



Bioclear TruContact Instructions For Use (IFU)

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

Indications:

The Bioclear TruContact (in all its variations) is intended for lightening the natural contact between teeth before the matrix is inserted. Please see the matrix system technique guide in the general instructions for further details on how to use the TruContacts.

Contraindications:

The Bioclear TruContacts 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 TruContact is intended for lightening the natural contact between teeth before the matrix is inserted 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 TruContact should be removed after the contact has been lightened. TruContacts 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 TruContact 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.



**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:

TruContacts are reusable and can be autoclaved and/or sterilized.

Used TruContacts 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 TruContact.

Use warm water and a soft nylon brush to gently wash the TruContact and then rinse in warm water.

Sterilization:

Sterilization is NOT a substitute for proper cleaning. Clean the TruContacts 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 saws using a standard steam heat autoclave (not dry heat) at 30 lbs of pressure for 15 minutes, with a maximum temperature of 286°F/141°C. After the cycle, allow the TruContacts to cool for at least 5 minutes.

Post Sterilization:

Allow the TruContacts 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

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

Composition:

See TruContact 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

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

Limitation of Liability

TruContacts 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 TruContacts:

REF	Product Name
613011	TruContact – Red
613021	TruContact – Orange
613031	TruContact – Blue

IFU Revision Date:

December 1, 2023

