

Device Technical File

ContactPro® Matrix System Instructions for Use

1.0 Product Description

- A. For placement of restorations in the posterior area of the oral cavity, the Microbrush ContactPro® Sectional Matrix System includes:
 - 1. ContactPro® sectional matrix ring
 - 2. Smartband® matrix bands (coated or plain)
 - 3. Wedges
 - 4. Matrix ring forceps
 - 5. Matrix band tweezers
- B. Matrix bands are suitable for use with all posterior restorative materials.
- C. Either one matrix ring may be used for the restoration, or multiple rings may be stacked together for performing MODs and multiple-tooth restorations.
- D. The advantages of the Microbrush ContactPro® Sectional Matrix System include:
 - 1. Consistent results with the ring made out of exclusively engineered memory metal
 - 2. Easy to open with a strong grip around the tooth
 - 3. Stackable
 - 4. Wide visibility
 - 5. Secure fit along the gingival margin for better overall adaptation
 - 6. Adaptable tips
 - 7. Better access for light curing
 - 8. More comfort for the patient and practitioner.

1.1 System Components

- A. Sectional Matrix Ring
 - 1. The Microbrush ContactPro® matrix Ring is for use in the posterior region of the oral cavity.
 - 2. It can be used either as a single ring or multiple rings stacked together for performing MODs and multiple-tooth restorations.

B. Matrix Bands

1. The coated versions of the Microbrush Smartband® matrix bands come in a variety of sizes, each with its own identifying color:
 - a. 3.5 mm (White)
 - b. 4.5 mm (Green)
 - c. 5.5 mm (Blue)
 - d. 6.5 mm (Red)
 - e. 7.5 mm (Gray)
2. Uncoated sizes are the same as the coated sizes and have a natural silver appearance.
3. Microbrush Smartband® matrix bands are suitable for use with all posterior restorative materials.

C. Wood Wedges

1. Sizes:
 - a. Extra small (Pink)
 - b. Small (Blue)
 - c. Medium (Green)
 - d. Large (Yellow)
2. The wedges are anatomically shaped for optimum adaptation along the tooth cervical margin.

1.2 Materials

- A. Sectional matrix ring: nickel-titanium and silicone
- B. Matrix bands: polished stainless steel with or without non-stick coating
- C. Wedges: maple wood
- D. Matrix ring forceps: stainless steel
- E. Matrix band tweezers: stainless steel

1.3 Indications

- A. The Microbrush ContactPro® Sectional Matrix System is indicated for Class II restorations to facilitate the direct placement of restorative materials.

1.4 Contraindications

- A. None known

2.0 General Safety Notes

- A. Be aware of the following safety notes in other chapters of these directions for use.

B. Always visit www.microbrush.com for the latest Instructions for Use.

Safety Alert Symbol

This is the safety alert symbol. It is used to alert you to potential personal injury hazards. Obey all safety messages that follow this symbol to avoid possible injury.

2.1 Warnings

- A. The Microbrush ContactPro® Sectional Matrix System consists of small parts. As with all intra-oral devices, care must be exercised to ensure stable handling and placement.
1. Wear applicable protective eyewear and gloves.
 2. Placement of a rubber dental dam is strongly recommended to prevent the potential for inhalation or ingestion of such parts.
 3. To avoid inadvertent swallowing or aspiration of the ring should it unexpectedly come loose from its seated position, tying the ring to a previously placed rubber dam clamp with dental floss is recommended.
 4. **Aspiration:** If aspiration of matrix band, wedge or retaining ring occurs, seek immediate medical attention.
 5. **Ingestion:** If accidental swallowing occurs, encourage patient to seek medical assistance to locate swallowed part. If nausea or illness develops, seek medical attention immediately.
 6. **Laceration:** Handling matrix bands with gloved hands and/or cotton dressing forceps or similar instrument is recommended. In the unlikely event a clean matrix band causes a skin laceration, employ usual first aid measures. Discard and properly dispose of matrix band.
 7. Used matrix bands and accessories are to be considered contaminated. Follow proper exposure control plans.
 - a. In the event of an accidental exposure, follow recommended post-exposure procedures.
 - b. Following the use of the Microbrush ContactPro® Sectional Matrix System, proper handling and disposal techniques are required.
 - c. Use precautions when handling or disposing contaminated items.
- B. Care should be taken to have good control of any instrument during use in order to protect patients from injury.

2.2 Precautions

- A. This product is intended to be used only as specifically outlined in the Instructions for Use. Any use of this product inconsistent with the Instructions for Use is at the discretion and sole responsibility of the practitioner.
- B. Care must be taken when placing the retaining ring. Ensure ring is fully seated in forceps.

- C. Excessive pressure on matrix, wedge, or retaining ring in an apical direction may result in injury to periodontal tissues.
- D. This product is provided in a non-sterile condition.
- E. Devices marked “single use” on the label are intended for single use only. Discard after use. Do not reuse in other patients in order to prevent cross-contamination.
- F. It is recommended that the tools supplied with the Microbrush ContactPro® Sectional Matrix System be used with the matrix rings and bands to reduce chances of injury.

2.3 Adverse Reactions

- A. Product misuse may cause failure resulting in respiratory, digestive, eye, skin, or mucosa injury. (See Sections 1.4 Contraindications, 2.1 Warnings, and 2.2 Precautions)
- B. Failure to properly employ accepted handling and disposal techniques may present biohazard. (See Sections 2.1 Warnings and 2.2 Precautions)

2.4 Pre-operative Sterilization

- A. Matrix bands are supplied non-sterile and are for single use only. Prior to clinical use, they should be cleaned with a mild detergent and then steam autoclaved one time at 121°C for 15 minutes, followed by a 25 minute air drying time.
- B. The matrix ring, forceps, and tweezers are supplied non-sterile, and they should be steam autoclaved prior to first and each subsequent use.

3.0 Instructions

3.1 Isolation of the Area

- A. Isolation of the area helps to prevent contamination from blood and saliva.
- B. As with many dental procedures, aspiration of small parts is a valid concern.
 - 1. Placement of a rubber dental dam is mandatory to prevent the potential for inhalation or ingestion of such parts.
 - 2. To avoid inadvertent swallowing or aspiration of the ring (should it unexpectedly come loose from its seated position), tying the ring to a previously placed rubber dam clamp with dental floss is recommended.
- C. Pre-Operative Placement of Ring for Separation (Optional)
 - 1. To effectively use a contoured matrix band, there must be enough interproximal space to position the matrix without force or distortion.

2. When placed prior to and left on during cavity preparation, the matrix ring creates the interproximal space required for matrix band placement.
- 3.2 Cavity Preparation
 - A. Complete preparation as usual.
 - B. After preparation is complete, follow the matrix band placement (Step 3.3), wedge placement (Step 3.4) and matrix ring placement (Step 3.5) instructions.
 - 3.3 Matrix Band Placement
 - A. Select a matrix band that most closely approximates the occlusogingival height of the tooth.
 - B. Using Microbrush ContactPro® tweezers, grasp the tab at the top-center area of the matrix band. Over-approximate tooth curvature buccolingually by rolling the matrix band with your fingers. This will help keep the band ends from interfering with the ring placement.
 - C. The matrix band should be oriented with the convex edge towards the gingival margin of the tooth, and the tab on top.
 1. The matrix band's placement tab may be bent over the adjacent marginal ridge to facilitate restoration marginal ridge contour.
 2. Ensure matrix band is apical to preparation margin with no gap.
 - 3.4 Wedge Placement
 - A. For optimal contour, gingival seal, and tooth separation, use Microbrush ContactPro® wedges, which are available in 4 sizes ranging from extra small to extra large.
 - B. Keep a finger on the matrix band placement tab to prevent the wedge from dislodging the matrix band during insertion.
 - C. As a high viscosity resin packed into the preparation may displace the matrix band away from the tooth, firmly insert the wedge.
 - 3.5 Matrix Ring Placement
 - A. For secure gripping of the matrix ring tips to the surfaces, dry the teeth thoroughly before placement.
 - B. Grasp the Microbrush ContactPro® matrix ring near the tips of the ring with the dedicated matrix ring forceps supplied, being sure the ring rests within the channels on the forceps tips.
 - C. Spread the matrix ring with the forceps only enough to clear tooth height of contour.

1. Do not over-expand the matrix ring. Over-expansion may result in permanent ring deformation.
 2. The locking slide on the forceps may be engaged to facilitate carrying and placement of the ring.
- D. To avoid hitting and possibly dislodging the matrix band when placing the ring, bring the matrix ring down at an angle over the adjacent tooth and then flatten out the ring as you place it into the interproximal space and over the top of the wedge.
- E. Place the matrix ring with the center of each tine in each interproximal space from buccal to lingual adjacent to the surface to be restored.
1. The direction the ring points, mesially or distally, does not matter. However, it may be easier to place it such that the ring points mesially because that side can be easier to access.
 2. The matrix ring needs to sit along the gingiva so that the tips grip the tooth below the height of the tooth contour.
- F. After aligning the slots on the bottom of the matrix ring tips with the wedge, fit the ring over the wedge.
- G. With the tips properly positioned interproximally, release the locking slide on the forceps and slowly release the tension on the forceps.
- H. When the matrix ring is securely seated, release the forceps completely and withdraw them.
- I. To avoid inadvertent swallowing or aspiration of the ring (should it unexpectedly come loose from its seated position), tying the ring to a previously placed rubber dam clamp with dental floss is recommended.
- 3.6 Contouring to Adjacent Tooth
- A. To form proper contours, it is important to push the matrix band firmly into contact with the adjacent tooth in the desired contact area.
- B. The matrix band's placement tab may be bent over the adjacent marginal ridge to facilitate restoration marginal ridge contour.
- ⚠ Small parts under tension**
1. Be sure the matrix ring is securely seated in the forceps before introducing into the patient field.
 2. Be sure the matrix ring is securely seated apically before withdrawing the forceps.

3.7 Restorative Application

- A. Use your preferred etching, disinfecting and bonding technique following manufacturer's instructions.
- B. Apply your preferred restorative material following manufacturer's instructions. Light cure and/or allow material to reach initial set.
- C. Gross contouring may be accomplished with matrix band in place.

3.8 Removal

- A. Remove matrix ring using the supplied dedicated matrix ring forceps.
- B. Remove wedge and matrix band using the supplied matrix band tweezers or similar instrument.

3.9 Finishing

- A. Finish the contouring.
- B. Verify the proximal contact.
- C. Polish the restoration.

4.0 Hygiene

4.1 Cleaning:

- A. The Microbrush ContactPro® ring placement forceps and ring may be cleaned by scrubbing with a disposable towel soaked with hot water and soap or detergent.

4.2 Sterilization:

- A. The Microbrush ContactPro® matrix ring, ring forceps, and band tweezers should be steam autoclaved at 121°C for 15 minutes, followed by air drying for 25 minutes.
- B. Use of other sterilization procedures or methods is at the discretion and sole responsibility of the practitioner.
- C. It is not recommended to immerse components into disinfection or cold sterilization solutions.
- D. Microbrush ContactPro® matrix bands and wedges are supplied non-sterile and are for single use only. Sterilize for use by steam autoclaving, 121°C for 15 minutes, followed by air drying for 25 minutes.

4.3 Post Sterilization

- A. Allow matrix ring, ring forceps, and band tweezers to dry prior to storage.
- B. The forceps require no additional maintenance and should not be oiled or greased.

Disposal of Single-use Components and Sterilization

To prevent cross-contamination:

1. Do not reuse matrix bands or wedges in a different patient.
2. Do not attempt to sterilize used matrix bands or wedges.
3. Properly dispose of the used and/or contaminated matrix bands and/or wedges in accordance with local regulations.

5.0 Part identification

- 5.1 The following numbers should be quoted in all communications with Microbrush International:
 - A. Kit or part number
 - B. Lot number on the package

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