

SpaceFile™

INTERPROXIMAL REDUCTION KIT

Caution: U.S. Federal law restricts this device to sale by or on the order of a dentist.

Prior to use with air-driven handpiece, please read the "Directions For Use" that was included with the Interproximal Reduction System (IRS) handpiece, sold separately. Do not apply excessive pressure on strips, which may lead to premature fracture of the plastic handle.

INDICATIONS FOR USE:

Intended for use as a method for achieving interproximal reduction of teeth.

CONTRAINDICATIONS:

- The IRS is contraindicated for use with patients if it has not been sterilized as recommended in the Directions For Use.
- The IRS is contraindicated for use in patients who:
 - Are hypersensitive,
 - Don't accept stripping,
 - Have low enamel density (hypoplasia) or a high caries index,
 - Display poor hygiene,
 - Have rectangular-shaped teeth, and/or,
 - Display a high degree of crowding.

WARNINGS:

- Files are made from stainless steel and contain 6-8% of nickel by weight. Nickel may cause allergic reactions in some patients.

PRECAUTIONS:

- Read the Directions for Use thoroughly and comply with them during use. Any use of this product inconsistent with these directions for use, is at the discretion and sole responsibility of the practitioner.
- Perform a visual inspection of the respective SpaceFile™. Do not use files that are damaged, bent, or broken.
- Prior to use on a patient, observe the recommended sterilization instructions below.
- Use care when installing File in Grip as Files may be sharp.
- Grip is provided for manual use only and must not be used with the air-driven handpiece.

ADVERSE REACTIONS: None known

INSTRUCTIONS FOR USE:

SpaceFile™ files can be used with the specified IRS handpiece or manually with or without the included Grip. If using the handpiece, refer to its Directions for Use.

Use the double-sided or single-sided File of appropriate grit in sequence as needed to create the desired space. A serrated File is also available to assist in breaking initial contact.

To insert SpaceFile™ in Grip:

1. Place the shank of the SpaceFile™ into the hole on the Grip until resistance is felt. The opposite side of the Grip can be bent out of the way to facilitate this.
2. With the base of the SpaceFile™ resting on a firm surface, press down on the middle of the Grip until positive engagement is felt.
3. Push the end of the Grip without the hole towards the File to complete engagement of the File within the Grip.



Figure 1: Shank of File fully inserted into Grip hole



Figure 2: Press down on mid-section of Grip until engagement is felt



Figure 3: File fully inserted in Grip

To Remove SpaceFile™ from Grip:

1. Grasping the Grip at the end with the shank, pull the opposite end of the Grip upwards and away from the File.
2. Pull the File straight out of the hole in the Grip.

CLEANING GUIDELINES:

• Scope

The SpaceFile™ and Grip should be both cleaned and then sterilized after each use. Refer to the Sterilization Guidelines for sterilization instructions. Cleaning should be completed immediately after use to avoid contaminants drying, thereby making cleaning more difficult.

• Manual Cleaning Procedure

1. Rinse under running cold water to remove gross contamination.
2. Keeping it immersed, brush thoroughly away from the body using an enzymatic cleaning/disinfecting agent validated for use on dental instruments. Follow the agent manufacturer's instructions.
3. Special care should be taken to clean crevices, holes and other hard-to-reach areas thoroughly.
4. Perform final thorough rinse and visual inspection to confirm the removal of debris. Repeat the cycle if needed.
5. Dry using a lint-free wipe or clean compressed air.
6. Inspect for damage or wear that could prevent proper function.

STERILIZATION GUIDELINES:

• Scope

The SpaceFile™ Interproximal Reduction Kit should be sterilized before and after each use.

• Packaging

1. Remove the inner tray from the outer case by pulling up on the tab. **DO NOT STERILIZE THE OUTER CASE.**
2. Pack the Grip and/or SpaceFiles™ in the insert.
3. Insert in pouches validated for sterilization.

• Steam Sterilization Procedure

Cycle Type	Minimum Sterilization Exposure Time	Minimum Sterilization Exposure Temperature	Minimum Dry Time
Gravity	10 minutes	134° (+3) C or 274° (+5.4) F	15 minutes

• Storage

The device should be stored in the sterilization pouch until required.

• Additional Information

These cleaning and sterilization processes have been validated as being capable of preparing the SpaceFile™ Interproximal Reduction Kit for use. Any deviation from these instructions should be properly validated for effectiveness and potential adverse results.



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RTE-102-12 ENG #MKSF Rev. 05/12