RheOx® Catheter
Models GTI-00005-01 and GTI-00005-02

Instructions for Use (IFU)

These Instructions for Use (IFU) are specific to the RheOx® Catheter (Models GTI-00005-01 and GTI-00005-02). Do not operate the RheOx® Catheter before thoroughly reading this IFU and the RheOx® User Manual.

TABLE OF CONTENTS

1. TRAINING

Galvanize Therapeutics provides user training prior to use to ensure safe and effective use of the primary operating functions of RheOx® with the RheOx® Catheter.

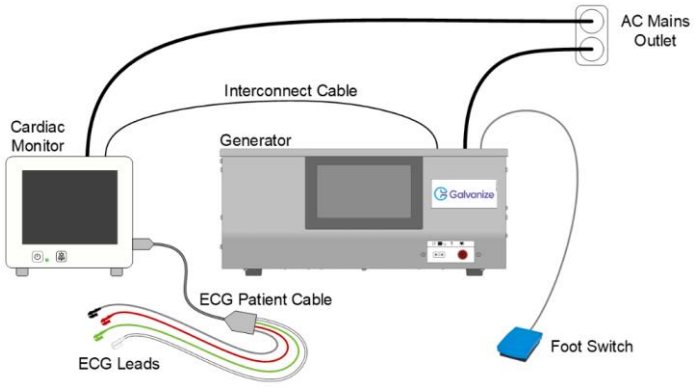
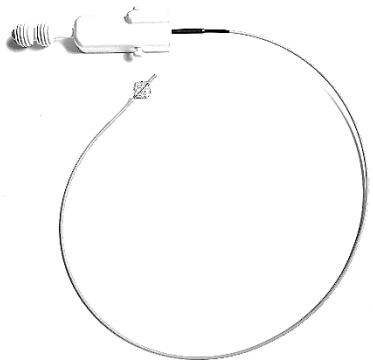
2. INDICATION FOR USE

RheOx with the RheOx Catheter is indicated for the ablation of bronchial epithelium and mucosa and the treatment of symptoms due to chronic bronchitis in patients with moderate to severe chronic bronchitis.

3. SYSTEM OVERVIEW

Table 1 provides an overview of RheOx with the RheOx Catheter and components not provided that are designed to work with RheOx. The components not provided with RheOx are suitable for use within the patient environment.

Table 1: RheOx

<table>
<tr>
<td>RheOx (GTI-00007)
Shown with the RheOx Generator (GTI-00006)
RheOx with the RheOx Catheter delivers energy at a predetermined dose setting to ablate the target tissue. For information on the use of RheOx, and other technical specifications, please refer to the RheOx User Manual.</td>
<td colspan="3"> 
</td>
</tr>
<tr>
<td rowspan="2">RheOx Catheter (GTI-00005-01 and GTI-00005-02)
The RheOx Catheter is provided sterile and is a single-use disposable device.
The RheOx Catheter is available in two different lengths for compatibility with multiple Olympus bronchoscopes. Refer to Table 2.</td>
<td colspan="2" rowspan="2">  </td>
<td>GTI-00005-01
Catheter Crossing Diameter: 2.70 mm
Working Length: 775 mm
Unexpanded Electrode Length: 30 mm</td>
</tr>
<tr>
<td>GTI-00005-02
Catheter Crossing Diameter: 2.70 mm
Working Length: 780 mm
Unexpanded Electrode Length: 30 mm</td>
</tr>
<tr>
<td>Components Not Provided
(Manufacturer and Reference)</td>
<td>Catheter Cable (reusable)

Kirwan 30-3003
  </td>
<td>Patient Dispersive Electrode (disposable)

3M 9165 or 9165E
  </td>
<td>Set of 4 ECG Electrodes (disposable)

Ivy Biomedical Systems, Inc. 590436 (discontinued) or 590494
  </td>
</tr>
</table>

4. BRONCHOSCOPE REQUIREMENTS

The RheOx Catheter is designed to be used with a therapeutic bronchoscope having at least a 2.8 mm working channel. The RheOx Catheter is supplied in two different configurations. Table 2 shows which catheter model is compatible with a certain Olympus bronchoscope.

Table 2 – Catheter and Bronchoscope Compatibility

Galvanize RheOx Catheter Model Number	Compatible Olympus Bronchoscope	Min. Working Channel Diameter (mm)
GTI-00005-01	BF-1T180 / BF-XT160	3.0
GTI-00005-02	BF-1TH190	2.8

5. APPLICATION SPECIFICATION SUMMARY

RheOx is intended to be used by a healthcare professional within a Bronchoscopy Suite or Operating Room. The user places the RheOx Catheter into the airway using standard bronchoscopy techniques. Upon catheter placement at the target tissue location, the user presses the RheOx footswitch to initiate energy delivery to the target airway tissue resulting in tissue ablation. The user then repositions the RheOx Catheter adjacent to the last location and the procedure is repeated until all target tissue has been treated.

6. CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

CONTRAINDICATIONS

1. Patients with an implantable cardioverter defibrillator, pacemaker, or any other implantable electronic device.
2. Patients with a history of ventricular tachyarrhythmia any clinically significant atrial tachyarrhythmia (i.e., abnormality with vital signs) and/or history of type II second or third degree AV block.
3. Patient has airway stent(s), valves, coils, or other lung implant/prosthesis.

WARNINGS and PRECAUTIONS

THIS IFU SHOULD BE READ IN CONJUNCTION WITH THE RHEOX (GTI-00007) USER MANUAL BEFORE USING RHEOX WITH THE RHEOX CATHETER. FAILURE TO FOLLOW INSTRUCTIONS OR FAILURE TO HEED WARNINGS OR PRECAUTIONS MAY RESULT IN HARM TO PATIENT.

1. Do not use the RheOx Catheter in the presence of flammable agents or in oxygen-enriched environments exceeding 40% FiO_2.
2. Avoid using flammable substances that can be ignited by sparks, such as alcohol or flammable bronchoscope lubrication materials.
3. Rubber catheters or other materials should not be used as a sheath on active electrode tips.
4. Cables should never be wrapped around metal instruments, as the current running through them can pass into the metal instrument and may result in harm to the patient and/or operator.

5. Do not use sharp towel clips or metal instruments to attach cables to drapes. Sharp metal clips can damage electrical cables or provide an unwanted point of contact with the patient's skin. Overlapping electrical wire around a metal clip creates an electrical transformer that can cause a hazard and may ignite drapes.
6. Do not operate RheOx with wet hands or wet gloves. If gloves have holes in them, electrical current can pass through.
7. Never operate electrosurgical equipment while standing on a wet surface. Keep the foot pedal dry.
8. Do not deliver energy if the dispersive electrode is not securely affixed on the patient in accordance with manufacturer's instructions. Do not apply the dispersive electrode where fluid may pool. A loosely or improperly connected dispersive electrode may result in harm to the patient and/or operator.
9. Do not allow fluids to pool in the body depressions and cavities before and during energy delivery.
10. Do not allow flammable liquids to pool in the body depressions and cavities before and during energy delivery.
11. Determine whether the patient has any metal implants. There is potential for harm if the dispersive electrode is placed on the skin over a metal orthopedic implant.
12. Do not use on patients with pacemakers, internal defibrillators, or any other implantable electronic devices.
13. For optimum safety, ensure the patient is not wearing any jewelry to avoid complications from possible current leakage.
14. Position and insulate the patient so that the patient is not touching any grounded metal objects.
15. Do not touch the catheter electrode and the dispersive electrode (also known as neutral electrode, return electrode, or grounding pad) at the same time during energy delivery.
16. Do not deliver energy if the RheOx Catheter's electrode is in contact with a metal object.
17. The energy output from RheOx may cause electrical sparking to occur. Do not perform procedures if flammable or explosive media are present, such as flammable anesthetics, skin preparation agents, or bio-intestinal gases.
18. Monitoring electrodes of any physiological monitoring equipment used on the patient should be placed as far as possible away from the intended treatment location. Needle monitoring electrodes are not recommended. Physiological monitoring equipment incorporating high frequency current limiting devices is recommended.
19. Patient injury resulting from neuromuscular stimulation is possible during energy delivery. RheOx has been designed to minimize the possibility of neuromuscular stimulation.
20. Do not deliver energy if the Catheter's electrode is not positioned at the intended treatment location.
21. Patients previously treated with RheOx should not be retreated in the same area(s). No clinical data is available studying the safety and/or effectiveness of repeat treatments.
22. Do not treat both the right and left lungs in a single bronchoscopic procedure. Do not advance the RheOx Catheter within the bronchoscope if there is significant resistance, as this may result in harm or injury to the patient and/or cause damage to the RheOx Catheter and/or bronchoscope.
23. Do not advance the RheOx Catheter into an airway in which the RheOx Catheter cannot be seen under bronchoscopic vision. Advancing the RheOx Catheter beyond the field of view could result in harm to the patient.

24. Do not reposition the bronchoscope and/or RheOx Catheter while the electrode is expanded as harm to the patient could occur.
25. Use of the RheOx Catheter with a non-Galvanize specified equipment may result in harm or injury to the patient and/or operator or may result in product malfunction.
26. Do not start the procedure if external defibrillator is not readily available as unintended cardiac arrhythmia may occur.
27. Do not use the RheOx Catheter if it is damaged. Use of a damaged RheOx Catheter may result in patient harm.
28. The RheOx Catheter is provided sterile and is SINGLE USE ONLY. Do not use the RheOx Catheter if the package is opened, torn, or damaged. Use of a RheOx Catheter from damaged packaging may result in patient harm or injury. Do not **re-sterilize or reuse** the RheOx Catheter, as this may result in patient harm, transmittal of infectious disease or product malfunction.
29. Do not use the RheOx Catheter if it comes in contact with a surface that is not aseptic (e.g., floor). This may result in patient infection.
30. Use care when handling the RheOx Catheter to avoid kinking the catheter shaft.
31. Before inserting or removing the RheOx Catheter from the bronchoscope working channel, ensure the electrode is collapsed. Do not use the RheOx Catheter if the electrode does not expand or collapse.
32. Before delivering energy, ensure the electrode is in good circumferential contact with the airway wall.
33. If the RheOx Catheter requires cleaning during the procedure due to excess mucus build-up, do NOT submerge in saline or other cleaning fluids. Gently wipe away excess mucus with a dry gauze.
34. RheOx should only be used in a fully equipped bronchoscopy suite with access to full resuscitation equipment to handle hemoptysis, pneumothorax, and other respiratory complications including acute exacerbation of asthma and respiratory failure requiring intubation.
35. Follow local governing ordinances and your institution’s biohazard procedures regarding disposal of the RheOx Catheter.

7. DIRECTIONS FOR USE

RheOx Catheter Inspection and Preparation

1. Confirm the RheOx Catheter *Use by* date has not passed.
2. Visually inspect the package for damage before removing the RheOx Catheter from the package. Do not use the RheOx Catheter if the package is damaged or has been previously opened or torn. Contact a Galvanize representative for a replacement if the IFU is damaged, not legible, or becomes lost.
3. Remove the RheOx Catheter from the package tray and inspect for any damage, such as kinks or broken components. Do not use the RheOx Catheter if any damage or irregularity is found.
4. Hold the RheOx Catheter handle in your hand. Pull on the knob, ensuring that the electrode expands. Verify that the electrode expands fully and evenly. See **Figure 1.**

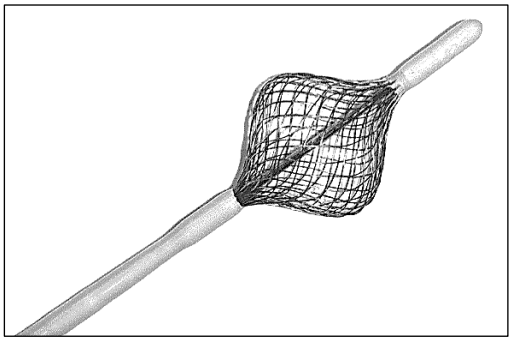


Figure 1: RheOx® Catheter Electrode Expanded

5. Collapse the electrode by pushing on the handle knob. See **Figure 2.** Do not use the RheOx Catheter if the electrode does not expand or collapse properly.

Figure 2: RheOx® Catheter Electrode Collapsed

RheOx Set-up and Operation

The RheOx Catheter is intended to be used in conjunction with the RheOx Generator. Power on the RheOx Generator before connecting the Catheter or catheter cable. Please read the RheOx User Manual before using RheOx for specific instructions on the following;

- Generator and cardiac monitor installation
- Generator and cardiac monitor power-up
- Connection of components and accessories
- Generator operational modes
- LCD screen messaging
- Cleaning of RheOx components
- Troubleshooting

Patient Preparation

1. Position ECG electrodes away from the treatment site and the current pathway through the body. The cardiac monitor requires specific ECG electrodes. Refer to the RheOx User Manual for more information.
2. Prepare the patient using standard technique for electrosurgery. Ensure the patient's entire body, including extremities, is insulated from contact with grounded metal parts. A Galvanize specified dispersive electrode must be used. Refer to the RheOx User Manual for more information. Follow instructions provided by the manufacturer of the dispersive electrode for proper use. Place the patient dispersive electrode securely on the patient's thigh. The location should be clean and dry. Avoid bony prominences, adipose tissue, scar tissue, skin over implanted metal prostheses, hairy surfaces, and pressure points. If necessary, shave the dispersive electrode site for good contact.
3. Place the cardiac monitor ECG leads on the patient using standard technique. Refer to RheOx User Manual for more information.
4. Connect the patient dispersive electrode cable connector to the Generator. Refer to RheOx User Manual for more information.
5. Unpackage the catheter cable and wipe with a disinfecting wipe or alcohol pad. Refer to the RheOx User Manual for more information.

WARNING: The Galvanize specified catheter cable has been tested for use with the energy output of RheOx and may not be substituted. The Galvanize specified catheter cable is packaged non-sterile.

6. Introduce the flexible bronchoscope through the nose or mouth as appropriate. See **Figure 3 below.** Avoid using flammable bronchoscope lubrication that can be ignited by sparks.

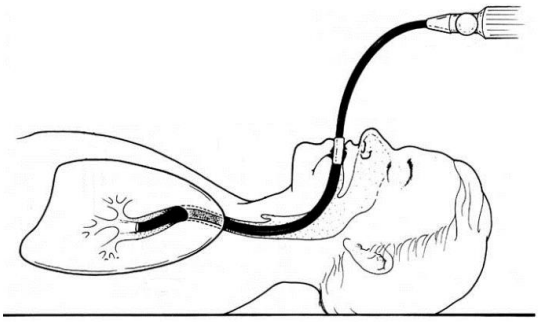


Figure 3: Bronchoscope navigation into patient's airways

7. Under direct visualization, navigate the bronchoscope to the main bronchus.

RheOx Catheter Use

WARNING: Ensure the catheter cable is NOT connected to the front panel of the Generator when powering on the system and preparing it for use.

1. Before inserting the RheOx Catheter into the bronchoscope and after the RheOx Generator is powered on, ensure the electrode is fully collapsed and connect the RheOx Catheter to the RheOx Generator using the catheter cable. Avoid draping the catheter cable over the patient and contact with other leads or cables.
2. Navigate bronchoscope to the distal segments of the lower lobe under direct bronchoscopic visualization.
3. Advance the RheOx Catheter into the bronchoscope working channel *being careful not to kink the catheter shaft.* If the device encounters significant resistance during insertion, do not force it. Remove the RheOx Catheter and inspect it and the bronchoscope for damage that caused the difficult insertion.

   Note: In tortuous anatomy, it may be necessary to relax the bronchoscope's deflection mechanism until the device passes smoothly.
4. Advance the RheOx Catheter through the bronchoscope until the distal tip of the RheOx Catheter is in bronchoscopic view. If the device encounters significant resistance during advancement, do not force it.
5. Advance the bronchoscope and RheOx Catheter to the targeted segmental airway location. Snap the catheter handle onto the port of the bronchoscope's working channel while directly visualizing the catheter's distal segment.

   Note: Positioning of the catheter's electrode is performed under direct bronchoscopic visualization to ensure proper space between electrode and distal end of bronchoscope. The user should see the blue catheter shaft with the displayed field of view.
6. The RheOx Catheter is designed to treat airway diameters between 3 – 18 mm.
7. Under direct bronchoscopic visualization, pull on the handle knob to expand the electrode so that the electrode is firmly touching the target airway wall circumferentially. Do not over-expand the electrode. Proper contact of the electrode should be confirmed visually.
8. Do not reposition the RheOx Catheter and/or bronchoscope while the electrode is expanded as this may result in patient harm or injury.
9. Deliver energy to the targeted region by pressing and holding the footswitch. The RheOx Generator will deliver energy automatically according to preset dose parameters.
10. To manually terminate energy delivery, if necessary, release the footswitch.

    Note: The RheOx Generator is programmed to alert the user with both audible and visual cues indicating that treatment has been initiated, is in process, completed, or stopped. Please refer to the RheOx Generator User Manual for more detailed instructions on these audible sounds and visual cues.
11. Once the activation time completes, the Generator will stop energy delivery. Remove foot from footswitch and push the RheOx Catheter handle knob to collapse the electrode.
12. Reposition the RheOx Catheter by COLLAPSING THE ELECTRODE and then moving the bronchoscope proximally to achieve adjacent treatment to ensure maximal treatment coverage throughout the airway. Slightly overlapping treatments are acceptable. Smaller diameter, distal airways will require more retraction of the bronchoscope to locate an untreated area, compared to larger main airways.

13. Repeat to treat the entire airway lobe.

WARNING: Do not treat the same location or airway twice as this may result in damage to the airway.

14. To move the bronchoscope and RheOx Catheter between different lung lobes, FULLY COLLAPSE THE ELECTRODE then withdraw the RheOx Catheter approximately 10 cm into the bronchoscope so the catheter electrode is proximal to the deflecting tip of the bronchoscope, as this will avoid damage to the airway while moving between different lung lobes. Support the catheter to avoid kinking of the catheter shaft while the catheter's handle is undocked from the bronchoscope.
15. Once located in an untreated airway lobe, repeat Steps 4 – 13.
16. Treat all accessible segments and subsegments of the right lower lobe, right middle lobe/lingula, right upper lobe and the right central airways proximally to the trachea.

    Note: During a separate bronchoscopic procedure, treat all accessible segments and subsegments of the left lower lobe, lingula, left upper lobe and the left central airways proximally to the trachea.

WARNING: Do NOT submerge the RheOx Catheter in saline or other cleaning fluids to remove excess mucus. Wipe gently with a dry gauze.

17. Once the procedure is complete, collapse the catheter electrode and un-snap the handle from the bronchoscope before removing the catheter from the bronchoscope.
18. Disconnect the RheOx Catheter from the catheter cable and RheOx Generator and dispose of the used RheOx Catheter per the institution's biohazard procedures.

8. ENVIRONMENTAL CONDITIONS

	Transport or Storage	**Operating**
Temperature	-30 °C to +60 °C	15 °C to 40 °C
Humidity (non-condensing)	15 % to 90 %	30 % to 70 %

9. MAINTENANCE AND TROUBLESHOOTING

- If mucus builds up in the airways and obscures visualization, remove the RheOx Catheter from the bronchoscope, provide irrigation with sterile saline, and suction the resulting fluid from the airways.
- If the electrode does not expand or collapse properly, remove the RheOx Catheter from the bronchoscope and pull and push the knob on the catheter handle to visually confirm that the electrode is functioning properly. If it is not functioning properly, replace the RheOx Catheter and continue with the procedure.
- If you are alerted to auditory or visual cues from the RheOx Generator, consult the RheOx User Manual for operating and troubleshooting guidelines.

10. SYMBOL LEGEND

CE 0459	CE marking with notified body identifying number
REF	Catalogue number
	Caution
STERILE EO	Sterilized using ethylene oxide (EtO). Sterility guaranteed if package unopened or undamaged.
EC REP	Authorized representative
LOT	Lot Number
	Manufacturer name
	Use-by date
	Do not resterilize
	Do not re-use. SINGLE-USE ONLY
	Date of manufacture
	Warning
	Keep dry during shipping
	Temperature limits during shipping
	Follow instructions for use
	Do not use if package is damaged
	Humidity limits during shipping
MD	Medical device
	Importer

CE
0459

EC REP

ICON (LR) Limited
South County Business Park
Leopardstown, Dublin 18
D18 X5R3, Ireland

CH REP

MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland

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Prinses Margrietplantsoen 33 - Suite 123
2595 AM, The Hague
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