



BRASSELER USA Hand Instruments

BRASSELER USA Hand Instruments are available in Non-Sterile models under various assortments and numerous working tips. The devices are reusable and are sterilized using steam sterilization in a gravity cycle.

Description

The BRASSELER USA Hand Instrument family includes hand instruments, mirrors, pliers, amalgam carriers, scissors, elevators and forceps. BRASSELER USA Hand Instruments are reusable devices.

Intended Use

BRASSELER USA Hand Instruments are intended for use in diagnostic, hygiene, restorative, laboratory or surgical dental procedures.

Warnings and Precautions

Warning:

- Do not use corroded instruments.
- Do not use worn-out or dull hand instruments.
- Do not use chemical or dry heat to sterilize BRASSELER USA Hand Instruments, as these processes have not been validated for use.
- Do not apply excessive pressure on the tip of the hand instrument as this could cause the tip to break.

- Hand Instruments must be thoroughly cleaned and steam sterilized prior to the first use and each subsequent reuse.
- Avoid applying pressure at too sharp an angle to avoid leverage and breakage.
- Carefully read package labels to ensure use of the appropriate device.
- Maintain hand instruments in good working condition to ensure maximum effectiveness of the device.
- Always wear gloves when handling contaminated instruments.
- BRASSELER USA Hand Instrument Cassettes are used to hold the devices for storage and steam sterilization. The Hand Instrument Cassettes are not intended to maintain sterility of the device.

General Instructions

1. The device is to be used on the instruction of, or by a dentist or other licensed practitioner.
2. Clean and sterilize non-sterile hand instruments in accordance with the validated procedures provided below prior to first use and prior to each reuse.

Cleaning and Sterilization Instructions

Scope	These instructions are applicable to all BRASSELER USA Hand Instruments. They are applicable before initial use and after each subsequent use. Hand Instruments are provided mechanically clean, but are not sterile. Therefore, Hand Instruments should be sterilized before first use.
Warnings	<ol style="list-style-type: none"> 1. Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must not be used. Cleaning agents with neutral pH are recommended. 2. Do not use Cold Sterilizing Methods for the sterilization of hand instruments. These agents often contain strong oxidizing chemicals that may attack the substrate that bonds the diamond particles to the steel blanks.
Reprocessing Limitations	The end of life is determined by wear and damage in use. Hand Instruments should be inspected for defects (i.e. broken tips, missing diamond particles, etc.) during the cleaning process.
Point of Use	Delay in reprocessing must be kept to a minimum to avoid contaminants drying thereby making cleaning more difficult.
Containment/ Transportation	Hand Instruments can be transported wet or dry and should be protected from damage. If transported wet there is an increased chance of staining or corrosion. Prolonged storage in disinfectant solutions may result in degradation of the product and must be avoided.
Manual Cleaning Procedure	<p>If hand cleaning is the only available option, Hand Instruments should be cleaned in a sink reserved for cleaning instruments.</p> <p>Rinse the Hand Instrument (and instrument cassette) in running cool tap water for one (1) minute.</p> <p>Prepare a fresh bath of neutral-pH, enzymatic cleaning solution (such as Enzol). Follow the agent's manufacturer's instructions. Immerse the Hand Instrument (and instrument cassette) and soak for at least ten (10) minutes.</p> <p>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.</p> <p>Special care should be taken to clean crevices, mated surfaces, and other hard to reach areas thoroughly. Visually inspect to confirm the removal of debris. Repeat the cycle if needed.</p> <p>Thoroughly rinse the Hand Instrument (and instrument cassette) under running warm water for a minimum of one (1) minute and until visibly clean.</p> <p>Dry the device using a non-shedding wipe or clean compressed air.</p>
Ultrasonic Cleaning Procedure	<p>Prepare a fresh bath of neutral-pH, enzymatic cleaning solution (such as Enzol); place the Hand Instrument in the sonication unit. Follow the 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.</p> <p>Perform a final thorough rinse of the device under running warm tap water for at least (1) minute.</p> <p>Visually inspect to confirm the removal of debris. Repeat the cycle if needed.</p> <p>Dry the device using a non-shedding wipe or clean compressed air.</p>
Inspection Testing	<ol style="list-style-type: none"> 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 are missing or worn parts.
- c. Do not use if there is evidence of corrosion.

Packaging

Singly: Pack the Hand Instrument in pouches validated for sterilization.

In Sets: Place the Hand Instrument in the dedicated instrument cassette.

Sterilization

Use the following cycle for steam sterilization

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	132°C (270°F)	30

Ensure that the sterilizer manufacturer’s maximum load is not exceeded.

Storage

The Hand Instrument should be stored in the sterilization pouch (or instrument cassette) until required.

Additional Information

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

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