

# R-Matrix

## Sectional Matrix

### DIRECTIONS FOR USE – ENGLISH

Caution: For dental use only.

USA: Rx only.

#### 1. PRODUCT DESCRIPTION

The R-Matrix Matrix System is designed to be used as a matrix to contain direct-placement restorative materials in posterior cavities involving proximal surfaces. The single-use, disposable R-Matrices allow proper subgingival and proximal contact adaptation while protecting against cross-contamination.

##### 1.1 INDICATION

The R-Matrix Matrix System is indicated where placement of a matrix band around a prepared tooth will facilitate contouring of a direct placement restorative material (e.g., Class II preparations).

##### 1.2 CONTRAINDICATIONS

None Known.

##### 1.3 DELIVERY FORMS

R-Matrix are available in one thin gauge (thickness) in 4 heights: 3.5mm, 4.5mm, 5.5mm, 6.5mm to fit a wide range of tooth sizes and shapes.

Separator Wedges are available in 4 sizes: Small, Medium, Large, Extra Large.

##### 1.4 COMPOSITION

- Matrix Bands: Polished stainless steel.
- Dental Wedges: Polyacetyl Thermoplastic.

### 2. GENERAL SAFETY NOTES

Be aware of the following general safety notes and the special safety notes in other chapters of these directions 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

1. The R-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 suitable protective eyewear and gloves.
2. Aspiration: If aspiration of band or any part occurs seek immediate medical attention.
3. Ingestion: If accidental swallowing occurs, encourage patient to seek medical assistance to locate swallowed part. If nausea or illness develop, seek medical attention immediately.
4. Laceration: R-Matrix bands are sharp, and may cut unprotected skin.
5. Handling bands with gloved hands is recommended. In the event a clean band causes a skin laceration, employ usual first aid measures. Discard and properly dispose of band.
6. Used matrix bands are contaminated. Follow proper exposure control plans. In the event of an accidental exposure, follow recommended post-exposure procedures. Following use of R-Matrices, proper handling and disposal techniques are required. Used matrix bands are contaminated and sharp. When handling or disposing, use precautions as when handling or disposing other contaminated sharps.

#### 2.2 PRECAUTIONS

1. This product is intended to be used only as specifically outlined in the Directions For Use. Any use of this product inconsistent with the Directions For Use is at the discretion and sole responsibility of the practitioner.
2. Devices marked "single use" on the labeling are intended for single use only. Discard after use. Do not reuse in other patients in order to prevent cross-contamination.
3. Avoid placing excessive pressure in an apical direction when placing or on placed bands. Apical force may result in injury to periodontal tissues. (See Warnings)

#### 2.3 ADVERSE REACTIONS

1. Product misuse may cause failure resulting in respiratory, digestive, eye, skin, or mucosa injury. (See Contraindications, Warnings and Precautions)
2. Failure to properly employ accepted handling and disposal techniques may present biohazard. (See Warnings and Precautions)

#### 2.4 STORAGE

Store R-Matrix at room temperature, away from moisture or excessive humidity.

#### Small parts-ingestion/inhalation

- Recover all pieces from the mouth immediately.



### 4. HYGIENE

#### Cross-contamination

- Do not reuse single use products.
- Dispose of in accordance with local regulations.



Sterilization of matrices and wedges pre-use (if desired) may be accomplished as outlined below:

Limitations on processing	Cold liquid immersion disinfection/sterilization, automated washer/disinfection have not been tested or validated for efficacy and are not recommended for use. Discard when corrosion and/or damage is noticed.
Packaging	Paper/plastic steam sterilization pouches may be used but are not required
Sterilization	Steam autoclaving: Pre-vacuum: Full cycle 132°C, 4 minutes Follow manufacturer's instructions for loading and operation cycle
Drying	Use the drying cycle of the autoclave, minimum 30 minutes.
Storage	Ensure the sterilized package is completely dry before storing. Store at room temperature, away from moisture or excessive humidity and ensure sterilization pouch/container is not compromised. Instruments steam autoclaved unwrapped should be used immediately.

### LOT NUMBER AND CORRESPONDENCE

The following should be quoted in all correspondences:

- Lot number on the package
- Copy of proof of purchase

Any serious incident in relation to the product should be reported to the manufacturer and the competent authority according to local regulations.



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