QwikStripTM Abrasive and Finishing Strips – **Manufacturer's Safety and Data**

OwikStrip¹⁰⁴ abrasive and finishing strips are hand-held strips used for breaking contacts, cement removal, finishing, polishing, and interproximal reduction (IPR).

OwikStrip^{*}

abrasive and finishing strips are available in serrated (used for breaking contacts or for cement removal), single-sided (for reduction from .07mm -.18mm), and double-sided (for reduction from .18mm-.50mm). The grits are as follows; super-fine, fine, medium, course, x-course, and xx-course), and are available in a straight or a curved strip (for maintaining the anatomical contour of most teeth).

Indications for Use

WikStrip[™] abrasive and finishing strips are indicated to break contacts, remove 'set' interproximal cement, finish, polish, or for IPR, and are indicated for use in either the anterior or the posterior teeth.

' Contraindications **OwikStrip**

QwikStrip[™] abrasive and finishing strips are contraindicated if one does not strictly follow the IFU, or in the event that a patient presents with poor enamel (hypoplasia), poor oral hygiene, severe tooth crowding, or even a high caries index.

Warning/ Safety Precaution

As a safety measure, prior to using a QwikStripTM, secure the QwikStipTM by tying a piece of floss through one of the tether holes located at the top of the QwikStripTM. Wrap the opposite end of the floss around one of your other fingers to secure the OwikStripTM, thus preventing ingesting or accidental swallowing by the patient.

Precautions

• Sterilize QwikStripTM prior to patient use. Follow sterilization details provided below.

• Prior to initial use, read and adhere to the "Instructions for Use" completely. Use of a QwikStrip™ that deviates from the "Instructions For Use" is at the sole discretion and sole responsibility of the user.

• Do not use any QwikStrip[™] that is damaged, bent, broken, or shows irregular or abnormal signs of wear.

• "Finish" with the appropriate curved QwikStrip for maintaining the anatomical contour of any teeth treated.

• Use a "gap gauge" during IPR procedures when gap width accuracy is desired.

Adverse Reactions

• None known.

Instructions for Cleaning and Sterilization, Storing, **Maintaining and Disposal**

Warnings:	DO NOT use dry heat sterilization processes. Cold sterilization is not an accepted or effective sterilization method.
Reprocessing:	QwikStrips [™] can be sterilized repeatedly (maximum 10 times)
	GENERAL INSTRUCTIONS

Prior to Use::	As instructed above, always sterilize before first use and between patients.
Decontamination Technique :	Wipe / scrub immediately after use in order to avoid having contaminants dry, making clean-up more difficult. Immerse or soak QwikStrips [™] in an approved, hospital grade enzymatic solution used for cleaning dental instruments for 15 minutes.
Cleaning: Manual Procedure	To ensure that QwikStrips are cleaned thoroughly, start by scrubbing all surfaces with stiff nylon cleaning brushes until all visible debris has been removed, ensuring that flutes and furrows are visibly and effectively cleaned. If needed, use smaller sized brushes to clean the furrows or smaller crevices. Re-inspect for visible debris, and if any is noticed, repeat the scrubbing procedure. Once the QwikStrip is deemed visibly clean and free from debris, immerse or soak in an approved, hospital grade enzymatic solution used for cleaning dental instruments for 15 minutes Rinse thoroughly under running water for 2 -3 minutes; visually inspect to confirm removal of all debris.
Cleaning: Automated	Not recommended
Disinfection:	Not recommended
Drying:	Allow to dry in autoclave drying cycle per autoclave manufactures' recommendation or to air dry in clean area
Inspection, testing, safety caution and disposal	Visually inspect broken, bent or worn abrasive strip that could prevent proper or safe use. Discard in "Sharps" container if necessary.
Packaging	QwikStrips can be bagged in FDA cleared sterilization pouches (I.E SafeSeal [™] by Medicom) or can remain in the autoclavable (proprietary) packages sold with the product
Sterilization: Use FDA approved sterilization pouch or provided auroclavable packaging.	US Autoclave Parameters Steam autoclave-Gravity (Wrapped) Minimum Exposure Temperature: 121°C (250°F) Minimum Exposure Time: 30 minutes Minimum Dry: 30 minutes US Autoclave Parameters Steam autoclave- Pre-Vacuum (Wrapped) Minimum Exposure Temperature: 135°C (275°F) Minimum Exposure Time: 3 minutes Minimum Dry: 30 minutes EU Autoclave Parameters Steam autoclave- Gravity (Unwrapped) Minimum Exposure Temperature: 134°C Minimum Exposure Time: 3 minutes Minimum Exposure Time: 3 minutes Minimum Dry: None
Storage	QwikStrips should be stored in the FDA approved sterilization pouch or in the provided autoclavable package until ready for use (up to 9 months). If sterilized unwrapped, one must use immediately after sterilization.
Manufacturer	Contact the manufacturer with questions or concerns: See Instructions for Use for contact information

Instructions for Use

<u>Cement Removal and Breaking Contacts</u> Use QwikStripTM (White) serrated strips to remove any cement left after seating crowns, inlays, onlays, veneers, or any other cemented restoration. QwikStripTM serrated strips are also used to break any contact that has been bonded together or is too tight to floss.

Start by holding the QwikStrip[™] serrated strip between your thumb and index finger. Insert the serrated strip between the teeth, and with a gentle "sawing motion", proceed to remove the cement or to break the contact.

Finishing and Polishing

Use QwikStrip[™] Single-Sided Abrasive Strips (Straight or Curved) for either anterior or posterior teeth. In order to maintain or restore the anatomical contour of posterior teeth, use QwikStrip[™] Curved strips, as they are better suited for this purpose.

- Select the desired grit (Yellow-Superfine, Red-Fine, Blue-Medium, Green-Coarse, Black-X-Coarse).
- Hold the QwikStrip[™] between your thumb and index finger.
- In an angled position, begin by using a gentle "sawing motion" until the strip passes through passively.
- If needed, continue to other grits until the proper finish/polish is achieved.

Interproximal Reduction (IPR)

Use QwikStrip[™] Single-sided strips followed by QwikStrip[™] Double-Sided strips in the sequence listed in the QwikStrip IPR Sequence Guide. When maintaining the anatomical contour of the teeth is desired, use the appropriate Curved Abrasive QwikStrips, as they are better suited to this purpose.

For creating IPR spaces from 0.07mm to 0.2mm, use the Single-Sided QwikStrip[™] Abrasive Strips (straight or curved); For IPR spaces greater than 0.2mm, use the Double-Sided QwikStrip[™] Abrasive Strips.

- Always begin by using the Single-Sided (straight or curved) superfine grit (Yellow) and proceed according to the QwikStrip[™] IPR sequence Guide.
- Hold the QwikStripTM between the thumb and index finger. In an angled position, begin a gentle "sawing motion" until the QwikStripTM passes through passively.
- Check the gap with a verified gap gauge before moving to the next color (grit) in the sequence. If the desired gap is achieved, there is no need to continue to the next larger grit size.
- If additional space is needed, continue to the fine grit (Red) and use in the same manner as described above. Check gap width. If the desired gap is achieved, there is no need to continue to the next larger grit size.
- If additional space is needed, continue to the medium grit (Blue). Check gap width. If the desired gap is achieved, there is no need to continue to the next larger grit size.
- If additional space is needed, continue to the coarse grit (Green). Check gap width. If the desired gap is
- achieved, there is no need to continue to the next larger grit size.
 If additional space is needed, continue to the x-coarse grit (Black). Check gap width. If the desired gap is achieved, there is no need to continue to the next larger grit size. Maximum space created by following the single-sided OwikStrip[™] sequence is .2mm

When IPR is needed to achieve spaces greater than .2mm, follow the same procedures as above using double-sided QwikStrips according to the QwikStrip[™] Sequence Guide.

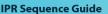
• **Once desired gap is achieved, continue to lesser grits until the proper finish/polish is achieved.

IPR Sequence Guide For Orthodontic Procedures

In order to create precise interproximal spaces for any Orthodontic procedures, use QwikStrip[™] color coded strips according to the sequence guide provided for IPR procedures. Begin the reduction process (IPR) with the yellow single-sided grit (0.07 mm), and continue in sequence until the desired space is achieved. Check the reduction with an approved "space measurement gauge" before moving to the next color (grit) in the sequence. Continue progressively until the desired space is achieved. Finally, use the superfine grit (curved or straight yellow) to finish or polish the reduced teeth.

Note: One can use any/all versions of QwikStrip[™] (single-sided, double-sided, and curved) in any area of the mouth. However, in order to maintain the anatomical contour of the posterior teeth and for refining the contours of the anterior teeth, finish all IPR procedures by using the appropriate curved version of QwikStrips.





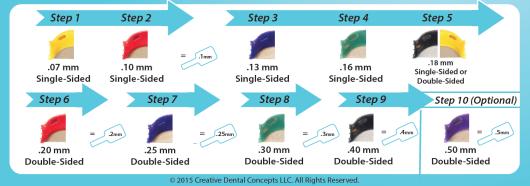


In order to create precise interproximal spaces for any Orthodontic procedure (including Invisalign™, Clear Correct™, Six Month Smiles™, or MTM™) use *QwikStrip*™ color coded strips according to the sequence guide outlined below. The reduction process (IPR) should begin with the yellow single-sided grit (.07 mm), and continue in sequence until the desired space is achieved up to .5mm.

Check the reduction with an approved measurement guide before moving to the next color (grit) in the sequence.

Note: Use all versions of QwikStrips (single-sided, double-sided, or curved) in any area of the mouth. However, for maintaining the anatomical contour on posterior teeth or when refining the natural anatomy of the anterior teeth, finish by using the curved version.

All widths are \pm .05 mm.







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