



Instructions for Use

*Relieva Luma*TM

Sinus Illumination System

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

STERILITY: The *Relieva Luma* Sinus Illumination System is sterilized with ethylene oxide gas.

SINGLE USE: The *Relieva Luma* Sinus Illumination System is intended for single patient use only. DO NOT resterilize and/or reuse, as it may result in compromised device performance and risk of improper sterilization and cross contamination.

STORAGE: Store in a cool, dry place.

DESCRIPTION

The *Relieva Luma* Sinus Illumination System is a 0.035"-compatible flexible instrument that transmits light from the proximal to distal tip. The *Relieva Luma* Sinus Illumination System consists of a Light Guide Cable connector, the flexible instrument body, and a distal Light Lens (see figure 1). It is supplied with a pre-shaped or straight distal tip.

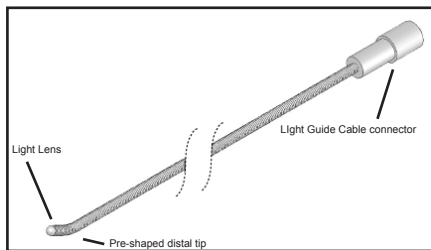


Figure 1.

INDICATIONS FOR USE

The *Relieva Luma* Sinus Illumination System is intended to provide a means to access the sinus space for diagnostic and therapeutic procedures in conjunction with other nasal and sinus products. It is also intended to illuminate within and transilluminate across nasal and sinus structures.

CONTRAINDICATIONS:

None.

WARNINGS

- Do not use a device where the integrity of the sterile packaging has been compromised or if the device appears damaged.
- Never advance or retract the *Relieva Luma* Sinus Illumination System against unknown resistance as this can cause tissue trauma or device damage.
- Only physicians trained in the use of *Balloon Sinuplasty™* technology should use this instrument.

PRECAUTIONS

- The *Relieva Luma* Sinus Illumination System is a precision optical instrument and must be handled with care. Do not pinch or kink the *Relieva Luma* Sinus Illumination System body.
- If supplied with a pre-shaped tip, do not attempt to alter the distal tip of the *Relieva Luma* Sinus Illumination System, as this may result in device damage.
- If using the *Relieva Luma* Sinus Illumination System to trans-illuminate the frontal sinus, pre-operative review of a CT, x-ray or other image is recommended to help facilitate identification of the frontal sinus.

COMPATIBILITY

The *Relieva Luma* Sinus Illumination System is compatible with all *Balloon Sinuplasty™* instruments that use 0.035" Sinus Guidewires. It is compatible with the custom *Relieva Luma* Light Guide Cable, and Xenon light sources. Please refer to the appropriate Instructions for Use when using with compatible devices.

INSTRUCTIONS FOR USE

- Remove the *Relieva Luma* Sinus Illumination System from the protective packaging.
- Ensure that the distal Light Lens and proximal Light Guide Cable connector surface are clean. A soft wetted towel may be used to clean the surfaces if necessary.
- Connect a *Relieva Luma* Light Guide Cable to the Light Guide Cable connector on the proximal end of the *Relieva Luma* Sinus Illumination System.

NOTE: Use only the *Relieva Luma* Light Guide Cable with the *Relieva Luma* Sinus Illumination System, as standard light guide cables may damage the optical components.

- Activate the light source. Confirm that light is visible at the distal end of the *Relieva Luma* Sinus Illumination System.

If using with a Relieva® family Sinus Balloon Catheter:

- Starting at the distal end of the *Relieva Luma* Sinus Illumination System, load the proximal end of the *Relieva Sinus Balloon Catheter* onto the *Relieva Luma* Sinus Illumination System. This must be performed prior to insertion into the nasal cavity.

If using to transcutaneously illuminate through sinus structures:

















- Advance the instrument into the target sinus until some light resistance is felt.

NOTE: Light from the tip of the *Relieva Luma* Sinus Illumination System may transcutaneously illuminate tissue structures. The location and intensity of the transcutaneous illumination will depend on the sinus entered, orientation of the Sinus Illumination System, and patient characteristics.

- To enhance the intensity of the transcutaneous illumination provided by the *Relieva Luma* Sinus Illumination System it may be necessary to reduce the number of competing light sources (i.e. endoscope or room lights) or to reposition the location of the instrument tip.
- Confirm placement and position of the *Relieva Luma* Sinus Illumination System with endoscopic, fluoroscopic and/or transcutaneous illumination visualization.

NOTE: Rinse the *Relieva Luma* Sinus Illumination System distal tip in saline after use in each sinus to ensure maximum light transmission for subsequent uses in the same patient.

GRAPHIC SYMBOLS CONTAINED ON DEVICE LABELING

	Batch Code		On Order of Physician Only
	Sterilized with ethylene oxide		Date of Manufacture
	Use by		Consult Instructions For Use
	Do not re-use		Device compatibility
	Length		Tip Shape
	Keep dry		Maximum temperature
	Keep Away from Sunlight		0123 CE Mark
	European Authorized Representative		Manufactured By

Product Information Disclosure

Acclarent, Inc. has exercised reasonable care in the manufacture of this device. Acclarent, 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 and storage of this device, as well as factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Acclarent, Inc.'s control, directly affect this device and the results obtained from its use. Acclarent, Inc. shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this device. Acclarent, Inc. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

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U.S. Patent Nos. 7,500,971 and 7,462,174 and other U.S. and foreign patents pending.