

Manufacturer:
Gebr. Brasseler GmbH & Co. KG
Trophagener Weg 25
32657 Lemgo · Germany

Distributor/Importer for USA and Canada:
Komet USA LLC
3042 Southcross Blvd, Suite 101
Rock Hill, SC 29730, USA

Phone: 888-566-3887
Fax: 800-223-7485
info@kometusa.com
www.kometusa.com

Instructions for use

Please read carefully and retain for future reference.

Conseils d'utilisation

A respecter scrupuleusement et garder cette copie pour une utilisation ultérieure.

Instrucciones de empleo

Leer detenidamente y guardar este ejemplar para uso más tarde.

Sonic tips for prophylactic treatment
© 08/2012, Gebr. Brasseler GmbH & Co. KG
307218 - Rev 08/2012

CAUTION: U.S. Federal law restricts the device to sale by or on the order of a licensed dentist.



REF Order number
Numéro d'ordre
Número de pedido

LOT LOT number
Numéro de lot
Número de lote

Consult instructions for use
Se reporter aux instructions
Observe indicaciones

Packing unit
Unité d'emballage
Unidad de embalaje

Prophylaxis
Prophylaxie
Profíflaxis

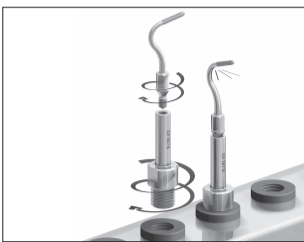


Fig. 1

Sonic tips for prophylactic treatment

1. Safety Notice

Please read the instructions for use prior to using sonic tips for prophylactic treatment. Sonic tips may only be used for their intended purpose according to the general rules for dental treatment, occupational safety and accident prevention. Sonic tips should only be used if they are in excellent condition. If the indication and use are unclear, treatment should be suspended until these points have been clarified. These sonic tips should only be used by qualified personnel with training and experience in prophylactic treatments and the use of sonic tips. It is the responsibility of the user to check the products prior to use to ensure that they are suited for the intended purpose. The user is responsible for the application of the instruments. The manufacturer declines any liability for possible damage caused in connection with the use of these instruments. Store out of children's reach. For dental use only. The product has been developed solely for use in dentistry. The user is responsible for testing the material for its suitability and use for any purpose not explicitly stated in the instructions. Descriptions and data constitute no warranty of attributes and are not binding.

2. Product description

The Komet Sonic tips are designed for oscillating work on teeth within a prophylactic treatment.

3. Indication for use

Used for sub- and supragingival scaling of calculus. Suited for pockets with a depth of up to 2 mm.

4. Applications

The sonic tips SF1, SF2 and SF3 shall be used in combination with the KOMET sonic handpiece SF1LM for prophylactic treatments.

5. Contraindications

There are no known contraindications.

6. Warnings

The tips are supplied in non-sterile condition. Therefore they must be sterilized prior to the first use on the patient and immediately after each use. The useful life of the sonic tips is limited. They therefore have to be used with utmost care. The sonic tips may only be used by dentists and medical personnel sufficiently trained in the relevant fields of prophylactic treatment. Premature wear! Due to the nature of their range of application, the functional parts of these sonic tips will always be subject to moderate wear, even when the tips are applied correctly and according to their intended use. The extent of wear can be determined with the test card (405444). Excessively worn tips have to be exchanged. Improper use can lead to damage to the tissue, premature wear, destruction of the instruments and injury to the operator, patient or third parties. Avoid excessive contact pressure! This can lead to damage to the instruments' working part. At the same time, extreme heat is generated which increases the risk of thermal necrosis. At worst, breakage of the instrument can occur if too high contact pressure is applied. Optimal results are achieved at a contact pressure of max. 2.5 N. This can be compared with the pressure which is applied when writing with a fountain pen. Avoid jamming of the instrument during treatment! Do not use as a lever! Since the sonic tips may fracture without warning even when used in accordance with their intended use, two sonic tips should always be planned for the treatment, i.e. one should remain at hand as a reserve so that the planned treatment can still be completed if one tip has broken. Caution: To avoid injury and infection, wear gloves or finger protection when inserting or removing the sonic tips from the sonic handpiece. Damaged and deformed instruments cause vibrations and lead to rough surfaces and damage to the hard dental substance. Very important: Damaged instruments lead to the user applying higher contact pressure which may result in an increased operating temperature. This may lead to thermal damage. Damaged instruments therefore have to be discarded immediately.

Safety check:

Fracturing may occur due to the tips being subjected to continuous or sudden stress (for example, if the tips are dropped on the floor or if the original shape is changed mechanically). Instruments with the following defects must be discarded:

- Damaged surface
- Deformation (warping, twisting, fracture)
- Surface corrosion

7. Cooling

It is absolutely essential to thoroughly and continuously irrigate the site at all times during the operation. To this end, at least 50 ml/min of a suitable cooling agent has to be supplied by the dental treatment unit.

8. Precautions/recommendations for maintenance

Important note: Never use the instruments as a lever! It is extremely important to handle all tips with care. Damage to their surface considerably impairs the performance of these instruments!

The tips are supplied in non-sterile condition. Therefore they have to be disinfected, cleaned and sterilized prior to first use.

- Do not allow residues from the treatment (blood, secretions, tissue) to dry
 - Place sonic tips in a cleaning/disinfection tank filled with suitable detergent/disinfectant immediately after use in the mouth to prevent drying of residues on the instruments (protein fixation)
 - Only use brushes with nylon bristles for pre-cleaning
 - Disinfect the sonic tips with disinfecting and cleaning agents for rotary instruments
- For recommendations for use (immersion time, concentration, suitability) of the disinfecting and cleaning agents please refer to the instructions provided by the manufacturer of the agents used.

Manual pre-cleaning (prior to mechanical and manual reprocessing):

1. Remove sonic tip from cleaning /disinfection tank immediately before reprocessing.
2. Check patency of the cooling passage by guiding the nozzle cleaner through the passage. Replace instrument if the passage is obstructed.

Mechanical reprocessing (validated):

1. Rinse sonic tip thoroughly under running water to prevent any residues of the detergent/disinfectant from getting into the washer/disinfectant.
2. Unscrew the nozzle on the injector bar of the washer/disinfectant. Then screw the external thread of the rinse adapter SF1978 in the silicon holders on the injector bar. Now screw the sonic tip in the internal thread at the top of the rinse adapter (fig. 1). Observe the directions in the instructions for use provided with the SF1978.
3. Put chemical detergent (mild alkaline cleaning agent e.g. Neodisher FA) into the washer/disinfectant, following the indications on the label and the instructions of the manufacturer of the washer/disinfectant.
4. Start the Vario TD programme including thermal disinfection. Thermal disinfection takes place allowing for the A₀ value and observing national provisions.
5. On completion of the cycle remove sonic tip from the washer/disinfectant and dry (preferably with compressed air). When drying the inside of the instruments, please make sure to hold the compressed air gun close to the cooling passage, in order to guarantee that sufficient air flows through the sonic tip.
6. Visual examination to ensure that the instrument is clean and undamaged. If after mechanical reprocessing there are still visible residues of contamination, repeat the cleaning and disinfecting process until no visible contamination is left.

Manual reprocessing (alternative):

1. Place sonic tip onto a 10ml syringe and rinse with detergent/disinfectant. In case of visible contamination emerging from the perforations, rinse again with detergent/disinfectant.
2. Remove stubborn contamination with a nylon brush under running water, turning the sonic tip constantly.
3. Rinse sonic tip thoroughly with running water.
4. Visual examination to ensure that the instrument is clean. If there are still visible residues of contamination, repeat the cleaning process until no visible contamination is left.
5. Place sonic tip in a suitable container into the ultra sonic device or instrument bath filled with detergent/disinfectant.
6. During chemical disinfection in the ultrasonic device or instrument bath, observe the instructions of the manufacturer regarding concentration and immersion time. Be sure to observe the full correct immersion time which does not start until the last tip has been immersed. Attention: do not exceed 45°C (risk of protein coagulation)!
7. On completion of the immersion time, rinse sonic tip thoroughly with suitable water (preferably with demineralised water to avoid residues of lime). Rinse the perforation of the sonic tip with at least 10 ml of demineralised water by means of a cannula, to ensure that no residues of the detergent are left in the cooling passage.
8. Dry sonic tip (preferably with compressed air). When drying the inside of the instruments, please make sure to hold the compressed air gun close to the cooling passage, in order to guarantee that sufficient air flows through the sonic tip.
9. Visual examination to ensure that the instrument is clean and undamaged. If there are still visible residues of contamination, repeat the cleaning and chemical disinfecting process until no visible contamination is left. Note: mechanical cleaning is preferable.

Sterilisation in the autoclave:

The sonic tips can be steam-sterilized at 134°C in a suitable device using the vacuum process. The sonic tips must be unscrewed from the rinse adapter before each sterilization cycle. Prior to sterilization, the sonic tips must be individually packed in sterilization pouches (to prevent contact corrosion). Alternatively, they can be placed in a suited sterilization cassette (e.g. Komet 9952) that is packed in sterilization pouch. The pouch must be sufficiently large to comfortably fit the cassette or tip without strain on the packaging. Sterilization is effected in an autoclave with fractionated pre-vacuum (type B) or simplified pre-vacuum (type S) with a holding time of at least 5 minutes (full cycle) and a drying time of at least 10 minutes at 134 °C +1. Alternatively, sterilization may also be effected in an autoclave with gravitation process at 121°C +1 with a holding time of at least 30 minutes. Note the range of application indicated in the manufacturer's instructions.

9. Use

The sonic tip is screwed into the Komet sonic handpiece SF1LM with the tip changer SF1980, turning in clockwise direction. To remove the tip, fit the tip changer over the tip and turn anticlockwise to unscrew it. Particularly in the case of curved tips, care must be taken to ensure that the working parts protrude into the half-radius of the tip changer in order to avoid injury and contamination. Also observe the instructions in the directions for use of the sonic hand piece SF1LM. Power level 1 or 2 is the standard level for this indication in combination with the SF1LM. Power level 3 can be used for short term treatment.

10. Special patient population

Patients must, as a matter of principle, be suitable for prophylactic treatment.

11. Adverse reactions

All known reactions on dental treatment have to be considered carefully which may include but are not limited to:

- Device failure
- Infection
- Tissue damage as a result of the dental treatment

12. Disclaimer of Warranties

ALL WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE EXPRESSLY DISCLAIMED. ALL INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING, BUT NOT LIMITED TO, LOST PROFITS, INJURY TO OTHER PROPERTY, LOSS OF USE OR OTHER COMMERCIAL LOSSES, ARE EXPRESSLY DISCLAIMED. If, not withstanding the foregoing, consequential and incidental damages cannot be excluded due to operation of law, such damages are expressly limited in amount to the purchase price of any defective products.

Store out of children's reach.
For dental use only..

