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INSTRUCTIONS FOR USE

P-I Implant system

IMPORTANT: PLEASE READ

INDICATIONS

The P-I components and instruments are intended to be used for anchorage of crowns, bridges or dentures to the surrounding bone in the upper and lower jaws. The procedures may range from replacement of a single tooth or to entire arch of bridgework. Crowns and bridges can be screw retained and/or cemented to implant and/or implant abutment.

CONTRAINDICATIONS

Pre –operative patient evaluation is necessary to determine any factors which put the patient at risk from the implant placement procedure itself, or factors that may affect healing capacities of either the bone or associated soft tissue.

Implants should not be used:

- In patients w itha health history that contraindicates surgical intervention
- Where bone is of insufficient quality or quantity or not available to produce adequate stability and support.
- When there is risk for overload due to unfavorable jaw relations and/or para function i.e bruxism.
- Where there is no space to place sufficient number of implants in an optimum position to support expected biomechanical loads.
- Where bone quality is not able to provide adequate initial primary stability.

POSSIBLE COMPLICATIONS

All surgical procedures include an element of risk, which makes it impossible to guarantee a 100% rate of success. Lack of adequate quantity and/ or quality of bone, infection, generalized diseases and surgical malpractice are some potential causes for failure of Osseointegration. Too early load of an implant, and overload from miss fitting bridgework, poor occlusion and articulation, para function i.e. bruxism and trauma may cause loss of an implant.

GENERAL PRECAUTIONS

The tissue integration implantation method as described as Osseointegration should only be utilized by qualified professionals trained in this method. Surgical workshops are available for clinicians to learn more about the method. Contact your local distributor for more information. Each patient must be carefully examined and evaluated to determine his/her psychological and physical status. The P-I system has specific design characteristics for mating implants, abutments and prosthetic components. Combining components that are not configured or dimensioned for correct mating can lead to mechanical failure of components, damage to tissue, loss of Osseointegration or compromised results. Close cooperation between the implant surgeon, restorative dentist and dental laboratory technician is essential for success.

The components are small and care must be taken that they are not swallowed or aspired by the patient.

PROCEDURAL PRECAUTIONS

Proper handling of abutments and prosthetic components after implant installation is important to avoid overload of the bone/ implant interface. The use of the torque wrench is recommended to reduce the risk of screws becoming loose. Recommended torques are:

Connection Platforms	External Hex Ø 3.5	External Hex Ø 4.1 | 5.1	*Amplified*® AMP Ø 3.5 | 4.3 | 5.1	Morse Taper MT Ø 3.5 | 4.1 | 5.1
Abutments	25	35	25	25
Conical Abutments – Angled	-	25	25	25
Cylinders over Implant	25	35	25	25
Cylinders over Abutment	15	15	15	15

To optimize implant surgery and minimize adverse reactions and risks for the patient requires that common sterile and implant surgical techniques are followed.

It is important to achieve proper and even stress distribution between the implants and to minimize transverse loading. This means that the opposite jaw may be adjusted and that the prosthetic framework must have passive fit.

If dentures are used after implant installation they should be relieved and relined with a soft liner to reduce premature loading.

All Instruments must be cleaned and sterilized before use. After cleaning, sterilization by autoclave and drying is recommended.

Clean instruments in Ph-neutral enzymatic detergent diluted in tap water according to manufacturers instruction. Rinse the instruments in tap water until all detergent is removed.

Depending on the type of sterilization equipment, different cycles can be used:

1. Prevaccum Sterilizer
   Wrapped cases, trays and instruments, or cases, trays and instruments should be exposed to 132°C to 135°C (270°F to 275°F) for at least four minutes. Dry for 20 to 40 minutes.

2. Gravity Displacement Sterilizer
   Wrapped cases, trays and instruments should be exposed to 132°C to 135°C (270°F to 275°F) for at least 30 minutes or 121°C to 123°C (250°F to 254°F) for at least 55 minutes. Dry for 20 to 50 minutes.

Variables that may affect drying times include: loading density of the case/tray, instrument configuration, total contents of the sterilizer, steam quality, equipment maintenance and others.

Procedures established in national standards and instructions of manufacturers of approved products and equipment for cleaning and sterilization should also be taken in consideration.

Avoid contact between instruments during the process of cleaning, sterilizing and drying. Instrument should never be stored without complete drying, in order to avoid oxidation.

PACKAGING AND HANDLING

Titanium components for implantation and single-use instruments are supplied in a sterile condition. Such products are sterilized by irradiation and marked "sterile". In the event of damage to the sterile blister packaging, or if the expiration date has passed, the component cannot be used and should not be re-sterilized. Components and instruments, which are supplied in a non-sterile condition by the manufacturer, must be cleaned and sterilized before use.

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