Neodent® Zygoma Implant System

Patient Information Leaflet

NEODENT®

NEODENT® ZYGOMA IMPLANT SYSTEM

Name and model of the device

Neodent® Zygoma Implant System	
Length	Art.-No.
109.1049	Zygoma GM 4.0 X 30 mm
109.1050	Zygoma GM 4.0 X 35 mm
109.1051	Zygoma GM 4.0 X 37.5 mm
109.1052	Zygoma GM 4.0 X 40 mm
109.1053	Zygoma GM 4.0 X 42.5 mm
109.1054	Zygoma GM 4.0 X 45 mm
109.1055	Zygoma GM 4.0 X 47.5 mm
109.1056	Zygoma GM 4.0 X 50 mm
109.1057	Zygoma GM 4.0 X 52.5 mm
109.1058	Zygoma GM 4.0 X 55 mm

Device Description

The Neodent® GM Zygomatic Implant are manufactured using commercially pure titanium (grade 4).

Zygomatic Implants are extra long to enable bone anchorage in the zygomatic bone. They are designed to stabilise the maxilla bone and provide a prosthetic interface that connects the prosthesis to the implant.

Intended Use

The Neodent® GM Zygomatic Implant is indicated for surgical intraoral installation and must be inserted in the posterior region of the maxilla and in the zygoma. It is indicated in cases of severe resorption of the maxilla and total edentulism (a situation in which the installation of conventional implants is contraindicated).

Post-Operative Precautions and Maintenance

Medication

Your surgeon will prescribe or recommend medication to assist in your pain management. It is important to follow the prescription provided by your surgeon.

Diet

Following surgery, protect the implants by not disturbing the wound.

Your surgeon will recommend a suitable diet, for example a soft diet for a few weeks. Good oral hygiene is essential to healing.

Oral Hygiene

Patients who have implants must commit themselves to a lifetime of stringent oral hygiene. This is to ensure that the gingival tissues surrounding the implant remain healthy, with no plaque accumulating around the implants, the prosthetic parts attached to them and around the teeth.

Follow the advice of your dental professional when it comes to regular checkups and professional teeth cleaning after your implant treatment. Ask your dental professional for personalised and detailed care instructions.

Side effects

The surgical placement of dental implants, as well as any other surgical procedure, may cause slight discomfort and localized swelling. More persistent symptoms can occur such as chronic pain related to the dental implant, and loss of sensation in facial regions.

Other complications can occur during or after the procedure such as maxillary bone fracture, implant fracture, surrounding soft-tissue infection, and irreversible injury of adjacent teeth.

The proper implant osseointegration depends on multiple factors including the adequate surgical protocol performed by the surgeon, favorable systemic condition by the patient for the healing process and proper oral hygiene.

Consult your dental professional for appropriate post treatment care and to discuss any side effects that you may be experiencing.

Lifetime

35 years.

Risks

Using this product can lead to the following residual risks: skin abscesses, anaphylaxis (severe allergic reaction), increased surgical time, increased healing time, severe surgical complications, trans-operative problems, severe post-operatory complications, oroantral communication, contamination of the environment, nerve damage, orbit damage, bone damage, unplanned surgical injury, damage to patient's digestive system, damage to patient's respiratory system, implant platform damage, damage in the vascularization, difficult in the removel, pain, insufficient primary stability, treatment/osseointegration failure, implant failure, impossibility of completing the surgical procedure, impossibility of prosthesis installation, impossibility of abutment installation, local infection, systemic infection, inflammation, local irritation, need for additional surgical interventions, need for additional interventions, death, bone loss, pyrogenic, periimplantitis, prosthetic and/or biomechanical problems, chronic sinusitis and implant replacement.

Consult your dental professional for appropriate post treatment care and to discuss any side effects that you may be experiencing.

Adverse Event Reporting

Any serious incident in relation to the device should be reported to the manufacturer and to the regulatory authority:

Australia Therapeutic Goods Administration (TGA)
contact www.tga.gov.au

New Zealand New Zealand Medicine and Medical Device Safety Authority (Medsafe)
contact www.medsafe.govt.nz

Magnetic Resonance Imaging (MRI) - Safety Information

This product is manufactured from a metallic material that can be affected in magnetic resonance field. Non-clinical testing and magnetic resonance (MRI) simulations have shown that Neodent implantable devices manufactured in metallic material are MR Conditional.

A patient that has a Neodent implantable medical device can be scanned safely under the following conditions:

- Static magnetic field of 1.5T and 3T, only.
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg and head average SAR of 3.2 W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.

Under the scan conditions defined, the implants, as well as clinically relevant implant constructs, from the Neodent Implant System are expected to produce a maximum temperature rise of 4.9°C after 15-minutes of continuous scanning (i.e., per pulse sequence). In non-clinical testing, the image artifact caused by the implants from the Neodent Implant System extend approximately 10 mm from this device when imaged with a gradient echo pulse sequence and a 3T MR system.

Distributed by

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