Instructions for use
SonicFill Handpiece

Kerr
SYBRON DENTAL SPECIALTIES
1 User instructions

Dear user,
Congratulations on purchasing this Kerr quality product. Following the instructions below will allow you to work smoothly, economically and safely.
### Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Exclamation Mark" /></td>
<td>Refer to the Chapter on Safety/Warning symbols</td>
</tr>
<tr>
<td><img src="image" alt="Information Symbol" /></td>
<td>Important information for users and service technicians</td>
</tr>
<tr>
<td><img src="image" alt="Thermodisinfektion Symbol" /></td>
<td>Thermodisinfektion</td>
</tr>
</tbody>
</table>

Refer to the Chapter on Safety/Warning symbols for more information.
### Target group

This document is intended for dentists and their assistants. The section on starting up is also intended for service technicians.
2 Safety

2.1.1 Description of safety instructions: Warning symbol

![Warning symbol]
2.1.2 Description of safety instructions: Structure

THE INTRODUCTION DESCRIBES THE TYPE AND SOURCE OF THE HAZARD.
This section describes the potential consequences of non-observance.

- The optional step includes necessary measures for hazard prevention.
2.1.3 Description of safety instructions: Description of danger levels

The safety instructions cited herein with the three levels of danger will help avert property damage and injury.

CAUTION

indicates a hazardous situation that can cause damage to property or mild to moderate injuries.
WARNING

WARNING
indicates a hazardous situation that can cause death or serious injury.

DANGER

DANGER
indicates a hazardous situation that can directly cause death or serious injury.
2.2 Safety instructions

**WARNING**

Hazard to the care provider and patient.
Stop working in case of damage, irregular noise during operation, excessive vibration, unusual build-up of heat or if the SonicFill Unidose tip cannot be firmly held.

- Before extended periods of non-use, the instrument must be cleaned, serviced and stored in dry condition according to the instructions.
Premature wear and malfunctioning from improper storage during long periods of nonuse. Reduced product life.

- The medical device should be cleaned, serviced and stored in a dry location, according to instructions, before long periods of nonuse.
CAUTION

Injury or damage due to wear.
If you notice uneven operating noises, excessive or unexpectedly low vibrations or the SonicFill Unidose tip coming undone.

- Stop working and contact service support.
CAUTION

Swallowing or aspiration of the SonicFill Unidose tip by the patient.

- Before each treatment involving the SonicFill handpiece, insert a rubber dam for safety reasons.

The following persons are authorized to repair and service Kerr products:

- Technicians specially trained by Kerr

To ensure proper function, the medical device must be set up according to the methods described in the Kerr instructions for use, and the care products and methods described therein must be
used. Kerr recommends specifying a service interval at the dental office for a licensed shop to clean, service and check the functioning of the medical device. This service interval should take into account the frequency of use. Service may only be provided by repair shops that have undergone training by Kerr and that use original Kerr replacement parts.
SonicFill handpiece

SonicFill handpiece is a dental handpiece in accordance with ISO 15606. The handpiece is designed for sound-activated dispensation of a composite material that has a greatly reduced viscosity during the dispensing process and subsequently quickly transforms into the more viscous state of a restorative composite.
3.1 Purpose – Proper use

Purpose:

The SonicFill handpiece is a dental delivery system intended to be used to dispense SonicFill, a dental restorative resin, directly into dental cavities.
This medical device is
• intended for dental treatment only. Any other type of use or alteration to the product is im-
  permissible and can be hazardous.
The SonicFill handpiece must be used exclusively in combination with the SonicFill Unidose
• tip for filling dental cavities with composite materials.
• A medical device according to relevant national statutory regulations.
Proper use:

According to these provisions, the medical device is only for the described use in conformance with:

- the applicable health and safety regulations,
- the applicable accident prevention regulations
- and these instructions for use.
According to these regulations, the user is required to:
  • only use properly operating equipment,
  • use the equipment for the proper purpose,
  • to protect himself, the patient and third parties from danger,
  • to avoid contamination from the product.

3.2 Technical Specifications

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Drive air</td>
<td>3 – 4.2 bar (43 – 61 psi)</td>
</tr>
<tr>
<td>Air consumption</td>
<td>20 – 40 NL/min</td>
</tr>
</tbody>
</table>
Frequency 5 – 6 kHz
Ejection force 0 to 170 N

Note that the values above apply to the pressure within the handpiece and not to the dental unit itself. If the dental unit is set between 2.1 - 3.5 bar (30 - 50 psi) (which is normally the case when a turbine is used), no adjustment should be necessary. If adjustment is required, please see the directions for proper measurement and calibration of the handpiece pressure on page 25 of this manual.

The SonicFill handpiece can be mounted on all MULTIflex couplings.
3.3 Transportation and storage conditions

[CAUTION]

It is hazardous to start up the medical device after it has been stored refrigerated. This can cause the medical device to malfunction.

- Prior to start-up, very cold products must be heated to a temperature of 20 °C to 25 °C (68 °F to 77 °F).
| **Temperature**: -20°C to +70°C (-4°F to +158°F) |
| **Relative humidity**: 5% RH to 95% RH absence of condensation |
| **Air pressure**: 700 hPa to 1060 hPa (10 psi to 15 psi) |
| **Protect from moisture** |
4 First use

Mediated by a MULTIflex coupling, the SonicFill handpiece can be connected to any turbine hose of a treatment unit.

WARNING

Hazard from non-sterile products.
Infection hazard for care provider and patient.

▸ Before first use and after each use, sterilise the medical device.
4.1 Connection to devices

**WARNING**

Damage from soiled and moist drive air. Contaminated and moist drive air can cause malfunctions and lead to premature bearing wear.

- Always make sure that the supply of drive air is dry, clean and uncontaminated according to ISO 7494-2.
4.2 Installing the MULTIflex coupling

- Screw the MULTIflex LUX/MULTIflex LED coupling onto the turbine hose and tighten with the wrench.
4.3 Check the O-rings

[CAUTION]
Missing or damaged O-rings.
Malfunctions and premature failure.
- Make sure that all O-rings are on the coupling and undamaged.

Number of available O-rings: 5
4.4 Check the pressure using a test manometer

A minimum drive pressure of 3 bar (43 psi) measured at the handpiece is required to operate the SonicFill handpiece. 3.5 bar (50 psi) is ideal. Between 3.5 - 4.2 bar (51 - 62 psi) the drive air will be automatically reduced within the SonicFill handpiece. The air consumption is approximately 20 - 40 NI/min. Insert the test manometer between the MULTIflex coupling and the SonicFill handpiece. Adjust regulating ring on level 5.

Pressure displayed:
- Drive air T.R. = 3 - 4.2 bar (43 - 61 psi)
- Return air R.L. < 0.4 bar (6 psi)
- No water or spray air are needed, though.
5 Operation

5.1 Attaching the SonicFill handpiece

- Place the SonicFill handpiece exactly on the MULTIflex (LUX) / MULTIflex LED coupling and push it to the rear until it audibly locks.
If your coupling system is equipped with a light, please wait for at least 5 seconds before you remove the SonicFill handpiece to prevent damage to the light source.

**CAUTION**

Ensure that the SonicFill handpiece is firmly seated on the coupling. The SonicFill handpiece can be a hazard for patient and user if it inadvertently comes undone on the coupling during the treatment.

- Before each treatment, pull on the SonicFill handpiece to check if it is securely seated on the coupling.
5.2 Detaching the SonicFill handpiece

- Hold the MULTIflex (LUX) / MULTIflex LED coupling tight, and pull the SonicFill handpiece forward while twisting slightly.
5.3 Inserting the SonicFill Unidose Tips

DANGER

The SonicFill handpiece must be used in combination with SonicFill Unidose tips exclusively. Noncompliance may lead to product damage. Ensure that the SonicFill Unidose Tips are firmly attached to the SonicFill handpiece. Before each treatment, pull on the SonicFill Unidose tip to see if it is securely attached to the instrument. If the SonicFill Unidose tip is difficult to screw-on, this is due to a defect and the SonicFill Unidose tip must not be used since it may become detached during use. Check if the SonicFill Unidose tips are firmly connected by briefly starting-up the SonicFill handpiece outside the mouth.
Push the SonicFill Unidose tips by hand into the corresponding opening of the SonicFill handpiece using moderate pressure and turn the handpiece in a clockwise direction, screwing it into the SonicFill tip.

5.4 Removing the SonicFill Unidose Tips

Unscrew the SonicFill Unidose tips by hand from the SonicFill handpiece through a counterclockwise rotation.
5.5 Power setting

Use the regulating ring of the SonicFill handpiece to adjust the dispensed quantity. Level 1 = low, level 5 = high

Dispensing with a variable foot control positions:
Variable foot controls allow the dispensing rate to be controlled with different foot pedals. In this case, it is recommended to set the regulating ring on the handpiece to 5.
6 Preparation methods according to ISO 17664

6.1 Preparations at the site of use

**WARNING**

Hazard from nonsterile products.
There is a risk of infection from contaminated medical devices.

- Take suitable personal protective measures.
- Remove all residual cement, composite or blood without delay.
The medical device must be dry when transporting it to the site of reprocessing. (do not place in any type of solution).

The medical device should be reprocessed as quickly as possible after the treatment.

6.2 Preparations before cleaning

Remove the SonicFill Unidose tips by hand from the SonicFill handpiece.
6.3 Cleaning

**CAUTION**

Malfunctions from cleaning in the ultrasonic unit.
Defects in the product.

- Only clean manually or in a thermodisinfector.
6.3.1 Cleaning: Manual cleaning - external

- Accessories required:
  - Tap water 30 °C ± 5 °C (86 °F ± 10 °F)
  - Brush, e.g. medium-hard toothbrush

Brush under running tap water using, e.g., a medium-hardness toothbrush.
6.3.2 Cleaning: Automated external cleaning

Kerr recommends thermodisinfectors in accordance with EN ISO 15883 that are operated with alkaline cleaning agents at a pH of max. 10 (e.g. Miele G 7781 / G 7881 – validation was performed with the "VARIO-TD" programme, "neodisher® mediclean" cleaning agent, "neodisher® Z" neutralisation agent, and "neodisher® mielclear" rinsing agent and extends only to the compatibility of materials with respect to Kerr products).

▶ For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfector (complying with max. pH value of 10).
In order to prevent negative effects on the medical device made by Kerr, make sure that the interior and the exterior of the medical device are dry, and then lubricate immediately with care agents from the Kerr care system.

6.4 Disinfection

*CAUTION*

Malfunctioning from using a disinfectant bath or disinfectant containing chlorine. Defects in the product.

- Only disinfect in a thermodisinfector or manually.
6.4.1 Disinfection: Manual disinfection - external

Kerr recommends the following products based on material compatibility.

- CaviCide made by Metrex
Consumables required:
Cloths for wiping off the medical device.

Spray the disinfectant on a cloth, then thoroughly wipe down the medical device and leave the disinfectant to soak in according to the instructions from the disinfectant manufacturer.

Note
Follow the instructions for use of the disinfectant.
6.4.2 Disinfection: Machine disinfection - external and internal

Kerr recommends thermodisinfectors in accordance with EN ISO 15883 that are operated with alcaline cleaning agents at a pH of max. 10 (e.g. Miele G 7781 / G 7881 – validation was performed with the "VARIO-TD" programme, "neodisher® mediclean" cleaning agent, "neodisher® Z" neutralisation agent, and "neodisher® mielclear" rinsing agent and extends only to the compatibility of materials with respect to Kerr products).

▶ For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfector (complying with max. pH value of 10).
In order to prevent negative effects on the medical device made by Kerr, make sure that the interior and the exterior of the medical device are dry, and then lubricate immediately with care agents from the Kerr care system.

6.5 Drying

Manual Drying

 Blow off the outside and inside with compressed air until water drops are no longer visible.

Automatic Drying

The drying procedure is normally part of the disinfection program of the thermodisinfector.
Note
Please follow the instructions for use of the thermodisinfector (compressed air quality - see the Warning under "Start-up").
6.6 Care products and systems - Servicing

CAUTION

Premature wear and malfunctions from improper servicing and care. Reduced product life.

- Perform proper care regularly!
Note
Kerr guarantees the proper function of Kerr products only if the care products listed by Kerr under accessories are used, as these have been tested for proper use on our products.

6.6.1 Care products and systems - Servicing: Servicing involving SonicFill Handpiece Lubrication Spray

Kerr recommends servicing the product after each use after each automatic cleaning and before each sterilization.
Note
If the oil leakage is bothersome, once weekly servicing is sufficient.

- Remove the SonicFill Unidose Tips.
- Cover the product with the cellulose bag.
Place the product on the SonicFill MULTIflex coupling, and press the spray button for one second.

6.7 Packaging

Note
The sterilization bag must be large enough for the instrument so that the bag is not stretched.

Seal each medical device individually in a sterilised item package!
6.8 Sterilization

Sterilization in a steam sterilizer (autoclave) in accordance with EN 13060/ISO 17665-1

⚠️ CAUTION

Premature wear and malfunctions from improper servicing and care. Reduced product life.

- Service the medical device before each sterilization cycle.
CAUTION

Contact corrosion due to moisture.
Damage to product.

- Immediately remove the product from the steam steriliser after the sterilisation cycle!

Note

Remove the SonicFill Unidose tip before sterilization. The SonicFill Unidose tips are non-sterilizable.
The medical device has a maximum temperature resistance up to 138 °C (280.4 °F).
(Depending on the available autoclave,) select a suitable procedure from the following sterilisation processes:

- **Autoclave with pre-vacuum:**
  - at least 3 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
  - Drying time: 20 min.

- **Autoclave using the gravity method:**
  - at least 10 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F) or alternatively
  - at least 60 minutes at 121 °C -1 °C / +4 °C (250 °F -1.6 °F / +7.4 °F)
  - Drying time for using one of the gravity methods is 30 minutes.

▷ Use according to the manufacturer's Instructions for Use.
6.9 Storage

Prepared products must be stored, protected from germs (as far as possible) and dust, in a dry, dark, cool room.

Note
Comply with the expiry date of the sterilised items.
7 Tools

Obtainable from an authorized Kerr distributor.

<table>
<thead>
<tr>
<th>Material summary</th>
<th>Mat. no.</th>
</tr>
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<tbody>
<tr>
<td>SonicFill Handpiece Lubrication Spray</td>
<td>35207</td>
</tr>
<tr>
<td>SonicFill MULTIflex coupling</td>
<td>35134</td>
</tr>
</tbody>
</table>
8 Terms and conditions of warranty

Kerr’s technical advice, whether verbal or in writing, is designed to assist dentists in using Kerr’s product. The dentist assumes all risk and liability for damages arising out of the improper use of Kerr’s product. In the event of a defect in material or workmanship, Kerr’s liability is limited, at Kerr’s option, to replacement of the defective product or part thereof, or reimbursement of the actual cost of the defective product. In order to take advantage of this limited warranty, the defective product must be returned to Kerr. In no event shall Kerr be liable for any indirect, incidental, or consequential damages. EXCEPT AS EXPRESSLY PROVIDED ABOVE, THERE ARE NO WARRANTIES, BY KERR, EXPRESS OR IMPLIED, INCLUDING WARRANTIES WITH RESPECT TO DESCRIPTION, QUALITY, OR FITNESS FOR A PARTICULAR PURPOSE.