

3NT MEDICAL

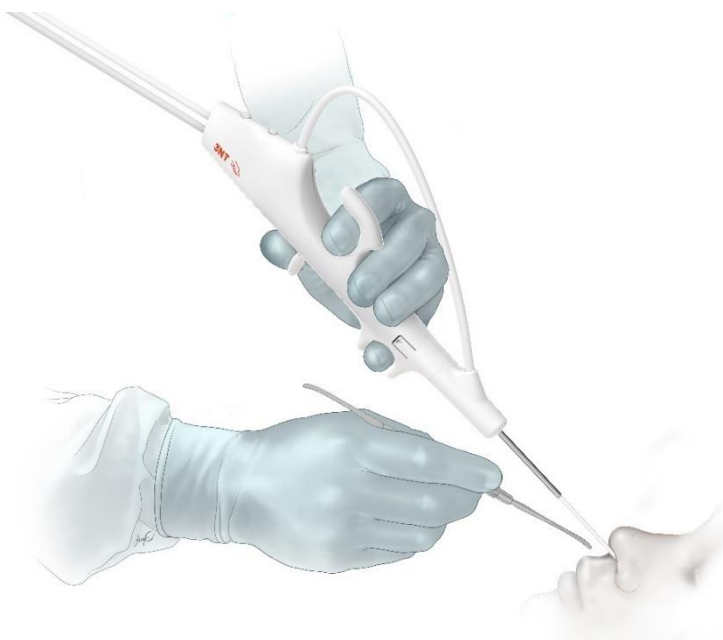


MD

RX Only

STERILE EO

User Manual (EN)



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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 only to Peregrine™ Drivable ENT Scope (item number SWY-0100), which is also interchangeably referred to in this document as Peregrine scope or Peregrine Endoscope, and is part of 3NT 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 the Peregrine™ Drivable ENT Scope.

Read this manual thoroughly prior to using the Peregrine Drivable ENT Scope 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 Peregrine™ Drivable ENT Scope 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 Peregrine Drivable ENT Scope is intended to visualize the internal cavities of the ear, airways, nose and sinus cavities during diagnostic and therapeutic endoscopy procedures.

3 PATIENT POPULATION

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 Peregrine Drivable ENT Scope should only be used by or under the supervision of a physician trained in endoscopy procedures with Peregrine scope at professional healthcare facilities.
3. The Peregrine Drivable ENT Scope is designed for single patient, single-use only and must be properly discarded after use.
4. Do not use the Peregrine Drivable 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 Peregrine scope. Reusing the Peregrine scope 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 Peregrine 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 Peregrine 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, straighten the Peregrine scope and slowly withdraw it from the patient.
9. The Peregrine Drivable 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 3NT endoscopy system to the Peregrine scope. Using incompatible equipment can result in patient or user injury, or damage to the system.
11. External suction or irrigation devices used with Peregrine scope should be medical grade only.
12. The light source (LED) at the tip of the Peregrine endoscope may heat up. Reduce periods of contact between scope tip and tissue, as sustained contact may cause patient injury.
13. Do not continue operation in a 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 Peregrine scope adjacent to or stacked with other electronic equipment should be avoided because it could result in improper operation. If such use is necessary, Peregrine scope and the other equipment should be observed to verify that they are operating normally.
16. Peregrine 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

1. Store the Peregrine scope in a cool and dry place.
2. Never use a device after its expiration date since the sterility and functionality of the device may be compromised.
3. 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.
4. Never drop the equipment or subject it to severe impact, as it could compromise the functionality and/or safety of the component or system.
5. Avoid excessive bending or twisting of the Peregrine scope's insertion tube and cable. Although they are designed to bend, excessive bending can damage internal components. In case the scope develops a severe kink or bend, do not attempt to straighten it.
6. Do not apply excessive pressure to the slider, as it could damage the scope and its components.
7. The irrigation extension line should only be used with saline. Never insert any improper liquid or gaseous media (such as medicine) to the patient through the irrigation extension line.
8. Do not look directly at the light emitted from the endoscope tip to avoid eye injury.
9. Always bring a spare Peregrine scope with you to the procedure, for use in case of non-sterile or damaged device.

7 SIDE EFFECTS

The side effects of the use of Peregrine scope may occasionally include gagging, nosebleeds or coughing as the scope is threaded through a nostril. Mucosal trauma and bleeding may rarely occur, particularly in susceptible patients with increased risk of bleeding.

8 SYSTEM DESCRIPTION

The Peregrine Drivable ENT 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 3NT endoscopy system includes the following components (Figure 1):

Product Name	Catalog Number
Peregrine™ Drivable ENT Scope	SWY-0100

Compatible Device	Catalog Number
3NT Video Console ²	CCU-0200

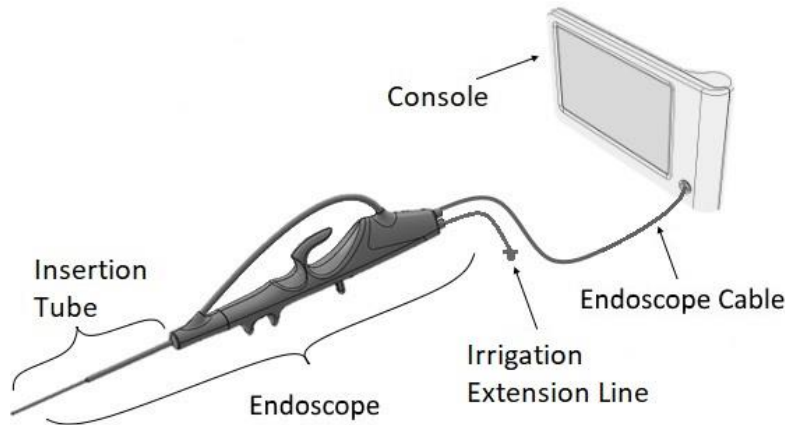


Figure 1 – 3NT Endoscopy System

Peregrine Drivable ENT Scope (single-use, EtO sterile, Figure 2) – includes a color imager that captures the video image and a light-emitting diode (LED), located at its distal tip, that provides white illumination. Additionally, the scope incorporates an integrated irrigation/suction channel with a standard luer connector. As the Peregrine endoscope is advanced into the anatomy, the slider located in the handle of the endoscope is slid forward to angulate the distal tip at angles of 0°-140°. Once the desired angle is reached, the toggle button is pressed and the slider is further slid forward to advance the tip of the endoscope over the angulation and into the anatomy. The Peregrine endoscope connects to the video console via the endoscope cable. The Peregrine endoscope is disposed of at the end of the procedure.

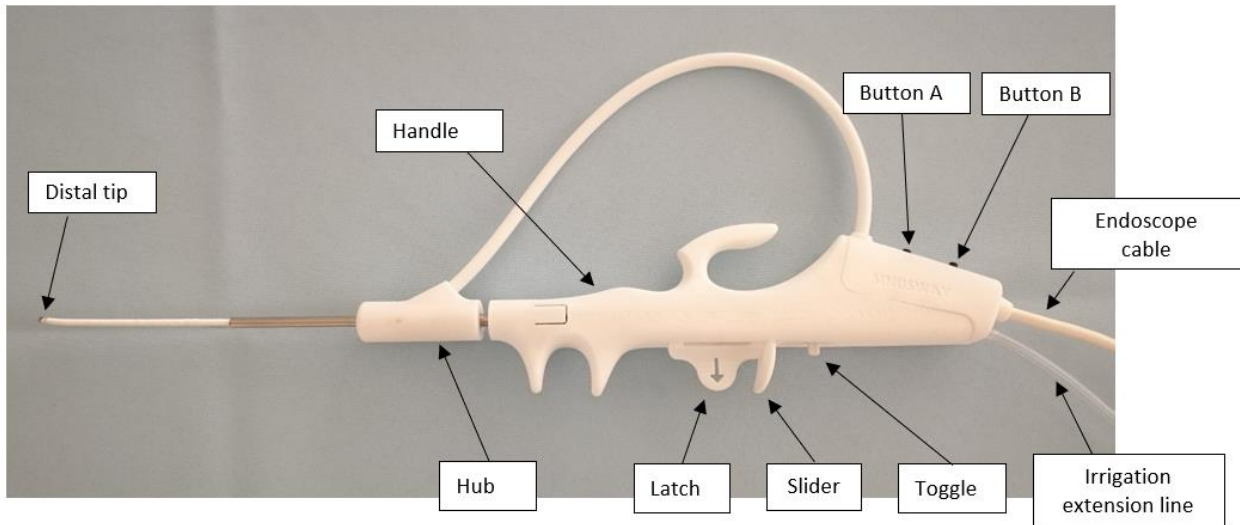


Figure 2 - Peregrine Endoscope

Ancillary Equipment for Irrigation and Suction

Suction:

The Peregrine™ is equipped with a standard luer connector at the end of its extension line.

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.

9 PEREGRINE SCOPE SPECIFICATIONS

Specification	Details
Distal tip diameter	0.114" (2.9 mm)
Distal tip shape & width	Rectangular, maximum width 0.106" (2.7 mm)
Maximum Insertion tube diameter	0.138" (3.5 mm)
Insertion tube working length	4.72" (120 mm)
Depth of field	0.196"-1.96" (5-50 mm)
Field of view (air)	90°, 120° Diagonal (air)
Direction of view	0°
Tip angulation range	0 - 140°
Tip extension beyond angulation point	Maximum 1.18" (30 mm)
Illumination method	LED
Working Channel	Integrated
Cable length	66.93" (170 cm)
Scope weight (excluding cable)	0.189 lbs. (86 gr)
Scope weight (including cable)	0.320 lbs. (145 gr)
Operating Environment Temperature	50° to 86° F (10° to 30° C)
Storage Environment Temperature	14° to 131° F (-10° to +55° C)
Relative Humidity	15%-85% RH
Atmospheric Pressure	50-106 kPa
Medical Endoscopes Optical Requirements	ISO 8600-1
Electrical & Thermal Safety	IEC 60601-1, IEC 60601-2-18
Electromagnetic Compatibility	IEC 60601-1-2
Degree of Protection Against Electrical Shock	Type BF (Body Floating)

10 UNPACKING

1. Visually Inspect 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 then the contents should be considered non-sterile.

Note: Sterilization indicator is attached on pouch. Green color indicate that the unit has been directly exposed to an EO sterilization process. Purple color indicate that the device is non-sterile.

Caution: Do not use the equipment if any defects are detected.

2. Open the sterile pouch from its short side with the wider margins (Figure 3) and take out the die-card.

Caution: While opening the sterile pouch, avoid contact of the Peregrine scope with the pouch external edge or closure or with potential contaminants (e.g. airborne particles, dust, etc.) in order to avoid disrupting sterility.

Caution: Handle the endoscope with care. While the distal tip of the insertion tube can articulate, excessive pressure can damage the device.



Figure 3 – Pouch opening

3. Remove the Peregrine scope from the die card, by following steps 1 through 4 marked on the die card (Figure 4).



Figure 4 – Die card

- 3.1. Pull aside cover no.1 which protects the endoscope distal tip (Figure 4).
- 3.2. Push down the latch to release the endoscope shaft (Figure 5)
- 3.3. Hold the Hub and pull it up from latch no.2 (Figure 6).
- 3.4. Pull up the device from latch no.3 to release the handle (Figure 7).
- 3.5. Push from the back both straps no.4 to release the cable and the irrigation extension line (Figure 8).

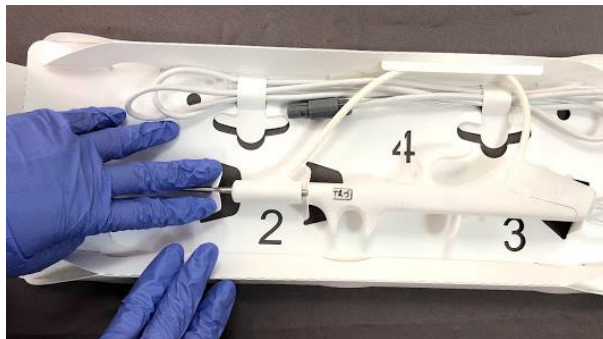


Figure 5 – Push down the latch



Figure 6 – Pull up the hub



Figure 7 – Pull up the device



Figure 8 – release cable

11 SYSTEM PREPARATION AND INSPECTION

1. Visually inspect the Peregrine scope integrity.
2. Remove the latch from the endoscope before use (Figure 9).

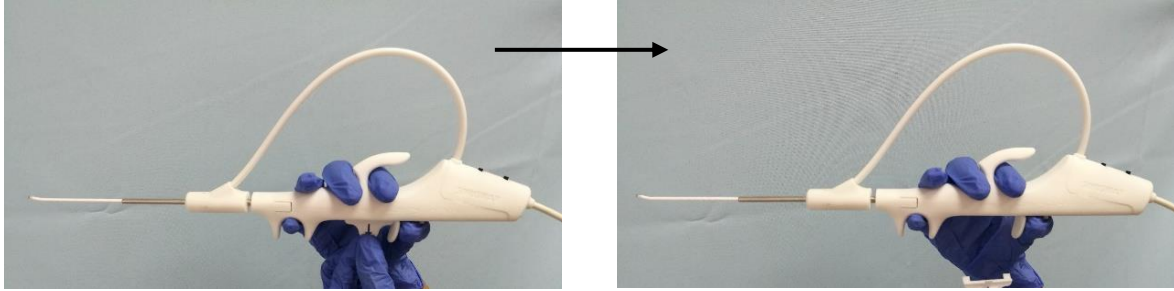
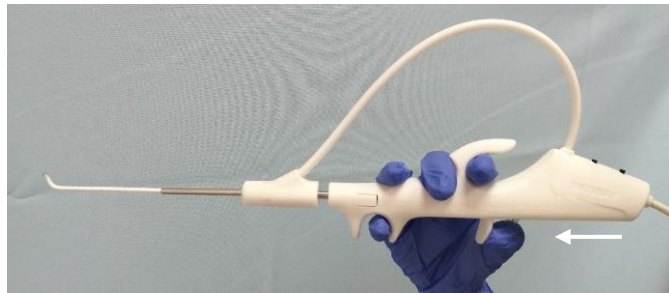
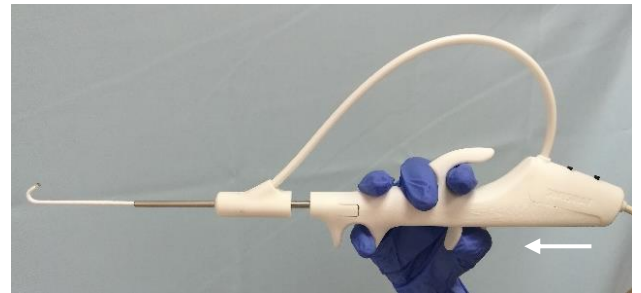


Figure 9 - Latch removal

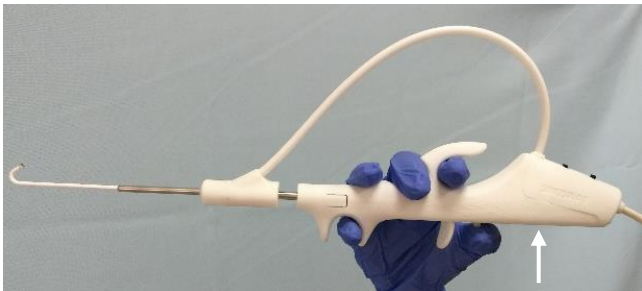
3. Advance the Slider forward (toward the left side, in Figure 10 (a+b)) and observe how the endoscope angulates. Slide it back (toward the right, in Figure 11) and observe how the endoscope straightens.



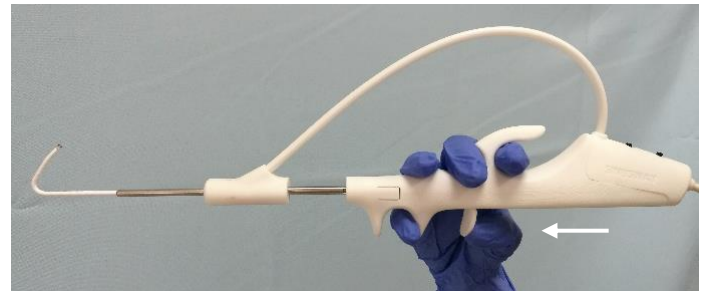
(a) Angulation



(b) Angulation



(c) switch to advancement



(d) Advancement

Figure 10 - Angulation and advancement of the Peregrine scope

4. Press and release the toggle to switch from angulation mode to advancement mode (Figure 10 c).
5. Advance the slider forward. Observe how the Peregrine scope advances and extends beyond the point of angulation (Figure 10d).
Note: Excessive pressure applied to the slider may damage the endoscope. Do not exert force to move the slider beyond its natural limits.
6. Retract the slider all the way backward (Figure 11) to retract the endoscope and straighten it.

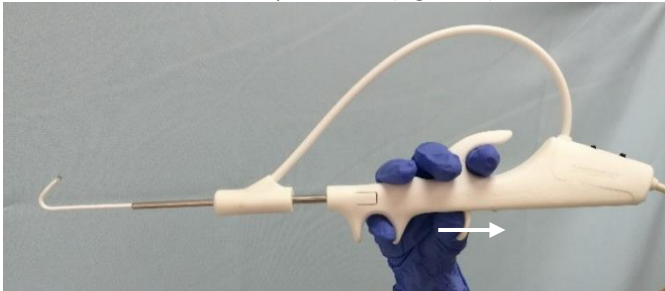


Figure 11- Retraction of the Peregrine scope

7. If needed, Peregrine endoscope can rotate around its axis in 45° increments (Figure 12).

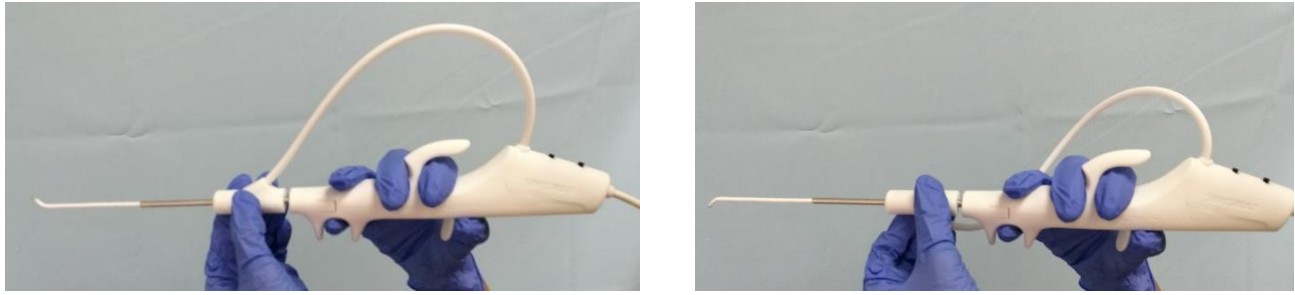


Figure 12 - Rotation of the Peregrine scope around its axis

8. Switch the console power button ON.
9. Connect the proximal end of the endoscope cable to the endoscope socket on the front panel of the console.
10. Verify that a live video image appears on the console screen and correctness of image orientation.
11. Ensure illumination is present at the scope distal tip.

Caution: Do not use the Peregrine scope if a video image and illumination do not appear.

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 the endoscope.
2. Introduce the endoscope into the patient. Operate the slider as necessary for advancement and observation.
3. If required, rotate the Peregrine scope around its axis. If necessary, press the 'A' button to cyclically rotate the image on the screen in 90° increments, until the desired orientation is reached.
4. If irrigation is required, connect a sterile syringe (not provided) to the irrigation extension line.
Warning: To prevent over irrigation ensure that sinus contents and irrigation fluid can exit the sinus cavity.
5. If suction is required, connect a medical grade suction source (not provided) to the irrigation extension line.
6. To begin recording video, press the 'B' button. Press the same button once more to end the recording.
7. To remove the Peregrine scope, retract the slider all the way backward, and withdraw the endoscope from the patient's body.
8. Turn off the console.
9. Disconnect the scope cable from the console.
10. Dispose of the Peregrine scope in accordance with applicable specific requirements relating to medical facility waste and potentially biohazardous materials.

13 STORAGE AND MAINTENANCE

Peregrine 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.
















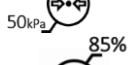
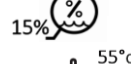




Note: Inspect every sterile package before use to ensure that the sterile pouch is not torn, perforated, shows signs of moisture or appears to be tampered with. If any of those conditions are present, then the contents should be considered non-sterile.

14 TROUBLESHOOTING

PROBLEM	SUGGESTED ACTION
System does not turn on	<ul style="list-style-type: none"> • Verify that the console is connected to external power and allow console to be charged for at least 15 • Turn on the console by pressing the power button for 2 seconds. • If problem persists, contact 3NT Medical representative for further instructions.
Unexpected resistance when articulating Peregrine scope	<ul style="list-style-type: none"> • Retract the Peregrine scope and remove it. Check proper articulation in free space. • Contact 3NT Medical representative for further instructions if the problem persists.
No video signal (No image)	<ul style="list-style-type: none"> • If the video signal is lost during a procedure and cannot be restored, straighten the scope and slowly withdraw it from the patient. • Verify that the video console is connected to external power and that it is turned on. • Check the cable connection between the Peregrine scope and the console. • If the problem is still not resolved, do not use the Peregrine scope. • If the problem is still not resolved replace scope. • If problem continues, Contact 3NT Medical representative for further instructions.
Poor quality image	<ul style="list-style-type: none"> • Clean the Distal Tip with an alcohol pad to remove material or stain. • Irrigate with sterile saline or sterile water to remove mucus and debris from lens at the Distal Tip. • If the problem is still not resolved replace scope. • If problem persists, Contact 3NT Medical representative for further instructions.
Poor or no illumination	<ul style="list-style-type: none"> • Clean the Distal Tip with an alcohol pad to remove material or stain. • Press on the reset button on the console rear side. • If the problem is still not resolved replace scope.

15 SYMBOLS

The symbols listed below can be found on the Peregrine Drivable ENT Scope.

	Type BF applied part (Safety degree specified by IEC 60601-1)
	Consult instructions for use
	Caution
	Manufactured by
	Batch number
	Catalog number
	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
	Humidity limitation
	Temperatures limitation
	Single sterile barrier system with protective packaging outside
	Medical Device symbol
	Consult electronic instructions for use

The Peregrine scope is not made with natural rubber latex.

16 LIMITED WARRANTY

THE WARRANTY PERIOD OF *PEREGRINE™ DRIVABLE 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.