BRASSELER USA®

Instructions for Use

Intended use

These instruments are intended for use by trained dental professionals in diagnostic, hygiene, restorative, laboratory, or surgical dental procedures.

Contraindications

Do not use on patients with hypersensitivity to nickel.

Inspection

Be sure to inspect the instruments for fissures, cracks, surface damage or other damage prior to each use.

Instruments that show any signs of corrosion, dull or weakened blades, misalignment or defects should be taken out of service immediately.

Care must be taken to inspect, clean, and sterilize instruments prior to each use. Instruments that show any signs of corrosion, dull or weakened blades, misalignment or defects should be taken out of service immediately.

Processing

Medical devices should not be distorted, bent, or overloaded, as this can cause loss of function, fracture, or destruction of the devices.

The instruments are delivered non-sterile.

Brand-new instruments, as well as instruments returned from repair, must be removed from their transportation packaging before including them in the sterile processing and supply cycle. This also requires removal of all protective devices (such as foils, caps, etc.).

Prior to sterilizing instruments for the first time, they must be thoroughly cleaned. In particular, all oil residues must be carefully removed. If cleaning is done manually, hot water must be used for this purpose, adding a suitable, commonly available washing-up liquid.

Instruments should always be stored in a dry room to prevent condensation and consequential corrosion damage. Prior to initial use, instruments must be sent through the entire processing cycle in the same way as used instruments. This may only be done by trained personnel and in compliance with the regulations in force at the time.

Ensure that all residues (blood, tissue particles, medicines) are carefully removed from the instruments immediately after surgical intervention.

Instruments should never be just “dropped”. Instead, put them down carefully to avoid damage.

Do not immerse instruments in NaCl solutions because this may cause pitting or stress corrosion cracking. Use only an approved detergent-disinfectant solution that has no protein-fixing effect (as regards the mix, be sure to follow the product manufacturer’s instructions for use).

Stainless Steel Instruments
Brasseler uses many different types of stainless steels in the production of instruments dependent upon the design and application of the instrument. All stainless steels have a high nickel and chromium content to maximize corrosion resistance but will corrode and discolor when subjected to high concentrations of certain chemicals.

Never expose stainless steel instruments to products that are not specifically formulated for use with dental instruments or for the purpose of cleaning and sterilizing dental instruments.
Do not expose stainless steel dental instruments to the following chemicals. These chemicals will cause an adverse reaction and may destroy your instruments: Chlorine or Chlorinated products, Household Bleach, Tarter and Stain Remover, Aluminum Chloride, Aqua Regia, Barium Chloride, Bichloride of Mercury, Calcium Chloride, Carbolic Acid, Chlorinated Lime, Citric Acid, Dakin's Solution, Ferric Chloride, Ferrous Chloride, Hydrochloric Acid, Iodine, Lysol®, Mercury Chloride, Mercury Salts, Phenol, Potassium Permanganate, Potassium Thiocyanate, Sodium Hypochlorite (bleach), Stannous Chloride, Sulfuric Acid and Tartaric Acid (Tarter & Stain Remover)

Water quality may influence the result of the cleaning and disinfection of the instruments. Corrosion could be caused by high contents of chloride or other minerals in the tap water. If problems with stains and corrosion occur and other reasons can be excluded, it might be necessary to test the tap water quality in your area. By using completely deionized or distilled water most water quality problems can be avoided beforehand.

Avoid overloading instruments and washing trays.

Process the instruments immediately after use (do not store them dirty). Jointed instruments must always be processed in open condition.

Titanium Nitride Coated (gold colored) Instruments
Titanium coatings are used to increase the surface hardness of instrument tips and reduce "pullback" when manipulating composite materials. Brasseler produces a selection of the following instruments with titanium nitride coating:

- Restorative Composite Placement Instruments (increases surface hardness for smoother restorations)
- Surgical Elevators (to maintain longer lasting sharpness)
- Surgical Periotomes (to maintain longer lasting sharpness)
- Surgical Luxation Blades (to maintain longer lasting sharpness)

Proper care should be taken to remove any residual composite materials from the blade within 5 minutes after use by wiping the blade with alcohol on a 2×2 gauze. Composite materials or residue can harden on the blade and affect the quality of future restorations. Composite residue left to harden on the blade cannot be removed without damaging the surface finish of the composite placement instrument. Never use abrasives to clean the surface of any titanium coated composite placement instruments, elevators, periotomes or luxation blades.

Titanium Nitride Coated instruments can be cleaned and sterilized using the same recognized acceptable methods as stainless-steel instruments (see stainless steel instruments portion of this document).

Anodized Aluminum Composite Placement Instruments
Anodized Aluminum composite placement (black colored) instruments such as the Felt Instruments should be kept separate during the cleaning and sterilization process. These instruments should be cleaned with a mild detergent under running water. They should never be ultrasonically cleaned. After cleaning they may be sterilized in a Steam Autoclave or Dry Heat sterilizer according to the manufacturer's instructions for aluminum instruments.

Hinged Instruments
Hinged Instruments should be allowed to thoroughly dry in an open position after ultrasonic and manual cleaning procedures. Care should be taken to keep hinges and joints of forceps, rongeurs, scissors, pliers, hemostats, crown placement pliers, etc. well lubricated. Only use lubricants specifically formulated for dental and surgical instruments and follow manufacturer's instructions for applications. Household lubricants, hand-piece lubricants and other lubricants not specifically formulated for dental and surgical hand instruments should never be used.

Automated/Machine Cleaning
Use an automated washer that is compliant with ISO 15883-1.

1. Completely disassemble the instruments, if applicable.
2. Rinse the instruments under running tap water for 30 seconds.
3. Transfer the instruments to the automated washer.
4. The following cycle settings have been validated for use. Follow the detergent manufacturer's instructions:

Stage	Recirculation Time	Temperature	Detergent Type
Pre-wash	15 sec.	Cold tap water	N/A
Enzyme Wash	1 min.	Hot tap water	Enzol Enzymatic Cleaner (or similar)
Wash 1	2 min.	43° C tap water	Valsure Neutral Detergent (or similar)
Rinse 1	15 sec.	Hot tap water	N/A
Dry Time	6 min.	98.8° C	N/A

5. Inspect the instruments to make certain that all residue, debris, and residual cleaning solution are removed from the instruments and that the instruments are free of defects and are safe to use.

Manual and Ultrasonic Cleaning
Use only cleaners and disinfectants suitable (approved) for stainless steel instruments. When manually cleaning or handling contaminated instruments, personnel should wear heavy duty, puncture resistant utility gloves in order to avoid injury or cross contamination. They should also wear a face mask, eye protection or face shield and a gown or jacket because splashing will likely occur.

1. Completely disassemble the instruments, if applicable.
2. Pre-Treat all contaminated instruments by soaking in an enzymatic cleaning solution

for at least 5 minutes. Contaminated instruments should be pre-treated within one hour of use, and it is necessary that all instrument surfaces are completely submerged.

3. Remove the instruments from the cleaning solution and remove any remaining debris or deposits using a soft brush. Do not use any brush with metal bristles or steel wool.
4. Rinse instruments completely with low contaminated and deionized water for at least 30 seconds, making certain that there is no remaining residue, debris or residual cleaner left on the instruments.
5. Prepare a detergent bath in an ultrasonic unit using an enzymatic cleaning solution such as Enzol Enzymatic Cleaner. Follow the detergent manufacturer's instructions.
6. Completely disassemble the instruments if applicable. Soak the disassembled instruments for the recommended soaking time in the cleaning solution, and make sure that the instruments are sufficiently immersed. Sonicate the instruments for at least 6 minutes. If utilizing a cassette system, use the processing time recommended by the manufacturer of the cassette system.
7. Do not overload the Ultrasonic Cleaning unit. Use "Sweep mode" if available.
8. Remove the instruments from the cleaning solution and post rinse them intensively with low contaminated and deionized water for at least 30 seconds.
9. Inspect the instruments to make certain that all residue, debris, and residual cleaning solution are removed from the instruments and that the instruments are free of defects and safe to use.
10. Thoroughly dry all instruments before packaging for sterilization using lint-free cloths and/or filtered compressed air.

Sterilization

Minimum cycle times for gravity-displacement steam sterilization cycles

Item	Exposure time at 121°C (250°F)	Drying time
Pouched instruments	30 minutes	Minimum 30 minutes

- NOTE—This table represents the variation in sterilizer manufacturers' recommendations for exposure at different temperatures. For a specific sterilizer, consult only that manufacturer's recommendations.

Minimum cycle times for dynamic-air-removal/pre-vacuum steam sterilization cycles

Item	Exposure time at 132°C (270°F)	Drying time
Pouched instruments	4 minutes	Minimum 30 minutes

- NOTE—This table represents the variation in sterilizer manufacturers' recommendations for exposure at different temperatures. For a specific sterilizer, consult only that manufacturer's recommendations.

Be sure to use only solutions and chemicals that are compatible with stainless steel hand instruments.

Never exceed temperatures 350° F / 177° C as this will have an adverse effect on the temper of the steel.

Notice: No liability is accepted for reuse of instruments which have been applied to patients who have Creutzfeldt-Jacob disease or who are HIV-positive.

Storage

Products must be stored in a dry and dust-protected place to avoid humidity and consequential corrosion. Some medical devices are very delicate and should be individually packed or stored in protective containers. Please ensure that instruments are not in contact with chemical substances.

Reusability

This device is a reusable medical device.

Material

Medical parts: 440A Stainless steel.
Method: High Gloss Surface Reference
standards: YY/T 0294.1

Brasseler USA does not accept liability to results caused by proved non- compliance of this instruction for use.

Glossary of Symbols: BrasselerUSAdental.com/resources

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