

Bioclear Matrices Instructions For Use (IFU)

These instructions apply to all Bioclear Matrices (see list of matrices at the end of the document)

Indications:

The Bioclear Matrix (in all its variations) is indicated for all anterior and posterior restorations where composite or amalgam is needed and the matrix will give a natural emergence profile and reduce finishing in the interproximal. Please see the matrix guide in the general instructions for guidance on which shaped matrix to use in each case.

Contraindications:

The Bioclear Matrices 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 Matrices are used as a mold to help form and hold composite in place 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 matrix should be removed after the composite has been cured. The matrices are placed interproximally and are shaped to give a natural, anatomic emergence profile and reduce the finishing required in the interproximal. Matrices 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 Matrix is a small, sharp component. Use of a rubber dam is mandatory to prevent inhalation of parts. Use of gloves and/or pliers are recommended to prevent lacerations.

Aspiration:

Seek immediate medical attention if any part is inhaled.

Laceration:

If laceration occurs by a clean matrix, use appropriate first aid measures and then discard the matrix according to local regulations. If laceration occurs by an unclean matrix, recommended post-exposure procedures should be taken in addition to the appropriate first aid treatment.

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.

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

Used matrices 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 Matrices are single use ONLY and should be appropriately disposed of in accordance with local regulations.

Composition:

See Matrix Safety Data Sheet (SDS). It can be found online at <https://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 <https://www.bioclearmatrix.com/resources/ifu-sds/>

Warranty

Matrices 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

Matrices 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 contactus@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 Matrices:

REF	Product Name
301011	Original Matrix A101 Upper Mesial
301021	Original Matrix A102 Upper Distal
301031	Original Matrix A103 Small Incisor Universal
301041	Original Matrix A104 Canine Mesial
301051	Original Matrix A105 Canine Distal
320011	HD Matrix A101 Upper Mesial
320021	HD Matrix A102 Upper Distal
320031	HD Matrix A103 Small Incisor Universal
320041	HD Matrix A104 Canine Mesial
320051	HD Matrix A105 Canine Distal
302011	Original Matrix DC201 Upper Mesial
302021	Original Matrix DC202 Upper Distal
302031	Original Matrix DC203 Small Incisor Universal
302041	Original Matrix DC204 Extra Large Mesial
319011	HD Matrix DC201 Upper Mesial
319021	HD Matrix DC202 Upper Distal
319031	HD Matrix DC203 Small Incisor Universal
317011	Veneer Matrix
301061	BT Matrix Small Incisor Blue
301062	BT Matrix Large Incisor Blue
301071	BT Matrix Small Incisor Green
301072	BT Matrix Large Incisor Green

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301081	BT Matrix Small Incisor Yellow
301082	BT Matrix Large Incisor Yellow
301091	BT Matrix Small Incisor Pink
301092	BT Matrix Large Incisor Pink
303011.B	Original Posterior Matrix B301 Avg Flat Biscupid Blue
303011.C	Original Posterior Matrix B301 Avg Flat Biscupid Clear
303021.B	Original Posterior Matrix B302 Avg Biscupid Blue
303021.C	Original Posterior Matrix B302 Avg Biscupid Clear
303031.B	Original Posterior Matrix B303 Avg Curved Bicuspid Blue
303031.C	Original Posterior Matrix B303 Avg Curved Bicuspid Clear
304011.B	Original Posterior Matrix M401 Avg Flat Molar Blue
304011.C	Original Posterior Matrix M401 Avg Flat Molar Clear
304021.B	Original Posterior Matrix M402 Avg Molar Blue
304021.C	Original Posterior Matrix M402 Avg Molar Clear
304031.B	Original Posterior Matrix M403 Tall Flat Molar Blue
304031.C	Original Posterior Matrix M403 Tall Flat Molar Clear
304041.B	Original Posterior Matrix M404 Tall Avg Molar Blue
304041.C	Original Posterior Matrix M404 Tall Avg Molar Clear
304051.B	Original Posterior Matrix M405 Universal Posterior Blue
304051.C	Original Posterior Matrix M405 Universal Posterior Clear
304061.B	Original Posterior Matrix M406 Avg Curved Molar Blue
304061.C	Original Posterior Matrix M406 Avg Curved Molar Clear
305011	Biofit Blue Matrix Molar 4.5
305021	Biofit Blue Matrix Molar 5.5

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305031	Biofit Blue Matrix Molar 6.5
306011	Biofit SS Matrix Molar 4.5
306021	Biofit SS Matrix Molar 5.5
306031	Biofit SS Matrix Molar 6.5
318011	Biofit HD Matrix Molar 4.5
318021	Biofit HD Matrix Molar 5.5
318031	Biofit HD Matrix Molar 6.5
318041	Biofit HD Matrix Premolar 5.5
327012	Bioclear Evolve Matrix Blue 5
327022	Bioclear Evolve Matrix Blue 6
327032	Bioclear Evolve Matrix Blue 7
327042	Bioclear Evolve Matrix Blue 8
327052	Bioclear Evolve Matrix Blue 9
327071	Bioclear Evolve Matrix Pink 6
327081	Bioclear Evolve Matrix Pink 7
327101	Bioclear Evolve Matrix Pink 9
327131	Bioclear Evolve Matrix Orange 6
327141	Bioclear Evolve Matrix Orange 7
327151	Bioclear Evolve Matrix Orange 9
327211	Bioclear Evolve Matrix Premolar 5
327221	Bioclear Evolve Matrix Premolar 6
327231	Bioclear Evolve Matrix Premolar 7
327241	Bioclear Evolve Matrix Premolar 8
327261	Bioclear Evolve Matrix Premolar 10

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328011	TSS, #6 M
328021	TSS, #6 D
328031	TSS, #7 M
328041	TSS, #7 D
328051	TSS, #8 M
328061	TSS, #8 D
328071	TSS, #9 M
328081	TSS, #9 D
328091	TSS, #10 M
328101	TSS, #10 D
328111	TSS, #11 M
328121	TSS, #11 D
328131	TSS, Lower Incisor, Small
328141	TSS, Lower Incisor, Medium

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