Brasseler USA ABRASIVE STRIPS Instructions for Use

BRASSELER USA Abrasive Strips

BRASSELER USA Abrasive Strips are single-handed, which are held by the thumb and forefinger, or double-handed devices. The devices are sterilized using steam sterilization in a gravity or prevacuum cycle.

Description

BRASSELER USA Abrasive Strips are available in the following configurations:

1. VisionFlex™ and Gateway™ Diamond Strips - Diamond coated stainless steel double-handed devices.
2. ET® Flex™ Strips - Diamond-coated strip or stainless steel saw-toothed edge strip single-handed devices. The abrasive strip is mounted on a plastic handle.
3. Steel Strips – Stainless steel strip with a saw-toothed edge double-handed devices.
4. VisionFlex™ Diamond/Saw Combo Strips – Double-handed combination strips incorporating diamond coated stainless steel with a stainless steel saw-toothed edge center.
5. ET® Composite Mylar Strips™ - Single use aluminum oxide coated Mylar double-handed devices.
6. Versaflex™ Strips – Single use diamond coated Mylar double-handed devices.

Intended Use

BRASSELER 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.

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

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

Contraindications

1. VisionFlex™ and Gateway™ Diamond Strips, ET® Flex™ Strips, Steel Strips and VisionFlex™ Diamond/Saw Combo Strips contain nickel and should not be used for individuals with known allergic sensitivity to this metal as it may cause hypersensitivity.
2. This product contains nickel, a chemical known to the state of California to cause cancer, birth defects or other reproductive harm.
3. Do not use these devices on individuals with known allergic sensitivity to any of the device components/materials as it may cause hypersensitivity.

Warnings and Precautions

4. The device is to be used on the instruction of, or by a dentist or other licensed practitioner.
5. Devices marked as single use are 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 and cause patient discomfort or injury or user injury.
6. ET® Composite Mylar Strips and Versaflex™ Strips are single-use devices. Do not clean or sterilize ET® Composite Mylar Strips or Versaflex™ Strips as these processes may damage the device. Cleaning and/or sterilization processes may result in ineffective abrasion or a broken device which could lead to patient discomfort or injury or user injury.
7. Ligate the ET® Flex™ Strip 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 to prevent accidental swallowing or aspirating of the device.
8. Abrasive Strips must be thoroughly cleaned and sterilized prior to the first use.
9. If the packaging for Abrasive Strips is opened or damaged, the device must be thoroughly cleaned and steam sterilized prior to use to prevent the risk of infection or cross-contamination.
10. Do not use chemical, dry heat or cold sterilization methods to sterilize Abrasive Strips, 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.
11. Failure to properly remove the accumulated debris may cause the device to break causing patient or user harm.
12. Use a rubber dental dam while using Abrasive Strips to avoid possible aspiration or swallowing of the device.
13. Always wear gloves when handling contaminated instruments to avoid possible infection/cross-contamination.
14. Eye protection must be worn to guard against ejected particles which could cause user injury.
15. Surgical masks must be worn to avoid inhalation of any aerosol or dust generated that could cause possible infection/cross-contamination.
16. Avoid overuse of Abrasive Strips to avoid finger and/ or hand fatigue.

17. Carefully read package labels and inspect the product to ensure use of the appropriate device. Failure to do so may cause procedural delays or patient or user injury.
18. Abrasive Strips are manufactured using thin metal or Mylar; care should be taken to avoid injury to patient or user caused by a sharp edge.
19. Always inspect the Abrasive Strip before use:
    - Use damaged Abrasive Strips could cause preparation site damage, procedural delays, injury to the patient or user, or aspiration or swallowing of a broken device by the patient.
    - Do not use if the ET® Flex™ Strip is loose or is not securely affixed to the handle as this could cause preparation site damage, procedural delays, injury to the patient or user, or aspiration or swallowing of a broken device by the patient.
20. Bur Blocks used to hold the devices for storage and steam sterilization are not intended to maintain sterility of the device. Abrasive strips should be stored in the sterilization pouch to prevent cross-contamination.
21. Do not force ET® Flex™ handles into Bur Blocks as this could cause damage to the device or cause it to become lodged in the Bur Block.
22. Do not apply excessive pressure on the ET® Flex™ Strip as this could cause the device to fail and result in injury to the patient or user, patient discomfort, or patient aspirating or swallowing of the broken strip.
23. 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 Abrasive Strip.

ET® Flex™ Strip Directions for Use

1. To make the ET® Flex™ Strip more taut for passing through contacts, IPR or other contact separation needs, hold the device above the cross-bar with your thumb and forefinger and apply the degree of pressure necessary to achieve the desired tautness.
2. In order to make the ET® Flex™ Strip more flexible for adapting to the curvature of the tooth while finishing a restoration or completing IPR, hold the device below the cross-bar with your thumb and forefinger and apply the degree of pressure necessary to achieve the desired flexibility and curvature.

General Instructions

1. Clean and sterilize VisionFlex™ and Gateway™ Diamond Strips, ET® Flex™ Strips, Steel Strips or VisionFlex™ Diamond/Saw Combo Strips in accordance with the validated procedures provided below prior to first use.
2. DO NOT clean or sterilize ET® Composite Mylar Strips™ or Versaflex™ Strips as this may damage the device.

Cleaning and Sterilization Instructions

Scope	These instructions are applicable to all Abrasive Strips made from stainless steel. They are applicable before initial use. Abrasive Strips are provided mechanically clean, but are not sterile. Therefore, Abrasive Strips should be cleaned and sterilized before first use.
Warnings	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 Diamond-Coated Strips. These agents often contain strong oxidizing chemicals that may attack the substrate that bonds the diamond particles to the steel blanks. 3. Devices marked as single use are 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 and cause patient discomfort or injury or user injury.
Containment/ Transportation	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, 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 Abrasive Strips in pouches validated for sterilization
In Sets: Pack select Abrasive Strips into the dedicated Bur Block for steam sterilization

Sterilization

VisionFlex™ and Gateway™ Diamond Strips, Steel Strips and VisionFlex™ Diamond/Saw Combo 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	30	121°C (250°F)	30

Ensure that the sterilizer manufacturer's maximum load is not exceeded.
The minimum dry time has been validated to ensure that the devices will not be left wet. Failure to achieve the

	minimum dry time may cause moisture to remain on the devices that could result in corrosion.
Storage	The 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.

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**
	**Do not re-use**	**ISO 15223-1**
Rx Only	**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)**
Made in	**Made in**	**N/A**
	**Manufacturer/Legal Manufacturer**	**ISO 15223-1**

 **Manufactured for**

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