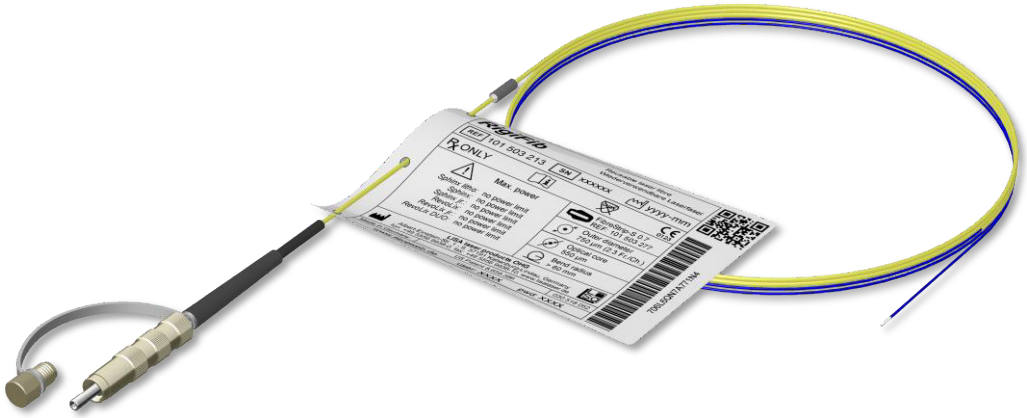
Instructions for Use - Reusable laser fibres



Valid for:

Laser fibre	***Order number***
LithoFib	101 503 188
FlexiFib	101 503 189
FlexiFib 5m	101 503 118
SureFib	101 503 364
PercuFib	101 503 128
RigiFib	101 503 213
RigiFib 800	101 503 287
RigiFib 1000	101 503 284
RevoSoft	101 503 514
RevoMed	101 503 515

Content

℞ ONLY Federal law restricts this device to sale by or on the order of a physician.

1 About these instructions for use

These instructions for use provide important information concerning the safe operation of reusable laser fibres manufactured by LISA Laser Products GmbH, Germany (LISA Laser Products) as listed on the front cover.
Before using the laser fibre read these instructions for use and those for the laser device thoroughly! Follow the given instructions!
The safety instructions in this document are intended to prevent possible injuries to the patient, user or third parties and material damage.
Please keep these instructions for use for future reference.

1.1 Signal words used in these instructions for use

The following table shows the meaning und classification of the signal word to the left of the safety instruction.

Signal word	Safety instruction
DANGER	Indicates a highly hazardous situation which, if not avoided, will result in death or serious injury.
WARNING	Indicates a hazardous situation which, if not avoided, could result in death or serious injury.
CAUTION	Indicates a fairly hazardous situation which, if not avoided, could result in minor or moderate injury.
NOTICE	Indicates imminent material damage, and suggests ways to avoid possible material damage.
INFORMATION	Provides recommendations, information, and advice for efficient use

1.2 Precautions and safety information

The laser fibre and the laser device may only be used by qualified personnel who have appropriate medical knowledge or professional clinical experience and have been trained in the correct and safe operation of the device on the basis of the instruction for use.

Please also read and observe the precautions and safety information in the other chapters.

Any serious incident (i.e., the death of a patient, user or other person, the temporary or permanent serious deterioration of a patient's, user's or other person's state of health or a serious public health threat) occurring in relation to the device must be reported immediately to LISA Laser Products and the national competent authority responsible for medical device surveillance.

WARNING

Laser radiation

Laser radiation can cause injury to the eyes and skin.

- **Observe the necessary safety measures for laser application.**
- **Avoid direct laser radiation to the eyes and skin.**
- **Do not look into the laser beam.**
- **Avoid scattered radiation, which for example may arise from reflection on reflective surfaces of instruments.**
- **Wear laser safety goggles adequate for the radiation.**

CAUTION

Detachment of fragments from damaged laser fibres.

Fragments can detach from damaged laser fibres. Unretrieved device fragments (UDF) can cause injuries or diseases in the human body.

- **Use only fibre fixations which exclude mechanical damage to the laser fibre.**
- **Use only instruments / endoscopes without sharp corners and edges. Check the instrument / endoscope before use.**
- **In combination with the laser fibre, use only compatible instruments / endoscopes. Compare the technical data such as bend radius and necessary working channel of the laser fibre and the provided instruments / endoscopes.**

WARNING

Rough handling of the laser fibre can lead to mechanical damage and fibre breakage.

Uncontrollable laser radiation can escape from the damaged laser fibre and cause burns and tissue damage.

- **Handle the product carefully to avoid kinks and other damage to the laser fibre and / or to the fibre connector.**
- **Check the integrity of the laser fibre before use.**

CAUTION

Rough handling during application or transportation of the laser fibre can lead to mechanical damage and fibre breakage.

Damaged laser fibres may not be used and may lead to a termination or delay of the procedure.

- **Handle carefully to avoid kinks and other damage to the laser fibre or the fibre connector.**
- **Check the integrity of the laser fibre before use.**
- **Keep suitable replacement ready.**

2 Product information

2.1 Product description

The described reusable laser fibres are products of LISA Laser Products and have been developed and tested for the use in combination with medical laser devices manufactured by LISA Laser Products.

See Table 1 for laser fibre – laser device - compatibility information and maximum laser power settings allowed.

The jacket of the laser fibres is made of high-quality plastics and protects the fibre against mechanical damage (Figure 1).

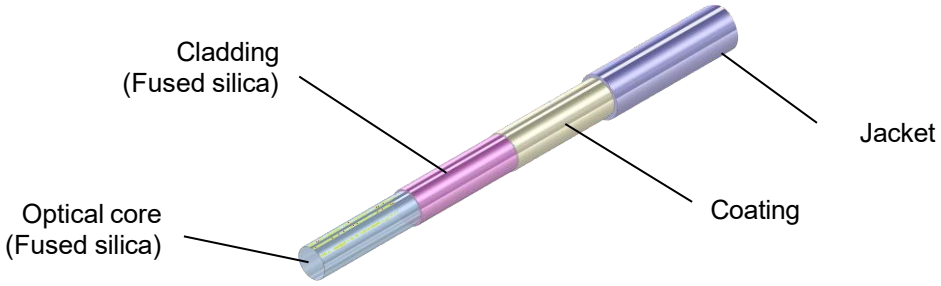


Figure 1: Laser fibre design

The terms used in Figure 1 for the elements of a laser fibre are not standardized and may differ from other publications.

The proximal end of the laser fibre material is bonded into a LISA F-SMA type fibre connector (Figure 2), with which the laser fibre is connected to the fibre port of the laser device.

The distal tip of the laser fibres decribed in these instructions for use are bare ended and may be reprocessed by the user after usage (chapter 4.1). The laser radiation emerging from the bare ended distal tip is diverging at a full cone angle of app. 26°.

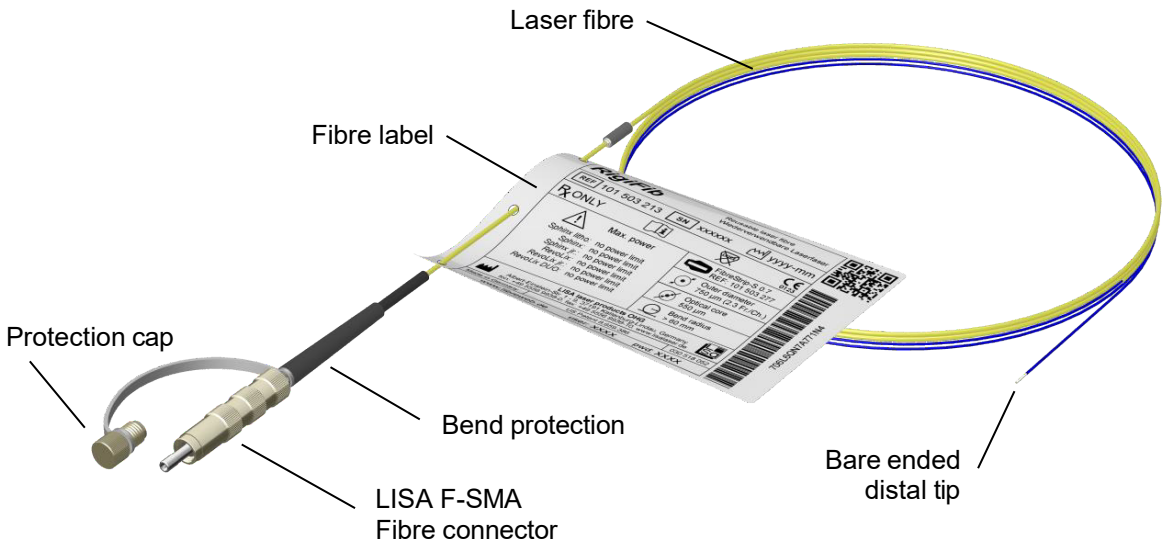


Figure 2: LISA Laser Products reusable laser fibre

2.2 Classification

Medical device classification according to MDD 93/42/EEC (Medical Device Directive): Class IIb

2.3 Patient Population:

Lisa laser fibers have not been tested and are not claimed to be included for use on vulnerable populations, including but not limited to children, pediatric, geriatric, pregnant/lactating women, immunocompromised individuals, elderly subjects, sepsis, anticoagulation therapy or bleeding disorders, or patients with implants, and risk of reproductive effects remain unknown. However, the state-of-the art, has demonstrated the use of Laser and fibers to be safe and effective when utilized by a qualified physician in a qualified clinical setting.

2.4 Contraindications

The laser fibres are not intended for direct application on the central nervous system and on the cardiovascular system.
Contraindications that are directly linked with the laser fibres are not known. The contraindications of surgical and endoscopic laser applications are the same as those of conventional endoscopy or surgery in the concerned field.
Contraindications to receive therapeutic laser procedures are a general inability to receive surgical or endoscopic procedures, pregnancy, sepsis, anticoagulation therapy or bleeding disorders. In each case the user must decide on the basis of the patient's condition whether the application of the laser system is appropriate.

2.5 Intended use

LISA Laser Products reusable laser fibres are designed for the transmission of laser radiation during therapeutic laser procedures. The reusable laser fibres are intended for transient use.

2.6 Potential side effects

Potential complications which may result from a surgical and endoscopic laser procedure are similar to those normally encountered in conventional surgery in the same field and may include but are not limited to: thermal damage to surrounding structures, pain, perforation, haemorrhage, infections, sepsis, tissue trauma, bleeding and oedema.

2.7 Delivery

Reusable laser fibres are supplied non-sterile rolled up in a zip lock bag. The reusable laser fibre needs to be cleaned, disinfected and sterilized before the first and any other subsequent use (chapter 4).

2.8 Laser fibre to laser device compatibility

LISA Laser Products laser fibres differ in optical properties, in design, in optical core and in outer diameter. Table 1 shows the compatibility of LISA Laser Products reusable laser fibres with LISA Laser Products laser devices and the maximum permissible power settings.

Table 1: Laser fibre to laser device compatibility

	⚠ Laser device compatibility[1]						
Laser fibre Order number	***Sphinx***	***Sphinx litho***	***Sphinx jr.***	***RevoLix 200 RevoLix 120***	***RevoLix DUO***	***RevoLix jr.***	***RevoLix HTL RevoLix HTL eco RevoLix HTL cw***
LithoFib 101 503 188	-	✓[6] 12 W and max. 15 Hz	✓[4] 12 W and max. 2.0 J and max. 14 Hz	-	-	-	✓ 20 W
FlexiFib 101 503 189	✓[2] 30 W and max. 3.5 J	✓[2] 30 W and max. 3.5 J	✓[2] 30 W and max. 3.5 J	✓ 40 W	✓[3] 40 W 20 W	✓	✓ 40 W
FlexiFib 5m 101 503 118	✓[2] 30 W and max. 3.5 J	✓[2] 30 W and max. 3.5 J	✓[2] 30 W and max. 3.5 J	✓ 40 W	✓[3] 40 W 20 W	✓	✓ 40 W
SureFib 101 503 364	-	✓[2] 30 W and max. 4.0 J	✓[2] 30 W and max. 3.5 J	✓[5] 40 W	-	✓	✓ 40 W
PercuFib 101 503 128	✓[2] 50 W and max. 3.5 J	✓	✓	✓ 50 W	✓[3] 50 W 20 W	✓	✓ 50 W
RigiFib 101 503 213	✓	✓	✓	✓	✓	✓	✓ 150 W
RigiFib 800 101 503 287	✓	✓	✓	✓	✓	✓	✓ 150 W
RigiFib 1000 101 503 284	✓	✓	✓	✓	✓	✓	✓ 150 W

continued next page

Reusable laser fibre

Laser fibre Order number	Laser device compatibility[1]						
	Sphinx	*Sphinx litho*	*Sphinx jr.*	*RevoLix 200* *RevoLix 120*	*RevoLix DUO*	*RevoLix jr.*	*RevoLix HTL* *RevoLix HTL eco* *RevoLix HTL cw*
RevoSoft 101 503 514	-	-	-	✓ 40 W	-	✓	✓ 40 W
RevoMed 101 503 515	-	-	-	✓ 50 W	-	✓	✓ 50 W

[1] - not compatible with laser, ✓ compatible with laser

[2] maximum power and maximum energy (meet both limits)

[3] upper value: max. power cw laser (Tissue Mode),
lower value: max. power pulsed laser (Stone Mode)

[4] providing *LithoFib* compatibility is shown on the start display and *LithoFib* is selected

[5] not for use with RevoLix 50, RevoLix 70 or power upgraded devices

[6] Sphinx 30 *litho* only

CAUTION

Absorption of laser power in the fibre connector by connecting the laser fibre to an incompatible laser device.

Absorption of laser power in the fibre connector may heat up the fibre connector and may cause burns when touching the hot fibre connector.

- **Comply with the specified compatibility requirements.**

NOTICE

Mechanical damage of the laser fibre caused by combining the laser fibre with incompatible instruments / endoscopes or laser devices.

Using incompatible instruments / endoscopes or laser devices can result in loss of function of the laser fibre.

- **Use only compatible instruments / endoscopes in combination with the laser fibre. The bend radius / curvature of the instrument / endoscope must not be less than the minimal bend radius of the laser fibre. The outer diameter of the laser fibre is required to be smaller than the working channel diameter of the instrument / endoscope.**
- **Comply with the specified compatibility requirements.**
- **Use only instruments / endoscopes without sharp corners, edges and / or kinked working channels. Check the instrument / endoscope before use.**
- **Use only fibre fixations which do not damage the laser fibre.**
- **Insert the laser fibre carefully into the instrument / endoscope.**

2.9 Technical data of laser fibres

Table 2: LISA Laser Products reusable laser fibres technical data

Laser fibre Order number	Optical core diameter	Outer diameter	Length	Min. bending radius during operation
LithoFib 101 503 188	200 µm	500 µm /1.5 Fr	3 m	≥ 15 mm
FlexiFib 101 503 189	272 µm	420 µm / 1.3 Fr	3 m	≥ 15 mm
FlexiFib 5m 101 503 118	272 µm	420 µm / 1.3 Fr	5 m	≥ 15 mm
SureFib 101 503 364	272 µm	420 µm /1.3 Fr	3 m	≥ 10 mm
PercuFib 101 503 128	365 µm	730 µm / 2.2 Fr	3 m	≥ 40 mm
RigiFib 101 503 213	550 µm	750 µm / 2.3 Fr	3 m	≥ 60 mm
RigiFib 800 101 503 287	800 µm	1200 µm / 3.6 Fr	3 m	≥ 70 mm
RigiFib 1000 101 503 284	940 µm	1400 µm / 4.2 Fr	3 m	≥ 120 mm
RevoSoft 101 503 514	272 µm	420 µm / 1.3 Fr	3 m	≥ 15 mm
RevoMed 101 503 515	365 µm	730 µm / 2.2 Fr	3 m	≥ 40 mm

2.10 Compatible instrument / endoscope

Any instrument / endoscope is deemed to be compatible with a laser fibre providing the instrument's / endoscope's working channel is

- curved at a bend radius equal or larger than tolerated by the laser fibre to be used,
- free from sharp corners and edges (including the fibre fixation),
- larger in diameter than the outer diameter of the laser fibre to be used.

A compatible instrument / endoscope will accept the insertion of a laser fibre without any force.

Emission of laser radiation caused by mechanical damage of the laser fibre. Laser fibres can be damaged by combination with incompatible instruments / endoscopes or laser devices.

Fibre breakage may cause unintended emission of laser radiation from the damaged laser fibre and may result in heat, tissue damage and burns.

- **Use the laser fibre only in combination with compatible instruments / endoscopes. Compare technical data of the laser fibre and the instruments / endoscopes provided, especially working channel and bend radius, prior to use.**
- **Comply with the specified compatibility requirements.**
- **Use only instruments / endoscopes without rough edges. Check the instrument / endoscope prior to use.**
- **Use only laser fibre fixations which prevent mechanical damage to the laser fibre.**
- **Insert the laser fibre carefully into the instrument / endoscope.**

Insufficient fixing of the laser fibre.

If insufficiently fixed the laser fibre can slip out of position into the instrument / endoscope and out of sight of the surgeon. Laser radiation can cause heating of the instrument / endoscope and tissue damage and burns to the patient.

- **Fix the laser fibre on / in the instrument / endoscope.**
- **Only use fixings that are suitable for the outside diameter of the laser fibre. Compare the specifications of the laser fibre (outer diameter) and the intended fixation.**

Excessive bending of a laser fibre.

If bent at a smaller bend radius than specified, laser radiation can escape at the bend. The generated heat may cause tissue damage and burns.

- **Do not fall below the minimum bend radius.**

2.11 Symbols used and their meaning

QTY	SN	REF	YYYY-MM
Quantity	Serial number	Order number	Date of manufacture

			
FibreStrip	Outer diameter	Core diameter	Minimum bend radius

	Made in Germany	CE 0123	Rx ONLY
Manufacturer	Country of origin	CE-Mark	US federal law restricts this device to sale by or on the order of a physician!

				MD
Not sterile on delivery	Be aware of warnings and safety precautions	Consult instruction for use	Latex free	Medical device

The packaging label (attached to the zip lock bag) comprises all necessary data for the identification of the laser fibre as well as safety relevant information.

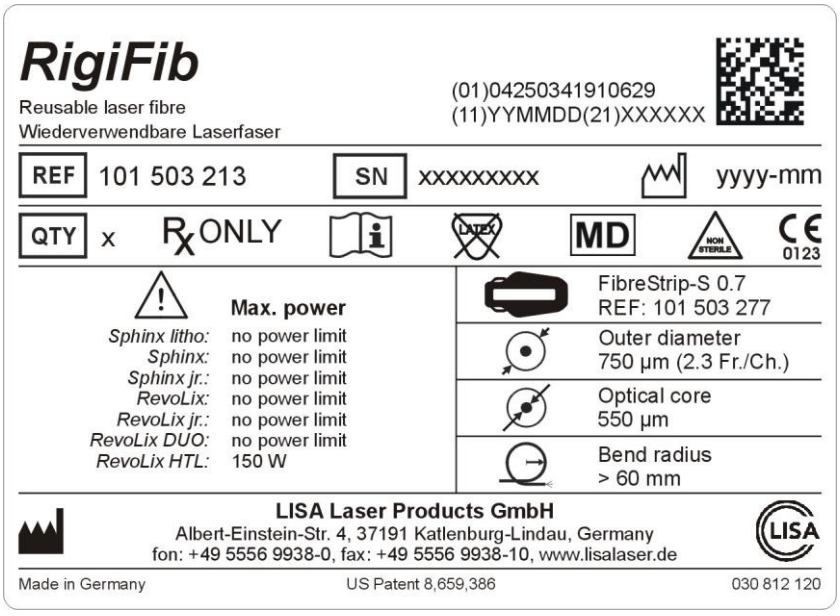


Figure 3: Packaging label of a *RigiFib* (example)

The fibre label (attached to the reusable laser fibre) comprises all necessary data for the identification of the laser fibre as well as safety relevant information. Do not cut off the fibre label from the laser fibre.

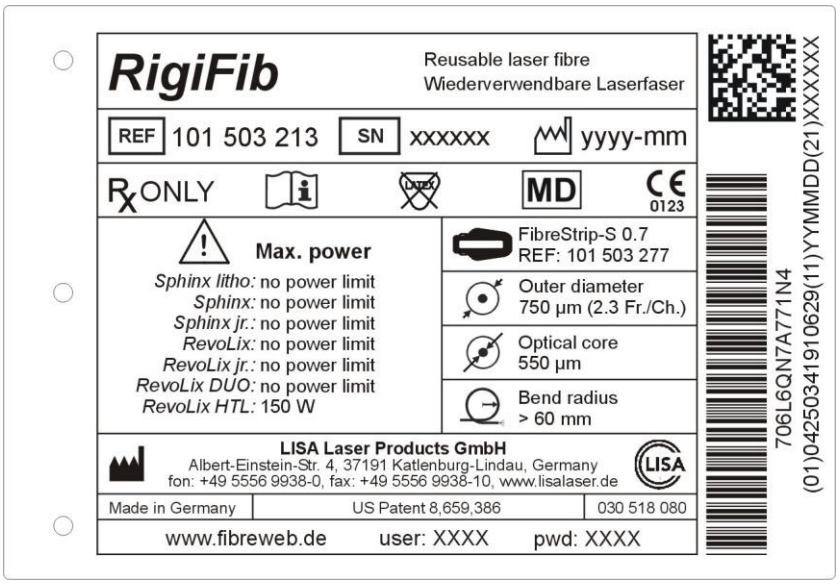


Figure 4: Fibre label of a *RigiFib (example)*

The information at the lower edge of the fibre label is the log-in information for the LISA Laser Products *FibreWeb* laser fibre to laser device assignment system (Figure 4).

www.fibreweb.de	user: XXXX	pwd: XXXX	Barcode / QR-code
LISA Laser Products *FibreWeb* URL	Username	Password	Fibre identification

For more information concerning the LISA Laser Products *FibreWeb* laser fibre to laser device assignment system please contact your national distributor and observe the instruction for use of *FibreWeb* system.

2.12 Accessories for reprocessing reusable laser fibres

Compatible laser fibre stripper:

Laser fibre order number	 **Compatible *FibreStrip* order number, colour code**
LithoFib 101 503 188	*FibreStrip-S 0.2* 101 503 273, light grey,
FlexiFib 101 503 189	*FibreStrip-S 0.3* 101 503 274, red
FlexiFib 5m 101 503 118	*FibreStrip-S 0.3* 101 503 274, red
SureFib 101 503 364	*FibreStrip-S 0.3* 101 503 274, red
PercuFib 101 503 128	*FibreStrip-S 0.5* 101 503 275, blue
RigiFib 101 503 213	*FibreStrip-S 0.7* 101 503 277, grey
RigiFib 800 101 503 287	*FibreStrip-S 1.0* 101 503 280, light grey
RigiFib 1000 101 503 284	*FibreStrip-S 1.1* 101 503 382, orange-red
RevoSoft 101 503 514	*FibreStrip-S 0.3* 101 503 274, red
RevoMed 101 503 515	*FibreStrip-S 0.5* 101 503 275, blue

Laser fibre cutter:

Laser fibre cutter order number	 **Product description**
FibreCut-CS 101 503 581	Tungsten carbide fibre cutter autoclavable

Cleaning and Sterilization tray:

Sterilization Tray order number	**Product description**
SteriTray-F 101 503 591	Reprocessing basket for all laser fibres

3 Use of the laser fibre

3.1 Transport and storage conditions

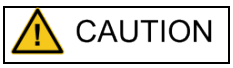
Table 3: Transport and storage conditions

	Temperature	Relative humidity	Atmospheric pressure
Transport **Storage (non-sterile)**	-18 °C to +60 °C 0 °F to 140 °F	30 % to 85 %	700 hPa to 1060 hPa

Mechanical and climatological stress during transport / storage of the laser fibre.

Mechanical damage and fibre breakage.

- **Comply with the transport and storage conditions.**
- **Check the integrity of the laser fibre and package before use.**



Rough handling in the application, processing or transportation of the laser fibre can lead to mechanical damage and fibre breakage.

Sharp edges can cause injury.

- **Handle carefully to avoid kinks in the laser fibre and other damage to the laser fibre or the fibre connector.**
- **Check the integrity of the laser fibre before use.**

3.2 Proper condition of a laser fibre

The proper condition is a prerequisite for the safe use of a laser fibre and needs to be verified before any use of a laser fibre.

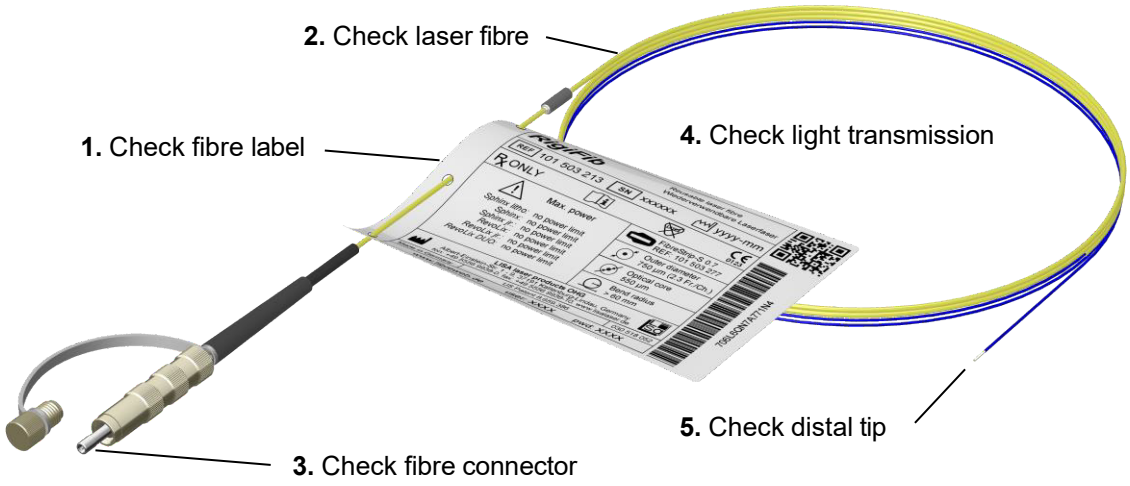


Figure 5: Proper condition checking steps

3.3 How to check the proper condition of a reusable laser fibre

1. Check the fibre label for legibility before using the laser fibre. Do not use the laser fibre, if the information is unreadable or unavailable.
2. Inspect the laser fibre for kinks, fractures and other damage. The laser fibre has to be free of any damage, fractures and kinks on its entire length.
3. Inspect the fibre connector, the fibre end in the fibre connector, the front face of the ferrule adjacent to the fibre end and the ferrule of the connector itself.
   - The connector has to be clean and free of any damage or moisture form the cleaning and sterilization process.
   - The front face of the fibre end in the fibre connector needs to be even, optically shiny, free of any damage and flush with the front face of the ferrule.
   - The metallic front face of the ferrule adjacent to the fibre end needs be shiny and free of any burns.
   - In case of a countersink at the front face of the ferrule the countersink needs to be shiny and to be free of any burns.

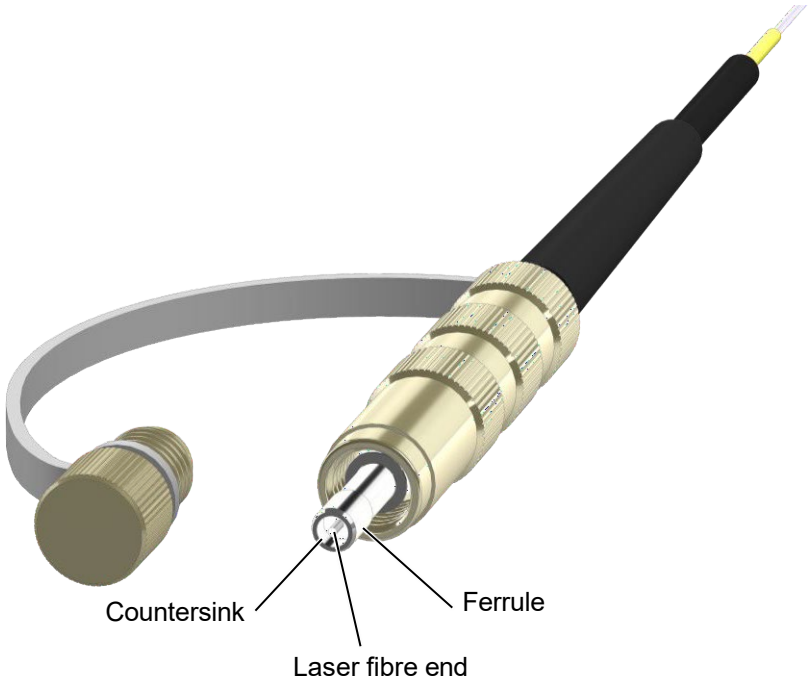
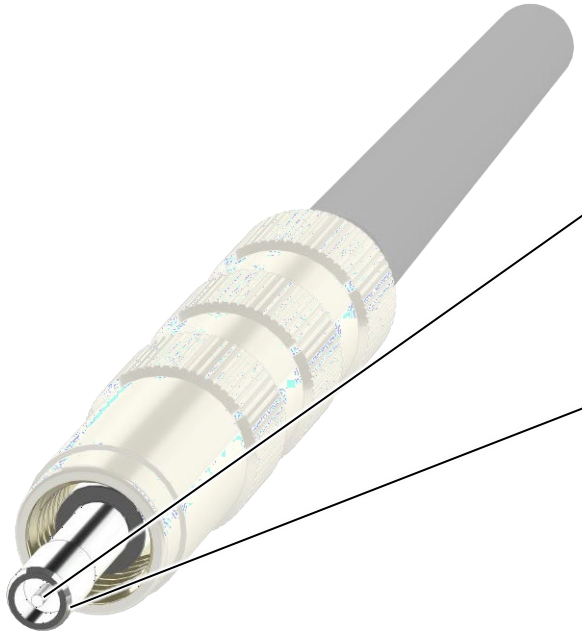


Figure 6: Fibre connector

4. Check the light transmission of the laser fibre from the distal tip to the fibre connector. Point the distal tip of the laser fibre to a light source like daylight or a ceiling light and face the fibre end in the connector. A proper laser fibre delivers the collected light from the distal tip to the end of the laser fibre in the fibre connector. The transmitted light should be clearly visible from the end of the laser fibre in the connector.



Proper condition – ready for use!

- light transmission from distal tip to the fibre end in the connector,
- no residual moisture form the cleaning and sterilization process,
- optically shiny front face of the fibre - flush with the front face of the ferrule,
- shiny metallic front face of the ferrule adjacent to the fibre end – no burn marks.

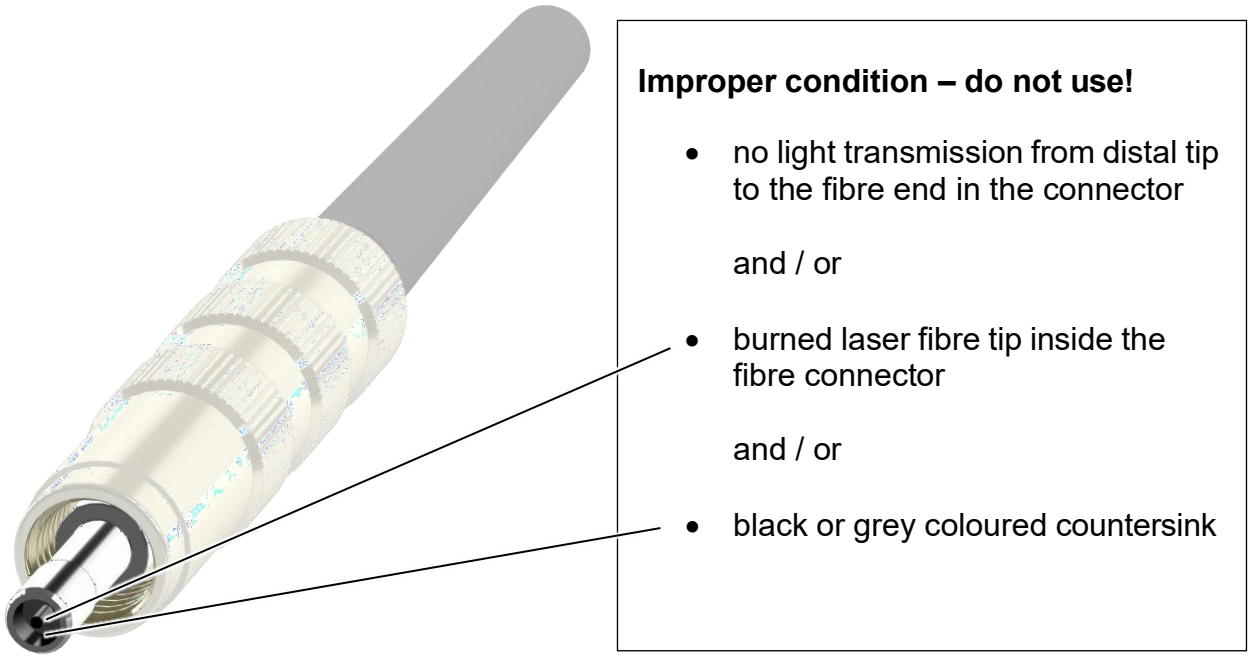


Figure 7: Light transmission and damage to the fibre connector

5. Check the optical quality of the distal tip by use of the aiming beam of a laser device. Connect the laser fibre to the fibre port of the laser device, activate the aiming beam and set the aiming beam to high intensity. Align the distal tip of the laser fibre tip to a white surface. The laser fibre is in proper condition if the projection of the aiming beam has circular symmetry.

Figure 8: Projection of the aiming beam has circular symmetry

3.4 Unpack and prepare the laser fibre for surgery – step by step

1. The o.r. scrub nurse removes the sterile laser fibre from the sterilization tray and inspects the laser fibre for kinks, fractures or other damage. Test the mechanical integrity of the distal tip by applying a sideways force as doing a full stop with a ballpoint pen (Figure 9).

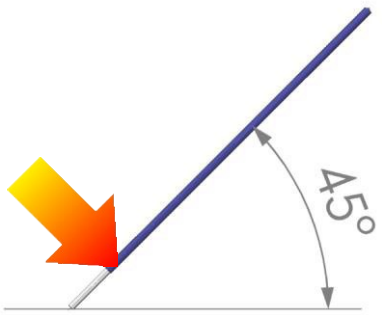


Figure 9: Test of mechanical integrity

2. The o.r. scrub nurse hands over the fibre connector to the circulating nurse, who operates the laser device.
3. The circulating nurse unscrews the protective cap from the fibre connector.
4. Connect the laser fibre to the laser device. Refer to instructions for use of the laser device for detailed information how to connect the laser fibre.
5. Set the aiming beam to a high intensity. Check if the aiming beam is emitted from the distal tip of the laser fibre and not from the length of the laser fibre. A proper laser fibre projects a circular image of the aiming beam on a white non-reflective target (Figure 8).
6. If the aiming beam is weak or poorly visible or appears somewhere along the length of the laser fibre or from the stripped length at the distal tip, do not use the laser fibre.
7. Insert the distal tip of laser fibre into the compatible instrument / endoscope (chap. 2.9).
8. The distal tip of the laser fibre burns off slightly during surgery. The burn off may alter the optical beam quality of the laser radiation emerging from the distal tip and may change the surgical effect. In any case the laser fibre tip has to protrude 1 - 3 mm from the instrument / endoscope.

⚠ WARNING

Emission of laser radiation with the distal fibre tip within the instrument / endoscope.

Emitted laser radiation may cause tissue damage and burns.

- **Never activate the laser unless the distal fibre tip protrudes from the instrument / endoscope by 1 mm at least.**

3.5 Mounting of the laser fibre into the SteriTray-F

1. Place the ***SteriTray-F*** on a suitable table and remove the lid.
2. Grab the fibre connector and twist the laser fibre into a circle with a diameter range from 12 cm to 19 cm.
3. First place the fibre connector to its clamp and afterwards fix the twisted fibre into the four remaining clamps. See Figure 10.
4. Make sure that the loose fibre end is well fixed and does not stick out of the SteriTray-F.

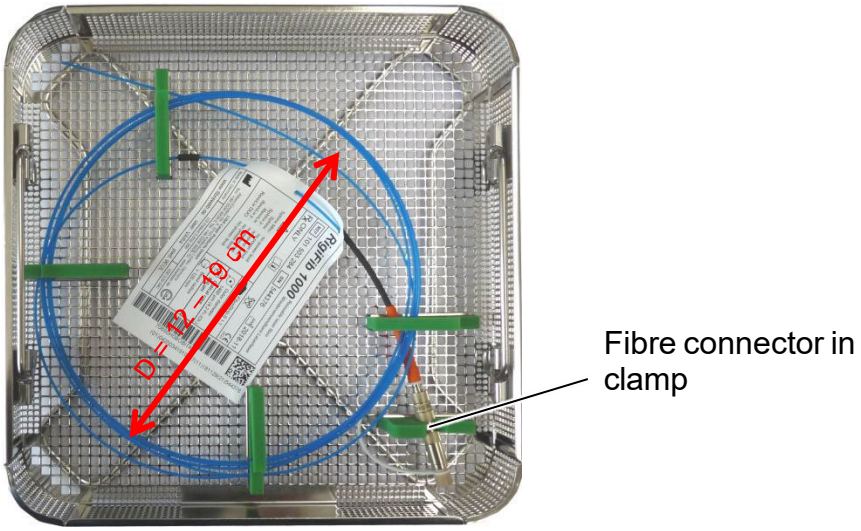


Figure 10: Laser fibre in SteriTray-F

4 Reprocessing of reusable laser fibres

WARNING

Insufficient reprocessing

Insufficient or improper cleaning, disinfection and sterilization process can cause infection due to lack of sterility.

- **Clean, disinfect and sterilize the laser fibres before each use as described in the instructions.**
- **Use suitable sterile packaging**
- **Do not sterilize the laser fibre in its sales packaging.**

CAUTION

Damage to the laser fibre during the reprocessing procedure.

Fragments can detach from damaged laser fibres. Unretrieved device fragments (UDF) can cause injuries or diseases in the human body.

- **Perform reprocessing only as described in this manual.**
- **Do not expose the laser fibre to excessive mechanical stress during reprocessing.**
- **Check the laser fibre for integrity after reprocessing.**

NOTICE

Damage to the laser fibre after exceeding the specified number of reprocessing cycles.

In case of too frequent reprocessing the laser fibre can detach between the fibre connector and the laser fibre, this may lead to a sliding laser fibre and loss of function.

- **Do not reprocess the fibre more than 15 times. The reprocessing process is validated for a 15-time application.**

NOTICE

Damage to the laser fibre during the reprocessing procedure.

An improper reprocessing process can result in the loss of function of the laser fibre.

- **Do not expose the laser fibre to excessive mechanical stress during reprocessing.**
- **Refit the laser fibre protection cap after use.**
- **Use only the cleaning and disinfecting agents described in this manual.**
- **Check the laser fibre for integrity after reprocessing.**

4.1 Reprocessing of the distal tip

1. After use disconnect the laser fibre from the laser device. Rescrew the protection cap onto the fibre connector immediately for protection against dust, moisture and damage.
2. Clean and disinfect the laser fibre after usage. Clean the jacket of the laser fibre with a damp cloth with a disinfectant.
3. Remove the eroded end of the laser fibre by shortening the laser fibre at the distal tip by a few centimetres. Refer to chapter 2.11 for compatible fibre cutters.

4. Strip the jacket at the distal tip of the laser fibre by using a ***FibreStrip-S*** fibre stripper (see chapter 2.11 for compatibility information). Check the fibre stripper for damage and cracks. The blades must be free of damage or deformation and corrosion. Strip the jacket in several short segments in order to reduce the force required for the stripping process. Remove the jacket at a length of about 20 mm from the distal tip of the laser fibre.

CAUTION

Damage to the laser fibre during mechanical re-processing.

Fragments can detach from damaged laser fibres. Unretrieved device fragments (UDF) can cause injuries or diseases in the human body.

- **Perform mechanical re-processing only as described in this manual.**
- **Use only the fibre stripper (FibreStrip-S), which is suitable for the respective fibre.**
- **Do not use any damaged or defective fibre stripper.**
- **Check the laser fibre integrity after re-processing.**

Figure 11: Stripping the jacket in short segments

5. Score the distal tip of the laser fibre circumferentially with a compatible fibre cutter app. 3 to 5 mm from the jacket. For scoring use the tip of the cutter branches and little force only.

Figure 12: Scoring the distal end

6. Create a cleave at the score by gently pulling the distal tip from the laser fibre in the direction of the red arrow (axial direction of the laser fibre note Figure 13). The cleave at the distal tip is a perfect optical window and improves laser beam delivery.

Figure 13: Cleaving the distal end

7. Test the mechanical integrity of the laser fibre by the ballpoint pen test of (Figure 9).
8. Check the quality of the cleaved laser fibre by use of the aiming beam of the laser device as described in (chapter 3.3).

4.2 Limitation of Reprocessing

The lifetime of a reusable laser fibre is defined, tested, and validated for 15 reprocessing cycles.

4.3 Instruction for Reprocessing

Pre-Cleaning in the area of use	Remove contaminations from the components by the use of a cloth soaked in tap water before the contamination start drying. Use the cleaning and sterilization tray ***SteriTray-F*** for transportation***.***
Preparation before cleaning	It is recommended to reprocess the distal tip of the laser fibre directly after use as described in Chapter 4.1. Install the laser fibre into the ***SteriTray-F*** as described in Chapter 3.5.
Automated Cleaning	For the automated cleaning process we recommend a cleaning and disinfection device according to ISO 15883. Use the following program for automated cleaning: - 2 min pre-cleaning with cold tap water (16 °C ± 2 °C) - Draining - 5 min cleaning with 55 °C tap water and 0.5 % cleaning solution neodisher MediClean forte (Dr. Weigert GmbH & Co. KG) - Draining - 3 min rinsing with cold deionized water (20 °C ±2 °C) - Draining - 2 min rinsing with cold deionized water (20 °C ±2 °C) - Draining
Disinfection	A thermal disinfection is recommended. Use a disinfection device according to ISO 15883. Temperature: 93 °C Holding time: 5 min ($A_0 \geq 3000$)
Control and maintenance	Perform a visual inspection of the laser fibre as described in Chapter 3.3.
Packing	Double wrapped the tray in sterilization sheets 100 (Sterisheet 100, size 900 mm x 900 mm; Broemeda Amcor Flexibles).
Sterilization	Pre-Vacuum steam sterilization process. Pre-vacuum phases: 4 Sterilization temperature: 132 °C Holding time: 3 min
Drying	20 min
Storage / Transport to the place of use	After each sterilization process, the laser fibre can be stored and transported in the ***SteriTray-F***. Observe the requirements for storage conditions of the manufacturer of the sterile barrier. If there are no special requirements the sterilized laser fibre should be stored at room temperature (15 °C - 25 °C) in a dry place and protected against direct light and heat radiation.

The instructions provided above have been validated by LISA Laser Products of the medical device as being capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

INFORMATION

When using automated cleaning follow the special handling instructions.

The use of acidic (pH < 5) solutions (citric acid/phosphoric acid) during the cleaning process may lead to colour change of the metal parts of the fibre. These alterations do not have any influence on the function or safety of the device.

INFORMATION

Please note different regulations for sterilization and cleaning, if products get in contact with patients with suspected Creutzfeld-Jakob-Disease, CJK-on-spec or its possible variants, Bovine Spongiform Encephalopathy or Transmissible Spongiform Encephalopathy.

Therefore country-specific regulations and laws concerning cleaning and sterilization of instruments have to be observed

5 Disposal

Dispose the reusable laser fibre in an unbreakable semi-solid container which encloses the disposed laser fibre safely.

The laser fibre gets in contact with tissue and body fluids. After surgery the laser fibre may present a potential source for infection.

Follow the regulatory, technical and organizational required safety precautions for the disposal of septic, pointed and breakable items.

WARNING

After use laser fibres are contaminated with biological material.

Contact with a used laser fibre may result in infections.

- **For the disposal of the laser fibre use containers that are suitable for biologically contaminated material or clean and disinfect the laser fibre before discarding it.**
- **Observe national regulations for disposal.**

LISA Laser Products GmbH
Albert-Einstein-Str. 4
37191 Katlenburg-Lindau
Germany
☎ +49 5556 9938-0
🖷 +49 5556 9938-10
info@lisalaser.de
www.lisalaser.de

CE
0123