

Maverix CryoBiopsy Probe

Instructions for Use

Rx ONLY

Warning: The MCB Probe may only be used by a qualified medical professional who has been trained in its use.

Table of Contents

1.	Device Description	3
2.	Indications for Use	3
3.	Compatibility	3
4.	Recommended Operating Conditions	3
5.	Contraindications	3
6.	Warnings	4
7.	Caution	5
8.	Device Components And Specifications	6
9.	How It Is Supplied	9
10.	Materials and Accessories Required	9
11.	Directions for Use	9
11.1.	Device Preparation	9
11.2.	Inspect for Damage and Functionality	11
11.3.	Inserting and Positioning Probe	13
11.4.	If Devitalizing Tissue	13
11.5.	If Removing a Tissue Sample or Foreign Object, Recanalization via Tissue Extraction.....	14
11.6.	Loading a Spare Refrigerant Cartridge	16
11.7.	Disposal	18
12.	Storage	18
13.	Glossary of Symbols	19
14.	Further Information	20

1. DEVICE DESCRIPTION

The Maverix CryoBiopsy (MCB) Probe is a sterile, single-use flexible cryoprobe used in interventional endoscopic procedures compatible with commercial access instruments (including endoscopes and bronchoscopes). The MCB Probe has a cryoprobe tip length that is user adjustable, with a setting of either short (approximately 3mm) or long (approximately 6mm). The MCB probe has an inline handle connected by a flexible tube to a single-use disposable N₂O refrigerant cartridge for its cryogenic function.

2. INDICATIONS FOR USE

The Maverix CryoBiopsy (MCB) Probe is intended for palliative devitalization (destruction) of tissue during interventional procedures by the application of extreme cold and cryo-adhesion for applications such as the removal of foreign bodies, mucus plugs, blood clots, necrotic tissue, tissue tumors (palliative recanalization) and tissue biopsies.

3. COMPATIBILITY

The Maverix CryoBiopsy (MCB) Probe is compatible with commercial access instruments (including endoscopes and bronchoscopes) with a minimum working channel inner diameter (ID) of 2mm .

The Maverix CryoBiopsy (MCB) Probe is compatible with only the Maverix single-use disposable N₂O refrigerant cartridge (Cryo Cartridge CC-1000).

4. RECOMMENDED OPERATING CONDITIONS

Recommended operating temperature: 64°F to 77°F (18°C to 25°C)

Recommended operating relative humidity: 30% to 75%

5. CONTRAINDICATIONS

In pulmonology, the following is a known contraindication during recanalization using devitalization of tissue:

Life-threatening obstruction of the respiratory tract and impending respiratory failure as a result of stenosis of the respiratory tract. The contraindication is due to the fact that as a result of the devitalization of tissue, immediate recanalization is not achieved.

6. WARNINGS

1. This product may only be operated by medical professionals who have been trained in its use.
2. Do not use for any purpose other than the intended use.
3. The effect of the cold can disrupt or damage cardiac pacemakers, internal defibrillators and other active implants. In the case of patients wearing active implants, consult the manufacturer of the implant prior to use.
4. Before use, visually inspect the MCB Probe's packaging for damage. Do not use if the sterile barrier is damaged as the contents may no longer be sterile.
5. Before use, visually inspect the MCB Probe, including all included components, to verify that no damage has occurred prior to use. Do not use a damaged MCB Probe.
6. Do not use a product that is not leak-tight or a product with inadequate freezing capacity. There is a risk that a patient or operator injury could develop if the instrument leaks.
7. Use only in environments with proper ventilation. The device should be used in procedure rooms meeting ASHRAE Standard 170-2021 ventilation requirements for endoscopy suites (minimum 6 ACH total air changes).
8. Tissue contact or sampling with this device may result in contamination or spread of pathological materials.
9. Do not modify the MCB Probe. Doing so may cause damage and may compromise device and patient safety.
10. The MCB Probe is supplied sterile and should be used by the "Use By" date on the device package. Do not use the device if past the "Use By" date.
11. The MCB Probe contains a retractable pointed tip at its distal end. Handle the MCB Probe with care when the pointed tip is not in its sheath.
12. For single use only. Do not resterilize, reuse or reprocess. Doing so may compromise functionality, resulting in patient injury.
13. Do not modify the device. The device has only been tested in the configuration supplied.
14. Use imaging modality such as fluoroscopy to visualize the MCB Probe during advancement and positioning.
15. Do not use with any refrigerant cartridges other than the Cryo Cartridge CC-1000. Doing so may compromise functionality resulting in patient or user injury.
16. Do not use excess force to pull sample into the access device working channel. Doing so can damage the MCB Probe. For samples that are large or difficult to remove, consider removal of MCB probe en bloc with the access device.

17. When positioning the cryotip, never apply excessive force to the product as this could result in damage to the product or patient.
18. At the cryotip, a freeze zone with temperatures significantly lower than 32° F (0° C) is established on activation of the freezing function. Avoid unintentional tissue contact.
19. Application of cryosurgical tools near blood vessels or vulnerable tissues may lead to bleeding, inflammation, tissue injury or tissue perforation. Additional interventions may be required to address tissue injuries, such as pneumothorax or bleeding.
20. Application of cryosurgical tools may result in tissue scarring, stenosis or functional impairment.
21. After use, this device is a biohazard. Handle and dispose of in accordance with hospital, administrative, and/or local government agency.
22. Prior to disposal, release the residual pressure inside refrigerant cartridge by partially unscrewing the Cryo Cartridge from the holder.

7. CAUTION

1. When operating, always wear appropriate personal protection equipment as blood, mucous, and other infectious material from the patient could pose an infection risk.
2. Prior to use, ensure that the work area is clear of obstructions that can entangle the extension line.
3. The refrigerant cartridge and the cartridge holder are non-sterile. After handling these components, disinfect hands appropriately prior to working with sterile portions of the MCB Probe.
4. The cartridge holder must be suspended in a vertical position for the MCB Probe to function correctly. If the cartridge holder is not vertically positioned, the probe may not function correctly.
5. When inserting the MCB Probe into the working channel of the access device, ensure that the Freeze button is in the **Off** position, that no tissue remains attached to the probe tip, and that the tip is sheathed and locked.

8. DEVICE COMPONENTS AND SPECIFICATIONS

Model names:	MCB Probe Cryo Cartridge
SKUs:	MCB-1000 CC-1000
Package contents:	MCB Probe (sterile) Biopsy scraper (sterile)
Required accessories:	Cryo Cartridge (non-sterile, separate package of 4)
Cryoprobe tip configuration:	Pointed, retractable, adjustable length
Cryoprobe tip outer diameter:	0.8 mm
Cryoprobe tip length:	User selectable: • Sheathed (retracted) • Short (approximately 3 mm) • Long (approximately 6 mm)
Shaft / sheath outer diameter:	1.3 mm
Working length:	115 cm (3.7 ft)
Radiopacity:	Cryoprobe tip and distal 6 mm of sheath
Extension line – length:	152 cm (5 ft)
Sterilization:	Radiation
Refrigerant type:	Nitrous oxide (N ₂ O) gas cannister, 14 g
Nominal endurance:	Approximately 160 seconds total freeze time, 80 seconds per cartridge
Working channel compatibility:	2 mm or larger inner diameter

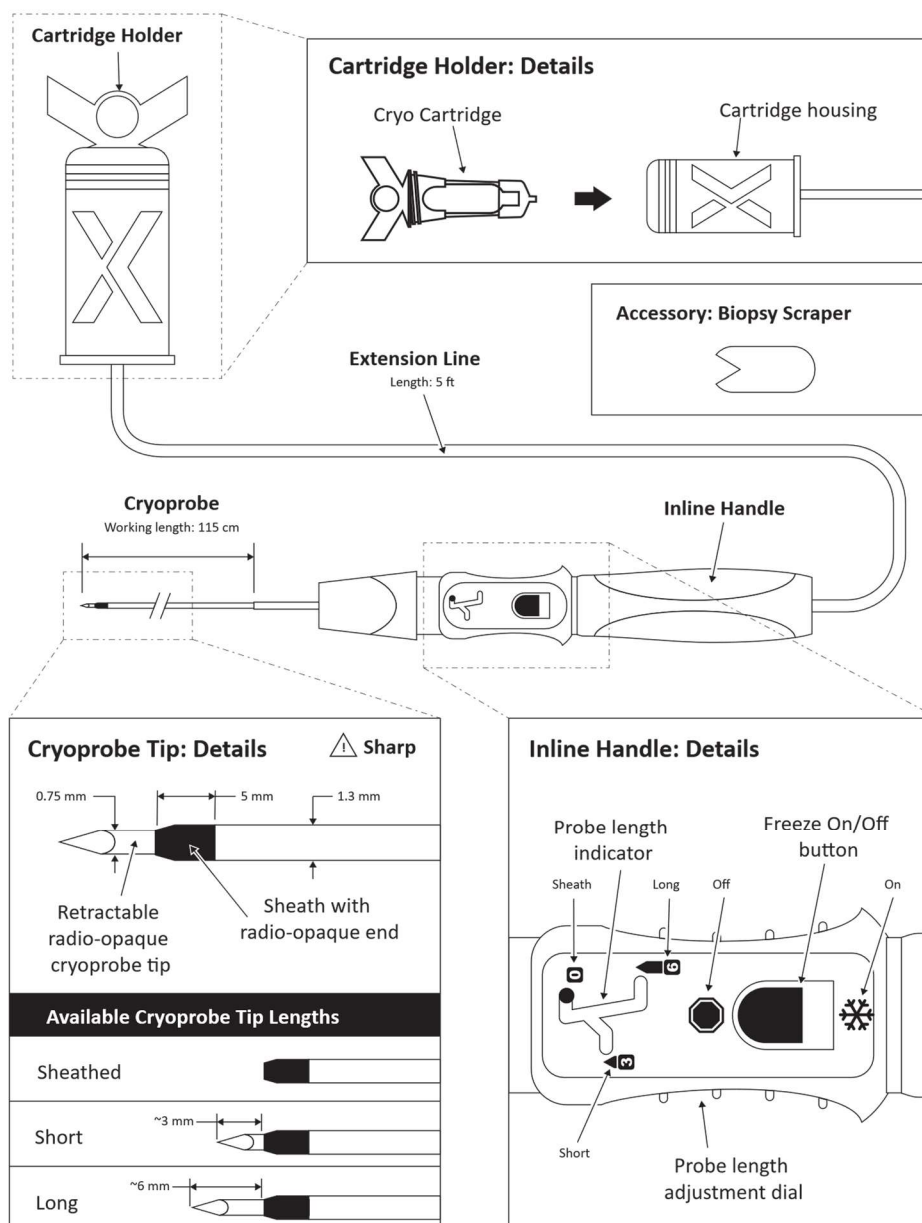


Table 1 - MCB Probe Component Description

Component	Description
Biopsy scraper	Accessory to facilitate removal of biopsy sample from cryoprobe tip.
Cartridge holder	Contains refrigerant cartridge during use, allows for vertical suspension of cartridge, available in a separate non-sterile package.
Cryoprobe	Representing the entire working length of the MCB Probe, comprising of the shaft, the sheath and the retractable cryoprobe tip.
Extension line	Connects cartridge holder to the cryoprobe, supplies the probe with refrigerant and evacuates exhaust gas back to the cartridge holder.
Freeze On/Off button	Controls the flow of refrigerant.
Inline handle	Provides gripping surface to stabilize the device, allows for the advancing and retracting of the cryoprobe within the access device, and provides access to freeze on/off button.
Probe length adjustment dial	Controls the extension and retraction of the cryoprobe tip from/into the sheath. It has 3 settings: Sheath (complete retraction), "Short" (~3 mm) and "Long" (~6 mm).
Probe tip length indicator	Indicates the length of the current cryoprobe and how to maneuver the probe length adjustment dial to reach the other length presets.
Retractable cryoprobe tip	Sharp tip that reaches cryogenic temperatures for cryobiopsy, its extension from and retraction into the sheath is controlled by the probe length adjustment dial.
Sheath	Houses the retractable cryoprobe tip, has a radiopaque distal end.
Cryo Cartridge	Contains refrigerant cartridge. Provides features to connect refrigerant cartridge to cartridge holder. (not sterile).

9. HOW IT IS SUPPLIED

The following components are supplied sterile with peel-off labels to facilitate device traceability:

MCB Probe

Biopsy Scraper

The following components are supplied non-sterile and separately:

Cryo Cartridge

In the event of damage or irregularities to the MCB Probe or its packaging, do not use the product and replace prior to use.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Do not use device if past the “Use By” date.

10. MATERIALS AND ACCESSORIES REQUIRED

IV pole or equivalent to suspend cartridge holder vertically when in use.

11. DIRECTIONS FOR USE

Please thoroughly review these instructions and all accessory equipment to be used in the procedure prior to using the MCB Probe. Observe all warnings, cautions, and notes in these instructions. Failure to do so may result in patient complications. Use only with access devices with compatible working channels (minimum ID: 2 mm), in accordance with the instruction manual.

If you have any questions about the contents of this manual, please contact your Serpex Medical representative.

Keep track of freeze time while using the MCB Probe and discontinue use of Cryo Cartridge after 80 seconds of total freeze time. Probe freeze performance may be reduced after 80 seconds of freeze time per Cryo Cartridge.

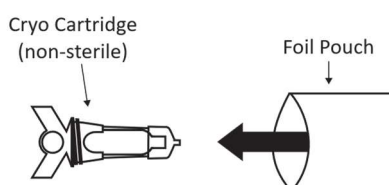
11.1. Device Preparation

1. Check labeling of MCB Probe and Cryo Cartridge to ensure both are within their expiration date.

2. Ensure that the work area is clear of obstructions that can entangle the extension line.
3. Inspect the MCB Probe and its packaging for any signs of damage.
4. Inspect the Cryo Cartridge and its packaging for any signs of damage.

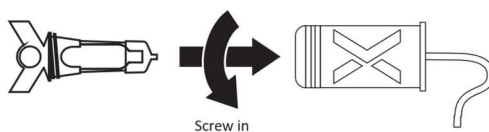
⚠ **Warning:** Do not use if the MCB Probe or the Cryo Cartridge if the packaging is damaged.

5. Remove the non-sterile Cryo Cartridge from its foil pouch and set aside. A small bag of desiccant inside of pouch may be disposed with opened pouch.



6. Using sterile technique, remove MCB Probe from packaging and pass cartridge housing outside of sterile field.
7. Outside of the sterile field, screw the Cryo Cartridge into the cartridge housing until a hard stop is felt.

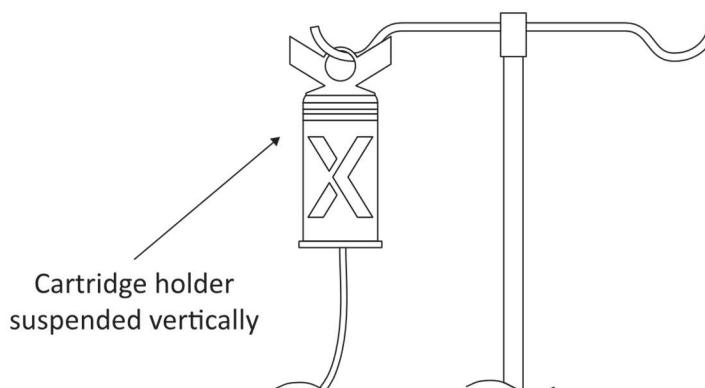
💡 **Note:** Always completely screw in the Cryo Cartridge. Do not leave the Cryo Cartridge only partially screwed in. Do not attempt to unscrew the Cryo Cartridge once it has been partially screwed in. Otherwise, refrigerant will be lost and will shorten the MCB Probe freeze time.



8. Suspend the cartridge holder vertically from an IV pole or equivalent outside of the sterile field. Ensure that the extension line is pointing downwards.

⚠ **Warning:** If the cartridge holder is not suspended in a vertical position, the refrigerant will not flow correctly to the cryoprobe and the MCB Probe performance will be compromised.

⚠ **Warning:** Cartridge holder manipulations are performed outside the sterile field. Please follow disinfection and sterile technique as per institutional policies before proceeding with the use of the MCB Probe.



11.2. Inspect for Damage and Functionality

⚠ **Warning:** the next steps are to be performed in a sterile field. Please follow disinfection and sterile technique as per institutional policies.

1. Remove inline handle, cryoprobe, and scraper from packaging tray.
2. Inspect the MCB Probe for any signs of damage.

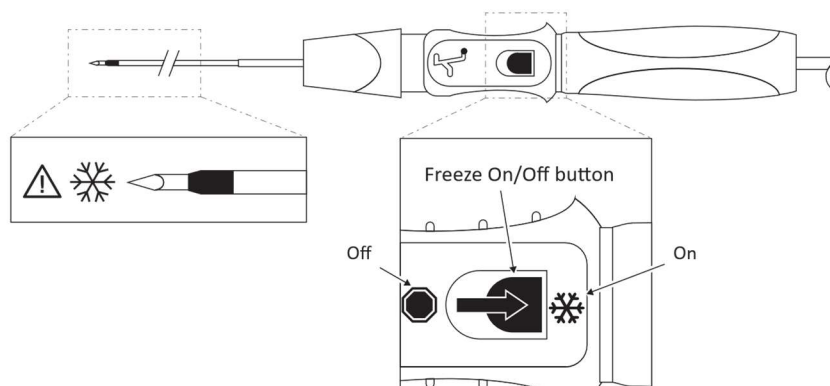
⚠ **Warning:** Do not use if the MCB Probe is damaged.

3. Twist and slide the *probe length adjustment dial* to the **Long** position. Ensure that the *probe length indicator* is **Locked**.

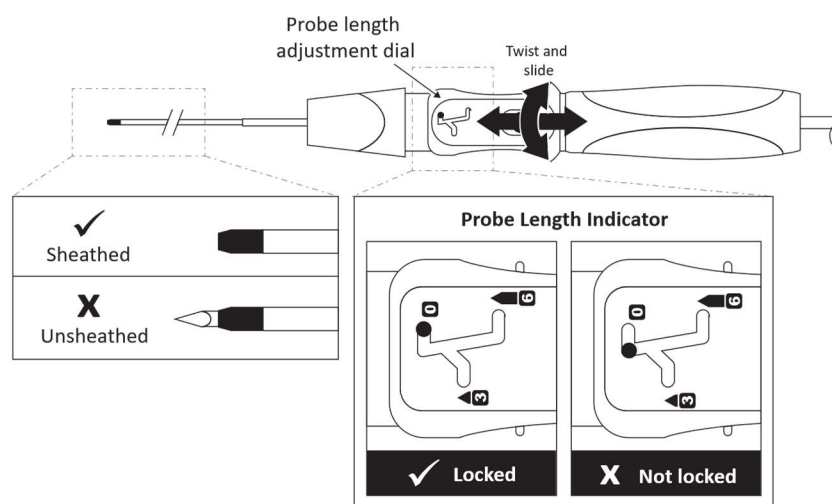
		Probe Length Indicator	
Cryoprobe Tip		✓ Locked	✗ Not locked
Short ~3 mm			
Long ~6 mm			

4. Immerse the tip to a depth of at least 1" (2.5cm) in sterile water or saline.
5. Turn on the Freeze button for 4 to 7 seconds to confirm that the MCB Probe is in working order. An audible signal should be emitted from the cartridge housing near the extension line to indicate refrigerant flow and a ball of ice must form at the tip of the device. Gas bubbles must not escape from the tip under any circumstance. If no audible signal can be heard, no ice is visible, or bubbles are escaping, replace the MCB Probe and Cryo Cartridge.

- 💡 **Note:** To turn on the Freeze button, pull *Freeze On/Off button* proximally. The button will latch in **On** position. To turn off the Freeze button, push the *Freeze On/Off button* distally to its **Off** position. The button will latch in **Off** position.



- ⚠ **Warning:** Avoid contact with the distal tip when the Freeze button is turned on, as the tip will reach cryogenic temperatures.
- ⚠ **Warning:** If the device does not pass the inspection, it is possible that a gas leak is present. If the device is used it can result in gas embolism and patient harm.
6. Turn off the Freeze button and allow any ice formation to fully melt. The MCB Probe is now ready for use.
- 💡 **Note:** To turn off the Freeze button, push the *Freeze On/Off button* distally to its **Off** position.
7. Twist and slide the *probe length adjustment dial* to the **Sheath** position. Ensure that the *probe length indicator* is in the **Locked** position. Visually verify that the tip is entirely covered by the sheath. If tip is visible outside of sheath, replace the MCB Probe.
- ⚠ **Warning:** Failure to sheath the MCB Probe tip could leave the pointed cryoprobe tip exposed during insertion into the access device working channel, causing damage to access device or probe.



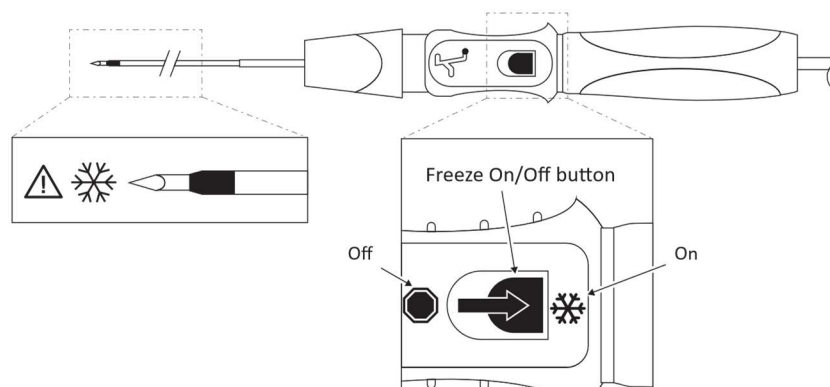
11.3. Inserting and Positioning Probe

1. Insert the sheathed MCB Probe into the working channel of the access device.
 - 💡 **Note:** Prior to insertion, ensure that the Freeze button is turned off. Otherwise, cryoprobe tip might stick to the inside of working channel.
2. Position the cryoprobe sheath in front of target tissue or foreign object using either endoscopic visual inspection, robotic navigation or fluoroscopy.
3. Ensure the sheath tip is at least 0.4 inches (1cm) from sensitive structures (such as pleura or blood vessels) to avoid tissue damage upon tip exposure.
4. Use the *probe length adjustment dial* to advance the cryoprobe tip. The exposed length is shown by the *probe length indicator*. The **Short** setting will expose approximately 3 mm of the cryoprobe tip. The **Long** setting will expose approximately 6 mm of the cryoprobe tip.
 - ⚠ **Warning:** For each length setting, ensure that the *probe length adjustment dial* is in the **Locked** position. Otherwise, the probe tip might move relative to the sheath during subsequent maneuvers.
5. Using the appropriate imaging modality for guidance, confirm that the probe tip is in the correct position prior to cryoprobe activation.

11.4. If Devitalizing Tissue

- ⚠ **Warning:** The devitalization result depends on multiple factors such as the characteristics of the target tissue, the activation time, moisture content, and the contact pressure.

1. Turn on the freeze button by pulling the *Freeze On/Off button* proximally. The button will latch onto its **On** position. An audible signal should be emitted from the cartridge holder to indicate refrigerant flow.



2. Allow the probe to dwell in the target area until devitalization has occurred.
3. When the tissue has been devitalized, turn off freeze function by pushing Freeze On/Off button distally
4. Carefully remove the probe from the access device. When the cryoprobe has thawed completely it can be removed with little force. Do not use excess force which might damage the probe.

11.5. If Removing a Tissue Sample or Foreign Object, Recanalization via Tissue Extraction

⚠ Warning: the biopsy size depends on multiple factors such as the characteristics of the target tissue, the activation time, moisture content, and the contact pressure.

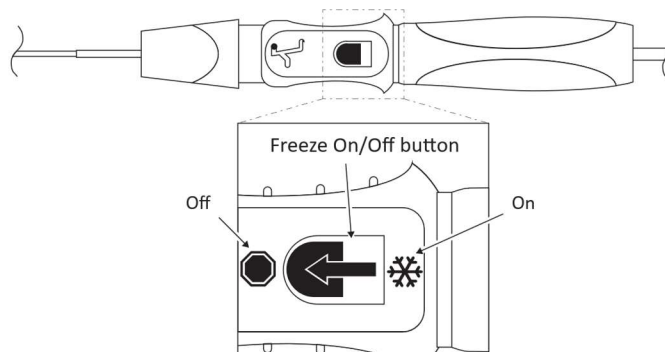
💡 Note: The biopsy sample size can be controlled via the activation time.

1. Turn on the freeze button by pulling the *Freeze On/Off button* proximally. The button will latch onto its **On** position. An audible signal should be emitted from the cartridge holder to indicate refrigerant flow.
2. Allow the probe to dwell in the target area. Adjust the duration as required depending on the size of the desired sample and nature of the tissue.
3. To extract the tissue, hold onto the inline handle and/or the proximal portion of the probe as well as endoscope and/or access catheter and remove from the patient.

⚠ Warning: Do not force a sample into the working channel of the access device. Doing so will damage the MCB Probe or the access device.

💡 Note: The Freeze button must be left on during sample retrieval to ensure continuous adhesion of the biopsy sample to the probe tip.

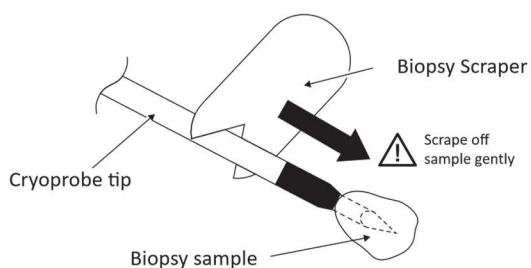
- Deactivate the Freeze button by pushing distally the Freeze On/Off button.



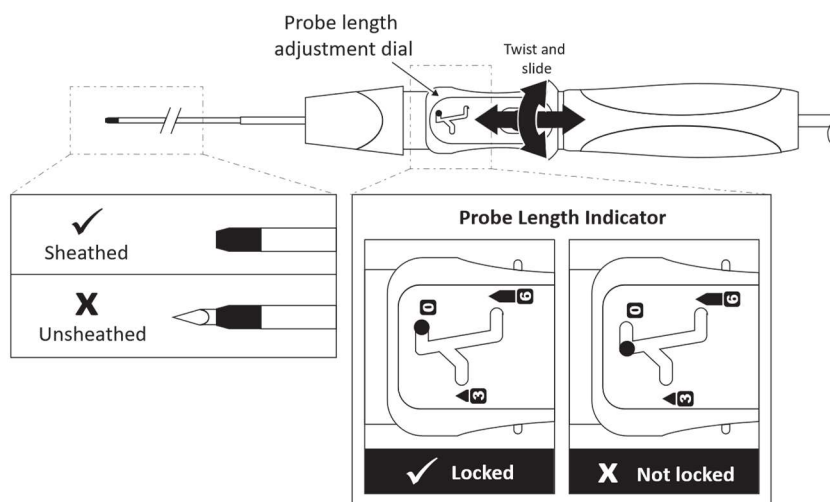
- Allow the instrument to thaw completely (e.g. dipped in a biopsy sample container filled with liquid)
- Use the provided sample scraper tool to gently remove the biopsy sample from the MCB Probe tip.

⚠ Warning: Do not use excess force, which might damage the probe.

💡 Note: Additional wait time might be required for the sample to thaw sufficiently for successful removal.



- Set the *probe length adjustment dial* to the **Locked Sheath** position and visually verify that the tip is entirely covered by the sheath.



The MCB Probe is now ready to retrieve the next sample.

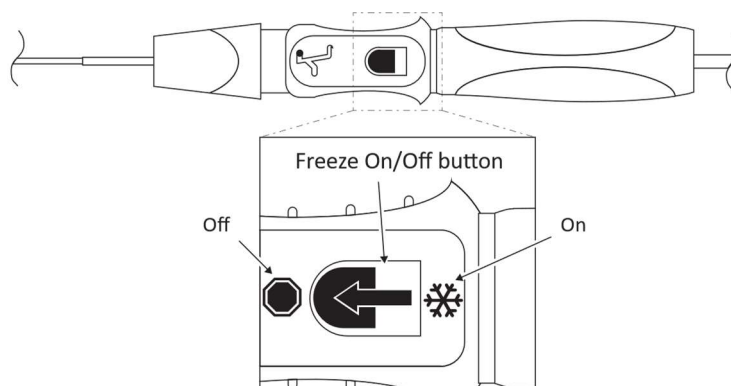
 **Note:** The MCB Probe with a new refrigerant cartridge has a nominal endurance of approximately 80 seconds of freeze time.

11.6. Loading a Spare Refrigerant Cartridge

The MCB Probe can be reloaded once with a spare refrigerant cartridge.

 **Warning:** Do not reload the MCB Probe more than once, for a total of two refrigerant cartridges. Otherwise, the probe might perform unpredictably, leading to user or patient injury.

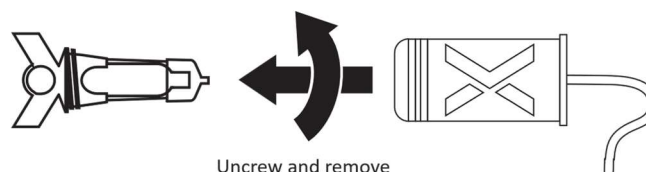
- Ensure that Freeze button is **Off** by pushing distally the *Freeze On/Off button*. There should not be an audible signal.



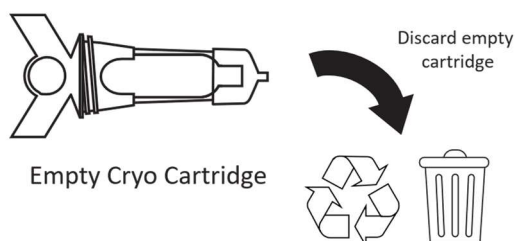
2. Outside of the sterile field, unscrew the Cryo Cartridge approximately one full rotation. Any remaining pressurized refrigerant will vent out.

⚠ **Warning:** Allow all refrigerant to vent before fully removing Cryo Cartridge from cartridge housing.

3. Fully unscrew and remove Cryo Cartridge.



4. Discard empty Cryo Cartridge following institutional policies.

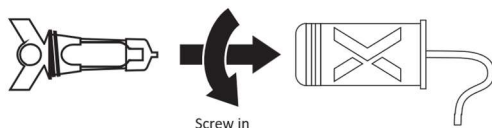


5. Open a new Cryo Cartridge and screw into the cartridge holder until a hard stop is felt.

💡 **Note:** Additional cartridges can be obtained from your Serpex Medical representative.

⚠ **Warning:** Always completely screw in the Cryo Cartridge. Do not leave the Cryo Cartridge only partially screwed in. Do not attempt to unscrew the Cryo Cartridge once it has been

partially screwed in. Otherwise, refrigerant will drain out and shorten the MCB Probe endurance.



6. Suspend the cartridge holder vertically. Proceed to Section 11.2.

⚠ **Warning:** Cartridge holder manipulations are performed outside the sterile field. Please follow disinfection and aseptic techniques as per institutional policies before proceeding with further use of the MCB Probe.

11.7. Disposal

1. Partially unscrew the Cryo Cartridge to release any remaining refrigerant.

⚠ **Warning:** Always release remaining refrigerant prior to disposal.

2. Dispose the used MCB Probe as per institutional policy.

⚠ **Warning:** Do not reuse. Do not resterilize.

12. STORAGE

The MCB Probe should be stored in its original packaging prior to use. Store in a cool dry place, per standard hospital procedures.

13. GLOSSARY OF SYMBOLS

Symbol	Description	Reference	Symbol	Description	Reference
	Manufacturer	ISO 15223-1; 5.1.1		Do not resterilize	ISO 15223-1; 5.2.6
	Single Sterile barrier system	ISO 15223-1; 5.2.11		Temperature limit	ISO 15223-1; 5.3.7
	Use-by date Formatted: Year-Month-Day	ISO 15223-1; 5.1.4		Do not use if package is damaged	ISO 15223-1; 5.2.8
	Lot number	ISO 15223-1; 5.1.5		Non-sterile	ISO 15223-1 5.2.7
	Catalog number	ISO 15223-1; 5.1.6		Quantity (x) of devices in package	NA
	Sterile via irradiation	ISO 15223-1; 5.2.3, 5.2.11		Unique device identifier	ISO15223-1; 5.7.10
	Consult Instructions for Use	ISO 15223-1; 5.4.3		Keep away from sunlight	ISO15223-1; 5.3.2
	Caution, consult accompanying documents	ISO 15223-1; 5.4.4		Keep dry	ISO 15223-1; 5.3.4
	Do not reuse	ISO 15223-1; 5.4.2		Prescription only	21CFR801.109

14. FURTHER INFORMATION

If further information is needed or required, contact your Serpex Medical representative.

**Serpex Medical Inc.**

3350 Scott Blvd, Suite 37B
Santa Clara, CA 95054
info@serpexmedical.com