

## INSTRUCTIONS FOR USE

### OF DENTAL PROSTHETIC ATTACHMENTS

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<sup>®</sup>** manufactured products.

#### **STORAGE AND HANDLING**

- All products manufactured by **emexact<sup>®</sup>**, should be stored at temperatures of between 15-25°C and a humidity of 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<sup>®</sup>**, products are not sterile. It is therefore recommended to sterilize products before use, following the methods indicated in the corresponding section.

#### **CONTRAINDICATIONS**

- The use of products is contraindicated in patients with conditions that rule out surgery to place dental implants.

#### **RISKS ARISING DURING THE USE OF THE PRODUCT**

- There is a risk of inhalation or ingestion of products, when they are used intraorally. Therefore, appropriate measures should be taken to avoid this.

## STERILIZATION METHODS

- **emexact<sup>®</sup>** 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.

Pressure [atm]	Temperature [°C]			
	Complete discharge of air	2/3 discharge of air	1/2 discharge of air	Without discharge of air
1/3	109	100	90	72
2/3	115	109	100	90
1	121	115	109	100
4/3	126	121	115	109
5/3	130	126	121	115
2	133	130	126	121

Influence of incomplete discharge of air at the temperature of the autoclave

#### Advantages

- Quick heating and penetration
- Quick destruction of bacteria and spores
- Leaves no toxic residues
- Low deterioration of exposed material
- Economical

#### Disadvantages

- Solutions which form emulsions with water cannot be sterilized
- Corrosive on certain metal instruments

## SYMBOLOLOGY 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<sup>®</sup>**, products are intended for use by qualified health professionals (Dental Technicians, Doctors and Dentists). Safety and efficiency of supplied **emexact<sup>®</sup>** products, both 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.
- emexact<sup>®</sup>** products are for single use before the expiry date, as indicated on the label. If 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

- A table is given below with the Torques recommended by the main manufacturers of implants applicable to **emexact<sup>®</sup>** products:

## RECOMMENDED TORQUE GUIDE

	Manual Tightening (10Ncm)	15 Ncm	15-35 Ncm	35Ncm
<b>Nobel Biocare® Branemark®</b>	<ul style="list-style-type: none"> <li>• Healing abutments</li> <li>• Impression Screws</li> <li>• Screws for provisional plastic abutments</li> </ul>	<ul style="list-style-type: none"> <li>• Prosthetic Screws</li> <li>• Multi-unit Angled Abutment Screws</li> <li>• Ball anchorage</li> </ul>	-	<ul style="list-style-type: none"> <li>• Other Abutment Screw</li> </ul>
<b>NobelReplace® Select®</b>	<ul style="list-style-type: none"> <li>• Healing abutments</li> <li>• Impression Screws</li> </ul>	<ul style="list-style-type: none"> <li>• Angled Abutments 17°-30°</li> </ul>	-	<ul style="list-style-type: none"> <li>• Abutment Screws direct to implant</li> <li>• Straight Abutments</li> </ul>
<b>Klockner®</b>	<ul style="list-style-type: none"> <li>• Healing abutments</li> <li>• Impression Screws</li> </ul>	<ul style="list-style-type: none"> <li>• Fixation micro-screws on angled attachments</li> </ul>	<ul style="list-style-type: none"> <li>• External connection:               <ul style="list-style-type: none"> <li>- 25 Ncm threaded attachments and screws direct to implant</li> </ul> </li> <li>• Internal connection:               <ul style="list-style-type: none"> <li>- 30 Ncm screws direct to implant</li> <li>- 25 Ncm screws threaded to an intermediate attachment</li> </ul> </li> </ul>	
<b>Straumann®</b>	<ul style="list-style-type: none"> <li>• Closure screws</li> <li>• Healing abutments</li> <li>• Impression Screws</li> </ul>	<ul style="list-style-type: none"> <li>• Provisional caps</li> <li>• Caps</li> <li>• Screws at abutment level</li> <li>• Screws M1,4</li> </ul>	<ul style="list-style-type: none"> <li>• Provisional Abutments</li> </ul>	<ul style="list-style-type: none"> <li>• Screws at implant level</li> <li>• Abutments</li> </ul>
<b>Multi-unit</b>	<ul style="list-style-type: none"> <li>• Healing abutments</li> <li>• Impression Screws</li> </ul>	<ul style="list-style-type: none"> <li>• Abutment Screws tilted 17°-30°</li> <li>• Screws at Abutment level</li> </ul>	-	<ul style="list-style-type: none"> <li>• Straight Abutment connected to implant</li> </ul>
<b>Astra®</b>	<ul style="list-style-type: none"> <li>• Sealing caps and abutments</li> <li>• Closure screws</li> <li>• Impression Screws</li> </ul>	<ul style="list-style-type: none"> <li>• Provisional straight abutments</li> <li>• Abutments 20°/45°</li> <li>• Retaining screws</li> <li>• Straight and 20° Angled Abutments for Astra Tech® Yellow cemented solutions</li> </ul>	<ul style="list-style-type: none"> <li>• 20 Ncm Straight and 20° Angled Abutments for Astra Tech® Aqua cemented solutions</li> <li>• 25 Ncm Straight Abutments and Angled 20° for cemented solutions Astra Tech® Lilac</li> <li>• 25 Ncm Abutments direct to Implant</li> </ul>	-
<b>Zimmer® Mis®</b>	<ul style="list-style-type: none"> <li>• Healing abutments</li> <li>• Impression screws</li> </ul>	<ul style="list-style-type: none"> <li>• Screws at Abutment level</li> </ul>	<ul style="list-style-type: none"> <li>• 30 Ncm Screws at Implant level</li> </ul>	
<b>Certain®</b>	<ul style="list-style-type: none"> <li>• Healing abutments</li> <li>• Impression screws</li> </ul>	-	<ul style="list-style-type: none"> <li>• 20 Ncm: Attachments threaded and Internal connection screws</li> </ul>	-
<b>3i®</b>	<ul style="list-style-type: none"> <li>• Healing abutments</li> <li>• Impression screws</li> </ul>	-	<ul style="list-style-type: none"> <li>• 32-25 Ncm: Threaded attachments Connection and External Screws</li> </ul>	-

\* Recommendations based on instructions from the Main Manufacturers of Dental Implants