



FinESS™ Endoscope INSTRUCTIONS FOR USE

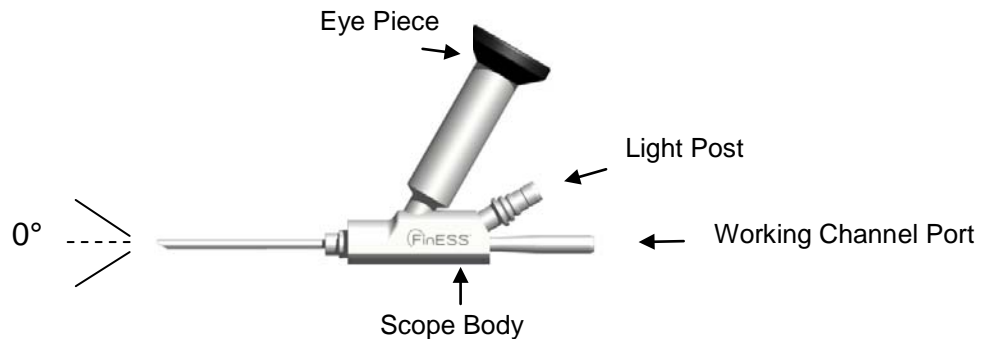
ALL INSTRUCTIONS, PRECAUTIONS AND WARNINGS SHOULD BE CAREFULLY READ AND UNDERSTOOD BEFORE USE. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS AND WILL VOID ANY EFFECTIVE WARRANTY.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

DESCRIPTION

The Entellus Medical FinESS Endoscope has the following features:

- The FinESS Endoscope has a 3.2mm outer diameter, a 0° direction of view, and a 1.75mm internal diameter working channel.
- The working length of the endoscope is 60mm
- The Eye Cup of the endoscope is compatible with standard “B” mount camera couplers.
- The endoscope is compatible with standard light cables and adapters



INDICATION FOR USE

The FinESS Endoscope is intended to provide a means to visualize the maxillary sinus cavity and deliver the FinESS balloon dilation catheter to treat the maxillary sinus ostium and the ethmoid infundibulum in adults with a trans-antral approach. The endoscope is part of the FinESS Sinus Treatment and is inserted via a sterile access sheath through the canine fossa.








CONTRAINDICATIONS

The use of endoscopes is not permissible in situations where endoscopic procedures are contraindicated for medical reasons.

WARNINGS

- !** The FinESS Endoscope is provided NON-STERILE and must be sterilized or high level disinfected prior to its first use and every subsequent use (see Care & Handling, Cleaning, High Level Disinfection, and Sterilization Instructions sections). Cleaning, Disinfection, and Sterilization of this product must be performed by staff skilled in the reprocessing of medical devices following the directions and guidelines provided. Refer to http://www.cdc.gov/ncidod/dhqp/bp_sterilization_medDevices.html for the CDC document titled “Sterilization or Disinfection for Medical Devices” for general information about preventing the spread of infection for reusable devices.

WARNINGS cont.

-  Do not sterilize the FinESS Endoscope in an autoclave or other types of steam sterilization. Exposure to temperatures greater than 65°C (150°F) may damage the device.
-  Do not clean the FinESS Endoscope with ultrasonic cleaning. Ultrasonic cleaning can permanently damage the endoscope lenses and fiber optic components.
-  Do not use an endoscope disinfected with CIDEX™ OPA on patients with CIDEX OPA sensitivity.
-  Do not use a FinESS Endoscope that has been damaged. Use of equipment that is not in good working condition may compromise patient safety.
-  Do not use reprocessing chemicals or channel cleaning instruments that are not specified in these instructions for use. Use of these chemicals or channel cleaning instruments may result in damage to the endoscope or may reduce the effectiveness of the disinfection or sterilization process.
-  Do not use the FinESS Endoscope with a xenon light source > 300W or a light guide (cable) > 5mm in diameter. High energy light radiated through endoscopes can result in high temperatures in front of the light outlet and at the connection point with the light cable, including the light guide adapters. Use of a higher wattage light source or larger diameter cable may result in burns or permanent tissue damage to the user or the patient.
-  Allow the endoscope system to cool for a few minutes before disassembling the endoscope from the light guide adapter and light guide cable.

PRECAUTIONS

- » Clean and disinfect or clean and sterilize the FinESS Endoscope prior to its first use and every subsequent use per the included Cleaning, Disinfection and Sterilization Instructions. If high level disinfection is the method chosen, this step must be performed immediately prior to use on a patient.
- » Observe the exposure times discussed in the Cleaning and Disinfection sections. The FinESS Endoscope may become slightly discolored by over-exposure to ENZOL™ Enzymatic Detergent (if soaked longer than 8 hours) or CIDEX OPA Solution (if soaked longer than 7 days). The potential discoloration will not alter the function of the instrument.
- » Inspect the FinESS Endoscope prior to each use for signs of wear and tear, damage, or failed or degraded image quality. Discontinue the use of an endoscope with severe bends, signs of corrosion, mechanical damage to the optical components at the tip, degraded or cloudy image quality or a complete loss of image. These devices should not be used and should be sent to the manufacturer for replacement, disposal, or repair. Consult the Return for Service section of this document for customer service contact information.
- » Use only non- or semi-abrasive instruments (FinESS balloon dilation catheter and cleaning brushes) that fit within the 1.75 mm working channel of the FinESS Endoscope. Sharp or abrasive metal instruments may damage the working channel of the endoscope.
- » Only use cleaning brushes listed in the Recommended Supplies section. Use of other brushes has not been tested and may damage device.

PRECAUTIONS cont.

- » Use solutions that are non corrosive to surgical stainless steel in the working channel. This includes 70% isopropyl alcohol, ENZOL enzymatic detergent, CIDEX OPA disinfectant and STERRAD™ processing agents.
- » Connect the FinESS Endoscope to a camera prior to each use to ensure the FinESS Endoscope projects an acceptable image. A cloudy image is a sign that a leak may have occurred in the endoscope.
- » Do not use the FinESS Endoscope with an endo sheath.
- » If the FinESS endoscope is dropped, contact a representative to assess if the endoscope is acceptable for use. Alternatively, return the endoscope to Entellus Medical for assessment using the guidance provided in the Return for Service section.
- » Do not hang the FinESS Endoscope in a storage cabinet or store in a tray other than the recommended storage tray.
- » Do not store the FinESS Endoscope or light post adapters in the foam-lined shipping box between uses because the foam liners can retain microbes.

RECOMMENDED SUPPLIES

- Sterile water
- Sterile gauze pads or sterile disposable cloth
- Sterile Anti fog pads
- ENZOL detergent for cleaning
- CIDEX OPA Solution for high level disinfection if desired
- Sterile plastic syringes with a male luer lock or luer slip tip for cleaning and disinfecting
- Disposable 5 mm nylon brush, ≥ 7 inches long for cleaning, such as the brush indicated as catalog number TR350354 from HealthMark Industries Co. (or equivalent)
- Syringe with ≥ 20 mL volume capacity having either a male luer lock or a luer slip tip
- FinESS Endoscope Sterilization Tray (Model RT-300) or any instrument tray approved for use in the STERRAD NX™ / 100NX™ sterilizers
- FinESS Sinus Treatment

Equipment for Imaging Enhancement

- Use a xenon light source with at least 150W but no more than 300W in power.
- Use a light guide (cable) that is at least 3.5 mm but not more than 5mm in diameter.
- A high definition camera system and a ≥ 19 " display is recommended. High definition camera systems with image enhancement options (i.e. – gain, zoom adjustment) are preferred for optimum viewing.
- For options on enhancing the projected image refer to the Instructions for Use supplied with camera, light source and display.

CARE AND HANDLING

- The FinESS Endoscope is constructed with glass fiberoptic and lens components. Special care must be taken to prevent damage to the optics and to maintain optimal functionality and longevity of the endoscope.
- Protect the endoscope system during procedural use and transportation between the procedural room and reprocessing location. Avoid harmful interaction with other surgical instruments or tools. The FinESS Endoscope contains glass optics that may be damaged if misused.

- Periodically inspect (10X magnification) the lens in the distal tip of the endoscope for signs of mechanical damage such as chipping, pitting, cracks, or nicks. Discontinue use of the endoscope or return to the manufacturer if damage is noted.

COMPATIBILITY

The FinESS Endoscope is compatible with the FinESS balloon dilation catheter and the FinESS access sheath. Please refer to the FinESS Sinus Treatment Instructions for Use for detailed information and instructions on the use of the FinESS Sinus Treatment system. The FinESS Endoscope is not compatible with the XprESS Multi Sinus Dilation Tool.

INSTRUCTIONS FOR USE

1. Verify that endoscope has been cleaned and disinfected or cleaned and sterilized.
2. Inspect the working lumen of the FinESS Endoscope to assure it is free of obstruction.
3. Prior to each use, check the image quality. If the picture is blurry and does not clear using standard cleaning methods, do not use the endoscope and contact Entellus Medical for servicing of the endoscope.
4. Connect the endoscope to the selected light source and camera using one of the adaptors provided, if necessary.
5. The FinESS Endoscope is introduced through the opening of the FinESS access sheath and guided under direct visualization assisted by video system. *Please refer to the FinESS Sinus Treatment Instructions for Use for detailed information and instructions on the use of the FinESS Sinus Treatment system.*
6. The FinESS balloon dilation catheter is introduced through the FinESS Endoscope working channel. *Please refer to the FinESS Sinus Treatment Instructions for Use for detailed information and instructions on the use of the FinESS Sinus Treatment system.*

Note: If suction or irrigation is desired during the procedure, remove the FinESS Endoscope from the sinus and perform standard irrigation or suction techniques.

CLEANING, DISINFECTION, AND STERILIZATION INSTRUCTIONS

Pre-Cleaning (Immediately After Use)

1. Remove heavy soil from the endoscope by wiping the exterior with a wet (using sterile water) disposable cloth.
2. Aspirate sterile water through the working channel until the rinsed solution is visibly free of organic matter (standard suction may be used). If the working channel becomes plugged, use the recommended nylon brush to clean debris out of the channel.
3. Transfer to the cleaning location for further cleaning and reprocessing as soon as possible.

Cleaning (Prior to Disinfection or Sterilization)

The FinESS Endoscope must be cleaned with an enzymatic cleaner / detergent (ENZOL Enzymatic Detergent is recommended) to remove all tissue, materials and debris prior to initial use; immediately after every procedural use; and before disinfection or further reprocessing.

All instructions provided by the enzymatic detergent manufacturer and provided below must be carefully followed.

Note: The entire FinESS Endoscope is submersible.

1. Wear all manufacturer recommended personal protective clothing / equipment when performing any cleaning procedure.

2. Use fresh cleaning solutions for each cleaning.
3. Prepare the enzymatic cleaner/detergent following the manufacturer's instructions (for ENZOL, use 1 ounce/gallon of water; if there is dried on organic soil on endoscope use 2 ounces/gallon and/or warm water.) Ensure there is sufficient enzymatic solution to fully submerge the endoscope.
4. Disconnect the light post adapter(s) from the endoscope (if present) by rotating it counter-clockwise in relation to the endoscope.
5. Fully Immerse the endoscope and light post adaptors into the detergent solution.
 - While fully submerged, use the recommended syringe to flush the working channel with approximately 20cc of the enzymatic solution and let it soak.
6. Soak the endoscope and light post adapters in the enzymatic cleaning solution for the recommended soak time provided by the enzymatic detergent manufacturer. For ENZOL, a minimum soak time of 1 minute is recommended. If endoscope has dried-on organic matter, extend soak time while performing step 7 below. Total soak time may take approximately 5-6 minutes if the endoscope has dried-on organic matter.
7. While fully submerged, clean the endoscope and light adaptors, paying close attention to the distal segment and the working channel.
 - Wipe the entire external portion of the endoscope and adapters using a cloth or towel while the endoscope and adapters are submerged in the enzymatic detergent solution. Heavily soiled areas can be scrubbed with the recommended nylon brush.
 - Wipe the distal end containing the lenses gently, but thoroughly, with the cloth or towel to remove any contaminants remaining on the endoscope.
 - Clean the inner diameter of the working lumen of endoscope and lumen of adapters using the recommended nylon brush. While the endoscope is submerged, insert the brush through the hub of the endoscope and advance it until the bristles of the brush extend out past the distal end of the endoscope. Remove any visible debris from the brush and pull back through the working lumen until completely removed. Clean any residual debris from the brush between passes through the lumen.



Note: The pictures are for illustration only. Brushing should be done with the endoscope fully submerged.

- Repeat the brushing of the working lumen until no visual signs of debris are present on the brush.
 - Brush the adapter lumens with a circular motion combined with a back and forth motion until no visible signs of debris are present on the brush.
8. Thoroughly rinse the outside of the endoscope and the light adaptors with water and aspirate at least 100cc of water through the lumen. Dionized or de-mineralized water is recommended.
 9. Dry the devices using low pressure, filtered air. Purge the working lumen with air until all visible water is removed. Note: The endoscope can withstand air pressure of up to 70 psi while drying. The endoscope may also be purged with air using the recommended syringe if house air is not available.
 10. Manually dry the external portions of the endoscope and adapters with a clean absorbent cloth or towel.
 11. Discard the enzymatic cleaner and the disposable cleaning brush used on the FinESS Endoscope after a single use.

12. Store cleaned endoscope in a clean container or instrument tray capable of securing and isolating the endoscope from other instruments. The container or instrument tray should be oriented with the endoscope vertical during storage. See “Storage Between Use” section for more details.

High Level Disinfection

The FinESS Endoscope can be disinfected with the manual high level disinfection process using the CIDEX OPA Solution (i.e., 0.55% ortho-phthaldehyde). Follow all instructions provided by the manufacturer of CIDEX OPA Solution when performing the disinfection process. The recommended temperature for CIDEX OPA Solution is a minimum of 20° C or 68° F. **Disinfect scope immediately prior to use.**

Note: The entire FinESS Endoscope is submersible.

1. Wear all manufacturer recommended personal protective clothing / equipment prior to performing disinfection with CIDEX OPA Solution.
2. Add the CIDEX OPA Solution into a compatible disinfection container. Ensure that there is sufficient CIDEX OPA solution to completely submerge the endoscope.
3. Confirm that the concentration of the disinfectant meets the minimum effective value using the test strip specified by the manufacturer prior to each use.
4. Ensure that the endoscope and light post adapters have undergone a cleaning process with an enzymatic detergent prior to the disinfection.
5. Disconnect the light post adaptor(s) from the endoscope (if attached) by rotating it counter-clockwise in relation to the endoscope.
6. Fully Immerse the endoscope and light post adaptors into the CIDEX OPA Solution.
 - o While fully submerged, use the recommended syringe to flush the working channel with approximately 20cc of the CIDEX OPA Solution and let it soak.
7. Soak the endoscope and light post adapters in the CIDEX OPA Solution for the minimum time recommended by the manufacturer (at least 12 minutes). The disinfectant should entirely fill the channel to have full contact for at least 12 minutes.
8. Rinse the light post adapters and the FinESS Endoscope
 - o Fully submerge the endoscope and light post adapters in a minimum of 2 gallons of sterile water for at least one minute.
 - o Flush the working channel with at least 100cc of sterile water using the recommended syringe.
 - o Remove the endoscope and light post adapters and discard the rinse water.
9. Repeat step 8 TWO additional times for a total of 3 rinse cycles using fresh water for each cycle.
10. Dry the outside of the device by using low pressure, filtered air or with a sterile wipe or cloth. Note: The endoscope can withstand air pressure of up to 70 psi while drying.
11. Flush the working lumen with 70% isopropyl alcohol (IPA) until the IPA can be seen exiting the opposite end of the endoscope.
12. Flush the working lumen with low pressure, filtered air (or syringe air) until no liquid can be seen exiting the lumen.
13. Remove residual fluid from the lenses of the FinESS Endoscope with a sterile alcohol wipe (if needed).
14. Dry the light post adapters and the FinESS Endoscope using a sterile towel or cloth.

Sterilization

The FinESS Endoscope may be sterilized with either the STERRAD 100NX standard cycle or STERRAD NX Advanced Cycle processes. Follow all instructions for use provided for the

respective STERRAD systems to load the sterilization chamber, to sterilize the FinESS Endoscope, to maintain sterility of the FinESS Endoscope and for proper aseptic presentation to the surgical field.

- Assure that the endoscope and light post adapters have undergone a cleaning process prior to conducting the sterilization process.
- Sterility can only be assured if the instructions provided for performing the STERRAD process are followed.
- Only use containment devices approved for use in the STERRAD NX and STERRAD 100NX sterilizers respectively (i.e. FinESS Endoscope Sterilization Tray, Model RT-300).
- Monitor the effectiveness of the sterilization process with a biological indicator approved for use with the STERRAD NX Advanced Cycle or STERRAD 100NX Standard Cycle based on the system used.

The following sterilization supplies were included in the sterilization validation for the FinESS Endoscope:

- STERRAD Instrument Tray PC 13837
- STERRAD Silicone Mat PC 99211
- STERRAD Chemical Indicator Strip PC 14100
- Test Organism: *G. stearothermophilus* BI coupons and discs
- STERRAD Sterilization Pouch (TYVEK™ Pouches)

The STERRAD NX and 100NX Sterilizers use a hydrogen peroxide gas plasma sterilization process which is well suited for thermo- sensitive items. In plasma sterilization, it is possible for the surfaces of aluminum alloys to discolor. The metal, cylindrical portion of the endoscope eye piece is fabricated from anodized aluminum. The potential discoloration to this component will not alter the function of the instrument.

Note: There are limits regarding the size, length and material of instruments with lumens which may be sterilized using STERRAD. Verify the compliance of the endoscope instrument with the instructions provided for either the STERRAD 100NX or STERRAD NX Sterilizer depending on which system is being used.

HOW SUPPLIED

The FinESS Endoscope is supplied non-sterile and must be sterilized before its first and every subsequent use. The items packaged with the FinESS Endoscope include the Instructions for Use and 2 light post adapters. Retain the light post adapters with the endoscope for use with various configuration light cables (e.g., light cables for ACMI™, RICHARD WOLF™, KARL STORZ™, or OLYMPUS™ systems).

STORAGE BETWEEN USE

Do not hang the FinESS Endoscope in a storage cabinet or store in a tray other than the recommended storage tray.

Adhere to the following for the storage of the FinESS Endoscope after cleaning:

- Store individual endoscopes in the FinESS Endoscope Sterilization Tray (Model RT-300) or separate clean containers. Interaction with other instruments may cause damage to the endoscope and reduce the useful lifespan. Any general instrument tray capable of securing and isolating the FinESS Endoscope from other instruments may be used to store the scope. The container or instrument tray should be oriented with the endoscope vertical during storage.
- If a dirty endoscope (un-cleaned) was accidentally stored in the instrument tray, or the tray is visibly dirty, clean and disinfect or clean and steam sterilize the tray before further use.

If high level disinfection is the method chosen, the step should be performed immediately prior to use on the patient. Storage in a tray does not maintain the level of disinfection. Thus, a high level disinfected endoscope placed into a clean tray, must be reprocessed again before use on a patient.

If sterilization by the STERRAD NX or 100NX process is chosen, follow the STERRAD instructions to maintain sterility of the endoscope between uses. Use a reprocessing tray for storing and sterilizing the FinESS Endoscope that complies with the STERRAD process and instructions (FinESS Endoscope Sterilization Tray, Model RT-300 is recommended).

WARRANTY ASSESSMENT / RETURN FOR SERVICE

If an endoscope becomes damaged or fails to project an image take the following actions to have the scope assessed for warranty coverage or replacement.

Contact Customer Service. Describe malfunction.

Phone: (866) 620-7615

Fax: (866) 620-7616









If returning devices for assessment all products must be cleaned and either disinfected or sterilized prior to shipping per one of the approved methods described within this document. Documentation must be provided stating the device has been reprocessed prior to shipping.

If disposing devices, discard devices and all waste products according to appropriated environmental health safety guidelines.

Limited Warranty

Entellus Medical, Inc. warrants that reasonable care has been used in the design and manufacture of this device. Entellus Medical, Inc. excludes all warranties, whether expressed or implied, by operation of law or otherwise including, but not limited to, any implied warranties of merchantability or fitness since handling, storage, cleaning and sterilization of the device, as well as other factors relating to the patient, diagnosis, treatment, medical procedures, and other matters beyond Entellus Medical, Inc.'s control, directly affect the device and the results obtained from its use. Entellus Medical, Inc. shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this device. Entellus Medical, Inc. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

Graphic Symbols Contained on Device labeling

 REF Reorder Number	 LOT Lot Number	 MODEL Model Number	 Manufacturer
 See Instructions For Use	 Rx Only Prescription Use Only	 NON STERILE Device Is Non Sterile	 Does not contain natural rubber latex



Manufactured for:
Entellus Medical Inc.
 6705 Wedgwood Court North
 Maple Grove, MN 55311
 (763) 463-1595
www.entellusmedical.com

U.S. and Foreign patents pending.

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