truFreeze®
Spray Cryotherapy

truFreeze® System

Rapid AV Spray Kit

Instructions for Use

REF

20-00177 truFreeze System Rapid AV Spray Kit

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CSA MEDICAL
Freeze disease®

Description

The CSA Medical (CSA) truFreeze® System consists of a truFreeze Console and a truFreeze System Spray Kit. The truFreeze Console is to be used only with the truFreeze Spray Kit. The spray kit contains a catheter that transports cryogen from the console to the targeted ablation area. When used, a CryoDecompression Tube (CDT) and onboard suction source provide a means of active evacuation (suction) of nitrogen gas at the ablation site.

The Rapid AV Spray Kit (20-00177) consists of:

- Rapid AV Catheter (20-00184): One box of 5 pouches, each containing one 2.1 mm OD Straight Tip Catheter and one Catheter Introducer.
- Active Venting CryoDecompression Tube (20-00181): One box of 5 pouches, each containing one Dual Lumen 16 Fr CryoDecompression Tube (CDT), Connector, and Suction Tubing.

Indications for Use

The truFreeze System is intended for cryogenic destruction of tissue using Liquid Nitrogen spray that has a boiling point of -196°C requiring either active or passive venting during surgical procedures.

The truFreeze System is indicated for use as a cryosurgical tool in the fields of dermatology, gynecology, and general surgery, to ablate benign (*e.g.*, Barrett's Esophagus with high grade dysplasia and/or low grade dysplasia) and malignant lesions.

Contraindications

Category	Contraindication
General	• During pregnancy. • Where food is identified in the stomach or proximal duodenum at the time of the procedure and cannot be removed, if using in the esophagus.
Compromised Tissue	• Where significant ulceration or mucosal break is evident in the ablation area or adjacent organs. • Where any procedure or pre-existing condition has significantly reduced tissue strength (e.g. Percutaneous Endoscopic Gastrostomy (PEG) tube). • Where any disease state has significantly reduced the elasticity of the ablation area (e.g. Marfan's Syndrome).
Anatomical Flow Resistance (Gas Evacuation)	• Where lumen narrowing exists that precludes advancing the CDT into the distal organ (e.g., stomach), if the CDT is used. • Where any procedure or anatomy proximal to the ablation site has significantly reduced or restricted the flow area of the lumen creating a restriction where gas created from liquid nitrogen cannot adequately vent.

Warnings and Precautions

Category	Warning
General	• For single use only. • Do not reuse, reprocess or resterilize. • Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure, which in turn may result in patient injury, illness or death. • Reuse, reprocessing or resterilization may also create risk of contamination of the device and/or cause patient infection or cross-contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. • Contamination of the device may lead to injury, illness or death of the patient. • Inspect the spray kit contents for damage prior to use. Do not use the spray kit if any part of the kit is damaged in any way. • Expired product should not be used. • Cutting or otherwise altering the truFreeze catheter may lead to sharp edges on the catheter and increase the flow of liquid nitrogen through the catheter, resulting in an increased risk of perforation, stricture, or other damage to the ablation area. • The optional pressure sense tube is not supported with this catheter. • This catheter kit should not be used for passive venting procedures.
Compromised Tissue	• The physician should carefully consider patient eligibility for cryospray ablation (i.e., cryosurgery and associated gas pressure), including patient presentation, medical history, co-morbidities (e.g., COPD, CAD), and prolonged use of steroids that may reduce the patient's tissue compliance and tissue strength affecting their ability to tolerate cryospray. • Any therapy or procedure compromising the integrity of the tissue, specifically in or adjacent to the targeted ablation area. • The physician should use caution when ablating thin tissue. • The physician should use caution when applying cryospray in any organ where stricture or collapse is likely.
Anatomical Flow Resistance (Gas Evacuation)	• The physician should use caution when considering cryospray for this high-risk patient situation, specifically regarding the ability to vent or extract gas: o A significantly large hiatal hernia with intrathoracic stomach, if using in the esophagus.

Category	Warning
	• Physician should use caution in any procedure or anatomy where a restriction or obstruction interferes with the adequate venting of nitrogen gas, resulting in increased gas pressure. • During cryospray, the patient must be monitored for abdominal distention and cryospray must be stopped if abdomen becomes distended, if using in the esophagus. • This catheter should not be used with low flow settings. • Do not use low suction setting with this catheter.

Symbol	Meaning
	Caution
	Consult Instructions for Use
	Manufacturer
	Date of Manufacture
	Keep Dry
	Use By Date
	Latex Free
Rx ONLY	Federal law (USA) restricts this device to sale by or on the order of a physician.
	Single Use. Use only once. Do not reuse.
	Catalog Number
	Lot Number/Batch Code
	Sufficient For Number of Procedures
	Do Not Use if Package is Damaged
	Do Not Resterilize
	Sterilized Using Ethylene Oxide
	Temperature Limitation. Maximum 30°C, Minimum 15°C
	Keep Away From Sunlight

Storage

Store within conditions indicated on product label.

Directions for Use of Spray Kit

Active Venting (With Suction)

Active venting (suction) is a venting method in which the onboard suction is used to evacuate gas from the ablation area via the Dual Lumen CryoDecompression Tube (CDT). Active venting may be used when spraying distal to an obstruction or flaccid organ that could potentially collapse (e.g., esophagus, colon, and rectum).

1. Two suction settings are available (normal and low) to accommodate different Spray applications and Flow settings. Normal suction is the recommended default. Verify suction setting with physician, and ensure setting is displayed in Setup tab on Run screen. Note: Normal suction during a 20 sec Cryogen for normal flow (~25W) is 55cmH_2O.

2. Place assembled suction canister (e.g. Bemis® Canister) in the recessed holder in the front of the console, with elbow port facing front.

3. Open a CDT Kit pouch. Remove the connector (short section of tubing in individual bag).

4. Connect blue end of the connector to the top port of the suction canister and the clear end of the connector to the suction port on the underside of the canister holder on the truFreeze console.

5. Remove the suction tubing (long tubing with no holes).

6. Connect the blue end of the suction tubing to the elbow port on the front of the suction canister.

7. Press the suction (gray) foot pedal to verify that the tubing draws suction. After verification that suction is working, depress the suction foot pedal again to disengage suction until start of procedure.

8. Leave the CDT (tube with holes) in the packaging until the physician is ready to place it for the procedure (prior to cryospray).

9. A guide wire should be used to aid in CDT placement using a Seldinger technique. The four black bands on the CDT should be placed at the GEJ if using in the esophagus. A minimum of one band should be visible from above the GEJ (See **Figure 1**).

NOTE: It is not required to visually confirm placement of the lines below the GEJ.

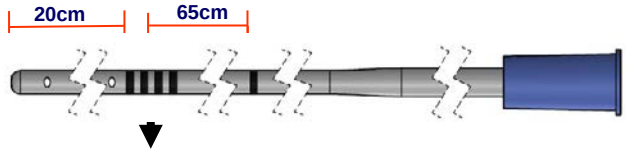
NOTE: When routing the CDT outside the patient's oral cavity, leave slack in the CDT to prevent tube kinking.

10. Attach the free end of the suction tubing to the CDT.

11. During cryospray, a person should physically monitor the patient for distention (i.e., "distention monitor").

⚠ **CAUTION:** Liquid nitrogen expands more than 700 times when changing from a liquid to a gaseous state. It is imperative for patient safety that adequate venting is used to remove gas created during cryospray.

Figure 1. Diagram of CDT



Cryogen Delivery Catheter

1. Confirming correct catheter; thoroughly inspect the catheter pouch label to ensure that the Rapid AV Catheter is being used for the procedure.
2. This catheter should only be used with the normal flow venting and the normal flow settings. Verify cryogen flow setting with physician, and ensure setting is displayed in Setup tab on Run screen. Refer to **Table 1** as needed. See **Figures 2A** and **2B** for an illustration of tissue depth of injury and surface area.

Dosimetry: Typical dosimetry using active venting with suction starts with 2 cycles of 20 s; adjust, as needed, based on the size of the region being ablated.

3. **Scanning the catheter;** select the RUN button on the Home Screen and then press the SETUP button. Hold the yellow RFID tag on catheter pouch against the yellow sticker on the blue RFID scan pad on the right side of the truFreeze console and press the SCAN button on the screen. You will hear an audible beep and then hear a gas egress sound indicating that COOL has automatically started to pre-cool the system. Confirm the SCAN TIME, SCAN #, MODEL # and LOT # buttons have turned green.

NOTE: RFID will not engage if the tag is moving. **Hold** the yellow RFID tag against the yellow sticker on the blue RFID scan pad for 3 to 5 seconds for proper RFID reading.

NOTE: Some consoles may not contain the circular yellow label.

4. While the system is pre-cooling, set the Timer using the increment or decrement buttons on the Run tab.

5. Remove the Introducer (individually wrapped 'spring') from catheter pouch. Place the tapered end of the introducer ~2 cm into the biopsy cap of the scope, if applicable.

6. Remove the catheter from the pouch and grasp the white hub extending from the protective tube, being careful not to kink the catheter. Discard the protective tube.

7. Insert the hub of the catheter into the catheter port on the front of the console. Confirm the CATHETER box on the upper left hand of the screen has turned green.

8. If a scope is not used, make provisions for handling the catheter during cryospray.

9. When using a scope, place the catheter through the catheter introducer and into the biopsy or working channel of the scope.

10. The catheter has three solid black bands distanced at 1cm increments. Extend the catheter through the channel to ~2 cm beyond the distal end of the scope to account for catheter retraction when cryogen is started. Position catheter tip 2-3 cm from targeted ablation area. Make sure the catheter does not touch the tissue during cryospray. (Refer to **Figures 2A** and **2B**).

11. Freeze times typically range from 5-30 seconds and are delivered for 1 to 5 cycles depending on the tissue and anatomic location. Repeated rapid freezes followed by passive thaw cycles may have a greater effect on cellular destruction. Extend the ablation zone beyond the target margins to ensure freezing of the entire area.

NOTE: Engaging the foot pedal releases the cryogen flow through the system thus the treating physician has complete control over the duration of the cryogen spray delivery.

NOTE: The physician should keep track of the duration of delivery by utilizing the timer's audible tone and by assigning an appropriate health care provider to audibly call out the timer's second by second display until the selected length of cryogen spray has completed.

12. Operate the console before, during and after cryospray following the instructions in the truFreeze System Operator Manual.

NOTE: Physician should monitor for significant changes in patient vital signs (e.g. bradycardia, hypotension) during cryospray that may affect patient safety; the procedure should be adjusted accordingly.

NOTE: If body fluid(s), expectorate etc. enters the biopsy channel during the procedure, the physician/staff should follow the clinically acceptable scope cleaning procedure at their facility to clear it during the procedure if deemed necessary by the physician. If a cleaning solution is used, such as saline, ensure that the cleaning solution is evacuated from the working channel as well.

⚠ **CAUTION:** If using a scope in the retroflexed position, ensure catheter and scope are completely defrosted before repositioning or withdrawing. Withdraw scope and catheter in the straight position.

⚠ **CAUTION:** Ensure catheter and scope are completely defrosted before repositioning or withdrawing catheter. Withdraw catheter in the straight position.

⚠ **CAUTION:** Care should be taken to avoid kinking or fracturing the catheter during handling and insertion into the catheter introducer.

⚠ **CAUTION:** Avoid directly touching the catheter without sufficient protection during use; it gets very cold. Additionally, care should be taken to ensure that the patient and other health care professionals do not come in incidental contact with the catheter and/or the liquid nitrogen cryogen while the system is in use.

⚠ **CAUTION:** If incidental contact with the catheter does occur, allow area to thaw before moving to avoid damaging tissue or creating a mucosal break. Use the defrost cycle to thaw catheter per instructions in the truFreeze System Operator Manual, as needed.

⚠ **CAUTION:** The truFreeze device should be operated with a separation distance of at least 10 cm (4 inches) from other devices, including implantable medical devices such as pacemakers and ICDs, for which radiated radio frequency (RFID) energy may cause interference that could disrupt normal performance.

Figure 2A. Top View: Typical Ablation Area (2 x 2-3 cm area, normal flow)

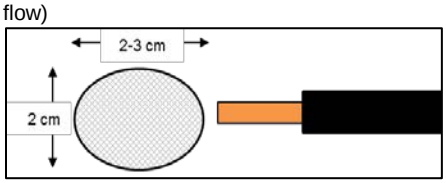
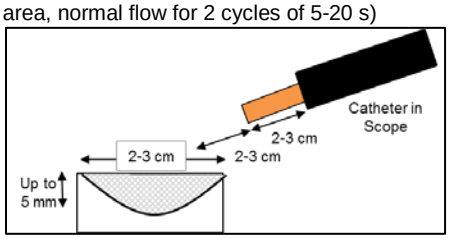


Figure 2B. Illustration of Side View: Typical Depth of Injury (2x2-3cm area, normal flow for 2 cycles of 5-20 s)



Note: Spraying with a painting motion may increase the targeted ablation surface area and may result in more uniform depth of injury.

Table 1. Guidelines for truFreeze® System Depth of Injury across Operational Settings

Dosimetry (Cycles x Duration)	Cryogen Flow Setting	
	Normal (25W)	
	Energy (J)	DOI (mm)*
2x20 s = 40 s	1000	4.5
4 x 5 s = 20 s	500	2.0

*DOI equivalent between normal and low suction settings

Performance Data - Barrett's Esophagus with High Grade Dysplasia

In a post-market registry study, 46 patients with Barrett's Esophagus with high grade dysplasia received ablation with the truFreeze device. Patients received an average of 1.89 ablation sessions consisting of an average of 2.23 cycles of 21.17seconds to achieve CE-D in 87% of the patients. Details are presented in the tables below.

	Response CE-D
Effectiveness Population	46
N Responders	40 (87.0%)
Response rate by BE segment length	
Unknown	2 (4.3%)
≤ 3 cm	27 (58.7%)
3-6 cm	7 (15.2%)
≥ 6 cm	4 (8.7%)

Safety	truFreeze Per Patient rate
Stricture	2.7%
Abdominal Pain	0%
Pancreatitis	0.9%
Chest pain	0%
GI Hemorrhage	0%
Mucosal Lacerations	0%

Performance Data - Barrett's Esophagus with Low Grade Dysplasia

In a post-market registry study, 22 patients with Barrett's Esophagus low grade dysplasia received ablation with the truFreeze device. Patients received an average of 2 ablations sessions consisting of an average of 2.19 cycles of 21.76 seconds to achieve CE-D in 95.5% of the patients. Details are presented in the tables below.

	Response CE-D
Effectiveness Population	22
N Responders	21 (95.5%)
Response rate by BE segment length	
Unknown	2 (10%)
<= 3cm	9 (43%)
3-6cm	3 (14%)
>=6cm	7 (33%)

Safety	truFreeze Per Patient rate
Stricture	2.7%
Abdominal Pain	0%
Pancreatitis	0.9%
Chest pain	0%
GI Hemorrhage	0%
Mucosal lacerations	0%