

CAUTIONS AND NOTES

Anew implants, attached with the manual carrier drivers, are delivered sterile and are designed for direct, safe, initial implant placement. Accessories, including drills and reamers, are delivered factory clean and after removing their wrappings, they should be sterilized in compliance with surgical protocols before use.

The implants are intended for single use, thereby avoiding risk of infectious cross contamination if re-used. Do not use an implant if the packaging is damaged or opened.

All devices used in the clinical procedures should be autoclaved with steam sterilization prior to use. The health facility should validate its own autoclave steam sterilization machine in accordance with a recognized standard (in the USA: FDA approved standard).

The following parameters have been validated in accordance with recognized standard ANSI/AAMI/ISO 17665-1:2006, to provide a Sterility Assurance of 10^{-6} . Temp: 132°C, Pressure: 30psi, Time: 8 minutes.

The CePo® Drills and reamers should be used with copious amounts of biocompatible isotonic sterile solution spray to prevent overheating damage and possible bone necrosis. When preparing osteotomies in mandibular D-1 and D-2 hard bone, only sharp drills and reamers should be used. As

a safety precaution, used dull drills should be discarded.

Extreme care should be observed to prevent accidental swallowing or aspiration of implants or other related small accessory components used in these procedures. When possible, tools should be attached with a fine cord to the patient's garment.

Caution - The printed guidelines, including Cautions and Notes, are to be regarded as additions to accepted clinical procedures and surgical protocols. In USA Federal law restricts the sale of this device to a licensed physician or dentist.

Dentatus Narrow Body Ti alloy implants are FDA designated for long-term use or for any length of time as decided by the healthcare provider.

These instructions inform the user about the recommended procedures when using Dentatus implant systems. They are intended for use by clinicians with at least a basic level of surgical and in-clinic implant training. It is the responsibility of the clinician to stay informed, educated and trained about general dentistry implant treatment techniques.

Laboratory Technical Procedures

After the model is made, the Analogs are cleaned before attaching the indexing Resin Castable Platform to the Analog with the black Screwcap.

NOTE: Made of non-hygroscopic resin, the Screwcaps require no lubricants to repel restorative material; however, when wax-up is delicate/thin the Screwcaps may be lightly coated with a suitable insulation liquid.

The wax patterns surrounding the platform and screwcaps can be cast in dental metal of choice with conventional lab procedures.

The cast metal frame with space is prepared for aesthetic ceramic or resin crown build-up.

NOTE: The castings are checked for fit on the platform and for unimpeded Screwcap insertion. Corrections made on the model or on the restoration should be clearly marked for the dentist's attention.

Chairside Assembly of Restorations

Adjustments and reduction of hard metal should be made extraorally to prevent adverse heat effect on the implant bone interface.

The white Screwcap used for attaching restoration is reduced slightly below crown level and blocked with a small dab of a cotton pellet. It is sealed with off-color resin for re-access.

Post-Operative Implant Care

Implants typically need a period of four to six months to integrate, depending upon the patient's healing properties and the type of bone they have. The patient must give every consideration to keep the surgical site clean and free of food particles. The following instructions are for your patient's care after surgery.

1. No Smoking, No Straws

Any type of suction can disturb the blood clot and loosen sutures. Smoking is to be avoided since it increases the heat in the surgical area and significantly lowers the body's ability to heal the site. Straws cannot be used for three days in most cases.

2. Gentle Rinsing

Frequent gentle rinsing with chlorhexidine solution for dental/oral use is recommended during a limited time. Read instruction from manufacturer of solution.

The use of commercial alcohol containing mouthwashes during the healing period is not recommended.

3. Ultra Soft Brush

Begin using an ultra-suave brush 24 hours after surgery to cleanse and stimulate the tissue. Gentle brushing will not harm the sutures. Brush the area at least 3 times a day. Rinse with dental chlorhexidine solution.