



Bioclear Metal Instrument Instructions For Use (IFU)

These instructions apply to all Bioclear Metal Instruments (see list of instruments at the end of the document)

Indications:

The Bioclear Metal Instruments are intended to be used during dental caries restoration procedures using composite as well as some aesthetic procedures, such as closing open gingival embrasures, closing open diastemas, etc.. Please see the matrix system technique guide in the general instructions for further details on how to use the Metal Instruments.

Contraindications:

The Bioclear Metal Instruments 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 Metal Instruments are intended to be used during dental caries restoration procedures using composite as well as some aesthetic procedures, such as closing open gingival embrasures, closing open diastemas, etc.. The instruments are used to perform functions such as examine teeth, manipulate other dental devices (such as matrices, wedges, rings, etc.), etc.. Contact with the patient is transient, meaning less than an hour. Bioclear Metal Instruments are invasive through a body orifice, specifically orally, but do not penetrate past the pharynx. Bioclear Metal Instruments are neither re-usable surgical instruments nor measuring devices.

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 Metal Instrument is a small component. Please make sure to keep control of it at all times.

Warnings specifically for the Adjustable Push-Pull (item id: 500132)

- It is strongly recommended that you use a rubber dam during the procedure to prevent a choking hazard.
- Do not spread the heads of the separator with anything other than the slider button.



**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.

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:

Metal Instruments are reusable and can be autoclaved and/or sterilized.

Used Metal Instruments 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 Metal Instrument.

Use warm water and a soft brush to gently wash the Metal Instrument and then rinse in warm water.

Note: do not use any sprays or wipes other than a soft soap. Harsh chemicals may damage the product.

Sterilization:

Sterilization is NOT a substitute for proper cleaning. Clean the Metal Instruments first then sterilize them.

Step 1: Either hand-clean with a cleaning solution or use an automatic washer for the initial clean to remove any fluid or debris. If fluid & debris are not removed, it causes the sterilization process to be ineffective

Step 2: Rinse with clean water and then visually check to make sure all fluid and debris have been removed





Step 3: Sterilize using a standard steam heat autoclave (not dry heat) at a maximum temperature of 270°F/132°C. After the cycle, allow the Metal Instruments to cool for at least 5 minutes.

Post Sterilization:

Allow the Metal Instruments 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

Metal Instrument can be disposed of with normal waste products after their usable life. in accordance with current legislation and local regulations.

Composition:

See Metal Instrument 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

Metal Instruments do not have a warranty. However, if the product is defective upon arrival, contact your local representative for a replacement.

Limitation of Liability

Metal Instruments 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
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USA
Ph: 855-712-5327



BIOCLEAR

Origin: Made in Pakistan

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 Metal Instruments:

REF	Product Name
500011	Clark Explorer
500021	Sculpting Point
500031	Curved Sculpting Paddle
500041	Micro-Hemostat
500051	Scalpel Handle
500061	Curved Micro-Pliers
500071	Matrix Sculpting Scissors
500081	TwinRing Forceps
500131	Push-Pull Instrument
500132	Adjustable Push-Pull Instrument

IFU Revision Date: December 1, 2023

