




BRASELER USA Abrasive Strips

BRASELER USA Abrasive Strips are single-handed, which are held by the thumb and forefinger, or double-handed devices. The devices are most often reusable and are sterilized using steam sterilization in a gravity or prevacuum cycle. Some devices are single use and are labeled with a graphical symbol, .

Description

BRASELER USA Abrasive Strips are available in the following configurations:

1. Diamond Strips - Reusable diamond coated stainless steel double-handed devices
2. ET Flex™ Strips - Reusable diamond-coated strip or stainless steel saw-toothed edge strip single-handed devices
3. Steel Strips – Reusable Stainless steel strip with a saw-toothed edge double-handed devices
4. ET Composite Strips - Single use aluminum oxide coated Mylar double-handed devices
5. Combo VisionFlex Strips – Reusable diamond coated and saw-toothed edge stainless steel double-handed devices

Intended Use

BRASELER USA Abrasive strips are designed to pre-polish, contour, finish polish and high shine polish interproximal areas of composite restorations and/ or used in interproximal reduction of enamel.

Diamond Strips, ET Flex™ Strips, Steel Strips and Combo VisionFlex Strips are reusable devices and are used to finish restorations interproximally along with interproximal enamel reduction during orthodontics.

ET Composite Strips are single use devices designed to finish and polish interproximal composite restorations and during interproximal reduction of enamel. Do not sterilize ET Composite Strips as damage may result.

Warnings and Precautions

- To prevent patient choking, ligate the ET Flex™ using dental floss tied to the cross bar of the device and secure the other end to a finger or drape the floss outside the patient's mouth
- Do not sterilize ET Flex™ more than three (3) times as the plastic handle may become distorted causing the strip to become loose
- Abrasive Strips are manufactured using thin metal or Mylar; Care should be taken to avoid injury to patient or user caused by sharp edge
- Avoid overuse of Abrasive Strips as patient or user injury may result from device wear
- Use neutral pH cleaning agents following manufacturer's directions
- Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must not be used
- Diamond Strips, ET Flex™ Strips, Steel Strips and Combo VisionFlex Strips must be thoroughly cleaned prior to the first use and prior to each subsequent reuse
- Do not use chemical, dry heat or cold sterilization methods to sterilize Diamond Strips, ET Flex™ Strips, Steel Strips and Combo VisionFlex Strips, as these processes have not been validated for use
- ET Composite Strips are single-use devices. Do not clean or sterilize ET Composite Strips as this may damage the device. Cleaning/ sterilization processes may result in ineffective abrasion or a broken device.



- Do not use if the Diamond Strip, ET Flex™ Strip, Steel Strip or Combo VisionFlex Strip is dull, chipped, missing diamond particles or is damaged in any manner
- Do not use if the Diamond Strip, ET Flex™ Strip, Steel Strip or Combo VisionFlex Strip exhibits signs of corrosion or damage
- Do not use if the ET Flex™ Strip is loose or is not securely affixed to the handle
- Do not use if the Reusable Diamond Strip, ET Flex™ Strip, Steel Strip or Combo VisionFlex Strip is broken in any manner
- Do not leave Diamond Strips, ET Flex™ Strips, Steel Strips or Combo VisionFlex Strips in wet condition as this may lead to corrosion or interaction with stored devices
- Carefully read package labels to ensure use of the appropriate device
- Eye protection must be worn to guard against ejected particles
- Surgical masks must be worn to avoid inhalation of any aerosol or dust generated during use
- Always wear gloves when handling contaminated instruments

General Instructions

1. Abrasive Strips are to be used on the instruction of, or by a dentist or other licensed practitioner.
2. Clean and sterilize Diamond Strips, ET Flex™ Strips, Steel Strips or Combo VisionFlex Strips in accordance with the validated procedures provided below prior to first use and each subsequent reuse.
3. Do not store the Diamond Strips, ET Flex™ Strips, Steel Strips or Combo VisionFlex Strips when wet as this may cause corrosion of the stainless steel or interaction with other stored instruments.
4. Do not clean or sterilize ET Composite Strips as this may damage the device.

Cleaning and Sterilization Instructions

Scope	These instructions are applicable to all REUSABLE BRASSELER USA Abrasive Strips made from stainless steel. They are applicable before initial use and after each subsequent use. Abrasive Strips are provided mechanically clean, but are not sterile. Therefore, Abrasive Strips should be cleaned and sterilized before first use and subsequent reuses.
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. 2. Do not use cold sterilizing methods for the sterilization of Diamond-Coated Strips. These agents often contain strong oxidizing chemicals that may attack the substrate that bonds the diamond particles to the steel blanks.
Reprocessing Limitations	<p>ET Flex must not be sterilized more than three (3) times as the handles may distort during sterilization causing the strip to become loose.</p> <p>The end of life is determined by wear and damage in use and REUSABLE Abrasive Strips should be inspected for defects (i.e. missing diamond particles, broken edges, etc.) during the cleaning process.</p>
Point of Use	Delay in reprocessing must be kept to a minimum to avoid contaminants drying thereby making cleaning more difficult.
Containment/Transportation	REUSABLE Abrasive Strips can be transported wet or dry and should be protected from damage. If transported wet there is an increased chance of staining or corrosion of the stainless steel. Prolonged storage in disinfectant solutions may result in degradation of the product.
Manual Cleaning Procedure	If hand cleaning is the only available option, REUSABLE Abrasive Strips should be cleaned in a sink reserved for cleaning instruments.



Rinse the device under cool running water for at least one (1) minute.

Prepare a fresh bath of neutral-pH cleaning solution (such as Enzol) following the manufacturer’s directions. Immerse the device 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, which may cause discoloration of stainless steel.

Special care should be taken to thoroughly clean perforations, crevices and other hard-to-reach areas using a pH neutral cleanser. Visually inspect to confirm the removal of gross debris. Repeat the cycle if needed.

Thoroughly rinse the device 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 following the manufacturer’s instructions for correct concentration, exposure time, water temperature and quality. Place the device in a sonication unit ensuring the device is completely submerged, 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 gross debris from perforations, crevices and other hard to reach areas. Repeat the cycle if needed until visibly clean.

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 Abrasive strip is dull, chipped, broken, missing diamond particles or is damaged in any manner
 - b. Do not use if Abrasive strip exhibits signs of corrosion or damage
 - c. Do not use if ET Flex Strip is not securely affixed to handle

Packaging

Singly: Pack REUSABLE Abrasive Strips in pouches validated for sterilization
 In Sets: Pack select REUSABLE Abrasive Strips into the dedicated Bur Block for steam sterilization

Sterilization

Diamond Strips, Steel Strips and Combo VisionFlex Strips (two-handed devices) must be sterilized using the following validated steam sterilization parameters ONLY:

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

ET Flex™ Strips (single-handed devices) must be sterilized using the following cycle for steam sterilization parameters ONLY:

Cycle Type	Sterilization Exposure Time (minutes)	Sterilization Exposure Temperature	Dry Time (minutes)
Gravity	15	121°C (250°F)	15



	Ensure that the sterilizer manufacturer's maximum load is not exceeded.
Storage	The REUSABLE Abrasive Strip should be stored in the sterilization pouch until required. The Bur Block is not intended to maintain the sterility of the contained devices.
Additional Information	These processes have been validated as being capable of preparing REUSABLE Abrasive Strips for reuse. Any deviation from these instructions should be properly validated for effectiveness and potential adverse results.

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