



Bioclear Wedges Instructions For Use (IFU)

These instructions apply to all Bioclear Wedges (see list of wedges at the end of the document)

Indications:

The Bioclear Wedge (in all its variations) is indicated for all anterior and posterior restorations where tooth separation by wedge is needed. Please see the matrix system guide in the general instructions for guidance on which shaped matrix to use in each case.

Contraindications:

The Bioclear Wedges 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 Wedges are for placement between teeth to aid in tooth separation, securing the matrix, and creating a tight margin 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 wedge should be removed after the composite has been cured. The wedges are placed through an embrasure and are shaped to give a natural, anatomic emergence profile and reduce the finishing required in the interproximal. Wedges 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 Wedge is a small component. Use of a rubber dam is mandatory to prevent inhalation of parts.

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 System as listed in the general anterior or 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.

Wedges are for SINGLE USE ONLY and can not be autoclaved or sterilized.

Used wedges are contaminated. Appropriate precautions should be taken to discard according to standard procedures for sharps.

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.

Hygiene:

Avoid Cross Contamination

Bioclear Wedges are single use ONLY and should be appropriately disposed of in accordance with local regulations.

Composition:

See Wedge 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

Wedges are intended for transient, single-use and so do not carry an extended warranty. If the





product is defective upon arrival, contact your local representative for a replacement.

Limitation of Liability

Wedges 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 Wedges:

REF	Product Name
112011	Diamond Wedge - Small
112021	Diamond Wedge - Medium
112031	Diamond Wedge - Large
112041	Diamond Wedge - Extra Large
112051	Diamond Wedge - Deep Caries
112061	Long Diamond Wedge - Small
112071	Long Diamond Wedge - Medium
112081	Long Diamond Wedge - Large
112091	Long Diamond Wedge - Extra Large
112101	Long Diamond Wedge - Furcal

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