

# 3NT MEDICAL

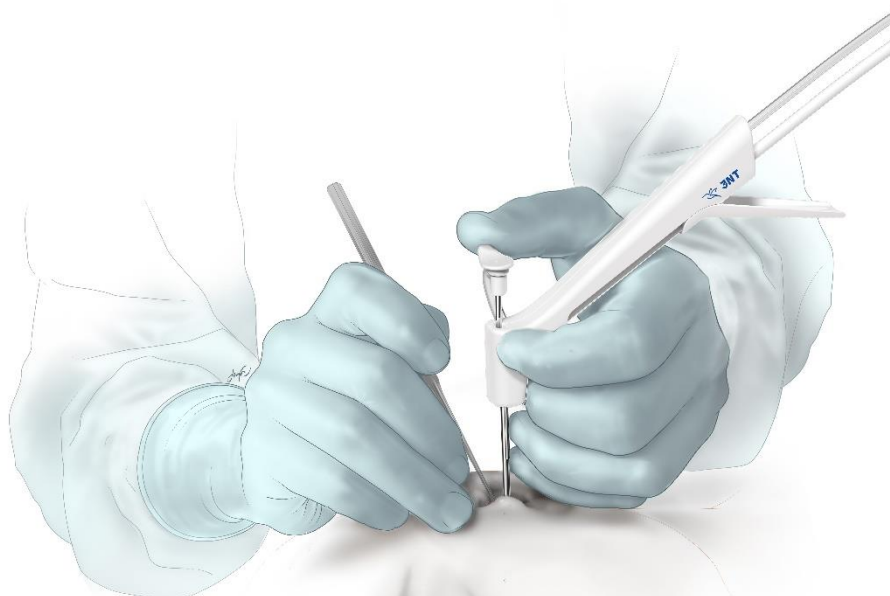


**MD**

**RX** Only

STERILE EO

## User Manual (EN)



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Part Number: ERW-0100, ERW-0200 part of 3NT-3000

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## 1 IMPORTANT INFORMATION

**Caution:** Federal U.S. law restricts this medical device to sale by or on the order of a physician.

These user instructions are applicable to Colibri™ Micro ENT Scope family of products:

A. Item number ERW-0100 - Colibri™ Micro ENT Scope, also referred to as 0° Colibri.

B. item number ERW-0200 - Colibri™ Micro ENT Scope with 20° Direction of View, also referred to as 20° Colibri.

These variants are also interchangeably referred to in this document as Colibri scope or Colibri Endoscope. The endoscope together with the supporting user console, are collectively referred to as Colibri Endoscopy System.

The instructions for use may be updated without further notice.

Please be aware that these instructions do not explain or discuss clinical procedures. The instructions describe only precautions and functions related to the operation of both Colibri™ Micro ENT Scope variants.

Read this manual thoroughly prior to using the Colibri Micro ENT Scope or its variant and ensure proper use and care of it is well understood.

The images in this document are provided for illustration purposes only.

Please contact 3NT Medical if further clarifications are needed. Additional copies of IFUs shall be provided free of charge upon request.

In case of any serious incident that has occurred in relation to Colibri Endoscopy System, report to 3NT Medical and to the local authorities.

Contact 3NT Medical Customer Service for any questions or comments:

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The following terms and definitions are used in this manual:

**WARNING** - Alerts the user of situations which, if not avoided, could result in death or serious injury.

**CAUTION** - Alerts the user of situations which, if not avoided, could result in moderate or minor injury to the user or patient. It is also used to alert the user of conditions and actions that could cause equipment damage.

**NOTE** - Indicates additional helpful information.

## 2 INTENDED USE

The Colibri Endoscopy System, is intended to visualize the internal cavities of the ear, airways, nose and sinus cavities during diagnostic and therapeutic endoscope procedures.

## 3 PATIENT POPULATION

The Colibri Endoscopy System is intended for use in patients in whom endoscopic evaluation of, or intervention in, the ear, airways, nose, and sinus cavities is indicated.

## 4 CONTRAINDICATIONS

The 3NT Endoscopy system is contraindicated for use when, in the opinion of a qualified physician, such use would create a condition that would be dangerous for the patient.

## 5 WARNINGS

1. **Do not use this equipment in the presence of a flammable anesthetic mixture containing air, oxygen or nitrous oxide. There is a possibility of fire or explosion.**
2. The Colibri Micro ENT Scope should only be used by or under the supervision of a physician trained in endoscopy procedures with Colibri scope at professional healthcare facilities.
3. The Colibri Micro ENT Scope is designed for single patient, single-use only and must be properly discarded after use.
4. Do not use the Colibri Micro ENT Scope if its package is breached or damaged since the sterility and functionality of the device may be compromised.
5. Do not reuse or reprocess the Colibri scope nor its add-on components. Reusing the Colibri scope and its add-on components presents an infection-control risk to the next patient and may result in degradation of scope performance.
6. Upon completing the procedure, dispose of the Colibri scope in accordance with applicable state policies and regulations relating to medical facility waste, potentially biohazardous materials and electronic equipment waste.
7. Never advance or withdraw the Colibri scope against any resistance. Do not use excessive force or torque to advance the device. Such actions could lead to tissue trauma, bleeding, or device damage.
8. In the event of malfunction during the procedure, slowly withdraw the Colibri scope from the patient.
9. The Colibri Micro ENT Scope shall be connected only to 3NT Video Console for display of live video.
10. Do not connect items which are not specified as part of the Colibri endoscopy system to the Colibri scope. Using incompatible equipment can result in patient or user injury, or damage to the system. To apply suction or irrigation with Colibri scope use the Colibri's suction add-on components provided with the scope.
11. Applicable to variant ERW-0100 (0° Colibri) only: external suction device used with Colibri's suction add-on should be medical grade only.
12. The light source (LED) at the tip of the Colibri endoscope may slightly heat up. Reduce periods of contact between scope tip and tissue, as sustained contact may cause patient injury.
13. Do not continue operation in case of no image, frozen image or unclear image and remove scope from patient body.
14. Remove scope from patient body before viewing recorded images or video files.
15. Use of Colibri scope adjacent to or stacked with other electronic equipment should be avoided because it could result in improper operation. If such use is necessary, Colibri scope and the other equipment should be observed to verify that they are operating normally.

- Colibri images must not be used as an independent diagnostic of any pathology. Physicians must interpret and substantiate any finding by other means in light of the patient's clinical characteristics.

**6 CAUTIONS**

- Store the Colibri scope in a cool and dry place.
- Never use a device after its expiration date since the sterility and functionality of the device may be compromised.
- 3NT endoscopy system components should be handled with care. Prior to use and during the procedure, inspect the packaging and components for bends, kinks, or other damage. Discontinue the use of any component that may have been damaged.
- Never drop the equipment or subject it to severe impact, as it could compromise the functionality and/or safety of the component or system.
- Avoid excessive bending or twisting of the Colibri scope's insertion tube and cable. Although it designed to bend, excessive bending can damage internal components.
- Applicable to variant ERW-0100 (0° Colibri) only: the suction add-on should be used only for suction or irrigation. Irrigation should only be used with saline. Never insert any improper liquid or gaseous media (such as medicine) to the patient through the suction extension line.
- Do not look directly at the light emitted from the endoscope tip to avoid eye injury.
- Always bring a spare Colibri scope with you to the procedure, for use in case of non-sterile or damage device.

**7 SIDE EFFECTS**

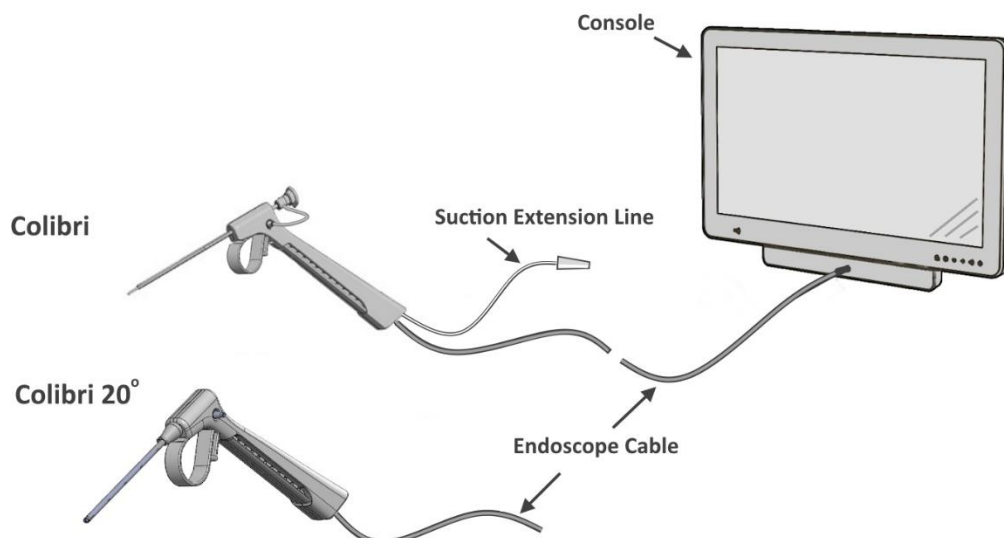
Side effects of endoscopic procedures in the ear, in which 3NT endoscopy system is indicated, are uncommon, but may include minor intraoperative complications such as chorda tympani injuries, transient postoperative facial palsy, sensorineural hearing loss (none corresponded to anacusis), accidental intraoperative tympanic membrane perforation, accidental disjunction of the ossicular chain and injuries to the inner ear. It may rarely include early postoperative complications such as postoperative otorrhea or infection and delayed postoperative complications such as dislocated ossiculoplasty graft and persistent iatrogenic eardrum perforation.

**8 SYSTEM DESCRIPTION**

The Colibri Endoscopy System comprises the 3NT Video Console (CCU-0200) and the Colibri™ Micro ENT Scope (0° or 20° direction of view: ERW-0100 or ERW-0200, respectively). Each scope shall be connected to the 3NT Video Console to enable its operation. For information about the 3NT Video Console refer to the 3NT Video Console instruction for use (LBL-0030).

The Colibri endoscopy system 3NT-3000 includes the following components (Figure 1):

Product	Catalog Number
Colibri™ Micro ENT Scope/ Colibri™ Micro ENT Scope 20° direction of view	ERW-0100/ ERW-0200
Compatible Device	Catalog Number
3NT Video Console <sup>2</sup>	CCU-0200



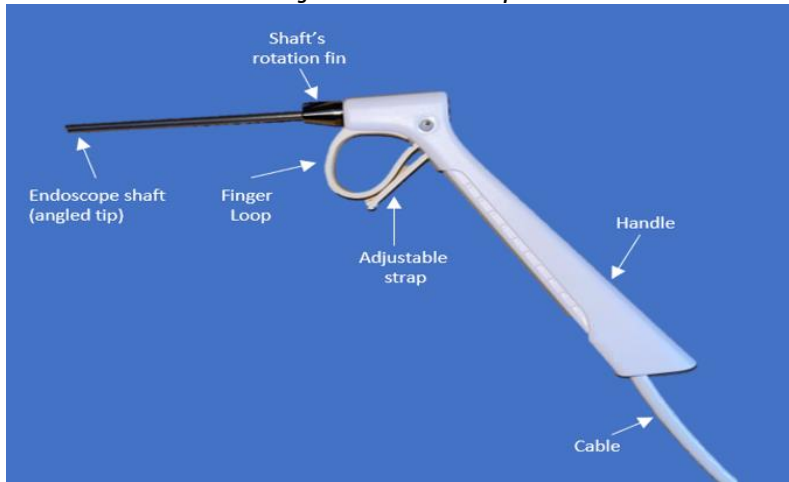
**Figure 1 – Colibri Endoscopy System**

Colibri Micro ENT Scope with 0° Direction of View (Figure 2) is a single-use ENT endoscope designed for visualizing anatomy. Provided sterile, it includes a distal tip video imager with a white LED light source and comes with an add-on suction cannula (Figure 4). The scope connects to the video console via the endoscope cable and is disposed of after use.

The Colibri Micro ENT Scope with 20° Direction of View (ERW-0200) (Figure 4) is a variant of the original model featuring an angled tip for enhanced visibility around corners. Like the original model, it includes a distal tip video imager with a white LED light source, connects to the video console via the endoscope cable, and is disposed of at the end of the procedure.



**Figure 2 - Colibri Endoscope**



**Figure 3 - Colibri Endoscope 20° direction of view**

**ANCILLARY EQUIPMENT FOR SUCTION AND IRRIGATION**

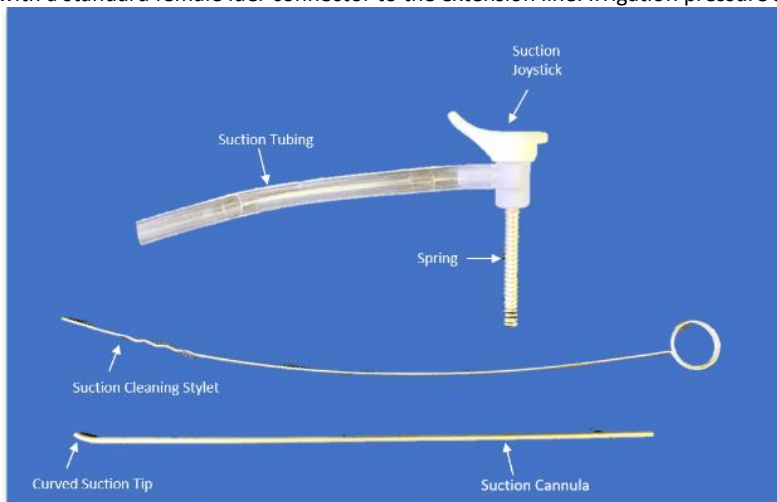
This feature is applicable for variant ERW-0100 with 0° Direction of View only.

**SUCTION:**

The Colibri™ suction extension line (Figure 2) provides a stepped connector allowing connection of suction tubes with inner diameters of 7-10 mm. Suction can be performed with either operation room wall suction or medical grade suction pump with pressure of up to -80 kPa.

**IRRIGATION:**

For irrigation, connect syringe with a standard female luer connector to the extension line. Irrigation pressure should not exceed 300kPa.



**Figure 4 - Suction add-on components**

9 COLIBRI SCOPE SPECIFICATIONS

Specification	Colibri™ Micro ENT Scope	
	0° Direction of View (ERW-0100)	20° Direction of View (ERW-0200)
Scope tip diameter	0.093" (2.35 mm)	0.1" (2.7 mm)
Suction cannula diameter (OD)	0.039" (1 mm)	N/A, No integrated suction channel
Insertion tube working length	3" (76 mm)	3.11" (79 mm)
Suction cannula extension beyond scope tip	0.039-0.39" (1-10 mm)	N/A
Field of view (air)	90°, 120° Diagonal (air)	90°, 120° Diagonal (air)
Direction of view	0°	20°
Depth of field	0.20-1.97" (5-50mm)	0.20-1.97" (5-50mm)
Illumination method	LED	LED
Curved Suction Tip angle	30°	N/A
Suction cannula rotation	360°	N/A
Shaft rotation	N/A	> 360°
Cable length	66.93" (170 cm)	66.93" (170 cm)
Scope weight (excluding cable)	0.044 lbs (20 gr)	0.037 lbs (17 gr)
Scope weight (including cable)	0.18 lbs (80 gr)	0.16 lbs (75 gr)
Operating Environment Temperature	50° to 86° F (10° to 30° C)	50° to 86° F (10° to 30° C)
Storage Environment Temperature	14° to 131° F (-10° to +55° C)	14° to 131° F (-10° to +55° C)
Relative Humidity	15%-85% RH	15%-85% RH
Atmospheric Pressure	50-106 kPa	50-106 kPa
Medical Endoscopes Optical Requirements	ISO 8600-1	ISO 8600-1
Electrical & Thermal Safety	IEC 60601-1, IEC 60601-2-18	IEC 60601-1, IEC 60601-2-18
Electromagnetic Compatibility	IEC 60601-1-2	IEC 60601-1-2
Degree of Protection Against Electrical Shock	Type BF (Body Floating)	Type BF (Body Floating)

10 UNPACKING

1. Visually Inspect the sterile pouch to ensure it is not torn, perforated, shows signs of moisture or appears to be tampered with. If any of those conditions are present, consider the content non-sterile.  
**Note:** Sterilization indicator is attached to the pouch. Green color indicates exposure to an EO sterilization process, while purple color indicates non-sterile status.  
**Caution:** Do not use the equipment if any defects are detected.
2. Remove the Colibri scope from its sterile pouch following the opening mark direction (Figure 5).  
**Caution:** While opening the sterile pouch, avoid contact with the pouch's external edge or closure to minimize the risk of contaminants.  
**Caution:** Handle the endoscope with care. Excessive pressure may damage it.



Figure 5 - Pouch opening

3. Remove the Colibri scope from the die card by following steps 1 through 3 marked on the die-card (Figure 6).



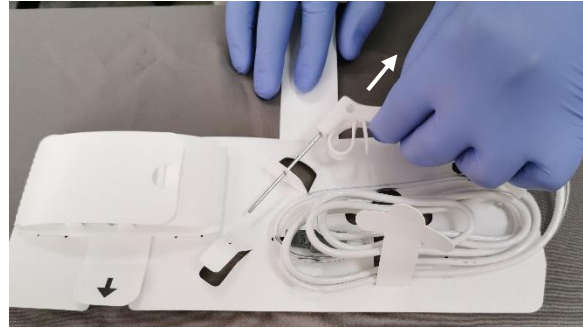
Figure 6 - Die card

- 3.1. Push back strap no.1 to release the cable.
- 3.2. Pull up strap no.2.

- 3.3. Release the device handle from latch no.3 (Figure 7).
- 3.4. Hold the device handle and pull the device backward (Figure 8).



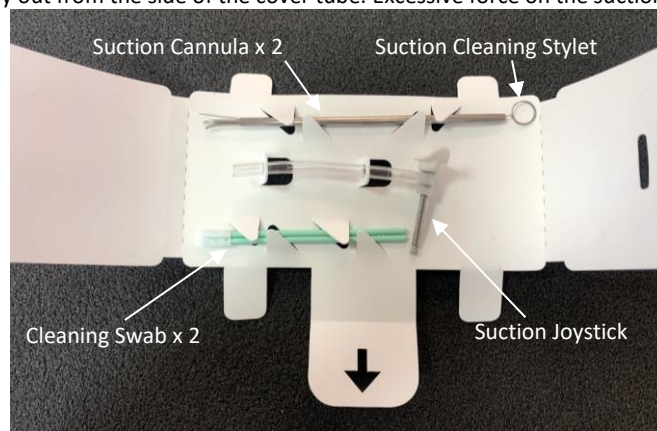
*Figure 7 - Pull up the device*



*Figure 8 - Pull the device backward*

- 3.5. For variant ERW-0100 – 0° Colibri (Figure 8):
  - 3.5.1. Pull up the pocket strap (marked with an arrow) to release it.
  - 3.5.2. Place the pocket on a sterile solid surface.
  - 3.5.3. Open the pocket to remove the suction add-on components.

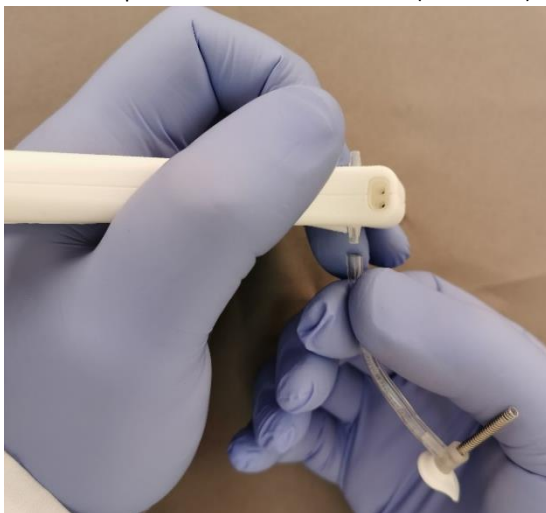
**Note:** Slide the suction cannula gently out from the side of the cover tube. Excessive force on the suction cannula may cause it to bend or break.



*Figure 9 - Suction add-on components*

**11 PREPARATION AND INSPECTION**

- 1. Visually inspect the Colibri scope integrity.  
For Colibri Micro ENT Scope with 20° Direction of View (ERW-0200): skip steps 2-3 and proceed to step 4.



*Figure 10 - Lefthanded connection*



*Figure 11 - Righthanded connection*

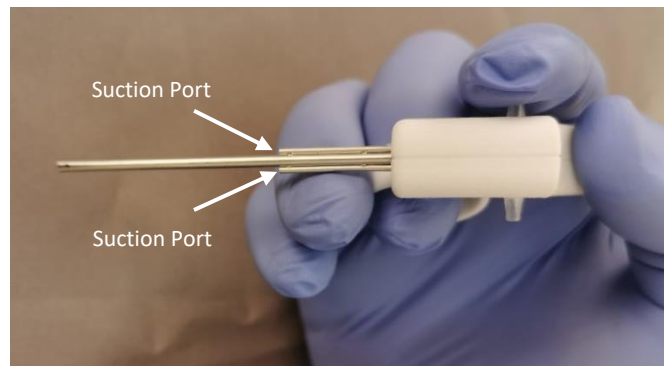


Figure 12 - Suction Ports

2. To install the suction add-on (where applicable), follow the steps below:

**Note:** The Colibri scope is designed for either right-handed or left-handed use. Pay attention to the position of the handle while connecting the suction add-on (where applicable) - see Figure 10, Figure 11.

2.1. Open the pocket and carefully remove one Suction Cannula and the Suction Joystick from the die-card.

**Note:** Pull the Suction Cannula from its protective tube without removing the protective tube from the die-card pocket.

**Note:** The Suction Cannula can be connected to either side of the Endoscope Shaft at surgeon's discretion (Figure 19 & Figure 20).

2.2. Connect the Suction Tubing to one of the Suction Control points, facing your index finger (Figure 13).

2.3. Insert the Spring to the back end of one of the two Suction Ports (Figure 14).

2.4. Press the Suction Joystick until it stops, holding it firmly in place (Figure 15).

2.5. Thread the Suction Cannula through the front end of the suction port (Figure 16).

2.6. Push the Suction Cannula towards the joystick all the way until it stops (Figure 17).

2.7. Release the Suction Joystick and verify the spring is released (Figure 18).

2.8. Push and rotate the Suction Joystick to confirm that the Suction Cannula can be advanced and rotated.

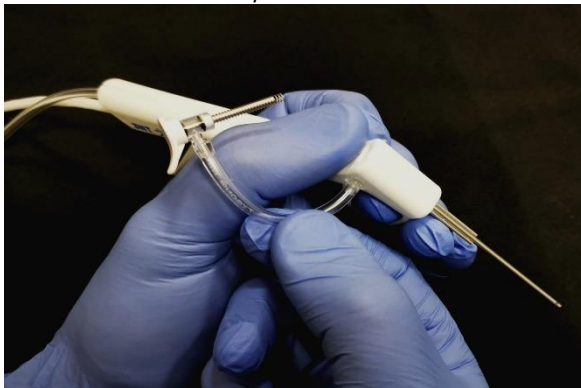


Figure 13 - Connecting Suction Tubing

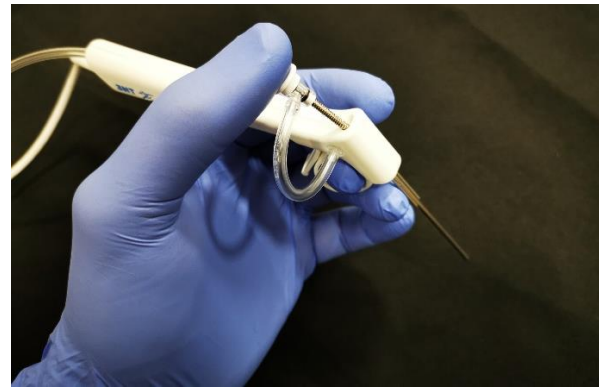


Figure 14 - Inserting Spring into Suction Port

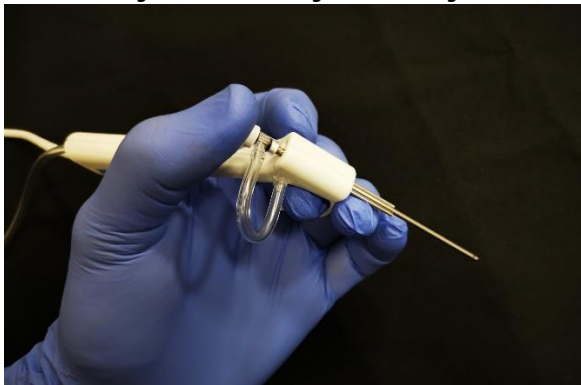


Figure 15 - Pressing Suction Joystick

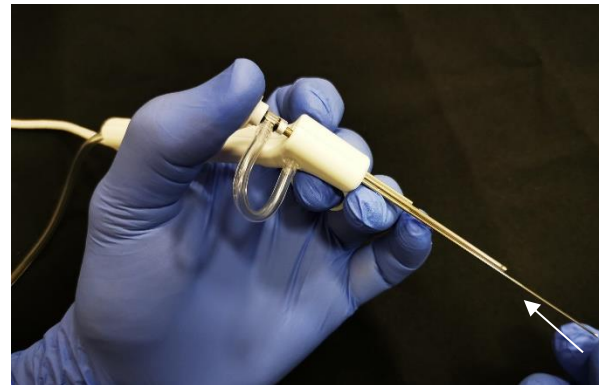


Figure 16 - Threading Suction Cannula through Suction Port

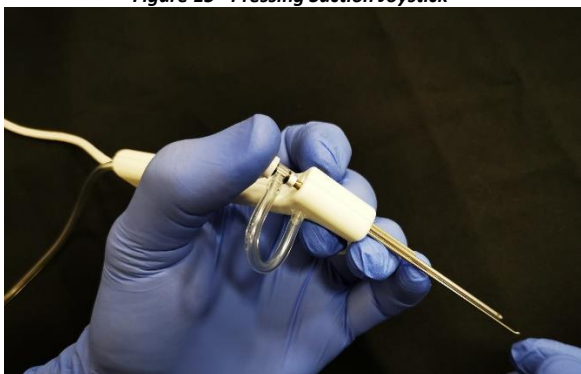


Figure 17 - Pushing Suction Cannula toward Joystick



Figure 18 - Verifying Release of Suction Joystick Spring



3. Hold the Colibri scope and insert your finger into the Finger Loop. Fasten the loop using the Adjustable Strap.

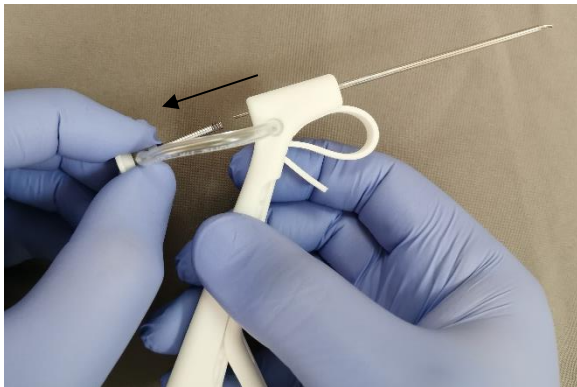


*Figure 19 - Lefthanded grip*

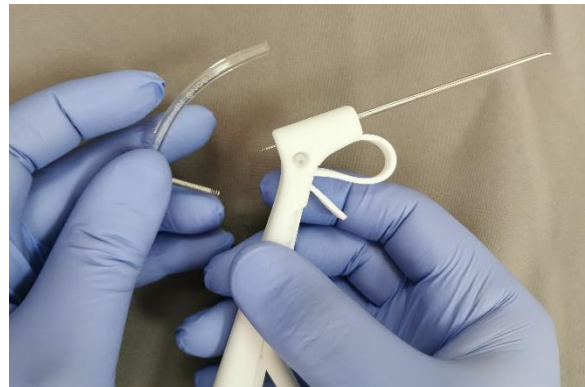


*Figure 20 - Righthanded grip*

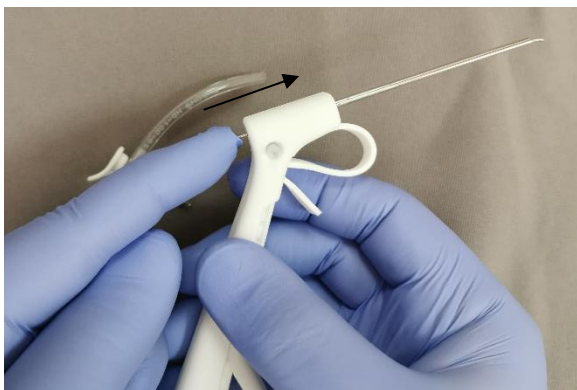
4. Switch the console power button ON.
5. Connect the proximal end of the endoscope cable to the endoscope socket on the front panel of the console.
6. Verify that a live video image appears on the console screen and that the orientation of the image as you require.
7. Ensure illumination is present at the distal tip of the scope.
- Caution:** Do not use the Colibri scope if a video image and illumination do not appear.
8. To replace the Suction Cannula or move it to the other side of the endoscope (applicable for 0° Colibri), follow these steps:
  - 8.1. Hold the Suction Joystick and pull it backward (Figure 21).
  - 8.2. Pull the Suction Tubing and detach it from the Suction Control (Figure 22).
  - 8.3. Push the Suction Cannula out of the Suction port (Figure 23) and pull it out (Figure 24).



*Figure 21 - Disconnecting the Suction Joystick*



*Figure 22 - Detaching Suction Tubing*



*Figure 23 - Removing Suction Cannula from Suction Port*



*Figure 24 - Pulling out the Suction Cannula*

## 12 PRINCIPLES OF OPERATION

1. Prepare the patient using standard clinical practice prior to an endoscopic procedure. Always verify that the endoscope is compatible with the patient's anatomy before using it.
2. When using the 20° direction of view endoscope, rotate the shaft continuously to the desired angle. To do so, use the fin located on the shaft's origin (proximal end) as depicted in Figure 24.

**Note:** Shaft rotation angle is slightly more than 360°, both clockwise and counterclockwise.

**Note:** When the fin is pointed upward, the camera looks downward (180°). This relationship remains consistent even as you rotate the shaft.



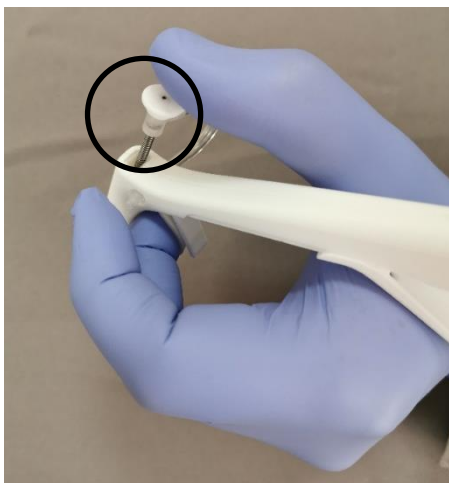
**Figure 24 Rotating the shaft to desired angle using the fin**

3. Introduce the endoscope into the patient.
4. If necessary, press the 90° rotation button on the video console screen to cyclically rotate the image on the screen, until the required orientation is reached.
5. If suction is required, connect a medical grade suction source (not provided) to the suction extension line (where applicable). Advance the suction cannula and rotate its curved tip by pressing the suction joystick down with your thumb and rotating it. Cover and uncover the Suction Control with your index finger to control suction power (Figure ).

**Caution:** Always verify that the curved suction tip remains within the visual field.

6. If irrigation is required, connect a sterile syringe (not provided) to the suction extension line (where applicable). Advance the suction cannula and rotate its curved tip by pressing the suction joystick down with your thumb and rotating it. Before irrigating, cover the Suction Control with your finger (Figure ).

**Caution:** Always verify that the curved suction tip remains within the visual field.



**Figure 25 – Suction Control**

7. For saving a screen shot or recording a video, press the corresponding buttons on the console screen.
8. At the end of the procedure, withdraw the Colibri endoscope from the patient's body.
9. Turn the console off.
10. Disconnect the scope cable from the console.
11. Dispose of the Colibri endoscope in accordance with applicable specific requirements relating to medical facility waste and potentially biohazardous materials.

### **13 STORAGE AND MAINTENANCE**

Colibri scope should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin and temperature/humidity extremes.























**Note:** Before use, Inspect every sterile package to ensure that the sterile barrier (e.g., wrap or pouch) is not torn, perforated, shows signs of moisture or appears to be tampered with. If any of those conditions are present, consider the contents non-sterile.

**14 TROUBLESHOOTING**

PROBLEM	SUGGESTED ACTION
<b>System does not turn on</b>	<ul style="list-style-type: none"> <li>• Verify that the console is connected to external power and allow console to be charged for at least 15 minutes.</li> <li>• Turn on the console by pressing the power button for 2 seconds.</li> <li>• If problem continues, contact 3NT Medical representative for further instructions.</li> </ul>
<b>No video signal (No image)</b>	<ul style="list-style-type: none"> <li>• If the video signal is lost during a procedure and cannot be restored, slowly withdraw the scope from the patient.</li> <li>• Verify that the video console is connected to external power and that it is turned on.</li> <li>• Check the cable connection between the Colibri scope and the console.</li> <li>• If the problem is still not resolved, do not use the Colibri scope.</li> <li>• If the problem is still not resolved replace scope.</li> <li>• If problem continues, Contact 3NT Medical representative for further instructions.</li> </ul>
<b>Suction cannula is clogged</b>	<ul style="list-style-type: none"> <li>• If suction cannula gets clogged and can't be cleared by suctioning saline, remove and replace with the spare suction cannula.</li> <li>• Thread the suction cleaning stylet (Figure 9) from either side to clean and unclog the suction cannula.</li> <li>• If problem continues, connect a sterile syringe to enable suction cannula flushing with saline, outside patient's body.</li> </ul>
<b>Poor quality image</b>	<ul style="list-style-type: none"> <li>• Clean the Distal Tip. Provided swab may be used.</li> <li>• If the problem is still not resolved replace scope.</li> <li>• If problem continues, Contact 3NT Medical representative for further instructions.</li> </ul>
<b>Poor or no illumination</b>	<ul style="list-style-type: none"> <li>• Clean the Distal Tip. Provided swab may be used.</li> <li>• Press on the reset button on the console rear side.</li> <li>• If the problem is still not resolved replace scope.</li> </ul>

## 15 SYMBOLS

The symbols listed below can be found on the Colibri Micro ENT Scope.

	Type BF applied part (Safety degree specified by IEC 60601-1)
	Consult instructions for use
	Caution
	Manufactured by
	Batch number
	Catalog number
	Package quantity (package contains 10 devices)
	Prescription Use Only
	Manufacturing date
	Use by date
	Do not reuse
	Ethylene oxide sterilized
	Keep away from sunlight
	Keep dry
	Do not use if package is damaged
	Waste electrical and electronic equipment (WEEE)
	Atmospheric pressure limitation (50-106 kPa)
	Humidity limitation (15-85%)
	Temperature limitation (10-55°C; 14-131°F)
	Single sterile barrier system with protective packaging outside
	Medical Device symbol
	Consult electronic instructions for use

The Colibri scope is not made with natural rubber latex.

## 16 LIMITED WARRANTY

THE WARRANTY PERIOD OF COLIBRI™ MICRO ENT SCOPE IS IN ACCORDANCE WITH THE EXPIRATION DATE OF THE DEVICE LABELING. IN CASE OF MATERIAL DEFECTS OR A DAMAGED DEVICE, 3NT MEDICAL SHALL, AT ITS OPTION, REFUND OR REPLACE THE DEVICE. 3NT MEDICAL LTD. WARRANTS THAT REASONABLE CARE HAS BEEN USED IN THE DESIGN AND MANUFACTURE OF THIS DEVICE. 3NT DISCLAIMS ALL OTHER WARRANTIES, REPRESENTATIONS, TERMS AND CONDITIONS (STATUTORY, EXPRESS, IMPLIED OR OTHERWISE) AS TO QUALITY, CONDITION, DESCRIPTION, MERCHANTABILITY, FITNESS FOR PURPOSE AND NON-INFRINGEMENT, AND ANY WARRANTY REGARDING RESULTS OBTAINED THROUGH THE USE OF THE PRODUCTS INCLUDING, WITHOUT LIMITATION, ANY CLAIM OF INACCURATE, INVALID, OR INCOMPLETE RESULTS, SINCE HANDLING AND STORAGE AS WELL AS OTHER FACTORS RELATING TO THE PATIENT, DIAGNOSIS, TREATMENT, MEDICAL PROCEDURES, AND OTHER MATTERS BEYOND 3NT MEDICAL'S CONTROL, DIRECTLY AFFECT THE DEVICE AND THE RESULTS OBTAINED FROM ITS USE. 3NT MEDICAL SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM THE USE OF THIS DEVICE. 3NT MEDICAL NEITHER ASSUMES, NOR AUTHORIZES ANY OTHER PERSON TO ASSUME FOR IT, ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THIS DEVICE.