



Bioclear Sectional Rings Instructions For Use (IFU)

These instructions apply to all Bioclear Sectional Rings (see list of rings at the end of the document)

Indications:

The Bioclear Sectional Ring (in all its variations) is indicated for all posterior restorations where separation by a sectional ring is needed. Designed for use in sectional Class II matrix adaption to help secure the matrix and create tight seals at the margins to contain uncured composite as it is applied. Please see the posterior matrix system technique guide in the general instructions for further details on how to use the rings.

Contraindications:

The Bioclear Sectional Rings are not intended for longer than transient use or permanent implants and is not intended for any procedure outside of the oral cavity.

Intended Purpose:

The Bioclear Sectional Rings designed for use in sectional Class II matrix adaption to help secure the matrix and create tight seals at the margins to contain uncured composite as it is applied until it has been cured when performing composite restorations, such as closing open gingival embrasures, filling cavities, etc.. Contact with the patient is intended to be transient, meaning less than an hour (60 minutes) and the ring should be removed after the composite has been cured. The rings are placed interproximally to help separate the teeth during the restoration and hold the matrix tightly in place to give a natural, anatomic emergence profile and reduce the finishing required in the interproximal. Sectional Rings are invasive through a body orifice, specifically orally, but do not penetrate past the pharynx.

Safety:

To offer your patients the safest, most comfortable procedure possible, carefully read the enclosed instructions and watch the tutorials on the website prior to use.

Note: Please check www.bioclearmatrix.com to find the most recently updated instructions and tutorials.

Warnings:

The Bioclear Sectional Ring is a small component. Use of a rubber dam is mandatory to prevent inhalation of parts. Use the Bioclear Twin Ring Forceps when seating and removing the Sectional Ring to ensure stability and control of the ring during use.





Please note: that the Sectional Rings are under tension. Make sure that they are appropriately placed on the Twin Ring Forceps prior to insertion or removal and that the rings are seated firmly prior to removing the forceps.

Aspiration:

Seek immediate medical attention if any part is inhaled.

Handling:

To protect patients from injury, please take care to remain in full control of all instruments and devices at all times.

It is recommended that you use ONLY accessory tools designed, supplied, and/or outlined for use with the Bioclear Matrix Posterior System as listed in the general posterior instructions.

Precautions:

Bioclear Matrix offers instructions and classes for using these products. Any use not specified in the instructions is not recommended and will be the responsibility of the attending practitioner.

Storage:

Store in a clean, dry environment at temperatures between 10-24C/50-75F, away from sunlight, moisture, excess humidity, flame or sources of ignition.

Hygiene:

Sectional Rings are reusable and can be autoclaved and/or sterilized.

Used Sectional Rings are contaminated. Appropriate precautions should be taken to clean and sterilize according to standard procedures listed here and in the general instructions.

Avoid Cross Contamination

Pre-Sterilization:

Rinse any contaminants from the Sectional Ring.

Use warm water and a soft nylon brush to gently wash the ring and then rinse in warm water.

Do NOT use alcohol wipes or other cold sterilizations methods – this will void the warranty.

Automated Washer Disinfector:

Rings can also be reused by cleaning them in a washer-disinfector.

Only properly maintained, calibrated, and approved washer-disinfectors should be used in accordance with ISO 15883-1.

Place tools in the washer-disinfector in such a manner as to allow the water and detergent to





enter and drain from device openings.

Follow washer-disinfector's Instructions for Use.

Run washer-disinfector program with A0 value > 3000 (e.g. 5 min at > 90C) using appropriate detergents. Rings can be reprocessed by washer-disinfector up to 500 times

Sterilization:

To ensure proper sterilization, prior to first use, and after every use thereafter, the Sectional Ring should be steam-autoclaved at 134C/273F for at least 3 minutes. Rings should not be left in the autoclave for long periods as this may result in staining from the autoclave itself.

Please note: Do NOT use chemical sterilization or ultrasonic cleaning techniques: the warranty will be voided if chemical sterilization or ultrasonic cleaning is used.

Sterilization methods other than steam are NOT recommended by Bioclear Matrix and, if used, are the sole responsibility of the practitioner.

Post Sterilization:

Allow the Sectional Rings to fully dry prior to storage.

Transport

Avoid prolonged transport in extremely high or low temperatures. Recommended transport temperatures are 20F (-7C) to 100F (38C). Moisture does not affect the product. Do not transport in direct sunlight.

Discard

Disposal must be carried out in accordance with current legislation and local regulations.

Composition:

See Ring Safety Data Sheet (SDS). It can be found online at www.bioclearmatrix.com/resources/ifu-sds/

How to use:

See Technique Guide for the matrix system you are using. It can be found online at www.bioclearmatrix.com/resources/ifu-sds/

Warranty

Sectional Rings do have a warranty of 6 months from the date of purchase. If the product is defective upon arrival or breaks during normal usage during the warranty, contact your local representative for a replacement.





Limitation of Liability

Sectional Rings are intended to be used by educated dental professionals, e.g., general dentists, dental assistants, dental hygienists, who have theoretical and practical knowledge on usage of dental products only. Any use not specified in the instructions is not recommended and will be the responsibility of the attending practitioner.



Manufacturer:

Bioclear Matrix Systems, LLC
3901 S Fife Street, Suite 100
Tacoma, WA 98409
USA
Ph: 855-712-5327

Origin: Made in the USA

Any serious incident (defined in the regulation (EU) 2017.745 as an adverse event that results in death or serious deterioration in the health of the subject) that has occurred in relation to the use of this device should be reported both to the manufacturer immediately either by mail at the address above or by email to jennifer@bioclearmatrix.com as well as to the competent authority of the Member State in which the user or patient is established. After we receive the information on the incident, Bioclear will also report it to the FDA and the EU Competent Authority and follow up as necessary.

Importer:

Find the importer for your country on our website at www.bioclearmatrix.com



EMERGO EUROPE B.V.
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands



Harmonized Symbols:





This IFU Applies to the Following Sectional Rings:

REF	Product Name
208011	TwinRing - Molar
208021	TwinRing - Premolar
208042	TwinRing - Universal

IFU Revision Date: December 1, 2023

