



PathAssist™ Light Seeker™ INSTRUCTIONS FOR USE

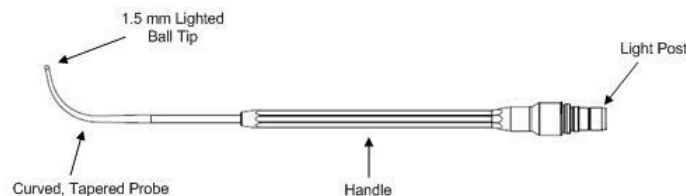
ALL INSTRUCTIONS, PRECAUTIONS AND WARNINGS SHOULD BE CAREFULLY READ AND UNDERSTOOD BEFORE USE. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS AND WILL VOID ANY EFFECTIVE WARRANTY.

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

DESCRIPTION

The PathAssist Light Seeker is a fiber optic based, manually operated, reusable sinus seeker that can be connected to a light source to emit light from its distal end. It also has the following design features:

- 1.5mm ball tip, with a 78° tip angle
- working length of 75mm
- compatible with a 2.5mm light cable and standard light post adapters, and a 300 W Xenon light source



Items packaged with the Light Seeker include two standard light post adapters (Wolf and Storz).

INDICATION FOR USE

The PathAssist Light Seeker is intended to locate, illuminate within, and transilluminate across nasal and sinus structures, including the frontal, ethmoid and maxillary sinuses, in patients aged 18 and over.

CONTRAINDICATIONS

None known

WARNINGS

- The Light Seeker is provided NON-STERILE and must be cleaned and high level disinfected or cleaned and sterilized prior to its first use and every subsequent use (see Care & Handling, Cleaning, High Level Disinfection and Sterilization Instructions sections). Cleaning, high level disinfecting, 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 the CDC website http://www.cdc.gov/HAI/prevent/sd_medicalDevices.html for “Sterilization or Disinfection for Medical Devices” and the document titled “Guidelines for Infection Control in Healthcare Personnel” for general information about preventing the spread of infection for reusable devices. If further information or a hard copy of the guidelines document is required, the CDC may be contacted at the website listed above or by telephone at 1-800-CDC-INFO (1-800-232-4636).
- Advance the Light Seeker under endoscopic visualization only.
- Never advance or withdraw the Light Seeker against unknown resistances as this can cause tissue trauma or bleeding.
- Do not clean the Light Seeker with ultrasonic cleaning. Ultrasonic cleaning can permanently damage the fiber optic components.
- Do not use the Light Seeker high level disinfected with CIDEX™ OPA Solution on patients with CIDEX OPA sensitivity.

- Do not use reprocessing chemicals that are not specified in these instructions for use. Use of these chemicals may result in damage to the Light Seeker or may reduce the effectiveness of the cleaning, high level disinfection or sterilization processes.
- Do not use the Light Seeker with a xenon light source > 300W and a light cable > 2.5mm. High energy light radiated through the Light Seeker can result in high temperatures in front of the light outlet and at the connection point to the light cable, including the light guide adapters. Use of a higher wattage light source or larger light cables may result in burns or permanent tissue damage to the user or the patient.
- Do not rest the Light Seeker on the patient during surgery while it is connected to a light source, as this could result in burns to the patient.
- Allow the Light Seeker to cool for a few minutes before disassembling from the light guide adapter and light guide cable.

PRECAUTIONS

- Due to the variability of sinus anatomy, review radiographic imaging (CT scan) prior to the procedure to understand anatomy.
- Do not use the Light Seeker for diaphanoscopy (e.g., external transillumination of maxillary sinus by applying Light Seeker to the hard palate) as this use has not been tested.
- Clean and high level disinfect or clean and sterilize the Light Seeker prior to its first use and before every subsequent use per the included Cleaning, High Level Disinfection and Sterilization Instructions.
- If high level disinfection is the method chosen, this step must be performed immediately prior to use on the patient.
- Confirm that a stored Light Seeker has been manually cleaned prior to manual high level disinfection or sterilization. If prior cleaning cannot be confirmed, clean the Light Seeker again as a precaution.
- Do not use “flash” or “immediate use” sterilization as this will not ensure sterilization and may damage the Light Seeker.
- Use only manual cleaning and manual high level disinfection processes as the fiber optic components of the Light Seeker may be damaged from automatic cleaning processes (instrument washers and washer/disinfector machines). Only manual cleaning and manual high level disinfection processes have been validated for the Light Seeker.
- Inspect the Light Seeker prior to each use for signs of wear and tear, damage, or failed or degraded light quality. Discontinue the use of a Light Seeker with severe bends, signs of corrosion, or mechanical damage to the fiber optic components at the tip. These Light Seekers should not be used and should be disposed of or sent to the manufacturer for evaluation. Consult the Return for Service section of this document for customer service contact information.
- Use solutions that are non corrosive to surgical stainless steel. These include 70% isopropyl alcohol, sterile water, ENZOL enzymatic detergent and CIDEX OPA Solution.
- Connect the Light Seeker to a 2.5mm light cable and 300W Xenon light source prior to each use to verify that the Light Seeker projects an acceptable light beam.
- If the Light Seeker is dropped, return it to Entellus Medical for assessment using the guidance provided in the Return for Service section.
- Do not store the Light Seeker 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 cotton cloth
- Sterile Anti fog pads
- ENZOL detergent for cleaning
- CIDEX OPA Solution (0.55% ortho-phthalaldehyde, Advanced Sterilization Products) for high level disinfection, if desired

- CIDEX OPA Solution compatible instrument tray or container for high level disinfection, if desired (refer to information provided by the manufacturer of CIDEX OPA Solution to aid in choosing a compatible container)
- Disposable 5mm nylon brush
- Alcohol pad 70% IPA
- Reprocessing double peel packs

CARE AND HANDLING

- The Light Seeker is constructed with glass fiber optic components. Special care must be taken to prevent damage to the fiber optics and to maintain optimal functionality and longevity of the Light Seeker.
- Protect the Light Seeker during procedural use and transportation between the procedural room and reprocessing location. Avoid harmful interaction with other surgical instruments or tools. The Light Seeker contains glass fiber optics that may be damaged if mishandled.
- Periodically inspect (10X magnification) the fiber optics in the distal tip of the Light Seeker for signs of mechanical damage such as chipping, pitting, cracks, or nicks. Discontinue use of the Light Seeker if damage is noted.

COMPATIBILITY

The Light Seeker is compatible with a 2.5mm light cable and standard light post adapters (ACMI, RICHARD WOLF, KARL STORZ), and a 300W Xenon light source.

INSTRUCTIONS FOR USE

1. Verify that the Light Seeker has been manually cleaned and manually high level disinfected or manually cleaned and sterilized, inspected and functions properly.
2. Connect the Light Seeker to the 2.5mm cable using one of the adaptors provided (if necessary). Connect the light cable to the 300W Xenon light source.
3. Use an initial light intensity setting of 50%. If the Light Seeker light output is not adequate increase the light intensity and/or use anti-fog solution or sterile water to clean the distal and proximal end of the device. If the light output is still not adequate, do not use the Light Seeker and contact Entellus Medical for servicing of the device.
4. Under Endoscopic visualization, advance the Light Seeker to the target location to illuminate within and transilluminate across nasal and sinus structures. Some tissue removal may be necessary to access the target location.

Note: To enhance the intensity of the transcutaneous illumination, it may be necessary to reduce the number of competing light sources (i.e. endoscope or room light) or to reposition the location of the instrument tip.

5. If the frontal sinus is the target, and illumination of the sinus is noted, the Light Seeker can be rotated medial to lateral to illuminate a larger portion of the sinus for additional confirmation.

CLEANING, HIGH LEVEL DISINFECTION AND STERILIZATION INSTRUCTIONS

Pre-Cleaning (Immediately After Use)

1. Remove heavy soil from the Light Seeker by wiping the exterior with a wet (using sterile water) disposable cloth.
2. Transfer to the cleaning location for further cleaning and reprocessing as soon as possible.

Cleaning (Prior to High Level Disinfection or Sterilization)

The Light Seeker must be manually 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 manual high level disinfection or sterilization.

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

Note: The entire Light Seeker 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 the Light Seeker use 2 ounces/gallon and/or warm water.) Ensure there is sufficient enzymatic solution to fully submerge the Light Seeker.
4. Disconnect the light post adapter(s) from the Light Seeker (if present) by rotating it counter-clockwise in relation to the Light Seeker.
5. Fully immerse the Light Seeker and light post adaptors into the detergent solution.
6. Soak the Light Seeker 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 the Light Seeker has dried-on organic matter, extend soak time while performing step 7 below. Total soak time may take approximately 5-6 minutes if the Light Seeker has dried-on organic matter.
7. While fully submerged, clean the Light Seeker and light adaptors, paying close attention to the distal tip and the threaded light post section.
 - Wipe the entire Light Seeker using a cloth or towel while the Light Seeker is submerged in the enzymatic detergent solution. Heavily soiled areas and the threaded light post section should be scrubbed with a nylon brush.
 - Wipe the distal end containing the fiber optics gently, but thoroughly, with the cloth or towel to remove any contaminants remaining on the distal tip.
8. Thoroughly rinse the Light Seeker and light adaptors with water. Deionized or de-mineralized water is recommended.
9. Verify no visible matter remains on the instruments. If the instruments are not visually clean, repeat the previous cleaning steps.
10. Manually dry the Light Seeker with a clean absorbent cloth or towel.
11. Wipe the Light Seeker tip with 70% alcohol pad.
12. Discard the enzymatic cleaner.
13. Store the cleaned Light Seeker in a reprocessing double peel pack capable of securing and isolating the Light Seeker from other instruments and label as clean. See "Storage Between Use" section for more details.

High Level Disinfection

The Light Seeker can be high level disinfected with the manual high level disinfection process using the CIDEX OPA Solution (i.e., 0.55% ortho-phthalaldehyde, Advanced Sterilization Products). Follow all instructions provided by the manufacturer of CIDEX OPA Solution when performing the high level disinfection process. The recommended temperature for CIDEX OPA Solution is a minimum of 20° C or 68° F. **High level disinfect Light Seeker immediately prior to use.**

Note: The entire Light Seeker is submersible.

1. Wear all manufacturer recommended personal protective clothing / equipment prior to performing high level disinfection with CIDEX OPA Solution.
2. Add the CIDEX OPA Solution into a compatible high level disinfection container. Ensure that there is sufficient CIDEX OPA solution to completely submerge the Light Seeker.
3. Confirm that the concentration of the high level disinfectant meets the minimum recommended concentration using the test strip specified by the manufacturer prior to each use.
4. Ensure that the Light Seeker and light post adapters have undergone a cleaning process with an enzymatic detergent prior to the manual high level disinfection.
5. Disconnect the light post adaptor(s) from the Light Seeker (if attached) by rotating it counter-clockwise in relation to the Light Seeker.

6. Fully immerse the Light Seeker and light post adaptors into the CIDEX OPA Solution.
7. Soak the Light Seeker and light post adapters in the CIDEX OPA Solution for the minimum time recommended by the manufacturer (at least 12 minutes). The high level disinfectant should have full contact for at least 12 minutes.
8. Rinse the light post adapters and the Light Seeker
 - Fully submerge the Light Seeker and light post adapters in a minimum of 2 gallons of sterile water for at least one minute.
 - Remove the Light Seeker 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 sterile water for each cycle.
10. Dry the outside of the Light Seeker by using low pressure, filtered air or with a sterile wipe or cloth.
11. Remove residual fluid from the distal tip of the Light Seeker with a sterile alcohol wipe (if needed).
12. Dry the light post adapters and the Light Seeker using a sterile towel or cloth.

Sterilization

The Light Seeker can be **steam** sterilized with the **Autoclave** pre-vacuum process. Use of any other sterilization process (including flash sterilization) will not ensure sterility, and may damage the Light Seeker.

Ensure the Light Seeker and light post adapters have been cleaned prior to conducting sterilization.

The following cycle parameters have been validated for the Light Seeker and should be used. Follow the manufacturer's instructions for the autoclave sterilizer, to ensure sterility of the Light Seeker:

| Autoclave Cycle Type | Pre-vacuum |
|-----------------------------------|-------------------|
| Device Configuration ¹ | Wrapped |
| Sterilization Temperature | 270°F / 132°C |
| Exposure Time | 4 minutes |
| Dry Time | 20 minutes |

¹ STERIKING See-through Self-sealable Pouches (double pouched) were included in the sterilization validation for the Light Seeker. The light post adapters were double peel pouched separately from the Light Seeker in the sterilization validation and thus this is recommended.

HOW SUPPLIED

The Light Seeker is supplied non-sterile and must be cleaned and high level disinfected or cleaned and sterilized before its first and every subsequent use. The items packaged with the Light Seeker include the Instructions for Use and 2 light post adaptors. Retain the light post adapters with the Light Seeker for use with various configurations of light cables (i.e. ACMI, RICHARD WOLF, KARL STORZ).

STORAGE BETWEEN USE

If high level disinfection is the method chosen, this 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 Light Seeker placed into a clean tray must be reprocessed again before use on a patient. If sterilization is chosen, follow the steam sterilization instructions to maintain sterility of the Light Seeker and light post adapters between uses. Use separate reprocessing double peel packs for storing and sterilizing the Light Seeker and adapters that comply with the steam sterilization process and instructions and maintain sterility between uses.

Do not store the Light Seeker or light post adapters in the foam-lined shipping box between uses because the foam liners can retain microbes.

WARRANTY ASSESSMENT / RETURN FOR SERVICE

If a Light Seeker becomes damaged or fails to provide adequate light output, take the following actions to have the device assessed for warranty coverage or replacement.

Contact Customer Service. Describe malfunction.

Phone: (866) 620-7615

Fax: (866) 620-7616






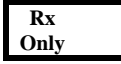

If returning Light Seekers for assessment all products must be cleaned and sterilized prior to shipping per the approved methods described within this document. Documentation must be provided stating the Light Seeker has been reprocessed prior to shipping.

If disposing of the Light Seeker, do so according to appropriate 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 other 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. Refer to *Entellus Medical, Inc. Standard Terms and Conditions*.

SYMBOLS

| | | | |
|---|--|--|---|
|  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 (raw materials contain no latex and no latex has been introduced during the manufacturing).

PathAssist and Light Seeker are trademarks of Entellus Medical.

ENZOL and CIDEX OPA are trademarks of Johnson & Johnson Corporation of New Brunswick, NJ.

ACMI is a trademark of Gyrus ACMI, Inc. of Southborough, MA.

RICHARD WOLF is a trademark of Richard Wolf GmbH of Knittlingen, Germany

KARL STORZ is a trademark of Karl Storz GmbH of Tuttlingen, Germany.

STERIKING is a trademark of Wihuri Oy Corporation of Nastola, Finland



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