Lysistech®

Disposable Laser Surgery Fiber (sterile)
Instructions for Use

To ensure that the laser probe is handled safely, users must have read and understood these instructions in full, as well as the instructions for use provided with the laser itself. These instructions for use must be kept together with those for the laser.
This product is only to be used by people who are properly trained and qualified.

Please heed the safety information provided below

⚠ Safety information

Instruments that are provided sterile do not require any kind of preparation prior to first use.
Instruments that are provided non-sterile must be cleaned, disinfected and sterilised prior to first use.
The symbols on the packaging label will tell you whether the product has been delivered sterile or non-sterile. In the case of reusable products, the symbols also indicate how many times they may be reused and, in turn, the maximum number of preparation processes. For an explanation of the symbols used, please go to the end of these instructions.
To ensure that the product is sterile, it is essential to check the condition of the packaging prior to use. There must not be any tears or holes in it. The use-by date must not have already passed.
The fiber must be kept sterile throughout the entire patient treatment session. Within this context, it is essential to heed the applicable rules and regulations for handling sterile products.

Reuse of the instruments is not permitted if they have been used on patients with an identifiable risk factor for CJD, vCJD or any other human TSE disease.

The distal end of the fiber must not – under any circumstances – be allowed to make contact with reflective surfaces of other instruments or products that are being used, as this poses a risk of stray radiation, which could destroy the fiber or cause tissue damage.

Check the fiber for visible damage (particularly cracks/breakage) both before and after you remove it from the packaging. If there are any signs of damage, do not use the product. Instead, return it to the supplier.

ATTENTION: If the fiber used is defective or if it is used incorrectly, there is a risk of serious eye or tissue damage, of accidently exposing patients or operating staff to laser radiation, or of causing a fire in the treatment area. Heed the detailed safety information in the instructions for use supplied with the respective laser as well as the instructions for ensuring protection against laser radiation.

Everyone present must wear safety glasses while the fiber is being used. The specific protective equipment requirements depend on the application. For details, please refer to the instructions for use supplied with the laser concerned.

The minimum bend radius for the fiber must be respected throughout the entire usage period.
Short-term minimum bend radii:

12.5 cm for fibers measuring up to 660 µm in diameter
20 cm for fibers measuring more than 660 µm in diameter

Scope of validity

These instructions for use cover the optical laser fibers described by the product code. These fibers are ETO- sterilized, sterile packaged products that are intended for short-term use during invasive and non-invasive procedures.

Products

Laser Surgery Fiber and Radial Emission Fiber

Indication

Laser Surgery Fiber products are designed to direct laser energy at soft tissue during contact and non-contact surgical procedures, including in applications that involve the use of rigid and flexible endoscopes.
They are suitable for use in the following contexts: general surgery, urology, gynaecology, gastroenterology, ENT, pulmonology, orthopaedics, dermatology, dentistry, aesthetic surgery and vascular surgery. They are also suitable for lithotripsy provided that they are used with a compatible laser that is approved for this type of application.
The following applications are supported: cutting, removal, tissue dissection, removal of external tumours or lesions, internal organ resection, tumour resection, lesion resection, tissue vaporisation, coagulation or haemostasis.

Contraindication

The laser optical fibers are not suitable for use in the central circulation system or the central nervous system!

Product description/product code

Lysistech® Laser Surgery Fiber products can be used with approved surgical lasers that feature a compatible standard SMA 905 or other connection. The following parameters are particularly important for ensuring that the Laser Surgery Fiber products are used safely: the wavelength range, the fiber diameter, the numerical aperture of the fiber and the laser, plus the design used for the distal end of the laser fiber. These parameters must be tailored to the laser and the application concerned.
For details of the radiation type, properties, intensity and distribution, please refer to the data provided by the manufacturer of the relevant laser.

The **product code** includes all the relevant information relating to the product. This can be found on the label attached to the outer sterile packaging.

OB AA 1111/2222BBCD-3.33/E-FG-H

AA	Fiber composition			
	AS	Quartz/quartz		
1111	Fiber core diameter [µm]			
2222	Fiber jacket diameter [µm]			
BB	Wavelength range			
	IR	Infrared	UV	Ultraviolet
C	Fiber coating material			
	HC	Hard-clad		
	S	Silicone		
D	Fiber coating material			
	T	Tefzel		
3.33	Product length [m]			
E	Connector type			
	SMA/S	SMA905 connector		
	SMA/H	SMA905 holmium connector		
	CC	Customer-specific connector		
F	Connector design			
	S	Standard	F	Free-standing
G	Union nut design			
	K	Knurled	H	Hexagonal
	W	Without		
H	Distal design			
	-F	Flat tip	-FR	Flat rounded tip
	-S	Spherical tip	-O	Orb tip
	-B	Ball tip	-CB	Curved ball tip

The batch number, date of manufacture, use-by date and product-specific barcode are also detailed.
Lysistech® Laser Surgery Fiber products (as indicated by the product code) are suitable for use with lasers that feature a compatible interface, do not exceed the maximum permissible input power and rely on compatible wavelengths for the purpose of supplying the product with laser energy.
Care must be taken to ensure that the numerical aperture of the laser fiber is compatible with that of the laser. The numerical aperture is specified on the label in the following format: na=x.xx (x.xx represents the numerical aperture value, e.g. na=0.22 or na=0.37). For further information, contact your supplier or refer to the technical documentation supplied with the laser concerned.

Using the product

- After extracting the product from the sterile packaging, remove the protective cap from the laser connection. While doing so, grip the nut of the male connector – never the anti-kink or strain relief devices. If necessary, the protective cap must also be removed from the distal end of the product.
- The faces of the male connector and of the distal end of the fiber must be checked for contamination or foreign substances. Damaged or dirty faces may damage or destroy the product and/or cause damage to the laser system used.
- Insert the male connector into the female connector on the laser and screw it hand tight; do not use tools.
- Switch on the laser in accordance with the instructions for use and set the target beam to a high level of intensity.

- Check the fiber again for kinks, breaks and any other defects. While doing so, pay careful attention to the target beam as it emerges from the distal end. The distal end must be pointed at a non-reflective surface. The target beam should generate a sharply defined light spot without any missing areas. If there are any signs of damage, do not use the fiber. Instead, return it to the supplier.


Defective


Acceptable


Ideal

- Once you have made the required parameter settings on the laser, you can start using the fiber.
- Start the treatment procedure with the laser in "STANDBY" mode. If using an endoscope, position the probe so that it is approximately 1 cm away from the distal end of the endoscope.
- Set the laser to the required output power in accordance with the maximum value recommended for the fiber size (see technical data below).

The users themselves are responsible for defining the maximum permissible input power for the product-specific fiber core diameter in accordance with the specifications of the laser manufacturer and the intended application. The values in the table below have been provided as a guide.

OB AA 1111/2222BBCD-3.33/E-FG-H

Fiber core diameter	Up to 272 µm	300 µm to 400 µm	500 µm and above
Max. input energy *	1.5 J	4.0 J	4.0 J
Max. input power *	20 W	40 W	100 W

* These values are intended purely as a guide. Other power ratings (including higher ones) may apply depending on the type of laser used.

It is the responsibility of the user to monitor the temperature of the coupling connector and the fiber during use. If these components heat up to more than 50°C, it is an indication that the fiber-coupled power is too high or that the numerical aperture is incorrect. In this case, the fiber-coupled power must be reduced or a more suitable laser probe should be used instead. The warranty does not cover any product damage caused by inappropriate use.

Storage

After undergoing sterilisation, the laser probe must be stored at room temperature and protected against ionising radiation, UV light and organic solvents.

Symbols


Manufacturer


Date of manufacture


Use-by date


Number of preparation processes


Attention


Instructions for use must be observed

Batch code

Article number

Sterilised with ethylene oxide

Non-sterile


If packaging is damaged, do not use!

Customer information

Manufacturer

Lysistech AG
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Customer support

Please contact
your supplier or visit
www.lysistech.com