



Bioclear Plastic Instrument Instructions For Use (IFU)

These instructions apply to all Bioclear Plastic Instruments

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.

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 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 10-24C/50-75F, 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: Sterilize using a standard steam heat autoclave (not dry heat) at a maximum temperature of 270°F/132°C. After the cycle, allow the Plastic Instruments to cool for at least 5 minutes.

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 20F (-7C) to 100F (38C). 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/

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

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.



Manufacturer:

Bioclear Matrix Systems by Dr. David Clark
3402 South 38th
Tacoma, WA 98409
USA
Ph: 855-712-5327

Origin: Made in the USA

Any serious incident that has occurred in relation to the use of this device should be reported to the manufacturer immediately either by mail at the address above or by email to jennifer@bioclearmatrix.com.



BIOCLEAR

Importer:

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



EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands



Harmonized Symbols:



IFU Revision Date:

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