

Instructions of Use: DENTOFLEX IMPLANTS



Osseointegratable Dental Implant

Rev.02/2007

DENTOFLEX Implants comprise five models: Cylindrical, Conic, Bicortical, Temporary, and Zygomatic. The Cylindrical model is available in two platform designs, Internal Hexagon and External Hexagon; the Conic model is available in four platform designs, Internal Hexagon, External Hexagon, Morse Cone, and Flex; the Zygomatic model is available only as External Hexagon, while the Bicortical and Temporary models do not have platform design. All have a wide variety of measures, specially developed to meet different situations in endosseous dental implantation. They are manufactured in titanium and have a porous surface, treated with aluminum oxide jet followed by acidic inactivation, except in the case of the Bicortical model. They are used as infra-structure for tooth-root replacement and serve as bases for fixing single-tooth to whole dental arch prostheses and as retention element for overdenture applications. They do not have articulation mechanisms and were not designed for cutting or perforating.

Icon Norm NF EN 980:



STERILE R

Sterilized by radiation



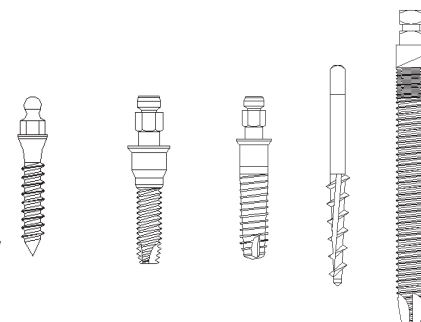
Store in dry, fresh place, protected from sunlight



ATTENTION: See instructions of use



One Use Only



General and Specific features and indications of use of products pertaining to each DENTOFLEX Implant model are listed below:

Indication	Accessory
<p>CYLINDRICAL</p> <p>Indicated in most cases. For implantation when there is a time span between extraction and implant surgery.</p>	Requires a DENTOFLEX Dental Implant Surgical Kit, separately sold
<p>CONIC</p> <p>Indicated for implantation performed immediately after extraction. Designed for immediate functioning, it is easy to screw because of its anatomic shape resembling that of a natural tooth root.</p>	Requires a DENTOFLEX Dental Implant Surgical Kit, separately sold
<p>ZYGOMATIC</p> <p>Indicated for atrophic maxilla treatments, using available osseous area of maxilla with access to palate. Techniques are: Intrasinusal Technique (IT): All active body of implant is threaded. Exteriorized Technique: (ET): The implant is not threaded in the</p>	Requires Helicoidal Spear Drill 2.3mm, Graded Conic Drill 3.50 and 4.00mm, extra long EH Digital Wrench 1.00mm, medium EH Digital Wrench 1.00mm, Calibrated Probe, and Ratchet Driver for Zygomatic Implant, separately sold
<p>TEMPORARY</p> <p>Indicated for temporary retention of overdentures. It allows for immediate activation after insertion and preserve the integrity of osseointegratable implants during the healing period.</p>	Requires Helicoidal Drill 1.8mm, Digital Wrench 2.40mm for Prosthesis o-ring or Torque Meter Wrench, and Ratchet Wrench or T Wrench, separately sold
<p>BICORTICAL</p> <p>Indicated for single implants and cement-held fixed prostheses and implantations performed immediately after extraction. Immediate functioning, easy screwing, anatomic form resembling that of a natural tooth root ensuring a better apical anchorage.</p>	Pipe wrench 45°; Pipe wrench 90°Torque meter wrench; folding devices, and Surgical Torque meter, separately sold.

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The DENTOFLEX Implant surgery must be performed under controlled conditions, with surgical asepticity, and must aim at a straight and solid connection of bone and implant, with the least possible trauma for the patient. Decision for a surgery must be preceded by a complete treatment plan, based on visual examination, panoramic and periapical radiographies, in order to determine anatomic limit, occlusal conditions, periodontal state, and osseous condition of the patient. This analysis may be enriched with lateral cephalometric radiography and computerized tomography.

Precautions:

The required surgical techniques for installing DENTOFLEX implants are highly specialized and involve complex procedures. Improper selection of patients and/or techniques may cause implantation failure and loss of osseous support.

Restrictions:

The surgery for installing DENTOFLEX Implants is not indicated in cases where bone is too small and does not offer proper height or width to house the implant.

Cylindrical and conic implants should not be fixed with less than 30N, and immediate functioning is indicated for implants placed with a minimum of 40N.

Warnings:

There may be lack of osseointegration or implantation failure in cases of insufficient or bad quality bone, lack of available space in bone, poor oral hygiene, tobacco abuse or uncontrollable medical conditions (such as blood disorder or diabetes).

The professional should handle the product only with titanium or titanium nitrated coated instruments. The surgery for installing DENTOFLEX implants must be performed by skilled professionals. Packaging should be opened only in a sterilized surgical field. Do not use the product if shelf life has expired or if packaging has been opened, violated or damaged. They are designed for ONE USE ONLY to ensure best performance. Reprocessing forbidden.

Storing:

DENTOFLEX Implants should be stored, with intact packaging, in a dry, fresh place, protected from sunlight.

Counter-indications:

DENTOFLEX Implants should be used only as indicated and therefore any other use is to be considered counter-indicated or devoid of scientific support. Local or general infections may jeopardize the aim of the intervention; major local inflammation; pregnancy; immune depressant pathologies; osseous immaturity; severe mental illness.

Pathologies in osseous metabolism may provide inadequate mechanical support for this kind of implant.

Product disposal:

When necessary, professionals should comply with prevailing laws for contaminated product disposal.

Side effects:

Risks arising from implantation involve edema, hematoma, hemorrhage, and paresthesia (numbness) of lower lip and chin areas in mandible surgery and tissues round the nose in maxilla surgeries. Although these are natural and temporary phenomena, in some rare cases numbness may be permanent. There may also occur mucous-gingival wound, tissue reaction or infection. However, these pathologies are generally successfully treated with proper medication.

Transportation:

The triple hermetically sealed package of DENTOFLEX Implants protects the product against falls and collisions. However, in long distance transportation, further protection is recommended.



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SAC

Serviço de
Atendimento
ao Cliente

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