



US

INSTRUCTIONS FOR USE

Premier® X5 Sectional Matrix System™

Comprehensive Solution for Class 2 Interproximal Restorations



premier® Inspired solutions
for daily dentistry®



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Intended Use:

Premier X5 Sectional Matrix System™ is indicated for all Class II composite resin restorations.

Description of Device & Contents:

The Premier X5 Sectional Matrix System™ employs a proprietary resin retaining ring, 3 sizes of interproximal wedges, and 4 sizes of sectional matrices for placement of restorations in the posterior region. There are two instruments designed to assist with the placement of the components. The Pin Holder for the matrices and wedges and forceps for the retaining ring.

Contraindications:

Do Not use if:

- There are not two adjacent teeth where the X5 ring can be placed securely
- There is moderate to severe tooth misalignment that would prohibit the secure seating of the X5 ring

PRECAUTIONS:

Care must be taken when placing the ring into the forceps.

Excessive pressure on matrix, wedge, or retaining ring in an apical direction may result in injury to periodontal tissues.

Premier X5™ rings offer tooth separation for creation of ideal interproximal contact creation.

Recommended ring use is 5 sterilization cycles before discarding. Excessive clinical use may result in insufficient interproximal separation force, resulting in less desirable clinical results.

Wedges and Matrices are single-use. DO not autoclave or reuse.

Do not use instruments or accessories other than those designed, supplied, and/or outlined for use with the X5 Sectional Matrix system. Injury may result.

WARNINGS:

1. The Premier X5 Sectional Matrix System consists of small, sharp parts. As with all intraoral instruments, care must be exercised to ensure stable handling and placement. Placement of rubber dam or other suitable isolation is advised prior to operative procedures. Wear appropriate protective eyewear and gloves.

Aspiration: If aspiration of matrix, wedge, or retaining ring occurs, seek immediate medical attention.

Ingestion: If accidental swallowing occurs, encourage patient to seek medical assistance to locate swallowed part. If nausea or illness develop, seek medical attention immediately.

Laceration: The matrices may cut unprotected skin. Handling matrices with gloved hands and/or pin tweezers or similar instrument is recommended. In the event a clean matrix causes a skin laceration, employ usual first aid measures. Discard and properly dispose the matrix.

2. Used matrices and accessories are contaminated. Follow proper exposure control plans. In the event of an accidental exposure, follow recommended post-exposure procedures. Following use of the Premier X5 Sectional Matrix, proper handling and disposal techniques are required. Used matrices are contaminated and sharp. When handling or disposing, use precautions as when handling or disposing other contaminated sharps.
3. Care should be taken to have good control on any instrument to protect patients from injury.

Adverse Reactions:

Product misuse may cause failure resulting in respiratory, digestive, eye, skin, or mucosa injury. (See Contraindications, Warnings and Precautions)

Failure to properly employ accepted handling and disposal techniques may present biohazard. (See Warnings and Precautions)

If a serious incident has occurred in relation to the device, please report the incident to the Manufacturer and/or competent authority of the Member State where the device was used.

Product Safety & Clinical Tips:

- Prior to use always isolate with rubber dam to prevent potential for aspiration of Premier X5 components. Seek immediate medical attention should inhalation or ingestion occur.
- Premier X5™ matrices and wedges are designed for single use only. Do not autoclave or reuse.
- Ring placement: For added security and possible retrieval, prior to placement, feed dental floss through the holes in the Premier X5™ ring. Improve efficiency by allowing dental assistant to pre-load Premier X5™ ring onto the ring placement forceps.
- Wedge & matrix placement: Both wedges & matrices can be accurately placed & pre-loaded using the Pin-Holders. When using the Pin-Holders, squeeze them at the back to open them and near the tip to increase the pressure on the wedges.

Directions for Use:

1. Placement of Matrix. Select matrix based on the approximate occlusogingival height. Place prongs of Pin-Holder through corresponding holes in the matrix with the gold side visible to easily disengage the instrument once the matrix is in place.

When placing the matrix before the wedge, place a finger at the occlusal aspect of the matrix to hold it in place & prevent it from dislodging, or use Pin-Holder to secure matrix, proceed with wedge placement. **(Figure 1)**

Fold the matrix tab towards you so you can insert the matrix apically into the gingival crevice & adjust matrix to the proper height to

obtain ideal benefit from the contour of matrix. (Figure 2)

2. Placement of Premier X5™ Ring. Use the ring forceps to grasp and slightly expand the ring. Carefully place the ring as low as possible with the tines of the ring close to the gingival margin and straddling the wedge(s). (Figure 3)

When you are ready to release the ring from the Ring Forceps, place your finger and press down on the matrix tab to prevent any unwanted movement. (Figure 4) Premier X5™ Ring in the ideal position from a buccal view. (Figure 5)

Dual-Wedging: The Premier X5™ system allows for the insertion of a second wedge, to prevent any leakage, to be placed from the opposite side without removing the ring. The second wedge should be inserted underneath the first wedge. (Figure 6)

Mesial & Distal Ring Placement: The ring may be placed mesially

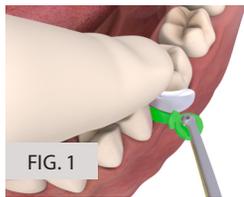


FIG. 1

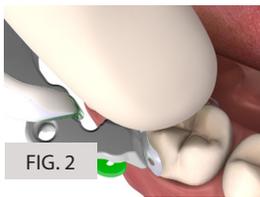


FIG. 2



FIG. 3

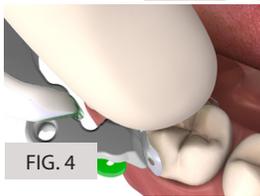


FIG. 4



FIG. 5



FIG. 6

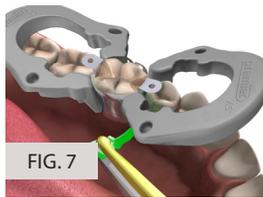


FIG. 7

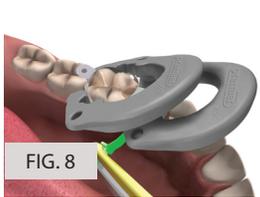


FIG. 8

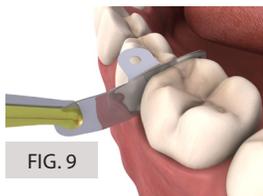


FIG. 9

and/or distally for better access such as the case with MOD restoration. (Figure 7)

Dual-Mesial Ring Placement: Premier X5™ ring may be stacked over each other for better access such as the case with MOD restoration. (Figure 8)

3. Perform Restoration: Proceed to fill entire cavity preparation with desired composite material.

4. Premier X5™ Removal: Remove ring using Ring Forceps, remove wedge(s) using Pin-Holder, separate matrix from composite using a thin bladed instrument by pushing the instrument into the embrasure. Fold matrix wings backwards and cure composite again from buccal and lingual surfaces. Remove matrix with Pin-Holder; grip one of the matrix holes with the Pin-Holder and gently wiggle the matrix out. (Figure 9)

If needed, you may use another Pin-Holder on the “opposite” side of the matrix and move the matrix back and forth, or upward, until loose.

5. Contour & Polish Final Restoration.

Cleaning: Manual Cleaning

1. Prepare enzymatic solution per manufacturer’s recommendation.
2. Using a lint-free cloth dampened with the prepared detergent thoroughly wet the rings and instruments with the prepared detergent.
 - If needed, using a soft bristled brush, brush the ring until all visible soil is removed
3. Rinse the rings and instruments under potable running tap water for a minimum of 30 seconds to remove detergent residue.
4. Dry the rings and instruments using a clean lint-free cloth.
5. Visually inspect each rings and instruments for visible soil. If soil is seen, repeat the cleaning procedure.

Reprocessing: Steam Autoclave Sterilization

1. Place each ring and instrument in a separate paper/plastic steam-sterilizing pouch. If using a sterilizing cassette, ensure that the sterilizer’s maximum load is not exceeded.
2. Place bagged rings and instruments into a steam autoclave, per the autoclave manufacturer’s instructions.
 - Gravity Steam Sterilization - Full Cycle: 135°C (275°F) for 10 minutes
 - Pre-vacuum Steam Sterilization - Full Cycle: 132°C (270°F) for 4 minutes
3. To dry, use the drying cycle of the steam autoclave. Set cycle for 20 to 30 minutes. Do not exceed 137°C (278°F).
4. Visually inspect to ensure that all contamination has been removed. Check for distortion, damage or wear. Discard damaged or worn rings.

NOTE: The rings and instruments should remain bagged until ready for use.

Disposal:

After procedure the wedge(s) and matrices should be disposed of accordingly.

For Further Information:

To obtain SDS or IFU, visit premierdentalco.com or call Premier at 610-239-6000.

| Symbols | Symbol Meaning |
|----------------|---|
| | Manufacturer |
| Rx ONLY | CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician |
| | Batch number |
| | Reorder number |
| | Medical device |
| | See IFU on premierdentalco.com |
| | UKCA |