



## BRASSELER USA Hand and Surgical Instruments

BRASSELER USA Hand and Surgical 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 or prevacuum cycle.

### Description

The BRASSELER USA Hand and Surgical Instrument family includes hand instruments, mirrors, pliers, amalgam carriers, scissors, elevators, forceps, trephines, mucosa membrane punches, chisels, mallets and cassettes. BRASSELER USA Hand and Surgical Instruments are reusable devices.

### Intended Use

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

### Contraindications

- Hand or Surgical Instruments contain nickel and should not be used for individuals with known allergic sensitivity to this metal as it may cause hypersensitivity.
- This product contains nickel, a chemical known to the state of California to cause cancer, birth defects or other reproductive harm.



### Warnings and Precautions

- The device is to be used on the instruction of, or by a dentist or other licensed practitioner.
- Attention should be paid to the speed of work (RPM) while using trephines or mucosa membrane punches:
  - Always refer to the product packaging for the Maximum RPM. Use of the instrument beyond the RPM range may cause the instrument to break and result in patient or user harm.
  - Operating a trephine or mucosa membrane punch with too high of an RPM may generate undesirable heat and cause patient discomfort, tooth or tissue necrosis, or patient burns.
- Proper irrigation is required while using trephines or mucosa membrane punches. Inadequate use of irrigation may generate undesirable heat and cause patient discomfort, tooth or tissue necrosis, or patient burns.
- Avoid applying too much pressure while using the device to avoid leverage and breakage which could cause user or patient injury.
- Hand and Surgical Instruments must be thoroughly cleaned and steam sterilized prior to the first use and each subsequent reuse.
- Do not use chemical or dry heat to sterilize BRASSELER USA Hand or Surgical Instruments, as these processes have not been validated for use. Use of these processes may be corrosive to the device and could result in premature device failure.
- Proper cleaning is required after use of the device to prevent cross-contamination. Failure to properly remove the accumulated debris may cause the device to break causing patient or user harm.
- Use a rubber dental dam while using Hand or Surgical Instruments to avoid possible aspiration or swallowing of the device.
- Always wear gloves when handling contaminated instruments to avoid possible infection/cross-contamination.
- Eye protection must be worn to protect against eject particles which could cause user injury.
- Surgical masks must be worn to avoid inhalation of any aerosol or dust generated that could cause possible infection/cross-contamination.
- Carefully read package labels to ensure use of the appropriate device. Failure to do so may cause procedural delays or patient or user injury.



- Always inspect the device before use:
  - Use of worn-out, dull or corroded instruments could cause the device to fail and result in patient or user injury.
  - Use of bent instruments could cause the device to fail and result in patient or user injury, patient discomfort or damage to the preparation site.
- Move the trephine or mucosa membrane punch continuously when in use to avoid localized heating and/or damage to the trephine or mucosa membrane punch. Undesirable heat generation can cause patient discomfort, tooth or tissue necrosis, or patient burns.
- Avoid removing the instrument at too sharp an angle to avoid leverage and breakage which could cause patient or user injury.
- Maintain instruments in good working condition to ensure maximum effectiveness of the device. Failure to properly maintain instruments may lead to procedural delays or injury of the patient or user, aspiration or swallowing of the device or damage to the preparation site.
- Ensure the trephine or mucosa membrane punch is fully seated and securely gripped in the handpiece collet prior to use. Failure to do so may cause the device to “walk out” of the handpiece and may lead to injury of the patient or user or aspiration or swallowing of the device.
- Never force a trephine or mucosa membrane punch into a handpiece as this could cause damage to the handpiece collet which could result in procedural delays.
- Maintain handpieces in good working condition to ensure maximum effectiveness of the device. Failure to properly maintain handpieces may lead to procedural delays or injury of the patient or user, aspiration or swallowing of the trephine or mucosa membrane punch or damage to the preparation site due to vibration of a worn chuck or turbine.
- BRASSELER USA Cassettes are used to hold the devices for storage and steam sterilization. The Cassettes are not intended to maintain sterility of the devices.
- Do not force trephine or mucosa membrane punch into Bur Blocks as this could cause damage to the trephine or mucosa membrane punch or cause it to become lodged in the Bur Block.
- Failure to follow these instructions may cause the following: preparation site damage, injury to the patient or user, or possible aspiration or swallowing of the instrument.

**General Instructions**

1. Clean and sterilize non-sterile instruments in accordance with the validated procedures provided below prior to first use and prior to each reuse.
2. Do not force a trephine or mucosa membrane punch into the handpiece. In case of difficult access, check both handpiece turbine and bur and refer to handpiece instructions for troubleshooting.

**Cleaning and Sterilization Instructions**

Scope	These instructions are applicable to all BRASSELER USA Hand and Surgical Instruments. They are applicable before initial use and after each subsequent use. Hand and Surgical Instruments are provided mechanically clean, but are not sterile. Therefore, Hand and Surgical Instruments should be sterilized before first use.
Warnings	<ol style="list-style-type: none"> <li>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.</li> <li>2. Do not use Cold Sterilizing Methods for the sterilization of Hand and Surgical Instruments. These agents often contain strong oxidizing chemicals that may dull or weaken the devices.</li> </ol>
Reprocessing Limitations	The end of life is determined by wear and damage in use. Hand and Surgical Instruments should be inspected for defects (i.e. broken tips, dull edges, 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 and Surgical 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 and Surgical Instruments should be cleaned in a sink reserved for cleaning instruments.</p> <p>Rinse the Hand or Surgical Instrument (and instrument cassette or block, if applicable) 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 cleaning agent manufacturer's instructions. Immerse the Hand or Surgical Instrument (and instrument cassette or block) 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, holes 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 or Surgical Instrument (and instrument cassette or block) 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 or Surgical Instrument in the 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.</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"><li>1. Carefully inspect each device to ensure that all debris has been removed.</li><li>2. Visually inspect the device for damage/ wear that would prevent proper operation.<ol style="list-style-type: none"><li>a. Do not use if the device is broken.</li><li>b. Do not use if there are missing or worn parts.</li><li>c. Do not use if there is evidence of corrosion.</li><li>d. Do not use if reference markings are illegible</li></ol></li></ol>
Packaging	<p>Singly: Pack the Hand or Surgical Instrument in pouches validated for sterilization.</p> <p>In Sets: Place the Hand or Surgical Instrument in the dedicated instrument cassette.</p>



Sterilization	Use the following cycle for steam sterilization												
	<table border="1"> <thead> <tr> <th>Cycle Type</th> <th>Minimum Sterilization Exposure Time (minutes)</th> <th>Minimum Sterilization Exposure Temperature</th> <th>Minimum Dry Time (minutes)</th> </tr> </thead> <tbody> <tr> <td>Gravity</td> <td>10</td> <td>135°C (275°F)</td> <td>30</td> </tr> <tr> <td>Pre-vacuum</td> <td>4</td> <td>132°C (270°F)</td> <td>30</td> </tr> </tbody> </table>	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
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Pre-vacuum	4	132°C (270°F)	30										
	Ensure that the sterilizer manufacturer’s maximum load is not exceeded.												
Storage	The Hand or Surgical Instrument (or instrument cassette or block) should be stored in the sterilization pouch until required.												
Additional Information	These processes have been validated as being capable of preparing Hand and Surgical Instruments for reuse. Any deviation from these instructions should be properly validated for effectiveness and potential adverse results.												

**Glossary of Symbols**

Symbol	Meaning	Standard
	Catalogue Number	ISO 15223-1
	Batch Code	ISO 15223-1
	Quantity	N/A
	Consult instructions for use	ISO 15223-1
	Caution	ISO 15223-1
	Non-sterile	ISO 15223-1
<b>Rx Only</b>	Caution: Federal law restricts this device to sale by or on the order of a “dentist/physician” licensed by the law of the State in which he/she practices to use or order the use of the device.	FDA 21 CFR Part 801.109 (b)(1)
<b>Made in</b>	Made in	N/A
	Manufacturer/Legal Manufacturer	ISO 15223-1

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