



## **Bioclear Plastic Instrument Instructions For Use (IFU)**

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

### **Indications:**

The Bioclear Plastic Instrument (in all its variations) is intended to use the color indicated on the gauge to help quickly determine the next step in a dental procedure. Please see the matrix system technique guide in the general instructions for further details on how to use the Plastic Instruments and the intended purpose statement below for examples.

### **Contraindications:**

The Bioclear Plastic 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:**

Bioclear Plastic Instruments are intended to use the color indicated on the gauge to help quickly determine the next step in a dental procedure. For example the BT Gauge uses the colored tip to help determine the correct matrix to use and the Go/No-Go uses the colored tip to help determine if a cavity prep can be cured in one layer or if it needs two. Contact with the patient is transient, meaning less than an hour, and the instrument should be removed after the appropriate matrix is determined. Bioclear Plastic Instruments are invasive through a body orifice, specifically orally, but do not penetrate past the pharynx. These are not 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](http://www.bioclearmatrix.com) to find the most recently updated instructions and tutorials.

### **Warnings:**

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

### **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°-24°C/50°-75°F, away from sunlight, moisture, excess humidity, flame or sources of ignition.

**Hygiene:**

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

Used Plastic 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 Plastic Instrument.

Use warm water and a soft brush to gently wash the Plastic 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 Plastic 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: Place instrument in a sterilization pouch. Then sterilize using a standard steam heat autoclave (not dry heat) using the following process:

1. Prevacuum conditioning
2. 4-minute, 132°C (270°F) exposure
3. 20-minute dry time.

**Post Sterilization:**

Allow the Plastic Instruments to fully dry prior to storage.

**Transport**

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

**Discard**

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

**Composition:**

See Plastic Instrument Safety Data Sheet (SDS). It can be found online at [www.bioclearmatrix.com/resources/ifu-sds/](http://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/](http://www.bioclearmatrix.com/resources/ifu-sds/)

**Warranty**

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

**Limitation of Liability**

Plastic 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.



# BIOCLEAR

**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](mailto: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](http://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
500111	Black Triangle Gauge
500121	Go/No-Go Probe
500122	Evolve Matrix Height Indicator

**IFU Revision Date:** May 28, 2024

