiFrost Surgical CryoAblation System for detailed instructions about connecting the probe to the console.

Directions for Use

IMPORTANT!

- Refer to the Operator's Manual for the SurgiFrost Surgical CryoAblation System for detailed instructions.
- Refer to the warnings and precautions at the beginning of this document.

1. All ablation procedures must be performed in a fully equipped operating room.
2. Prior to placing the probe and clamp assembly on tissue to be ablated, test the probe by pressing the **Start Freeze** button on the console for at least 2 seconds while the probe is in the air with the jaws, opened or closed.
3. Place the ablation segment of the probe on tissue to be ablated and close the clamp. Ensure that adjacent and sub adjacent tissue is protected to avoid inadvertent freezing.
4. After completing the ablation, wait until the temperature reading on the control panel is above 0°C before releasing the locking mechanism of the FrostByte Clamp.
5. When you have finished using the clamp, you can remove the probe from the clamp and use the probe alone, as described in the next steps.

   Tip: If using the FrostByte Clamp in a procedure, it is highly recommended that you do not disassemble the probe from the clamp until AFTER you have finished using the clamp, because it is difficult to reassemble.

6. When the probe warms up, manipulate the ablation segment and shaft into the desired shape. You can straighten and bend them as needed although, to ensure optimal probe performance, manipulate only to the extent needed to achieve the appropriate shape. Avoid excessive bending of the ablation segment and the probe shaft. Avoid bending the ablation segment, when it is covered by the insulating sleeve. Always pull away the insulating sleeve prior to bending the ablation segment.
7. The length of the probe's freeze zone is variable up to 70 mm, depending on the placement of the insulated sleeve. Adjust the length of the freeze zone by manually moving the insulated sleeve up and down the shaft to expose more or less of the freeze zone.
8. Prior to ablating tissue, set the desired time and temperature for the ablation on the control panel.
9. Place the ablation segment of the probe onto the tissue to be ablated and ensure that adjacent and sub adjacent tissue is protected to avoid inadvertent freezing.

Initiation and Completion of Freeze

1. A freeze is initiated by pressing the green **Start Freeze** button on the control panel for approximately 2 seconds.
2. Freezing ends automatically at the end of the preset freeze duration.Freezing can be terminated prior to the preset time by pressing the red **Stop Freeze** button on the control panel.
3. The freeze duration depends on the clinical situation and whether the FrostByte Clamp is being used.

Note: When the FrostByte clamp is used, the freezing originates at the passive jaw and goes through the tissue to the active jaw.

Symbols Used

	Expiration date		Protect from elements
LOT	Lot number		This side Up
REF	Reference number	0°C 32°F	Store above 0°C/32°F
	Single-use		Recyclable packaging
	Consult Instructions for Use	STERILE R	Sterilized by radiation
	Fragile		