Clinical Screw, Abutment Screw, Prosthetic Screw

Instructions for use

Working the first time with a colleague, experienced with the new device/treatment method, avoids eventual complications. Nobel Biocare has a global network of mentors available for this purpose.

Special attention has to be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g., cigarette smoking, poor oral hygiene, uncontrolled diabetes, pro-facial radiotherapy, steroid therapy, infections in the neighboring bone). Special caution is advised in patients who receive bisphosphonate therapy.

In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships reappraisal of the treatment option may be considered.

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.

All instruments and tooling used in surgery must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient.

To secure the long term treatment outcome it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.

Never exceed the recommended maximum prosthetic tightening torque. Over tightening may lead to screw fracture.

Handling procedure:

1. Select appropriate screw for the abutment or framework. Correct choice of screw can be found in the respective Instructions for Use for the prefabricated or NobelProcera® abutment or framework.
2. Following conventional procedures insert the screw into the abutment or framework and place the assembly onto the implant.
3. Tighten the Clinical Screw, Abutment Screw or Prosthetic Screw using the screwdriver and torque wrench or drilling device. Correct choice of tooling (e.g. screwdriver and torque wrench) and the recommended maximum prosthetic tightening torque can be found in the respective Instructions for Use for the prefabricated or NobelProcera® abutment or framework.

Caution: Never exceed recommended maximum tightening torque detailed in applicable Instructions for Use for the abutment or framework for the Clinical Screw, Abutment Screw and Prosthetic Screw. Overtightening of abutment may lead to screw fracture.

Materials:

Titanium alloy 90% Ti, 6% Al, 4% V with or without DLC (Diamond Like Carbon) coating.

Cleaning and sterilization:

The Clinical Screw, Abutment Screw and Prosthetic Screw are delivered non-sterile for single use. Prior to use clean, disinfect and sterilize the product using the recommended parameters.

Warning: Use of non-sterile components may lead to infection of tissues or infectious diseases.

Caution: This is a single use product that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Re-use could cause cross contamination.

For USA: Seal single device in a pouch and steam sterilize at 270°F, max 279°F for 3 minutes.

For outside USA: Seal single device in a pouch and steam sterilize at 132°C–135°C, max 137°C (279°F–275°F, max 279°F) for 3 minutes.
Symbols Glossary:

The following symbols may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.

- **EC REP** Authorized representative in the European Community
- **LOT** Batch code
- **REF** Catalogue number
- **Caution**
- **Batch code**
- **Consult instructions for use**
- **Contains hazardous substances**
- **Contains or presence of phthalate**
- **CE marking**
- **Date** Date of manufacture
- **Date**
- **Date of manufacture**
- **Do not re-use**
- **Do not re-use**
- **Do not resterilize**
- **Keep away from sunlight**
- **Do not use if package is damaged**
- **Double sterile barrier system**
- **Rx Only** For prescription use only
- **Keep dry**
- **Keep dry**
- **Magnetic resonance conditional**
- **Manufacturer**
- **Medical device**
- **Non-pyrogenic**
- **Non-sterile**
- **Patient identification**
- **Patient information website**
- **Patient number**
- **Serial number**
- **Single sterile barrier system**
- **Single sterile barrier system with protective packaging inside**
- **Single sterile barrier system with protective packaging outside**
- **Sterilized using ethylene oxide**
- **Sterilized using radiation**
- **Temperature limit**
- **Tooth number**
- **Upper limit of temperature**
- **Sterilized using steam or dry heat**
- **Unique Device Identifier**
- **Use-by date**

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