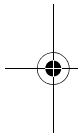




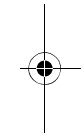
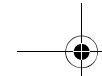
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Bleaching set

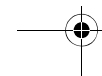
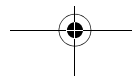


sirona
The Dental Company



English

Operating Instructions



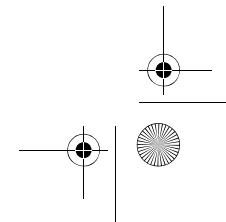
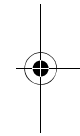
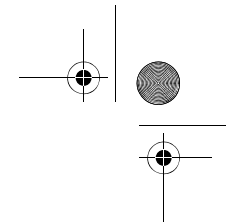
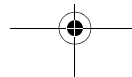
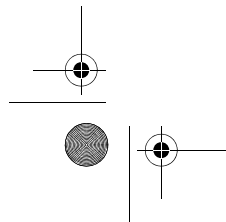
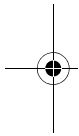
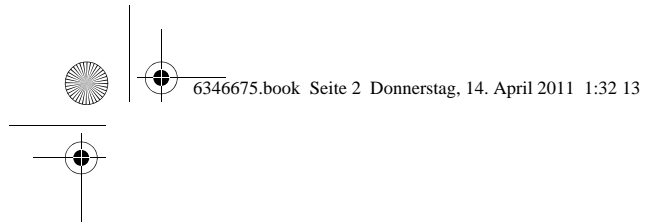


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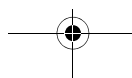
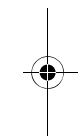
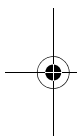
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Operating Instructions Bleaching-Set



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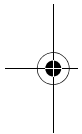




Operating Instructions Bleaching-Set

Intended use

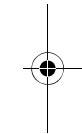
Contraindications



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Before you begin ...



5



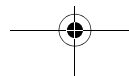
1 Before you begin ...

The bleaching set is intended for the therapeutic treatment of discolored, contaminated teeth and must only be used in connection with SI-ROLaser Advance / Xtend and a bleaching gel.

- Patients, who suffer from photodermatosis and photosensitized patients (photo allergies)
- Minors, expectant mothers and those who are breast-feeding
- In the case of cancerous tumors and obligate premalignment lesions, special care must be taken to ensure that the appropriate treatment is selected, by taking the patient's individual needs into account.

No further contraindications are known.

IMPORTANT: Please also observe the contraindications in the bleaching gel manufacturer's operating instructions.

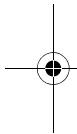




Before you begin ...

Target group

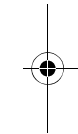
Warranty claim



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Operating Instructions Bleaching-Set



This product has been exclusively designed for use by appropriately trained and qualified personnel (dentists).

The warranty only applies if the original delivery state is maintained.

1.1 Structure of the document

1.1.1 Identification of danger levels

To prevent personal injury and material damage, please observe the warning and safety information provided in this document. Such information is highlighted as follows:

⚠DANGER! Imminent danger that can result in serious bodily injury or death.

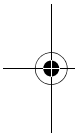
⚠WARNING! Potentially dangerous situation that can result in serious bodily injury or death.



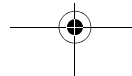
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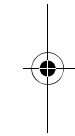
Operating Instructions Bleaching-Set



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Before you begin ...



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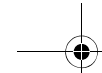


⚠ CAUTION! Potentially dangerous situation that can result in minor bodily injury.

⚠ NOTICE! Potentially harmful situation that can lead to damage to the product or an object in its environment.

IMPORTANT: Application information and other important information

Tip: Information on simplifying work



Before you begin ...

Operating Instructions Bleaching-Set

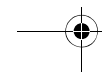
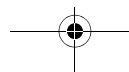


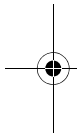
1.1.2 Formats and characters

The symbols and character formats used in the present manual have the following meaning:

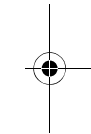
✓ Prerequisite	Requests you to do something.
1. First action step	
2. Second action step	
or	
> Alternative action	
↪ Result	
Use of formats and characters [→ 8].	Identifies a reference to another text passage and indicates the relevant page number.
• List	Identifies a list.

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Preventing cross-contamination



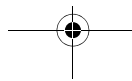
2 Safety information

Read these operating instructions carefully before putting the bleaching set into operation. This document supplements the operating instructions of your SIROLaser Advance / Xtend. Both documents need to be consulted to obtain full details. You should always keep these operating instructions within reach for further reference. Technical documentation forms an essential part of the product and, if sold, must be passed on to the purchaser.

Observe all safety information and warnings, including the following:

Prevent cross-contaminations between patients, users and third parties as follows: Sterilize the instrument after each patient.

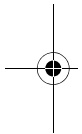
Adopt appropriate hygienic measures, such as wearing protective gloves.





Safety information

Laser beams



Fiber-optic cable and connection socket



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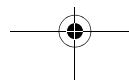
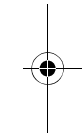
Operating Instructions Bleaching-Set

Please ensure that neither yourself nor others accidentally knock or injure themselves on the fiber-optic cable. This also applies to the laser handpiece when it is positioned in its holder.

The pilot and laser beams must not be directed into a person's eyes. They comprise an intensive light source even when set to a low power level. All persons entering the treatment room must wear protective goggles.

Make sure that no dust, dirt and/or foreign bodies enter the fiber-optic cable connection or the optical system. For this reason, always cover the connection socket with the protective screw in the laser handpiece when removing the fiber-optic cable.

The fiber-optic cable must not be distorted, otherwise there may be a risk of the cable breaking.





Operating Instructions Bleaching-Set

Bleaching set



Flexibility of the fiber-optic cable



Protecting the fiber-optic cable

Accessory parts



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Safety information



The bleaching set may become hot if the fiber-optic cable breaks. If this should happen, shut down the SIROLaser Advance / Xtend immediately.

Prior to use, always check that the bleaching set is securely positioned.

The fiber-optic cable may be damaged if it is severely bent or improperly routed inside the handpiece. This may constitute a health hazard for patients, users and third parties. The minimum bending radius of the fiber-optic cable is 4.5 cm (\varnothing 9 cm). The fiber-optic cable must not be pressed against or torn during use or cleaning operations.

Always safeguard the fiber-optic cable using transport and sterilization protection, as well as the protective cap.

Use only original accessory parts produced by the manufacturer.

If you have any questions, please contact your dental depot or the manufacturer.



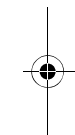
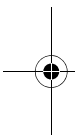
3 Technical description

3.1 Technical data

Operating conditions	
Ambient temperature	+10° C - +33° C
Relative humidity in %	10 - 95
Air pressure in hPa	800 - 1060

IMPORTANT: The operating requirements during a bleaching treatment are determined by the operating requirements overlap between the bleaching set and bleaching gel.

Please refer to the manufacturer's documentation for further details regarding operating requirements for the bleaching gel.



3.2 Standards and regulations

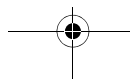
To install and operate the bleaching set in connection with SIROLaser Advance / Xtend, the manufacturer lays down the following requirements:

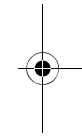
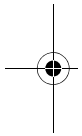
- Conformity with IEC 60825-1 and corresponding modifications
- Observance of any supplementary national acts and regulations

Public legal requirements may include special safety regulations concerning protection against laser radiation. These requirements must be fulfilled.

The bleaching set has been manufactured in compliance with the provisions of Directive 93/42/EEC concerning medical devices.

National directives regarding electrical installations must be observed.



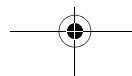


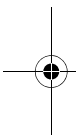
3.3 Physical functionality

Using the bleaching set, the laser radiation is transmitted to the teeth prepared with the bleaching gel. During the bleaching procedure, free oxygen radicals are diffused into the dental enamel and dentine. The free radicals are extremely electrophilic and unstable, attacking and thereby destroying the most organic of molecules.

3.4 Scope of supply

The product comprises a bleaching set and fiber-optic cable (320µm), which can be used in connection with SIROLaser Advance / Xtend.





4 Operation

4.1 Installing the bleaching set

IMPORTANT: Any national or local regulations stipulating that the bleaching set may be installed only by trained personnel must be strictly observed.

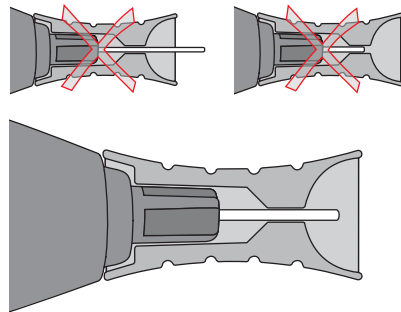
✓ The SIROLaser Advance / Xtend is switched off.

1. Inspect the bleaching set for damage and replace, if necessary.
2. Prior to installing the fiber-optic cable, secure the bleaching set to the handpiece.

4.2 Installing the fiber-optic cable and testing the pilot beam

Install the fiber-optic cable and test the pilot beam as described in the section entitled "Installing the fiber-optic cable" in the operating instructions of your SIROLaser Advance / Xtend.

Operation



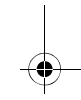
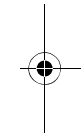
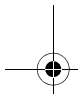
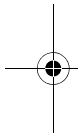
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Operating Instructions Bleaching-Set

✓ The pilot beam generates an even light pattern.

1. Place the handpiece unit back into its sleeve, ensuring that the fiber-optic cable is guided through the bleaching set without experiencing a high level of resistance. In doing so, lock the latches in place on the sleeve.
2. Check the length of the fiber-optic cable. The fiber-optic cable should be located in the center of the bleaching set "cup". To do so, you can either shorten the fiber-optic cable accordingly with fiber cutters and/or adjust it using the sliding mechanism on the handpiece.
IMPORTANT: The tip of the fiber-optic cable must not be projected over the bleaching set or come into contact with the channel of the bleaching set.

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4.3 Selecting a suitable bleaching gel

A successful bleaching result and potential side effects are dependent on various factors. In addition to the teeth to be treated, this includes selecting the right bleaching gel.

The bleaching gel must be suited to applications with the laser diode SIROLaser Advance / Xtend and its wave length of $970 \pm 15 \text{ nm}$.

IMPORTANT: Please observe documentation provided by the bleaching gel's manufacturer (including the operating instructions) and only use bleaching gel, which the manufacturer has specified setting parameters for SIROLaser Advance / Xtend.

We recommend using "JW Power Bleaching" gel from Heydent. In the download area of www.heydent.com, the corresponding setting parameters can be found.

4.4 Preparing the bleaching treatment

Always perform the bleaching treatment in accordance with the documentation provided by the bleaching gel manufacturer. In doing so, ensure that all safety information is followed.

We recommend documenting the initial state and result with images in order to demonstrate the success of the respective treatment.

- ✓ You have installed the bleaching set [→ 15] and fiber-optic cable [→ 15].
- ✓ You have prepared the laser in accordance with the operating instructions of your SIROLaser Advance / Xtend, and have set the power parameters.

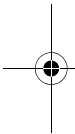
1. Clean the patient's teeth to a professional standard, ensuring that plaque and other residual matter are completely removed from the tooth surface.



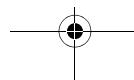
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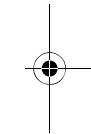
Operating Instructions Bleaching-Set



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Operation



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2. Determine the hue of the patient's teeth digitally or manually by means of a corresponding color scale.
3. Apply the gingival protection to the patient's gums and allow this to set.

Operation

Operating Instructions Bleaching-Set

4.5 Performing the bleaching treatment

⚠ CAUTION! Any persons present in the room must wear laser protection goggles.

- ✓ As a general rule, use the power settings recommended by the bleaching gel manufacturer.

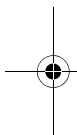
Tip: You can save these settings for a new program under "My settings" in your SIROLaser Advance / Xtend. We recommend checking on a regular basis to ensure whether the bleaching gel manufacturer has changed its recommended performance settings.

⚠ CAUTION! Higher power settings can result in damage to the tooth and pulp. There is a risk of overheating and burning.

IMPORTANT: The patient should not be able to feel any heat developing on his/her tooth.



Operating Instructions Bleaching-Set



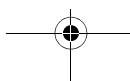
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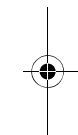
- ✓ Prevent the bleaching set and fiber-optic cable from coming into contact with the bleaching gel. Following accidental contact, the parts affected must be cleaned.
- ✓ Ensure that the power settings and duration of exposure comply with those specified by the bleaching gel manufacturer.

1. Prior to each use, test the intactness and length of the fiber-optic cable [→ 15].
2. Apply the bleaching gel to all teeth that are to be treated. Remove any bubbles in the gel.

⚠ CAUTION! When applying the bleaching gel, ensure that it does not come into contact with the patient's gums, tongue or lips. Adopt appropriate precautionary measures to prevent the patient from swallowing the gel. If the patient has a sensitive reaction to the gel, the treatment must be discontinued. Monitor the patient's wellbeing on a continual basis.



Operation

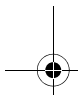
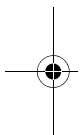


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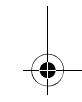
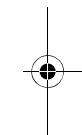
Operation



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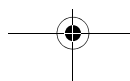
Operating Instructions Bleaching-Set

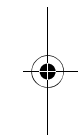
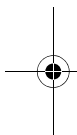


3. Maintain a distance of approximately 2 cm between the distal end of the bleaching set and the surface of the bleaching gel. Start by equally exposing the tooth/gel surface to the radiation. In doing so, adhere to the times specified by the bleaching gel manufacturer.
4. Following exposure to the radiation, thoroughly remove the bleaching gel and rinse well with air and water spray. All residual matter must be completely removed.
5. Measure the achieved hue. The dentist can repeat the process a further two times at their discretion.

4.6 Repeating the treatment

1. Remove the gingival protection.
2. Depending on the patient's sensitivity, perform a desensitization.





5 Care and maintenance

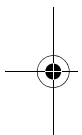
5.1 Manually cleaning and disinfecting the surface

5.1.1 Cleaning the surface

Manual cleaning must always be combined with disinfection.

- ✓ Prior to disassembly, the fiber-optic cable and bleaching set must be freed from contaminants and disinfected.

1. Remove the bleaching set from the handpiece and clean it with a brush under running water. In doing so, clean the fiber-optic channel with an interdental brush ($\varnothing < 1 \text{ mm}$).
2. Remove the handpiece sleeve from the handpiece unit.



3. Remove the fiber-optic cable from the handpiece.

⚠NOTICE! There is a risk of damage to the optical system. Immediately after disassembling the fiber-optic cable, position the protective cap on the optical system of the handpiece and on the proximal end of the fiber-optic cable ferrule. Carefully clean the fiber-optic cable with a cloth under running water (at least of drinking water quality).

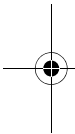
5.1.2 Disinfecting the surface

- ✓ The disinfectants that are approved in your country must have proven bactericidal, fungicidal and virucidal properties.

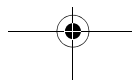
1. Spray the surface with disinfectant.
2. Wipe the disinfectant with a cloth.

You can use the following, for example:

- MinutenSpray classic, by Alpro



95°C
203°F



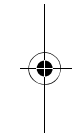
- MinutenWipes, by Alpro

Please observe the manufacturer's instructions for using instrument disinfectants.

5.2 Automated cleaning and disinfecting

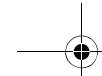
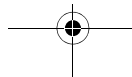
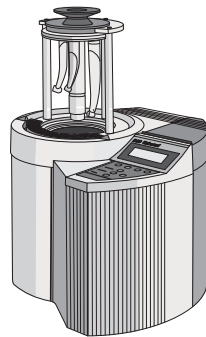
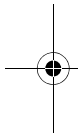
The individual parts can also be cleaned and disinfected in a suitable thermosinfectant.

The thermosinfectant used must be approved by its manufacturer for the cleaning and disinfection of dental instruments and comply with EN ISO 15883-1 (e.g. 95°C (203°F) and 10 min. holding time).





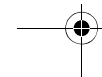
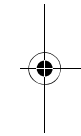
Care and maintenance

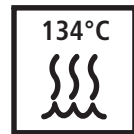
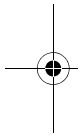


Operating Instructions Bleaching-Set

We recommend **Sirona DAC UNIVERSAL** for automated cleaning, disinfection and care.

For further details, refer to the operating instructions supplied with the unit.





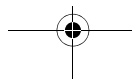
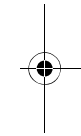
274°F

5.3 Sterilizing

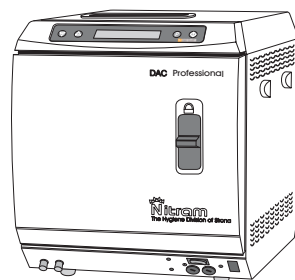
1. Clean and disinfect the fiber-optic cable and bleaching set [→ 23].
2. Wipe away any water residue.
3. Sterilize the instrument in the steam sterilizer with saturated water vapor.

Saturated water vapor: 134°C (274°F)

Holding time: 3 min. (2.04 bar; 29.59 psi overpressure)



Care and maintenance

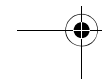
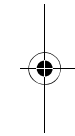
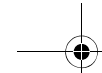
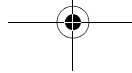
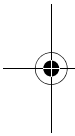


Operating Instructions Bleaching-Set

Steam sterilizers that fulfill the requirements of EN 13060, class B or S and are suitable for the sterilization of straight/contra-angle handpieces are approved, e.g.: DAC PROFESSIONAL.

⚠ NOTICE! Do not exceed 140°C (284°F), even during the drying phase.

For sterilization purposes, use transport and sterilization protection.



6 Spare parts and consumables

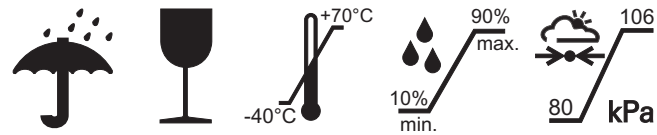
Use only original parts produced by the manufacturer.

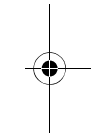
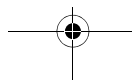
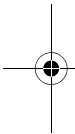
	Order No.:
Set of fibers 320 µm	62 56 759

Storage and transport conditions

Operating Instructions Bleaching-Set

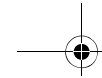
7 Storage and transport conditions





8 Disposal

- To the best of our current knowledge, the product does not contain any substances which are hazardous to the environment.
- Please observe the disposal regulations applicable in your country.



We reserve the right to make any alterations which may be required due to technical improvements.



D3545.201.03.01.02 03.2011

Ä.-Nr.: 000 000



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