Brasseler USA Endodontic Ultrasonic Tips Instructions For Use

Description

Brasseler USA's ultrasonic tips are manufactured of the finest materials and methods and have been designed to function in most brands of Piezo dental ultrasonic power units (M3x0.6 thread). Refer to your ultrasonic power unit owner's manual for further details on the use of these types of devices.

The operator should be aware that diamond coated tips (indicated by "D") are generally more aggressive than non-diamond coated tips and that ultrasonic tips with small diameters are subject to breakage at any time. In order to reduce the incidence of premature breakage or failure only very light pressure should be applied by the operator and the suggested intensity settings should be follows.

Intended Use

Endodontic tips are to be used for endodontic root preparation procedures including removal of supragingival and subgingival calculus and retro-prep of roots ends for permanent filling in the canal.

Warnings

- The device is to be used on the instruction of, or by a dentist or other licensed practitioner.
- Failure to follow these instructions may cause the following: apex perforation, insufficient cleaning of the root canal, preparation site damage, injury to the patient or user, or possible aspiration or swallowing of the file.
- Attention should be paid to the Power Range:
  - Use of the tip beyond the intended power range may cause patient or user harm.
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Brasseler USA Ultrasonic Tips must be thoroughly cleaned and steam sterilized prior to the first use to prevent infection or contamination.
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Products E9D and E14D are marked as single use and not intended to be used on more than one patient. Use on more than one patient may lead to decreased cutting efficiency which could result in device failure, generation of undesirable heat resulting patient discomfort, tooth or tissue necrosis, or patient burns and cross contamination.
- Do not use chemical or dry heat to sterilize Ultrasonic Tips, as these processes have not been validated for use. Use of these processes may be corrosive to the files and could result in premature file failure.
- Carefully read package labels to ensure use of the appropriate device. Failure to do so may cause patient or user injury.
- Always wear gloves when handling contaminated instruments to avoid possible infection/cross-contamination.
- Surgical masks must be worn to avoid inhalation of any aerosol or dust generated which could cause user injury.
- Eye protection must be worn to protect against eject particles which could cause user injury.

Precautions

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Do not use if the package is damaged. Tips may become damaged or contaminated if the packaging is compromised.
- Move the Tip continuously when in use to avoid localized heating and/or damage to the tip. Undesirable heat generation can cause patient discomfort, tooth or tissue necrosis, or patient burns.
- Maintain handpieces in good working condition to ensure maximum effectiveness of the device. Failure to properly maintain handpieces may lead to patient discomfort, injury of the patient or user, aspiration or swallowing of the Tip or damage to the preparation site due to vibration of a worn chuck or turbine.

- Ensure the Ultrasonic Tip is fully seated and securely gripped in the handpiece collet prior to use. Failure to do so may cause the Tip to "walk out" of the handpiece and may lead to injury of the patient or user, or aspiration or swallowing of the Tip.
    - Never force a Tip into a handpiece as this could cause damage to the handpiece collet.

General Instructions

B.E.S.T
Brasseler Endodontic Surgery Tips

BEST-1D -Power Range: Min-3
Angled 80° at the working end, with a 0.5mm diameter x 3.0mm cutting surface. Designed as a general purpose tip for anterior and posterior areas.

BEST-2D -Power Range: Min-3
Similar to the BEST-1D, with a 0.7mm diameter x 3.0mm cutting surface for larger diameter roots.

BEST-3D -Power Range: Min-3
A double angled, 75° instrument designed for use on the buccal root of the mandibular right molar and mesial buccal of the maxillary left molar. 0.5mm diameter x 3.0mm cutting surface.

BEST-4D -Power Range: Min-3
A double angled, 110° instrument designed for use on the lingual root of the mandibular left molar and distal buccal of the maxillary right molar. 0.5mm diameter x 3.0mm cutting surface.

BEST-5D -Power Range: Min-3
A mirror image of the BEST-3D, for use on the buccal roots of the mandibular left molar and mesial buccal of the maxillary right molar. 0.5mm diameter x 3.0mm cutting surface.

BEST-6D -Power Range: Min-3
A mirror image of the BEST-4D, for use on lingual roots of the mandibular right molar and distal buccal of the maxillary left molar. 0.5mm diameter x 8.0mm cutting surface.

E4 -Power Range: Min-3
Designed for root canal cleaning; water cooled

E9 -Power Range: Min-4
Designed for removal of filling and foreign material; water cooled

E9D -Power Range: Min-4
Designed for access refinement and troughing; water cooled; diamond coated

E14D –Power Range: Min-4
Designed for enlargement of root canal wall; water cooled; diamond coated

E15 -Power Range: Min-3
Often referred to as the "Ball Tip," the E15 can be used to safely remove a variety of posts retained with various cementing agents. The E15 is activated and placed directly on the post and moved circumferentially around for approximately 10 minutes. If this does no loosen and free the post, then an alternate method should be used. If using a post removal system or steiglitz pliers you may place the E15 tip directly on device. This transfers vibration to the post that aids the post loosening process. This process is called "indirect ultrasonics." CAUTION! DO NOT PLACE THE E15 DIRECTLY ON A CERAMIC CROWN OR BRIDGE. The E15 should be placed 2-3mm above the metal margin to vibrate it loose. It may cause severe damage to the prosthesis if placed directly on ceramics.

E15D -Power Range: Min-3
The shank of the E15D is similar to the E4 or E14D but the head/tip design is that of a round bur (slightly smaller than a #2 round bur). It is used for troughing and pulp stone removal.

E16D -Power Range: Min-4
The E16D is an all-purpose tapered instrument used primarily within the pulp chamber. The E16D is used for eliminating pulp stones, removing dentin, trephine around obstructions within the pulp chamber and locating hidden orifices such as MB2 systems. The E16D can also be used to safely and efficiently remove restorative materials and

amalgams and is capable of eliminating materials extending below the orifice.

E17D, E18D, & E19D -Power Range: Min-3
Due to their small cross sectional diameters and lengths, these tips must be used with a very low power setting. It is not necessary to apply force to these instruments as the diamond coating will aggressively remove dentin and debris along the lateral sides of the tip. These tips should be used in the coronal, middle and apical one-third of roots. Each instrument gets progressively smaller in the cross sectional diameter and longer in the overall length. The three sizes allow the clinician greater control as the instruments are selected according to safe access and depth of the procedure. Uses include: Trephine around posts, chasing calcified canals, eliminating brick hard paste type material, broken instrument removal and other intra canal obstructions.

E20, E21, & E2 -Power Range: Min-3
Due to their small cross sectional diameters and lengths, these tips must be used with a very low power setting. The instruments are made of titanium alloy, not NiTi. They will hold a bend if applied forcefully. The titanium alloy results in a smoother cutting action with less chatter, thereby increasing tactile sense. They are generally used in the mid and apical portion of the root with illumination and magnification. These instruments are end cutting inly and are commonly used to ditch around broken files, aiding in their removal.

Return Policy/Disclaimer

Due to the nature of how ultrasonic tips are used (gradually worn down), Brasseler USA does not accept returns or exchanges unless it is determined by Brasseler USA that there is a manufacturers defect. Brasseler USA does not assume any responsibility or liability for incorrect diagnosis or failed procedures due to operator error or equipment/instrumentation malfunction.

Special Note

All Brasseler USA ultrasonic power units and ultrasonic tip kits come with a tip wrench but individual replacement tips do not. The order code for the tip wrench is CR-2.

Cleaning and Sterilization Instructions

Scope	These instructions are applicable to all Brasseler USA Ultrasonic Tips. Ultrasonic Tips are provided mechanically clean, but are not sterile. Therefore, the Tips should be sterilized before first use.
Warnings	1. Cleaning agents with chlorine or chloride as the active ingredients are corrosive and must not be used. Cleaning agents with neutral pH are recommended. 2. Do not use Cold Sterilizing Methods for the sterilization of the Tips. These agents often contain strong oxidizing chemicals that may dull or weaken Tips. 3. Vigorous scrubbing of the Tips may cause damage. Care should be taken to ensure that files are not broken or damaged during the cleaning process.
Reprocessing Limitations	The end of life is determined by the wear and damage in use. Ultrasonic Tips should be inspected for defects during the cleaning process.  Products E9D and E14D are single use. Do not reuse.
Containment/ Transportation	If transported wet, there is an increased chance of staining or corrosion.
Manual Cleaning Procedure	If hand cleaning is the only available option, Ultrasonic Tips should be cleaned in a sink reserved for cleaning instruments.

Rinse the Ultrasonic Tip (and dedicated instrument block, if applicable) under cool running water for at least one (1) minute.

Prepare a fresh bath of neutral-pH cleaning solution. Follow the cleaning agent's manufacturer's instructions. Immerse the Ultrasonic Tip (and instrument block) and soak for at least ten (10) minutes.

After soaking, and keeping it immersed, brush thoroughly away from the body using the neutral cleaning agent for at least one (1) minute. Care should be taken to avoid spreading contaminants by spraying or splashing during the brushing process. Use wire brushes with caution as brass particles may result in galvanic corrosion and steel particles may cause discoloration of stainless steel.

Special care should be taken to clean crevices and other hard to reach areas thoroughly. Visually inspect to confirm the removal of debris. Repeat the cycle if needed.

Thoroughly rinse the Ultrasonic Tip under running warm water for at least one (1) minute and until visibly clean.

Dry the device using a non-shedding wipe or clean compressed air.

Ultrasonic Cleaning Procedure

Prepare a fresh pH-neutral cleaning solution; place the Ultrasonic Tip in the dedicated instrument block (if applicable) and then place in a sonication unit. Follow the cleaning agent manufacturers' instructions for correct concentration, exposure time, temperature, and water quality. Completely submerge the device in the cleaning solution and sonicate for at least fifteen (15) minutes.

Perform a final thorough rinse of the device under running warm tap water for at least (1) minute.

Visually inspect to confirm the removal of debris. Repeat the cycle if needed.

Dry the device using a non-shedding wipe or clean compressed air.

Inspection Testing

1. Carefully inspect each device to ensure that all debris has been removed.
2. Visually inspect the device for damage/ wear that would prevent proper operation.
    a. Do not use if the tip is broken.
    b. Do not use if there is a broken section of a file.
    c. Do not use if there is evidence of corrosion.
    d. Do not use if the reference markings are illegible.

Packaging

Singly: Pack the Ultrasonic Tips in pouches validated for sterilization

Sterilization

Use the following steam sterilization cycle for : BEST 1D-6D; E15, E15D, E16D, E17D, E18D, E19D, E20D, E21D, and E22D

Cycle Type	Minimum Sterilization Exposure Time (minutes)	Minimum Sterilization Exposure Temperature	Minimum Dry Time (minutes)
Gravity	10	135°C (275°F)	30
Pre-vacuum (4 Pulses)	3	134°C (273°F)	30

Use the following steam sterilization cycles for : E9D and E14D

Cycle Type	Minimum Sterilization Exposure Time (minutes)	Minimum Sterilization Exposure Temperature	Minimum Dry Time (minutes)
Gravity	15	132°C (270°F)	15
Gravity	10	135°C (275°F)	30
Pre-vacuum	4	132°C (270°F)	20
Pre-vacuum	3	134°C (273°F)	30
Pre-vacuum	3	135°C (275°F)	16

Use the following steam sterilization cycles for : E4 and E9

Cycle Type	Minimum Sterilization Exposure Time (minutes)	Minimum Sterilization Exposure Temperature	Minimum Dry Time (minutes)
Gravity	20	121°C (250°F)	10
Gravity	15	132°C (270°F)	10
Gravity	10	135°C (275°F)	10
Pre-vacuum	10	135°C (275°F)	15

Ensure that the sterilizer manufacturer's maximum load is not exceeded.
The minimum dry time has been validated to ensure that the files will not be left wet. Failure to achieve the minimum dry time may cause moisture to remain on the files that could result in corrosion.
DO NOT wipe or clean or immerse in high acid water or sterilizing solutions.

Storage

The Ultrasonic Tip should be stored in the sterilization pouch and in a dry and dust-free location up to the period specified by the sterilization pouch manufacturer. If sterility cannot be confirmed, sterilize again prior to first use.

Additional Information

These processes have been validated as being capable of preparing Ultrasonic Tips for use. Any deviation from these instructions should be properly validated for effectiveness and potential adverse results.

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