



## ***Accessories for MASTER lase and EXPERT lase***



## **Instructions for Use**

English

**CE 0124**

Include the present Instructions for Use with the Instructions for Use of the laser unit.

Order number of the present Instructions for Use: 1.010.0274



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EC	REP
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## 1. Description

Accessories for MASTER laser and EXPERT laser include:

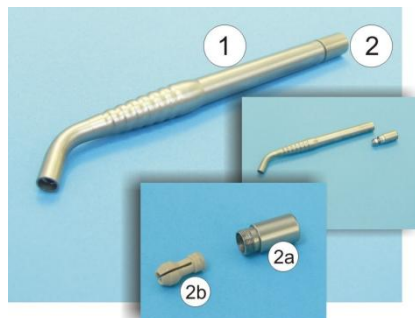
- Handpiece BareFiber Tip
- BareFiber Tip FT0-303609-BF-0 (hereinafter: BareFiber-Tip)
- BareFiber Tip FT0-242809-BF-0 (hereinafter: BareFiber-Tip)
- Optical fibre handpiece for use without fixation sleeve and with handpiece BareFiber-Tip; (hereinafter: transmitting optical fibre)
- Handpiece for Saphir-Tip
- Saphir-Tip handpiece (hereinafter: Saphir-Tip)
- Bleaching handpiece
- Optical fibre handpiece for use with fixing sleeve and handpiece for Saphir-Tip, handpiece BareFiber-Tip, and bleaching handpiece

For order numbers for the above-mentioned products, please refer to chapter

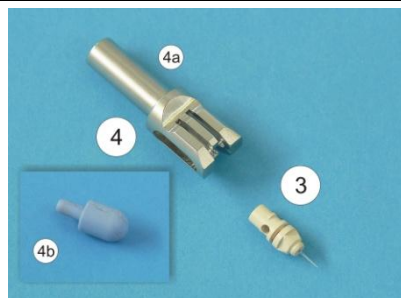
Technical Specifications and Order Numbers, page 55.

For scope of delivery, please refer to the Instructions for Use for MASTER/EXPERT laser.

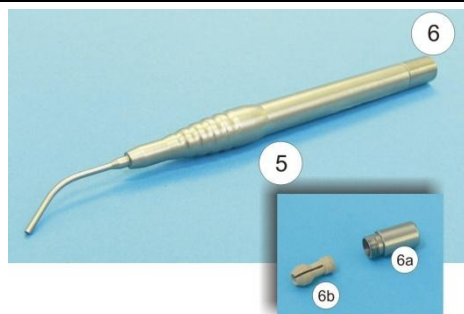


**Figure 1. Handpiece for Saphir-Tip**

- 1 Handpiece for Saphir-Tip
- 2 Clamping
  - 2a Fastening sleeve
  - 2b Chuck

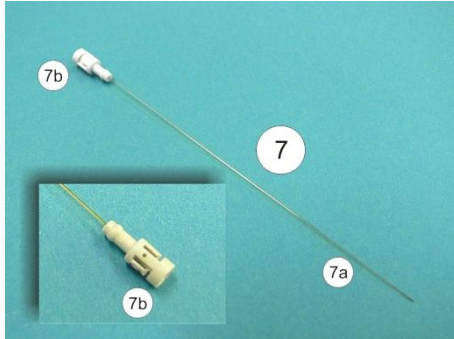
**Figure 2. Saphir-Tip**

- 3 Saphir-Tip
- 4 Installation and cleaning accessories for Saphir-Tip
  - 4a Tool for Saphir-Tip
  - 4b Cleaning cap

**Figure 3. Handpiece for BareFiber-Tip**

- 5 Handpiece for BareFiber-Tip
- 6 Clamping
  - 6a Fastening sleeve
  - 6b Chuck for transmitting optical fibre



Figure 4. *BareFiber-Tip*


- 7** BareFiber-Tip  
**7a** Optical fibre  
**7b** Adaptor

Figure 5. *Bleaching handpiece*


- 8** Bleaching handpiece  
**9** Clamping  
**9a** Fastening sleeve  
**9b** Chuck for Transmitting fibre optic conductor  
**10** Lens system with front sleeve  
**10a** Lens system  
**10b** Front sleeve

Figure 6. *Transmitting optical fibre*


- 11** Transmitting optical fibre  
**12** Fixation sleeve (transmitting optical fibre with fixation sleeve)  
**13** Ferrule (distal end of the transmitting optical fibre)  
**14** Protective caps  
**15** SMA plug (proximal end of the transmitting optical fibre)



## 2. Safety

For safety information regarding the use of laser radiation, please refer to the Instructions for Use for the MASTER laser and EXPERT laser. The user must be familiar with laser operation and have read and understood the entire Instructions for Use.

Special care is required with regard to the use of the *accessories*. Professional handling and reprocessing prolongs the service life of the products.

### 2.1. Intended use



**The Accessories for MASTER laser and EXPERT laser must be used in compliance with the intended use only.**

The manufacturer shall not be liable for any use other than intended or manipulation of the products through non-authorised persons.

The Accessories for MASTER laser and EXPERT laser are intended for use in combination with the *MASTER laser and the EXPERT laser*.

The intended use of the laser unit also applies to the accessories.

Please comply with the Instructions for Use in this regard.

The transmitting optical fibre is used to transmit the therapy and pilot laser light from the laser unit to the therapy accessories (e.g. BareFiber-Tip, Saphir-Tip).

The transmitting optical fibre with fixing sleeve can be used with the Saphir-Tip handpiece, the BareFiber-Tip handpiece, and the bleaching handpiece.

The transmitting optical fibre without fixation sleeve can be used with the handpiece BareFiber-Tip exclusively.

Saphir-Tip incl. handpiece Saphir-Tip:

- Cutting applications (e.g. incision).

BareFiber-Tip FTO-303609-BF-0 incl. handpiece BareFiber-Tip:

- Cutting applications (e.g. incision)
- Coagulation applications (e.g. hemostasis)
- Disinfection applications (e.g. endodontics)

BareFiber-Tip FTO-242809-BF-0 incl. handpiece BareFiber-Tip:

- Disinfection applications (e.g. endodontics)

Bleaching handpiece:

- Activation of bleaching material



## 2.2. Re-use



**Limited re-use:** The service life of the products is determined by wear and tear, reprocessing procedures (chemicals), and damage from use.



**Inappropriate handling may significantly reduce the re-usability below the specified number.**

The *Accessories for MASTER lase and EXPERT lase* can be re-used, if handled appropriately:

- Handpieces – typically up to 200 times
- Saphir-Tip – typically up to 5 times
- Tool – typically up to 200 times
- Lens system (for bleaching handpiece) – typically up to 50 times
- Transmitting optical fibre - typically up to 100 times

Any re-use of damaged or contaminated products is not permissible.



**The BareFiber-Tip is an article for single use and must not be re-used.**



### 3. Operation

#### 3.1. Safety instructions

The preparation and operation of the accessories for the lasers of the *MASTER/EXPERT lase* series are described in the following.

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**⚠ WARNING**

**The products must be handled by trained and qualified personnel only. It must be ensured before and during use that the sterility of the products is maintained. In addition, compliance with the applicable guidelines for the handling of products to be sterilised is required.**

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**⚠ WARNING**

**It is mandatory to comply with all safety information of the Instructions for Use of the laser unit.**

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**⚠ WARNING**

**Never trigger any laser radiation unless the BareFiber-Tip or the Saphir-Tip is connected to the transmitting optical fibre.**

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**⚠ WARNING**

**Never trigger any laser radiation if the tip of the optical fibre is situated inside the handpiece.**

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**⚠ WARNING**

**Do not point the Saphir-Tip or the BareFiber-Tip in the direction of people that are present in the room. All persons that are present in the laser area must wear protective goggles. For the protective goggle requirements, please refer to the Instructions for Use of the laser unit.**

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**⚠ WARNING**

**Irreversible eye damage may occur. Retina and skin must not be exposed to direct or reflected (e.g. through glossy materials) laser radiation. Laser goggles provide only for short-term protection from direct laser light.**

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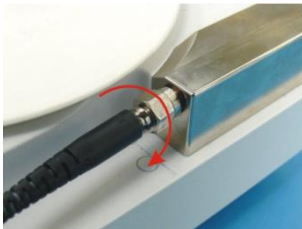
### 3.2. Starting up the transmitting optical fibre

The part of the transmitting optical fibre that is not needed for the treatment can be reeled up completely below the fibre reel (bending radius 25 mm).


**WARNING**

#### **Risk of contamination!**

**The transmitting optical fibre must be disinfected before and after each application and before its first use (see page 50).**



Connect the transmitting optical fibre to the laser unit.



The plug of the optical fibre must be screwed down completely. Approximately 5 clockwise turns are necessary for this purpose.

Check if the plug of the optical fibre is attached firmly.


**CAUTION**

**To prevent the transmitting optical fibre from being damaged:**

**keep the transmitting optical fibre in the guide groove while you roll up the fibre (a);**

**while winding, grasp the transmission fibre optic conductor at a distance of 1 cm to 2 cm from the edge of the fibre winding (b, c), so that the fibre optic conductor can be wound under the white silicone disc through slight pulling.**



**Avoid touching the distal and proximal ends of the transmitting optical fibre**

**The part of the transmitting optical fibre that is not needed for the treatment can be reeled up completely below the fibre reel (bending radius 25 mm).**





1. Roll the transmitting optical fibre up or off the fibre reel as needed to have a sufficient length of optical fibre for the treatment.



2. Attach the lid of the housing, guiding the transmitting optical fibre through one of the recesses provided for this purpose.



3. Check the eye protection.
4. Switch on the laser unit.

The laser unit recognises that the optical fibre is attached.

The message, *"Connect optical fibre to the unit"*, is displayed no longer.

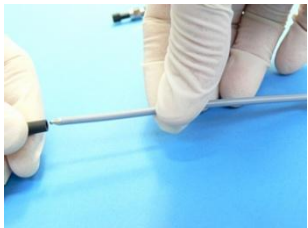
The laser status bar is displayed.

## **WARNING**

**Risk of cross-contamination!**

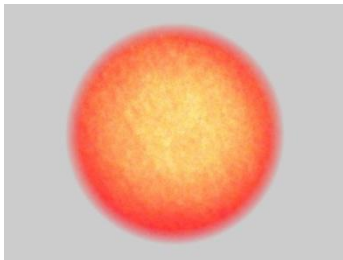
**Do not attach the protective cap between applications.**

**The protective cap only serves as protection at the time of delivery or if the unit is stored in the case for prolonged periods of time.**



5. You may need to remove the protective cap of the transmitting optical fibre.





6. Point the distal end of the transmitting optical fibre (at a distance of 20 cm) perpendicularly at a bright, level surface and observe the spot of light produced by the pilot laser beam (emission characteristics).

If the transmitting optical fibre is free of any technical defects, an even circular spot of light is generated whose intensity decreases strongly from inside to outside.



**WARNING**

**If the emission characteristics are not consistent with the description above, the optical fibre cannot attain its full functionality. This means that the success of treatment cannot be guaranteed. You may need to replace the optical fibre and check the new fibre again.**



### 3.3. Installation and first use of the Saphir-Tip handpiece



The handpieces and Saphir-Tips are delivered in non-sterile condition by the manufacturer.

In order to allow them to be used in sterile condition, the handpieces and Saphir-Tips as well as the tool need to be reprocessed before each application and before their first use.



Any contamination of the sterilised handpieces and Saphir-Tips contacting the patient needs to be prevented.

Please comply with the information regarding aseptic removal and installation of the handpieces and Saphir-Tips.



**Risk of contamination!**

If the sterile packaging is damaged, previously sterilised handpieces and Saphir-Tips must not be used without first re-sterilising them.



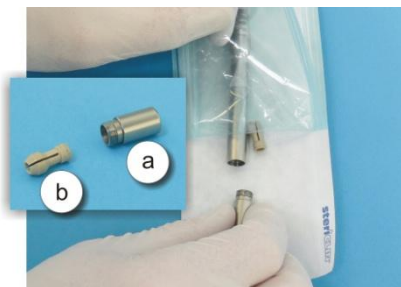
**Risk of contamination!**

If possible, keep the handpiece in your hand and do not put it down on a non-sterile support surface. Avoid touching the Saphir-Tip.

Use a sterile support surface exclusively throughout the entire procedure!

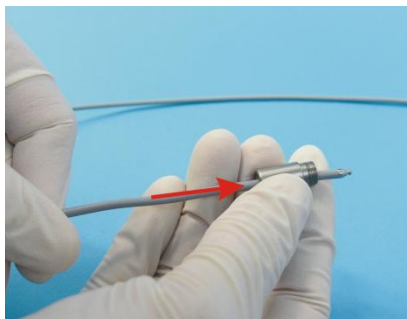




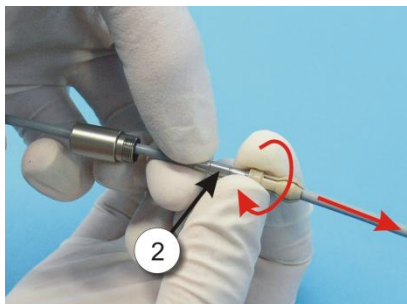


The transmitting fibre optic conductor with fixation sleeve must be connected to the unit (see page 9)

1. Open the package at the handle-side of the handpiece and take out the fastening sleeve (a) and the chuck (b).



2. Guide the transmitting optical fibre through the opening of the fastening sleeve.



3. Guide the transmitting optical fibre through the opening of the chuck and screw the chuck onto the fixation sleeve (2) of the transmitting optical fibre.



The chuck must be screwed onto the fixation sleeve of the optical fibre to be hand-tight. Check the chuck for firm seating before you proceed.



4. Install the fastening sleeve through pressing lightly on the chuck.





5. Take the handpiece out of the packaging.

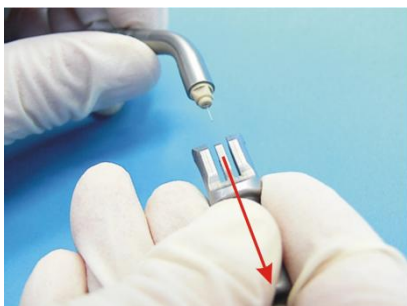


6. Open the packaging of the Saphir-Tip at the tool side.

7. Take the tool including Saphir-Tip out of the packaging making sure not to touch the Saphir-Tip.



8. Screw the Saphir-Tip into the handpiece proceeding in clockwise direction.



9. Pull the tool off the Saphir-Tip.





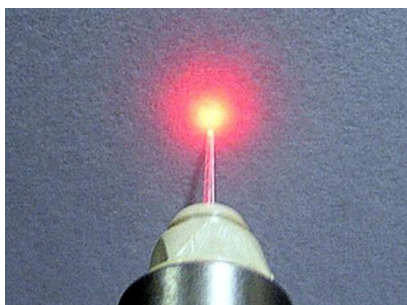
10. Guide the transmitting optical fibre into the handpiece until you reach the limit stop and screw the fastening sleeve tightly to the proximal end of the handpiece.



Guide the transmitting optical fibre slowly through the curvature of the handpiece using no more than mild pressure. Pressing too strongly compresses the transmitting optical fibre and increases the resistance.



11. Check that there is no gap at the screw connection of clamping and handpiece and check if the transmitting optical fibre is attached firmly.



12. Switch the laser unit on and check if the pilot light at the distal end of the Saphir-Tip is clearly recognisable. You may need to check the screw connections of the clamping on the fixation sleeve and on the handpiece.
13. Set the parameters on the laser unit as desired and commence the treatment.

If the Saphir-Tip is free of any technical defects, an even circular spot of light is generated whose intensity decreases rapidly from inside to outside.



**If the radiation characteristics do not correspond to the above-mentioned description or depiction, the handpiece might heat up inadmissibly, which may lead to burn injury. You may need to replace the Saphir-Tip and re-check with the new Saphir-Tip.**



### 3.4. Installation and first use of the BareFiber handpiece

**⚠ WARNING**

The BareFiber handpieces are delivered in non-sterile condition by the manufacturer.  
In order to allow them to be used in sterile condition, BareFiber handpieces need to be reprocessed before each application and before their first use (see chapter "Reprocessing", page 29).

**⚠ WARNING**

Any contamination of the sterilised handpieces and BareFiber-Tips must be prevented.  
Please comply with the information regarding aseptic removal and installation of the handpieces and BareFiber-Tips.

**⚠ WARNING****Risk of contamination!**

If the sterile packaging is damaged, handpieces that have already been sterilised must not be used without reprocessing them.

**⚠ WARNING****Risk of contamination!**

If possible, keep the handpiece in your hand and do not put it down on a non-sterile support surface. Avoid touching the BareFiber-Tip.  
Use a sterile support surface exclusively throughout the entire procedure!

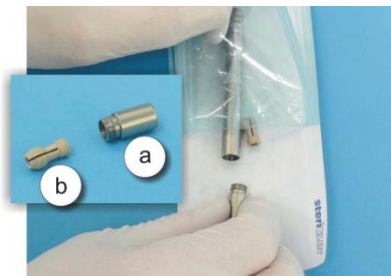
STERILE

EO

**⚠ WARNING**

The BareFiber-Tips are delivered in sterile condition by the manufacturer (EO = ethylene oxide).

BareFiber-Tips from damaged sterile packages must not be used.



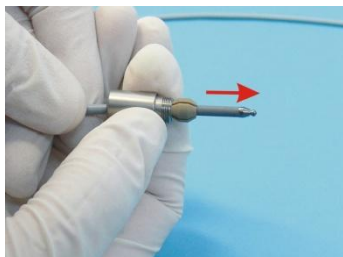
The transmitting fibre optic conductor without fixation sleeve must be connected to the unit (see page 9)

1. Open the package at the handle-side of the handpiece and take out the fastening sleeve (a) and the chuck (b).





2. Install the fastening sleeve through pressing lightly on the chuck.

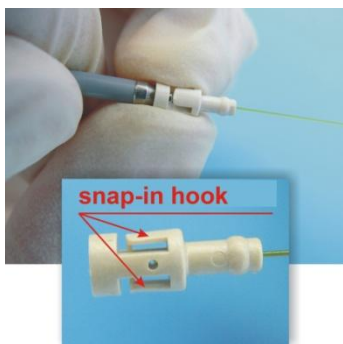



3. Guide the transmitting optical fibre through the opening in the fastening sleeve and in the chuck.



4. Open the packaging on the adaptor side of the BareFiber-Tip.

5. Take the BareFiber-Tip out of the packaging making sure not to touch the fibre of the optical fibre.



-  Hold the BareFiber-Tip without touching the snap-in hooks.

6. Plug the adaptor of the BareFiber-Tip onto the distal end of the transmitting optical fibre until the adaptor can be felt to snap into place.



7. Take the handpiece out of the packaging making sure not to touch the distal end of the handpiece.

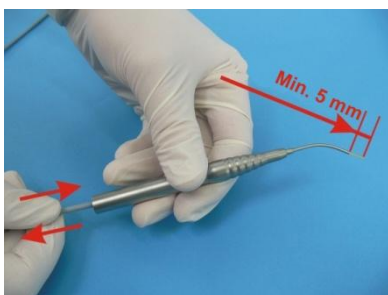




8. Guide the transmitting optical fibre with the BareFiber-Tip installed into the handpiece.



9. Screw the fastening sleeve to the proximal end of the handpiece such that the transmitting optical fibre still has some play.

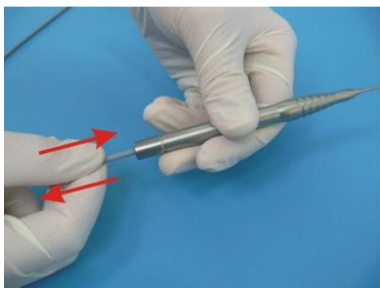


10. Set the required length of the BareFiber-Tip at the distal end. The distal end of the transmitting optical fibre must project at least 5 mm from the handpiece.

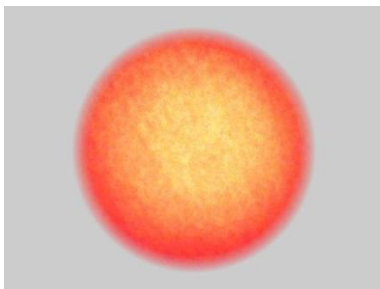


11. Tighten the clamping on the proximal end of the handpiece.





**12.** Check if the transmitting optical fibre is seated firmly.



**13.** Switch on the laser unit. Point the distal end of the BareFiber-Tip (at a distance of 20 cm) perpendicularly at a bright, level surface and observe the spot of light produced by the pilot laser beam (emission characteristics). You may need to check the screw connection of the clamping on the handpiece.

If the BareFiber-Tip is free of any technical defects, an even circular spot of light is generated whose intensity decreases rapidly from inside to outside.



**WARNING**

## **Risk of burn injury!**

If the radiation characteristics do not correspond to the above-mentioned description or depiction, the handpiece might heat up inadmissibly, which may lead to burn injury. You may need to replace the BareFiber-Tip and re-check with the new tip



**WARNING**

Undesirable side effects may be produced during contact cutting (e.g. overheating of underlying tissue layers).

In order to avoid complications, the Saphir-Tip or BareFiber-Tip needs to be burned-in for contact cutting (see page 20).

**14.** If you selected an indication that does not involve contact cutting, set the parameters on the laser unit as desired and commence the treatment.



**CAUTION**

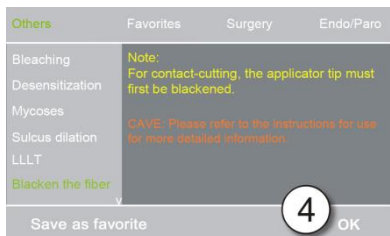
Please comply with the maximal laser power of the fibre tips (see Technical Specifications and Order Numbers).



### 3.5. Blackening the Saphir-Tip / BareFiber-Tip

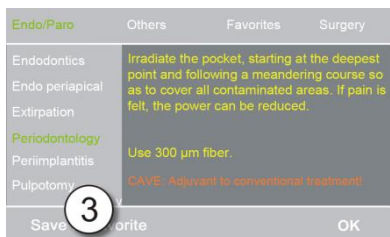


1. Touch the indication element (top left of the touchscreen).

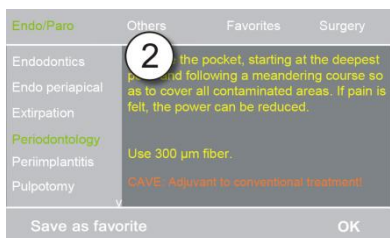


2. Touch the display Other.

The display *Other* changes its colour to green and shifts towards the left.



3. Select blacken fibre from the list.



4. Confirm by touching OK in order to switch to therapy mode.



The parameters for blacken are set automatically.





5. Touch the distal end of the Saphir-Tip / BareFiber-Tip against the dark quadrangle printed onto the packaging of the BareFiber-Tips.



6. Trigger the laser light.

If the blacken process on the printed quadrangle was successful, a small hole and is generated and fumes are produced briefly; you may need to repeat this process, if applicable (step 5).

7. Set the laser unit to the desired indication.

8. Commence the treatment.

## CAUTION

In order to prevent the Saphire-Tip from being destroyed, a cutting depth of 2 mm must not be exceeded in contact cutting.

## WARNING

At the end of their service cycle (service life) dispose optical fibres and handpieces in accordance with local regulations for contaminated products. This minimises the hazard for the environment and the staff that may be caused by contamination and residues of spent fibres and handpieces.



### 3.6. Installation and first use of the bleaching handpiece

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**⚠ WARNING**

The bleaching handpieces are delivered in non-sterile condition by the manufacturer.  
In order to allow them to be used in sterile condition, bleaching handpieces need to be reprocessed before each application and before their first use (see chapter "Reprocessing", page 29).

---

**⚠ WARNING**

Any contamination of the sterilised handpieces must be prevented.  
Please comply with the information regarding aseptic removal and installation of the handpieces.

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**⚠ WARNING****Risk of contamination!**

If the sterile packaging is damaged, handpieces that have already been sterilised must not be used without reprocessing them.

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**⚠ WARNING****Risk of contamination!**

If possible, keep the handpiece in your hand and do not put it down on a non-sterile support surface. Use a sterile support surface exclusively throughout the entire procedure!

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**⚠ WARNING****Risk of injury!**

The use of the bleaching handpiece requires a larger safety distance due to the collimated laser beam (Nominal Ocular Hazard Distance – NOHD =  $160 \pm 60$  m). If there are any windows and/or glass doors in the treatment room, persons outside the room are also at risk. Use suitable protective measures (e.g. laser protection curtains). Please comply with the laser safety regulations.

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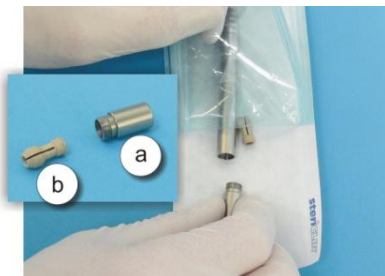
**⚠ WARNING**

**Irreversible damage to health could be caused in soft and hard tissue.**

The bleaching material to be used must be released for use with the MASTER / EXPERT laser by the manufacturer of the bleaching material. Please comply with the Instructions for use of the manufacturer of the bleaching material to be used.

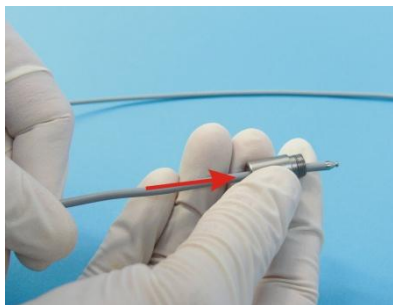
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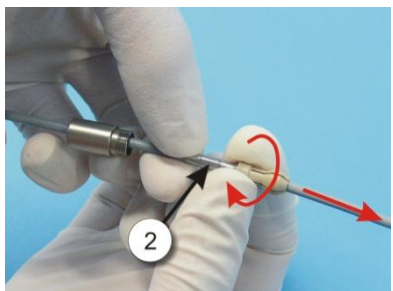


The transmitting fibre optic conductor with fixation sleeve must be connected to the unit (see page 9)

1. Open the package at the handle-side of the handpiece and take out the fastening sleeve (a) and the chuck (b).



2. Guide the transmitting optical fibre through the opening of the fastening sleeve.



3. Guide the transmitting optical fibre through the opening of the chuck and screw the chuck onto the fixation sleeve (2) of the transmitting optical fibre.

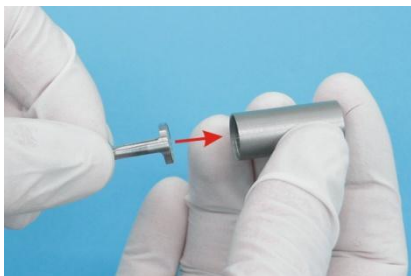


The chuck must be screwed onto the fixation sleeve of the optical fibre to be hand-tight. Verify the firm seating of the chuck before you continue.



4. Install the fastening sleeve through pressing lightly on the chuck.

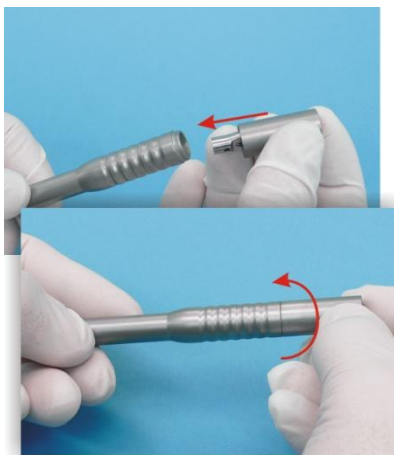




5. Take the front sleeve out of its packaging.
6. Take the lens system out of its packaging making sure not to touch the lens.
7. Insert the lens system into the front sleeve.

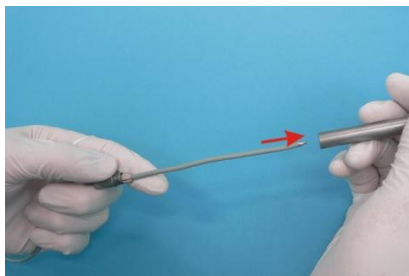


8. Take the handpiece out of its packaging.



9. Screw the front sleeve to the distal end of the handpiece.

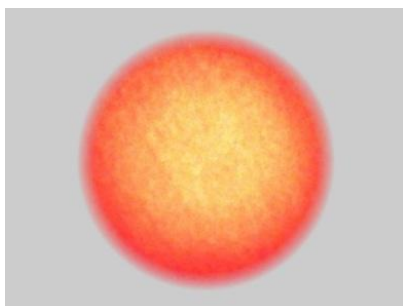




10. Insert the transmitting optical fibre into the handpiece.



11. Screw the fastening sleeve to the proximal end of the handpiece.



12. Switch on the laser instrument. Point the distal end of the bleaching handpiece (at a distance of approx. 10 mm and approx. 60 mm) perpendicularly at a bright, level surface and observe the spot of light produced by the pilot laser beam (emission characteristics).

If the optical fibre is free of any technical defects, at both distances, an even circular spot of light 5 - 6 mm in diameter is generated whose intensity decreases rapidly from inside to outside.



## WARNING

**If the radiation characteristics do not correspond to the above-mentioned description or depiction, the handpiece might heat up inadmissibly, which may lead to burn injury. If applicable, check the screw connection of the clamping and the screw connection of the front sleeve on the handpiece, and also re-check the emission characteristics.**

13. Set the *Bleaching* indication on the unit and commence treatment.



### 3.7. Dismantling the Saphir-Tip handpiece



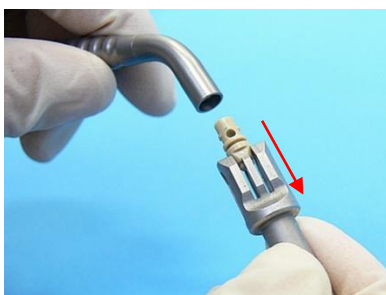
1. Unscrew the fastening sleeve fully from the handpiece and slowly pull the transmitting optical fibre out of the handpiece using the chuck and the fastening sleeve.



2. Unscrew the chuck from the fixation sleeve and pull the chuck off the transmitting optical fibre using the fastening sleeve.



3. Unscrew the Saphire-Tip from the handpiece using the tool.



4. Pull the Saphir-Tip off.

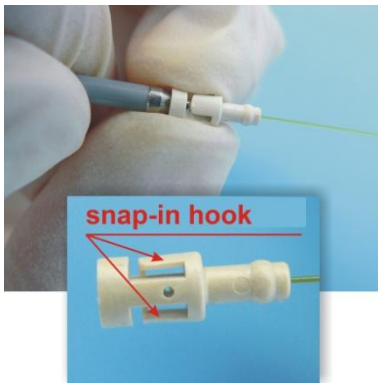
5. Then perform the reprocessing process (see page 29).




### 3.8. Dismantling the BareFiber handpiece

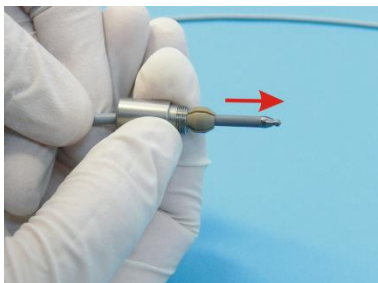


1. Unscrew the fastening sleeve fully from the BareFiber-handpiece and pull the transmitting optical fibre out of the handpiece using the BareFiber-Tip.



-  Hold the BareFiber-Tip without touching the snap-in hooks.

2. Pull the adaptor of the BareFiber-Tip off the distal end of the transmitting optical fibre.



3. Pull the chuck the chuck off the transmitting optical fibre using the fastening sleeve.
4. Then perform the reprocessing process (see page 29).


**WARNING**

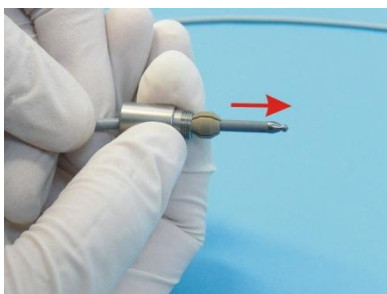
**At the end of their service cycle (service life) dispose optical fibres and handpieces in accordance with local regulations for contaminated products. This minimises the hazard for the environment and the staff that may be caused by contamination and residues of spent fibres and handpieces.**



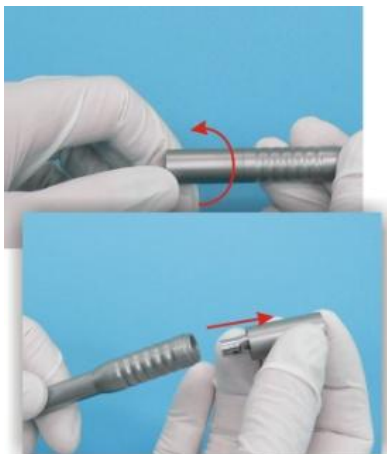
### 3.9. Dismantling the bleaching handpiece



1. Unscrew the fastening sleeve of the clamping from the bleaching handpiece and pull the transmitting optical fibre including the clamping (chuck including the fastening sleeve) out of the handpiece.



2. Unscrew the chuck from the fixing sleeve and pull the chuck with the fixing sleeve off the transmitting optical fibre.



3. Unscrew the front sleeve of the lens system from the bleaching handpiece and pull the lens system including the front sleeve out of the handpiece.
4. Then carry out the reprocessing process (chap. "Reprocessing", page 29).



**At the end of their service cycle (service life) dispose the handpieces in accordance with local regulations for contaminated products. This minimises the hazard for the environment and the staff that may be caused by contamination and residues of spent fibres and handpieces.**



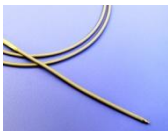


## 4. Reprocessing

After each use, the MASTER/EXPERT laser accessories need to be subjected to the following steps of reprocessing:

1. Pre-treatment
2. Automated or manual cleaning / disinfection
3. Maintenance, controls
4. Packaging
5. Sterilisation
6. Storage

For more information on the individual steps, see the subsequent chapters.

		Handpiece for Saphir-Tip and handpiece for BareFiber-Tip with clamping	Saphir-Tip	Transmitting optical fibre
Dismantling		 ✓	 -	 -
Pre-treatment		✓ Chap. 4.4.1, p. 35	✓ with mechanical cleaning Chap. 4.5.1, p. 41	-
Cleaning / Disinfection	automatic	✓ Chap. 4.4.2.1, p. 35	--	--
	or manual	✓ Chap. 4.4.2.2, p. 38	✓ Chap. 4.5.2, p. 44	



	Handpiece for Saphir-Tip and handpiece for BareFiber-Tip with clamping	Saphir-Tip	Transmitting optical fibre
Disinfection by means of wiping	-	-	✓ Chap. 4.9, p. 50
Check	✓ Chap. 4.6.1, p. 45	✓ Chap. 4.6.2, p. 46	✓ Chap. 0, p. 52
Maintenance	✓ Chap. 4.6.1, p. 45	✓ Chap. 4.6.2, p. 46	✓ Chap. 0, p. 52
Packaging	✓ Chap. 1.1, p. 47	✓ Chap. 1.1, p. 47	-
Sterilisation	✓ Chap. 4.8, p. 49	✓ Chap. 4.8, p. 49	--
Storage	✓ Chap. 4.11, p. 54	✓ Chap. 4.11, p. 54	✓ Chap. 4.11, p. 54

- ✓ = mandatory;  
 - = not required  
 -- = not permitted



 **WARNING**

The BareFiber-Tip is an article for single use and must not be re-used.



## 4.1. Safety instructions

All re-usable products of the MASTER/EXPERT laser *Accessories* must be reprocessed appropriately before reuse in accordance with the table in chapter 4. Reprocessing. Effective cleaning and disinfection is an indispensable prerequisite of effective sterilisation.

Make sure to use product-specific validated procedures for cleaning/disinfection and sterilisation only. Make sure that the devices used (disinfectant, steriliser) are serviced and checked regularly. Make sure that the validated parameters are indeed used in each cycle.

The user is responsible for keeping a protocol of the reprocessing and for compliance with the maximal re-usability.

Please comply with the applicable national regulations concerning sterile goods supplies and staff training as well as the hygiene regulations of the medical office or hospital. This applies, in particular, to the different requirements for effective prion inactivation.

## 4.2. Pre-treatment

Please note the following in the pre-treatment process:

- There must be no more than 24 hours between pre-treatment and cleaning/disinfection.
- Please note that the disinfectant used in pre-treatment serves only for personal protection and cannot substitute for the disinfection step to be performed subsequently - after 'completed cleaning.
- Use only a very soft brush or a clean, soft, lint-free cloth, dedicated for this purpose, for removing contamination.  
Do not use metal brushes or wire wool.
- Use an efficacy-tested, aldehyde-free disinfectant to prevent blood contamination from becoming fixed (e.g. VAH/DGHM or FDA approval and/or CE mark).
- Make sure to use a disinfectant that is suitable and compatible for handpiece disinfection (see 4.3 "Cleaning/Disinfection").



### 4.3. Cleaning/Disinfection

When you select the cleaning and disinfection agents, please make sure that neither of the following ingredients is present:

- strong or concentrated organic, mineral or oxidising acids (minimal permissible pH 5.5)
- strong or concentrated bases (maximal permissible pH 8.5\*, neutral enzymatic detergents are recommended)
- organic solvents (e.g. alcohols\*\*, ethers, ketones, benzines, ...)
- Phenol
- strong or concentrated oxidising agents (e.g. peroxides, ozone)
- strong reducing agents
- Halogens (chlorine, bromine, iodine), chloride
- aromatic/halogenated hydrocarbons
- Alkali metal (Na, Ka) compounds
- Ammonia, ammonium compounds, amines
- Tri-/perchloroethylene
- Oils, fats

\* Exception: Saphir-Tip incl. tool are compatible with the recommended agent for pre-treatment (chapter 4.5.1)

\*\* Exception: For short exposure times (e.g. disinfection through wiping), the transmitting optical fibre is compatible with the recommended agent (chapter 4.9)



**Do not use metal brushes or wire wool for cleaning any of the accessories. Do not expose any of the accessories to temperatures above 141°C (286°F).**



### 4.3.1. Automated cleaning / Disinfection



**Chemical disinfection is associated with the risk of residual disinfectant remaining on the products.**

Please clean and disinfect the accessories of the *MASTER lase* and the *EXPERT lase* in a disinfectant machine.

The requirements for this unit are listed in chapter "Automated cleaning / Disinfection", page 33.

Due to the significantly lower efficacy and reproducibility, a manual procedure should be used only if no machine procedure is available.

When you select the disinfectant, please make sure:

- that the disinfectant is efficacy-tested (e.g. VAH/DGHM or FDA approved and/or bears the CE mark in accordance with *DIN EN ISO 15883*),
- that a tested programme for thermal disinfection with a minimal  $A_0$  value  $> 3,000$  (or, for older units, 10 minutes at  $93^\circ\text{C}$ ) needs to be used,
- that de-ionised water should be used throughout the entire reprocessing process,
- that only sterile or low-germ (max. 10 germs/ml) and low-endotoxin fully-desalted (max. 0.25 endotoxin units/ml) water should be used for rinsing (e.g. aqua purificata),
- that the air used for drying needs to be filtered,
- the disinfectant must be serviced and checked regularly.

When you select the cleaning agent, please make sure:

- that the agent must be generally suitable for the cleaning of handpieces made of sapphire glass, metals, and plastic materials,
- that the chemicals that are used must be compatible with the products (see Chap. 4.3 "Cleaning/Disinfection"),
- that an additional disinfectant of proven efficacy (e.g. VAH/DGHM- or FDA-approved and/or bearing the CE mark) is used - unless thermal disinfection is used - and is compatible with the cleaning agent.

Compliance with the concentrations specified by the manufacturer of the cleaning agent and/or disinfectant is mandatory.



### 4.3.2. Manual cleaning and disinfection

**⚠ CAUTION**

**Chemical disinfection is associated with the risk of residual disinfectant remaining on the plugs /optical fibres.**

When you select the cleaning and disinfection agents, please make sure:

- that the agents must be generally suitable for the cleaning and/or disinfection of handpieces made of stainless steel, plastic materials, quartz and sapphire glass (see Chapter 4.3, page 32),
- that a disinfectant of proven efficacy (e.g. VAH/DGHM- or FDA-approved and/or bearing the CE mark) is used and is compatible with the cleaning agent.
- that the chemicals that are used are compatible with the products (see Chap. 4.3 "Cleaning/Disinfection"),

Compliance with the concentrations specified by the manufacturer of the cleaning agent and/or disinfectant is mandatory.

Combinations of cleaning agent/disinfectant may be used only if the contamination of the dental handpiece is low (no visible contamination). Please use only freshly prepared solutions, only sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. aqua purificata/valde) and/or only filtered air for drying.



## 4.4. Handpieces Reprocessing

### 4.4.1. Pre-treatment



1. Dismantle the handpiece (for details, see pages 26, 27 and 28).
2. Remove gross contamination from both parts of the clamping and handpiece right after use (within no more than 2 hours).

For manual removal of contaminations, use only a soft brush or moist gauze pad, dedicated to this purpose, but make sure to never use metal brushes or wire wool.

Use an interdental brush for cleaning any sites of the lens system that are difficult to access.

3. Use running water or disinfectant solution for pre-treatment.

### 4.4.2. Cleaning/Disinfection

#### 4.4.2.1 Automated cleaning/Disinfection

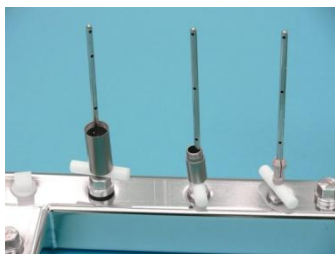
Please note the general information for cleaning and disinfection in Chapter 4.3.



1. Place the disassembled and pre-treated lens system in a basket of appropriate size and place it into the disinfector (only if bleaching handpiece is used).



The lens system damages easily. In order to prevent any damage, always clean/disinfect the lens system separately.



2. Place the pre-treated front sleeve (bleaching handpiece) and the pre-treated parts of the clamping on MIC injector tubes (max. diameter = 3 mm, closed end) in the disinfector.





3. Screw the Luer adaptor included in the delivery into the pre-treated handpiece in place of the clamping.



4. Screw the Luer adaptor of a rinsing hose of the disinfectant into the Luer adaptor of the handpiece.
5. Connect the other end of the hose to the rinsing connector of the disinfectant.



6. Start the programme.
7. Take the handpiece and parts of the clamping out of the disinfectant once the programme is completed.

8. Dry again, if required.



9. Unscrew the Luer adaptor and the rinsing hose from the handpiece.

10. Check the well-dried handpiece (please note the item "Checks").





11. Package the individual parts of the handpiece without delay; please note the items "Packaging", "Storage".



Proof of the general suitability of the handpieces and clamping for effective automated cleaning and disinfection was produced by an independent accredited testing laboratory using the G 7836 CD disinfectant (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the detergent, neodisher® MediZym (Dr. Weigert GmbH & Co. KG, Hamburg). The procedure described above was taken into account.

For optimal cleaning of the lens system without stains, we recommend alkaline cleaning agents (e.g. neodisher® MediClean forte). This prolongs the service life of the lens system.



### 4.4.2.2 Manual cleaning / Disinfection

Please note the general information for cleaning and disinfection in Chapter 4.3, page 32 .

#### Cleaning

Due to the significantly lower efficacy and reproducibility, a manual procedure should be used only if no machine procedure is available. Manual cleaning of the lens system of the bleaching handpiece reduces the service life of the lens system as compared to automated cleaning.



1. Place the dismantled and pre-treated handpiece and the dismantled and pre-treated parts of the clamping in a cleaning bath for the given period of time such that all parts are fully immersed.

For optimal cleaning, handpieces should touch against other objects as little as possible. Brush all parts with a soft brush that is used for this purpose only. Use an interdental brush for cleaning any sites of the lens system that are difficult to access.



2. Screw the Luer adaptor included in the delivery into the handpiece in place of the clamping.
3. Screw the disposable syringe to the Luer adaptor of the handpiece. Use a disposable syringe (min. 10 ml) that has a Luer lock.
4. Rinse the lumens of the handpiece and clamping five times with the rinsing solution (placing the syringe loosely against the part).
5. Take the handpiece and parts of the clamping out of the cleaning bath after the exposure time is elapsed and thoroughly rinse all of these parts five times with water.







6. Re-rinse the lumens of the handpiece and clamping thoroughly with water (placing the syringe loosely against the part).
7. Check the cleaned handpiece (please note Chap. "Checks").



### Disinfection

Please note the general information for cleaning and disinfection in Chapter 4.3. page 32.



1. Place the pre-treated and cleaned handpiece and the pre-treated and cleaned parts of the clamping and of the lens system in the disinfection bath for the given period of time such that all parts are fully immersed.  
For optimal disinfection, handpieces should touch against other objects as little as possible.
2. Rinse the lumens of the handpiece and clamping five times with the disinfectant solution (placing the syringe loosely against the part).





3. Take the handpiece and parts of the clamping out of the disinfection bath after the exposure time is elapsed and thoroughly rinse all of these parts five times with water.
4. Re-rinse the lumens of the handpiece and clamping thoroughly with water (placing the syringe loosely against the part).
5. Unscrew the Luer adaptor and disposable syringe from the disinfected handpiece.
6. Dry the disinfected handpiece and the parts of the clamping thoroughly.
7. Package the disinfected, checked, and well-dried individual parts of the handpiece without delay (please note the items "Checks", "Packaging", "Storage").



Proof of the general suitability of the handpieces for effective manual cleaning and disinfection was produced by an independent accredited testing laboratory using the cleaning agent, Cidezyme<sup>®</sup>, and the disinfectant, Cidex OPA<sup>®</sup> made by ASP, Johnson & Johnson. The procedure described above was taken into account.



## 4.5. Saphir-Tip Reprocessing

### 4.5.1. Pre-treatment

The first reprocessing requires no pre-treatment. Initiate cleaning/disinfection (Chap. 4.5.2, page 44).



1. Use the tool to place the dismantled Saphir-Tips in an ultrasonic bath (35 kHz).

Ultrasonic bath containing neodisher MediClean forte, Dr. Weigert:  
concentration: 2%  
temperature: 50 - 55°C  
duration: > 3 min.



**The efficacy has been tested only for the specified agents and parameters. The manufacturer shall not be liable if agents and parameters other than those described above are used. If the described procedure is not available, please contact the manufacturer.**



2. Take the Saphir-Tip out of the ultrasonic bath after the exposure time has elapsed.
3. Take another tool and screw the Saphir-Tip into the cylindrical end of the second tool.





4. Perform a visual inspection (at least 10x magnification) of the entire Saphir-Tip using a watchmaker's magnifying glass or, preferably, a microscope .

Check the tip from the side while rotating it fully in front of a bright background. Minor contamination are most easily recognised on the away-side as dark enlarges shadows due to the lens effect of the tip.

If no contamination is evident, continue with step 8.

If you do detect contamination during the visual inspection, continue with step 5 (mechanical cleaning).



5. Mechanical cleaning:

Screw the blue cleaning cap into a second tool.

To ensure hygiene and the efficacy of mechanical cleaning, the cleaning cap needs to be replaced after 10 uses.

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**CAUTION**

**Saphire-Tips are fragile especially when forces act from the side. Be very gentle during mechanical cleaning making sure not to lodge the Saphire-Tips.**

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**CAUTION**

**Saphire-Tips still showing residues or damage after renewed mechanical cleaning need to be removed from the materials cycle and disposed appropriately.**

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6. Puncture the Saphir-Tip repeatedly fully into the blue cleaning cap while rotating it.

Repeat this process 2 to 3 times. Use a different puncture site in the cleaning cap each time.

7. Repeat the visual inspection of the Saphir-Tip (for details, see step 4) and repeat the mechanical cleaning if any contamination is evident.
8. If no contamination is evident in the visual inspection, unscrew the Saphir-Tip from the tool used thus far using a second tool.
9. Use the tool to place the Saphir-Tip in an ultrasonic bath (35 kHz).

Ultrasonic bath containing neodisher  
MediClean forte, Dr. Weigert.  
concentration: 2%  
temperature: 50 - 55°C  
duration: > 10 min.

For manual removal of contaminations on the plastic part of the Saphir-Tip, use only a soft brush or moist gauze pad, dedicated to this purpose, but make sure to never use metal brushes or wire wool.

10. Take the Saphir-Tip out of the ultrasonic bath after the exposure time has elapsed and rinse off all residual cleaning agent with water.



## 4.5.2. Cleaning/Disinfection

### 4.5.2.1 Manual cleaning / Disinfection

Please note the general information for cleaning and disinfection in Chapter 4.3. page 32.



1. Place the pre-treated Saphir-Tips in the cleaning bath such that the Saphir-Tips and the tool are fully immersed. Brush the tool and the attachment of the Saphir-Tips with a soft brush that is used for this purpose only. For optimal cleaning, Saphir-Tips should not touch against other objects, if possible.

Keep the Saphir-Tip in the cleaning bath for the exposure time specified by the manufacturer of the cleaning agent.

2. Take the Saphir-Tips out of the cleaning bath after the exposure time has elapsed and rinse off all residual cleaning agent with water. Rinse the lumens of the tools with the Saphir-Tips thoroughly with water (5 times, placing the Saphire-Tips loosely against the tool).
3. Check the cleaned Saphir-Tips (see "Checks").
4. Place the pre-treated and cleaned Saphir-Tips in the disinfection bath such that the Saphir-Tips and the tool are fully immersed. For optimal disinfection, the Saphir-Tips should not touch against other objects, if possible.

Keep the Saphir-Tips in the disinfection bath for the exposure time specified by the manufacturer of the disinfectant.

5. Take the Saphir-Tips out of the cleaning bath after the exposure time has elapsed and rinse off all residual cleaning agent with water. Rinse the lumens of the tools with the Saphir-Tips thoroughly with water (5 times, placing the Saphire-Tips loosely against the tool).
6. Dry the disinfected Saphir-Tips carefully (using filtered air).
7. Package the disinfected, checked, and well-dried Saphir-Tips without delay (please note the items "Checks", "Packaging", "Storage").



Proof of the general suitability of the handpieces for effective manual cleaning and disinfection was produced by an independent accredited testing laboratory using the cleaning agent, Cidezyme<sup>®</sup>, and the disinfectant, Cidex OPA<sup>®</sup> (both made by ASP, Johnson & Johnson). The procedure described above was taken into account.



## 4.6. Checks and Maintenance

### 4.6.1. Handpieces



**MASTER lase und EXPERT lase accessories still showing residues or damage after renewed mechanical cleaning, needs to be removed from the materials cycle and disposed appropriately.**



**Instrument oils and other grease must not be used during maintenance work.**

Please make sure that all tools used in the controls are cleaned and disinfected. Maintain personal hand hygiene. The use of protective gloves is recommended.

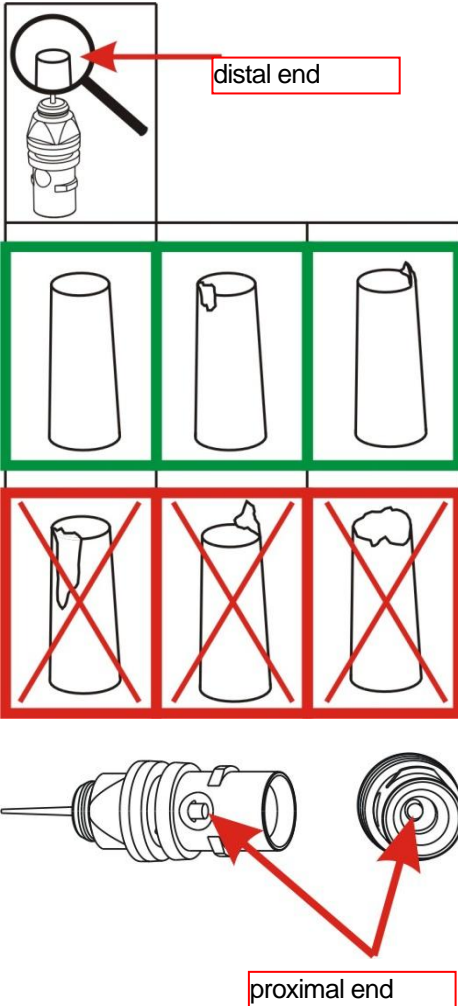
1. Use a magnifying glass or microscope (at least 10x magnification) to check all handpieces for the presence of corrosion, damaged surfaces, flaking, and contamination after cleaning/disinfection.
2. Use a magnifying glass or microscope (at least 10-fold magnification) to check the lens system of the bleaching handpiece for stains and contamination after cleaning/disinfection.
3. Discard damaged handpieces (for information concerning the restrictions on reuse, please refer to item "Re-use ", page 7 and "Technical Specifications and Order Numbers", page 55).
4. Clean and disinfect still contaminated handpieces/lens system of the bleaching handpiece.



## 4.6.2. Saphir-Tip

**CAUTION**

There must be no technical or functional defects and contamination on the entire Saphir-Tip.



1. Check if the pilot laser is switched off.
2. Check the distal end of the Saphir-Tip with a magnifying glass or microscope (at least 10x magnification).  
The distal end of the Saphir-Tips must show no contamination and its end surfaces must be smooth and perpendicular to the tip to the extent possible.
3. Check the proximal end (coupling surface) in the mount with a magnifying glass or microscope (at least 10x magnification).  
The end surface of the proximal end of the Saphir-Tips must be as smooth as possible and be free of contamination.



## **4.7. Packaging**

The accessories of the MASTER lase and EXPERT lase must be cleaned and disinfected before packaging.

We recommend the use of disposable sterilisation packages (single or double packaging) and/or sterilisation containers.

The disposable sterilisation packages and sterilisation containers must meet the following requirements:

- conformance with EN ISO 11607 / ANSI AAMI ISO 11607
- suitability for steam sterilisation  
(temperature resistance up to at least. 141 °C, (286 °F),  
sufficient permeability for steam)
- sufficient protection of dental handpieces and/or sterilisation packages from mechanical damage
- regular maintenance in accordance with the manufacturers specifications (sterilisation containers)

The clampings may be packaged and sterilised only after dismantling.





Package the disinfected individual parts of the handpiece for BareFiber-Tip.



Package the disinfected individual parts of the handpiece for Saphir-Tip.



Package the disinfected Saphir-Tip jointly with the tool used during disinfection.



Package the disinfected individual parts of the bleaching handpiece.



The lens system damages easily. In order to prevent any damage, always package the lens system separately.



## 4.8. Sterilisation

### ⚠ CAUTION

**Steam sterilisation should be used for sterilisation. Other sterilisation procedures, such as flash, hot-air, radiation, formaldehyde, ethyleneoxide or low temperature plasma (NTP) sterilisation, are not permissible.**

Due to the significantly lower efficacy, the gravity-displacement procedure should be used only if no fractionated vacuum procedure is available.

Please note the following parameters:

- Fractionated vacuum procedure or gravity-displacement procedure with sufficient product drying must be ensured
- Steam steriliser in accordance with *EN 13060* and/or *EN 285*
- validated in accordance with *EN ISO/ANSI AAMI ISO 17665* (valid commissioning and product-specific assessment of performance)
- maximal sterilisation temperature 138 °C (280 °F) incl. tolerance in accordance with *EN ISO/ANSI AAMI ISO 17665*)
- Sterilisation time (exposure time at sterilisation temperature) at least 20 min at 121 °C (250 °F) or  
3 min at 132° C (270° F)/134° C (273° F) - fractionated vacuum procedure or  
5 min at 132° C (270° F)/134° C (273° F) - gravity-displacement procedure



Depending on the quality of the water used to produce steam for sterilisation, stains on the lens system may develop. This has no adverse effect on the successful use. These stains are removed during the next proper cleaning.



Proof of the general suitability of the handpieces for effective steam sterilisation was produced by an independent accredited testing laboratory using the Systec V-150 steam steriliser (Systec GmbH Labor-Systemtechnik, Wettenberg) and the fractionated vacuum procedure and the gravity-displacement procedure. Typical conditions as experienced in clinics and dental offices as well as the above-mentioned process parameters were used in the process.



## 4.9. Transmitting optical fibre Reprocessing

**The transmitting optical fibre is not suitable for disinfection through steam sterilisation or other sterilisation procedures. Wipe disinfection must be used, which also removes minor soiling. The transmitting optical fibre must not be immersed in a disinfectant.**



**Wipe disinfection must be performed right after use and shortly before the next use.**

**No wipe disinfection is required if the time between applications is less than 30 minutes.**

Risk of cross-contamination!



Do not attach the protective cap between applications.

The protective cap only serves as protection at the time of delivery or if the unit is stored in the case for prolonged periods of time.



Unreel the needed length of transmitting optical fibre and perform a wipe disinfection right after use (within 30 minutes).

After wipe disinfection, roll up the transmitting optical fibre on the unit while complying with the minimal bending radius (see Technical Specifications and Order Numbers, 55).

When you select the disinfectants, please make sure:

- that the selected disinfectant is generally suitable for disinfection of handpiece and device surfaces in the wipe disinfection procedure,
- that the selected disinfectant is efficacy-tested (e.g. VAH/DGHM or FDA approved and/or bear the CE mark),
- that the selected disinfectant is free of perfume and aldehydes, leaves no critical residues on the handpieces, and possesses short-term efficacy (quick disinfection),
- that the selected disinfectant is compatible with transmitting optical fibres (see Chapter "4.3", page 32).



**Compliance with the procedure and exposure time specified by the manufacturer of the disinfectant is mandatory.**

**If the disinfectant is to be used after dilution, a fresh solution must be used that was prepared complying with the manufacturer's specified concentration.**



**Use fresh, lint-free disposable wipes only (no unbleached recycling goods!).**

**During wipe disinfection, make sure not to re-contaminate already disinfected surfaces by contacting contaminated surfaces and/or the hands.**

1. Wipe the entire exposed length of the transmitting optical fibre including the end surface on the handpiece-side carefully and completely with the disinfectant-soaked wipe until all visible contamination is removed and all surfaces are treated. In particular, sites that are difficult to access must be wetted and wiped carefully. Wipe the surface of the unit that bears the reeling device.
2. If the contamination is extensive, repeat the wiping procedure with a fresh disinfectant solution and a fresh lint-free disposable wipe until no contamination is visible any longer.
3. Allow the cleaning agent/disinfectant solution to act for the time specified by the manufacturer.
4. Then dry all treated surfaces with a fresh, dry, lint-free disposable wipe.
5. Check and roll up the transmitting optical fibre on the reeling device of the unit while complying with the minimal bending radius (see Chapter Technical Specifications and Order Numbers)



The general suitability of the transmitting optical fibre for effective wipe disinfection was tested by an independent accredited testing laboratory using the rapid disinfectant, Bacillo® AF (made by Bode Chemie Hamburg). Typical conditions as experienced in clinics and dental offices as well as the above-mentioned procedure were used in the process. The cleaning/disinfection process complies with the following standards: *AAMI TIR30 and DIN EN 1040.*

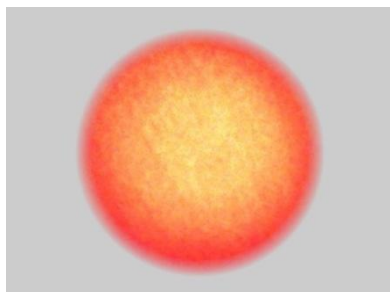


## 4.10. Checking the transmitting optical fibre

**CAUTION**

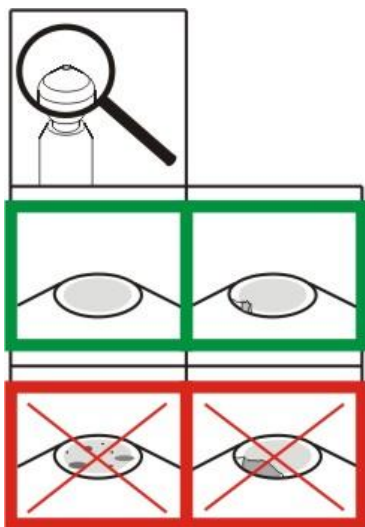
**There must be no technical or functional defects and contamination on the entire transmitting optical fibre, especially on the two end surfaces of the fibre.**

1. Check the transmitting optical fibre for corrosion, damaged surfaces, flaking, and contamination and discard any damaged transmitting optical fibre. Transmitting optical fibres that are still soiled need to be cleaned/disinfected again.
2. Connect the transmitting optical fibre to a pilot light source, for example to the optical fibre coupling of the laser unit.
3. Switch the pilot laser on.
4. Point the distal end of the transmitting optical fibre (at a distance of approx. 20 cm) perpendicularly at a bright, level surface and observe the spot of light produced by the pilot laser beam (emission characteristics).



If the optical fibre is free of any technical defects, an even circular spot of light is generated whose intensity decreases rapidly from inside to outside.





5. Switch the pilot laser off.
6. Carefully test if the ferrule is attached firmly and check the connection between ferrule and hose.

7. Check both fibre ends with a magnifying glass or microscope (at least 10x magnification).
8. If any contamination is visible, remove the soiling with a soft lint-free cloth or cotton swab soaked in isopropanol (70% solution).

Alternatively, you can use a steam jet degreaser. Hold the contaminated fibre end into the steam jet for a few seconds for this purpose.

9. Dry the cleaned fibre end. Use a compressed air gun (with filtered air) for this purpose.



**Transmitting optical fibres still showing residues or damage after repeated cleaning, need to be removed from the materials cycle. Replace the transmitting optical fibre and contact Service to have the damaged transmitting optical fibre repaired.**



## 4.11.Storage

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**Danger of injury from inappropriate storage.**

**Non-compliance with the storage instructions and/or conditions may lead to some radial emission of laser radiation and/or fracturing of the optical fibre during operation of the laser possibly leading to serious injury.**

**Compliance with the storage instructions and/or conditions based on the Instructions for Use of the laser unit is mandatory.**

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- Saphir-Tips need to be stored in the original package in a clean, dry place until reprocessing prior to their first use.  
BareFiber-Tips need to be stored in the original package in a clean, dry place
- Reprocessed accessories need to be stored in a suitable storage package in addition to the sterile packaging. Please comply with the time of storage and ambient conditions specified by the manufacturer of the sterile packaging.
- Reprocessed accessories must be stored in a dry and dust-free place.
- Reprocessed accessories must not be exposed to excessive sunlight, heat, cold, dust or moisture.
- Do not use the accessories if the sterile package is damaged. In this case, full reprocessing and functional testing (see Reprocessing instructions) are required.
- Saphir-Tips are fragile and need to be handled with extreme caution.
- Handling or using the transmitting optical fibre, do not bend, kink, knot or loop the fibre more strongly than corresponds to the minimal long-term bending radius specified by the manufacturer (see item Technical Specifications and Order Numbers).




## 5. Technical Specifications and Order Numbers




**Limited re-use:** The service life of the products is determined by wear and tear, reprocessing procedures (chemicals), and damage from use.




Handpiece Saphir-Tip		
 Maximal outer diameter		11 mm
Length including clamping		approx. 135 mm
Bending		50 °
Weight including clamping		53 g
REF	Order number:	<b>1.009.5363</b>
Packaging unit:		1 unit, non-sterile
Use with		Transmitting optical fibre with fixation sleeve, Saphir-Tip
Ambient conditions:		
Operation		Temperature: + 15°C to + 30°C (+ 59°F to + 86°F) Relative humidity: 30 % - 85 %
Reprocessing		<div> <b>CAUTION</b></div> Please note the information in Chapter "Reprocessing"!
Maximal permissible sterilisation temperature		141 °C (286 °F)
Minimal permissible sterilisation parameter:		Fractionated vacuum procedure : 20 min at 121 °C (250 °F) 3 min at 132 °C (270 °F)/134 °C (273 °F) Gravity-displacement procedure : 20 min at 121 °C (250 °F) 5 min at 132 °C (270 °F)/134 °C (273 °F)
Re-use (max.)		approx. 200 times









<b>Saphir-Tip handpiece</b>		
Distal diameter:	200µm	
Outer diameter including mount	5.3 mm	
Length including mount	16.4 mm	
<b>REF</b> Order number:	<b>1.009.5368</b>	
Packaging unit:	2 units, non-sterile incl. 1 unit cleaning cap	
Maximal laser power	6 W (cw = continuous wave), 8 W (cw)	
Duty cycle	6 W (cw), max. on-time 1 min, 25% duty cycle (degree of utilisation); 8 W (cw), max. on-time 45 sec, 25% duty cycle (degree of utilisation); e.g. after a max. on-time of 1 minute, there must be 3 minutes of pause.	
Suitable for wavelength	900 – 1,000 nm	
Ambient conditions:		
Operation	Temperature: + 15°C to + 30°C (+ 59°F to + 86°F) Relative humidity: 30 % - 85 %	
Reprocessing	<div style="background-color: yellow; border: 1px solid black; padding: 2px; display: inline-block;"> <b>⚠ CAUTION</b> </div> Please note the information in Chapter "Reprocessing"!	
Maximal permissible sterilisation temperature	141 °C (286 °F)	
Minimal permissible sterilisation parameter:	Fractionated vacuum procedure : 20 min at 121 °C (250 °F) 3 min at 132 °C (270 °F)/134 °C (273 °F) Gravity-displacement procedure : 20 min at 121 °C (250 °F) 5 min at 132 °C (270 °F)/134 °C (273 °F)	
Re-use (max.)	5 times	



Handpiece BareFiber Tip			
	Maximal outer diameter	11 mm	
Length of handpiece including clamping		approx. 148 mm	
Bending		40 °	
Weight including clamping		47 g	
REF	Order number:	<b>1.009.5360</b>	
Packaging unit:		1 unit, non-sterile	
Use with		Transmitting optical fibre without fixation sleeve; BareFiber-Tip FT 0-303609-BF-0 and BareFiber-Tip FT0-242809-BF-0	
Ambient conditions:			
Operation		Temperature: + 15°C to + 30°C (+ 59°F to + 86°F) Relative humidity: 30 % - 85 %	
Reprocessing		 <b>CAUTION</b> Please note the information in Chapter "Reprocessing"!	
Maximal permissible sterilisation temperature		141 °C (286 °F)	
Minimal permissible sterilisation parameter:		Fractionated vacuum procedure : 20 min at 121 °C (250 °F) 3 min at 132 °C (270 °F)/134 °C (273 °F) Gravity-displacement procedure : 20 min at 121 °C (250 °F) 5 min at 132 °C (270 °F)/134 °C (273 °F)	
Re-use (max.)		approx. 200 times	



BareFiber-Tip FT0-303609-BF-0		
Adaptor colour	white	
 Fibre core diameter	300µm	
Nominal diameter of optical fibre	355 µm	
 Maximal outer diameter	360 µm	
Fibre length	85 mm	
Minimal bending radius:		
short-term	20 mm	
long-term	66mm	
Maximal laser power	8 W (cw = continuous wave), 10 W (pulse mode)	
Duty cycle	8 W (cw), 10 W (pulse mode), max. on-time 1 min, 60% duty cycle (degree of utilisation); e.g. after a max. on-time of 1 minute, there must be 40 s of pause.	
Numerical aperture	0.22	
Suitable for wavelength	800 – 1,200 nm, 1,450 – 1,600 nm	
REF	Order number:	<b>1.009.5366</b>
Packaging unit:	20 units, sterile	
Ambient conditions:		
Storage	Temperature: + 10°C to + 35°C (+ 50°F to + 95°F) Relative humidity: 30 % - 85 %	
Operation	Temperature: +15°C to +30°C (+59°F to +86°F) Relative humidity: 30 % - 85 %	
 2 Reprocessing	Disposable article! Do not re-use!	





**BareFiber-Tip FT0-242809-BF-0 is suitable exclusively for disinfection applications (e.g. endodontics, etc.).**

### BareFiber-Tip FT0-242809-BF-0

Adaptor colour

Light Blue



Fibre core diameter

240µm

Nominal diameter of optical fibre

280 µm



Maximal outer diameter

285 µm

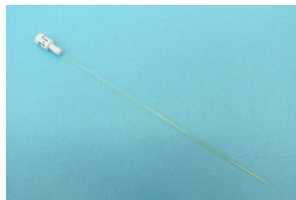
Fibre length

85 mm

Minimal bending radius:  
short-term  
long-term

17 mm

32 mm



Maximal laser power

3 W (cw = continuous wave), 3 W (pulse mode)

Duty cycle

3 W (cw), 3 W (pulse mode), 100%

Numerical aperture

0.22

Suitable for wavelength

800 – 1,200 nm, 1,450 – 1,600 nm

REF

Order number:

**1.009.5367**

Packaging unit:

20 units, sterile

Ambient conditions:

Storage

Temperature: + 10°C to + 35°C (+ 50°F to + 95°F)

Relative humidity: 30 % - 85 %

Operation

Temperature: +15°C to +30°C (+59°F to +86°F)



Relative humidity: 30 % - 85 %



Reprocessing

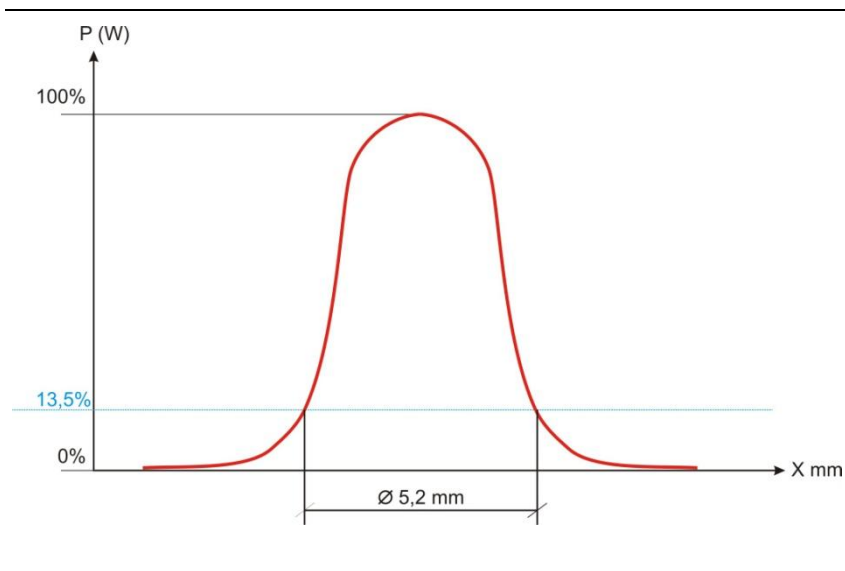
Disposable article! Do not re-use!



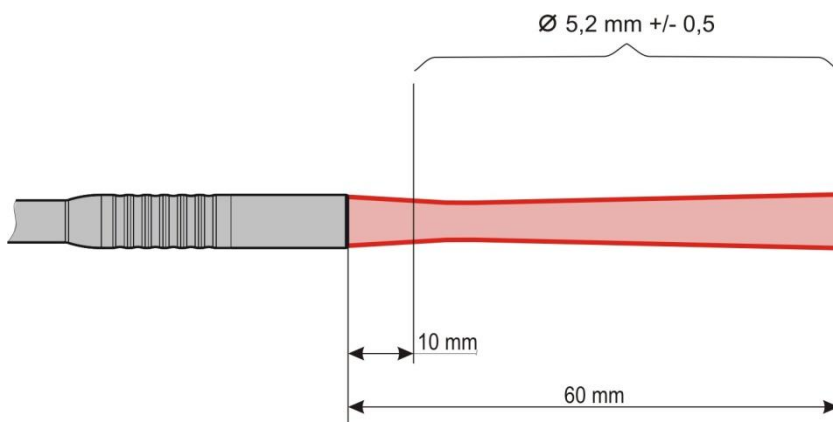
Bleaching- handpiece D12		
Maximal outer diameter	12 mm	
Length of handpiece including clamping	approx 164 mm	
Weight including clamping	77 g	
Beam profile, spot diameter (see Figure 7)	Gauss-like, 5,2 mm (13,5%)	
Working distance (see Figure 8)	10 mm to 60 mm	
REF	Order number:	<b>1.010.0965</b>
Packaging unit:	1 unit, non-sterile	
Use with	Transmitting optical fibre	
Maximal laser power	3 W (cw = continuous wave), 3 W (pulse mode)	
Duty cycle	3 W (cw = continuous wave), 3 W (pulse mode), 100%	
NOHD (Nominal Ocular Hazard Distance)	160 ± 60 m	
Suitable for wavelength	800 – 1200 nm	
Ambient conditions:		
Operation	Temperature: + 15°C to + 30°C (+ 59°F to + 86°F) Relative humidity: 30 % - 85 %	
Reprocessing	<div> <b>CAUTION</b></div> Please note the information in Chapter „Reprocessing“!	
Maximal permissible sterilisation temperature for handpiece without lens system	141 °C (286 °F)	
Minimal permissible sterilisation parameter for handpiece without lens system:	Fractionated vacuum procedure : 20 min at 121 °C (250 °F) 3 min at 132 °C (270 °F)/134 °C (273 °F) Gravity-displacement procedure : 20 min at 121 °C (250 °F) 5 min at 132 °C (270 °F)/134 °C (273 °F)	
Re-use (max.)	Handpiece including clamping approx. 200 times Lens system approx. 50 times	





**Figure 7. Beam profile, spot diameter**




**Figure 8. Working distance, spot diameter**





KaVo Optical Fibre handpiece (transmitting optical fibre)		
	Fibre core diameter	200µm
	Maximal distal outer diameter	3.25 mm (incl. distal ferrule, without clamping)
	Optical fibre length:	2.0 m
	Numerical aperture (NA)	0.22
	Suitable for wavelength	800 – 1,200 nm, 1,450 – 1,600 nm
	Minimal bending radius:	long-term ≥ 25 mm
	Maximal laser power	8 W (cw = continuous wave), 10 W (pulse mode),
	Duty cycle	8 W (cw), 10 W (pulse mode), max. on-time 3 min, 50% duty cycle (degree of utilisation); e.g. after a max. on-time of 3 minutes, there must be 3 minutes of pause
<div>REF</div>	Order number:	<div><div><b>1.009.5357</b> with fixation sleeve MASTER lase</div><div><b>1.009.5359</b> without fixation sleeve EXPERT lase</div></div>
	Packaging unit:	1 unit, non-sterile
	Use, laser unit	Handpiece Saphir-Tip Handpiece BareFiber Tip MASTER lase, EXPERT lase
	Ambient conditions:	
	Operation	Temperature: +15°C to +30°C (+59°F to +86°F) Relative humidity: 30 % - 85 %
	Reprocessing	<div>⚠ CAUTION</div> <div>Please note the information in Chapter "Reprocessing"!</div>
	Re-use (max.) Procedure	approx. 100 times wipe disinfection only





Transmitting optical fibres are not compatible with devices from other manufacturers.



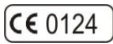







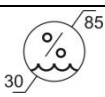

**The manufacturer shall not be liable for any use of the re-usable transmitting optical fibre (optical fibre handpiece) in combination with laser units from third-party manufacturers.**



## 6. Accessories and consumables

Description	KaVo article number
Lens system for bleaching handpiece	1.010.1384
Tool for Saphir-Tip, 1 unit	1.009.5365
Adaptor handpiece rinsing 1 unit ( Luer adaptor)	1.009.5364

## 7. Explanation of additional symbols

Symbol	Description
	CE mark (European approval symbol bearing the identifying number of the Notified Body)
	Sterility - Expiry date
	Batch (lot number of the manufacturer)
	Product contains no latex
	Packing unit / no. per package
	Product contains no DEHP
Symbols for transportation and storage	Description
	Avoid exposure to sunlight
	Protect from rain
	Rel. humidity in %
	Temperature limit



### **8. Guidelines and procedure for complaints**

Before you return a product, please contact your local KaVo representative to request a return permit and a return permit number (return material authorization, RMA). Please specify the product's part number and batch number. Products should be returned in their original boxes, if possible. Specify the RMA number on the outside of the packaging. Return the product to the address given. Products must be cleaned, disinfected and sterilized before return. Returned products that have not been cleaned, disinfected and sterilized will not be accepted.

### **9. Disposal of products**

At the end of their service cycle, dispose optical fibres and handpieces in accordance with local regulations for contaminated products. This minimises the hazard for the environment and the staff that may be caused by contamination and residues of used medical products.