



GIMA

PROFESSIONAL MEDICAL PRODUCTS

CAVI A FIBRE OTTICHE FIBER OPTIC CABLES

Manuale d'uso - User manual



- È necessario segnalare qualsiasi incidente grave verificatosi in relazione al dispositivo medico da noi fornito al fabbricante e all'autorità competente dello Stato membro in cui si ha sede.

- All serious accidents concerning the medical device supplied by us must be reported to the manufacturer and competent authority of the member state where your registered office is located.

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830-327-23

830-340-30



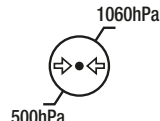
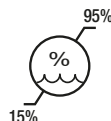
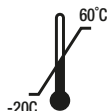
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ENGLISH

Attention:

Thank you for purchasing our product. The Fiber Optic Cable meets the most stringent requirements regarding the selection of manufacturing material, performance, safety, and final control. This operating instruction manual is related to the "R-Line" and "Crystal Line" Fiber Optic Cables manufactured by Medical Devices Pvt (Ltd). These instructions must be followed to ensure the performance and durability of Fiber Optic Cables. The operator/user must read and understand this manual thoroughly to keep the product performance durable and reliable for a defined period.

After opening the package, it is necessary to check all the components against the standard configuration. Check that these are all present and in perfect condition.

Intended Use:

Our Fiber Optic cables are an accessory to medical devices and are engineered to provide illumination when coupled with a medical-grade Fiber optic light source.

These Fiber Optic cables are available in different Fiber optic bundle diameters, depending on the required surgical discipline, and can easily be recognized as these are color-coded.

Discipline	Color	Bundle Diameter
Urology	Yellow	2.5mm
Arthroscopy	Red	3.5mm
Endoscopy	Green	4.8mm
Surgery	Grey	Special Surgery

The Fiber Optic Cables are available in the following two types;

Crystal Line:

Manufactured using Solid Quartz Glass, the "Crystal Line" Fiber Optic Cables are designed for XENON and LED light sources and can sustain high temperatures.

R-Line:

Containing standard glued cables, this line is designed to be used exclusively with a Halogen Light source.

Intended Use:

Fiber Optic Cable is an accessory to a medical device intended to be used for the transmission of light from the light source end to the projector end for examination.

Patient Population:

F.O. Cable is not designed to be used directly on patients. It is used only for light transmission.

Features:

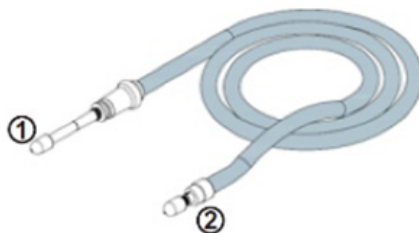
Fiber optic cables are offered in a variety of lengths

and with multiple diameters for fiber optic bundles, ensuring compatibility with diverse requirements and applications.

The specific features of Fiber Optic Cables are mentioned below;

- Flexible high-temperature resisting Silicon Cover tubing that does not deteriorate like rubber and latex sheathing.
- High-density fiber packing and polished fiber end ensure maximum light transmission.
- Comes with a standard Storz Light Source adaptor; other appropriate adaptors can be used to make the light cable compatible with other light sources.
- Color-coded for easy connection to Endoscopes.

Product Overview:



Operating Instructions

1. Remove the caps from both end adaptors before using the Fiber Optic Cable.
2. Plug the light source end adaptor (1) into the respective light source.
3. If required, screw in the desired adaptor/connector with the instrument end adaptor and connect the instrument end adaptor (2) with the endoscope and the device is ready for use.

 R-Line Fiber Optic cables should not be, under any circumstance, used with any other light source.

 In the case of "Crystal Line" Cables, ensure the light source is filtering at least 90% of infrared radiation (IR) to prevent high heat.

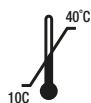
 FIRE HAZARD: Never drape or cover the end of the F.O. cable with anything flammable.

Cleaning and Disinfection

These devices do not require any sterilization because of their non-invasive nature. However, the Fiber Optic Cables can be cleaned with a cloth soaked with disinfectant.

Operating Environment:

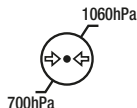
Temperature limit



Humidity limit

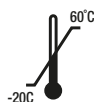


Atmospheric pressure limit

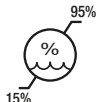


Storage Environment:

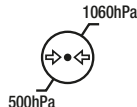
Temperature limit



Humidity limit



Atmospheric pressure limit



Maintenance:

The device is maintenance free.

Service:

The device has no components serviceable by the end user.

Note:

Any serious incident that has occurred concerning the device should be reported to the manufacturer at www.mdevices.com, and to the respective competent authority of the Member State in which the incident has occurred.

Cautions/General Warnings:

1. Read the label before unpacking.
2. Do not use the device in case it is damaged. Apply to your retailer/distributor.
3. Always inspect cables for any evidence of damage before use. Pay particular attention to optical surfaces for scratches or dings.
4. Do not look into the end of the F.O. cable while it is connected to a light source and the light source is on. This can result in eye injury or blindness.
5. FIRE HAZARD: Never drape or cover the end of the F.O. cable with anything flammable.
6. Reduce the intensity of the light source when working near body tissue or flammable material.
7. Before usage, thoroughly check the product. The same operation shall be carried out after cleaning.
8. This product is not allowed to enter or be used in areas with strong magnetic fields e.g. MRI scanners.
9. Ultrasonic cleaning is not recommended.
10. Any unauthorized modification/service is strictly prohibited at the user end so, always contact the authorized person or send the unit back to the authorized agent.

11. Store the device in a clean and recommended environment.

Shelf-life:

The shelf-life of F.O. cable is 5 years.

	Medical Device compliant with Regulation (EU) 2017/745
	Medical device
	Product code
	Lot number
	Manufacturer
	Date of manufacture
	Temperature limit
	Humidity limit
	Atmospheric pressure limit
	Consult instructions for use
	Keep in a cool, dry place
	Keep away from sunlight
	Caution: read instructions (warnings) carefully
	Authorized representative in the European community
	Imported by
	Unique device identifier

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.