

GENERAL INSTRUCTIONS FOR USE

LOCATORS (SCAN-BODIES)

Please carefully read the instructions below to guarantee the correct use of the product with complete safety.

In compliance with Directive 93/42/EEC and the later modification to Directive 2007/47/EEC, the required information is provided for efficient use of **emexact[®]** manufactured products.

STORAGE AND HANDLING

- All products manufactured by **emexact[®]** should be stored at temperatures of between 15-25°C and a humidity of between 50-60%. Products should be protected from direct sunlight and any artificial ultraviolet light. They should be protected against acids and bases. The product comes perfectly packaged and heat-sealed. Any default in this packaging could lead to a loss of decontamination and disinfection properties, hence it is recommended not to be used.
- Under no circumstances should material be extracted from the original packaging and handled without being used.
- **emexact[®]** products are not sterile. It is therefore recommended to sterilize products before use, following the methods indicated in the corresponding section.

INDICATIONS

- **emexact[®]** Locators are designed to facilitate both clinical and laboratory work. It is therefore recommended to carefully read the instructions for use.
- They are manufactured in biocompatible, non-translucent, anti-reflective plastic (Peek), which does not have to be sprayed.

- Use the **emexact[®]** Locator to determine the position of the dental implant or the corresponding implant analogue, in intraoral or extraoral scanning procedures.
- **emexact[®]** Locators are attached to the dental implant connection of the patient, or in the analogue, by inserting in the laboratory dental model. They are fixed with the screw supplied.
- After scanning, the location and orientation of the laboratory analogue or implant is transmitted to the design software, depending on whether the locator is used extraorally or intraorally.
- CAD/CAM libraries associated to **emexact[®]** Locators, can be downloaded from the website: www.emexact.com
- Their easy recognition and high precision in repositioning in the STL, makes them ideal for practice. They are also compatible with the main CAD/CAM systems (these can be consulted in our website: www.emexact.com).
- With CAD software, the prosthesis can then be designed directly to implant or on titanium interfaces. When designing the prosthesis, the insertion of the screw can be corrected by between 0 and 30°.
- They are provided with laser marking in order to identify the scanning abutment.

CONTRAINDICATIONS

- The use of products is contraindicated in patients with conditions that rule out surgery to place dental implants.
- In order to achieve an accurate reading in scanning, the locators should not be marked or modified, as this could mean it would not be recognized by the software.
- The locator should be replaced if any wear indicator is detected.

- **emexact[®]** Locators are designed for use with the corresponding compatible implant system, specified in the description, and only for the specific platform (diameter).
- Locator abutments should not be used with an incompatible connection.
- There is a risk of inhalation or ingestion of products, when they are used intraorally. Therefore, appropriate measures should be taken to avoid this.

RISKS ARISING DURING THE USE OF THE PRODUCT

STERILIZATION METHODS

- **emexact[®]** products are non-sterile, hence it is recommended to follow the wet, heat sterilization method (autoclave). The product should first be extracted from the packaging and inserted into a bag suitable for autoclave sterilization, to then continue with the method described below.
- This is the most commonly used method in dental clinics and laboratories. Sterilization occurs through a physical agent, damp heat, which causes denaturation, and coagulation of proteins. These effects are mainly due to two reasons:
 - Water is a highly reactive chemical species. Many biological structures (DNA, RNA, proteins, etc.) are produced by reactions that eliminate water. Therefore, reverse reactions could damage the cell as a result of the production of toxic products. The secondary and tertiary structures of proteins are also stabilized, through intermolecular bonding forces of hydrogen, which can be replaced and broken down by water at high temperatures.
 - The water steam has a heat transfer coefficient much higher than air. Therefore, damp materials conduct heat much quicker than dry materials, owing to the energy released during condensation.
 - The autoclave is the most widely used apparatus for temperatures over 100°C. A temperature of 121°C (overpressure atmosphere), with an exposure time over 15 minutes, following the recommendations of the autoclave manufacturer, is used to destroy spore-forming organisms.

SYMBOLGY AND DESCRIPTION

Symbol	Description
	Date of manufacture
	Date of Expiry
	Single use. Do not reuse
	Batch Number
	Article reference number
	Attention! See instructions for use
	Details of the manufacture
	Non-sterile product
	MDD CE marking

PRECAUTION

- emexact[®], products are intended for use by qualified health professionals (Dental Technicians, Doctors and Dentists). Safety and efficiency of supplied emexact[®] products.
 Screws, abutments and other surgical and prosthetic dental accessories are only guaranteed when they are used by qualified professionals.
- Qualified health professionals (Dental Technicians, Doctors and Dentists) are recommended to regularly check for possible changes in the functioning of the product every 6 months.
- Always use the screw supplied to fix the dental implant or implant analogue.

- Before intraoral use of the locator, the product should be cleaned and disinfected. To do this, use cleaning products and disinfection solutions suitable for dental use. The product should also be sterilized, following the methods described in the corresponding section
- **emexact[®]** products are for single use before the expiry date, as indicated on the label. The repeated use of the same locator may lead to inaccurate scanning results. In intraoral use, when the product is withdrawn from the patient, it should be disposed of, as it could have been in contact with biological materials of the patient (blood, tissue, etc.), and traces of these could pass to another patient, if it is reused without proper cleaning and disinfection.

RECOMMENDED TORQUE GUIDE

- The screw supplied with the locators require a manual torque. Slightly tightening the screw is sufficient, as its only function is for clamping during scanning. Recommended manual torque (maximum 15 N cm)