

USER INSTRUCTIONS

ENGLISH

1. **Disclaimer of liability**
This product is part of the Cortex Dental Implant System and may only be used in conjunction with the corresponding original components and instruments. Use of products made by third parties detracts from the efficient function of the Cortex Dental Implant System and will void any warranty or other obligation, expressed or implied, of our products, which are provided verbatim, in writing, by electronic media or in demonstrations. It does not relieve the use of Cortex products of the responsibility of determining whether or not any product is suitable for the intended purpose, indications and procedures. Use of this product is not within the control of Cortex Dental Implants Industries, it is the responsibility of the host/dry for loss or damage attributable to the use of this product is excluded.

2. Indications

Cortex Dental Implant System is intended for use in partially or fully edentulous mandibles in support of single or multi-unit restorations including cement-retained, screw-retained, and over denture restorations, and terminal or intermediate abutment support for fixed bridgework. Specific indications for 3.0 diameter implants:
Because of the reduced surface area for anchorage in the bone, these implants are to be used solely for the following indications:

a. As an additional implant together with longer implants to support prosthetic restoration.
b. As an auxiliary implant for implant bar constructions supporting full dentures in a seriously atrophied mandible.
3. **Contraindications**
It is contraindicated placing dental implants in the following patients:

1. Medically unfit for oral surgery procedure on corticosteroids, or anticoagulants or bisphosphonates, and those receiving radiation or other immunosuppressive therapy.
2. Lactating or pregnant women are not candidates, nor are patients with abnormal laboratory results.

3. Patients with diabetes, cardiovascular disease and Hypertension above 170/110 mm Hg.
4. Osteoporotic crush fractures, respiratory disease, thyroid or parathyroid as well as patients with osteoporosis and unexplained lump or masses in the head or neck.

5. Patients with uncontrolled disease such as; Hemophilia, Granulocytopenia or other bleeding problems, steroid use, Prophylactic antibiotics use, Brittle Diabetes, Osteoporosis, Osteoarthritis, Osteoradionecrosis, Renal failure, organ transplantation, Anticoagulation therapy, unexplained hypersensitivity, Fibrous dysplasia, regional enteritis.

6. Disease or treatment that severely compromise healing, e.g. including radiation therapy.
7. Lack of adequate training of practitioner.

8. Poor patient motivation, such as; Psychiatric disorders that interfere with patient understanding and compliance with necessary procedures, Unrealistic patient expectations, Unattainable prosthodontic reconstruction, Inability of patient to manage oral hygiene, Patient hypersensitivity to specific component of the procedure.

9. Allergy to dental implants are made of a metallic alloy; therefore they are characterized by high conductivity. For this reason, electrocautery is strictly contraindicated near dental implants.

4. **Additional Specific Contraindications**
Consider not using the device if there are one or more of the following medical situations: Chronic bleeding problems, psychological impairment, treatment with chemotherapeutic agents, metabolic bone or connective tissue diseases, treatment with corticosteroids, certain cardiac and vascular diseases, diabetes (uncontrolled), tobacco usage, chronic renal disease, poor patient oral hygiene, bruaxism, alcoholism.

5. **Temporary Contraindications**
1. Systemic infection, local oral and respiratory infection
2. Anatomic or pathological implications such as:

a. Insufficient alveolar bone width and height to surround the implant with at least 1.5 millimeter of bone

b. Inadequate bone height where proper implant placement would encroach within 2mm of the mandibular canal, sinus floor, etc.

3. Malnigancies
4. Pregnancy
5. Inadequate bone volume unless augmentation procedure can be considered.

6. **Warnings**
1. These devices are only to be used by trained professionals. The surgical and restorative techniques required to properly utilize these devices are highly specialized and complex procedures. Improper technique may lead to implant failure.

3.0直径种植牙的专门适应症
Cortex 6 mm种植牙的专门适应症

因在牙槽骨植入区表面积不足, 此类种植体只能在以下情况使用:
b. 在严重萎缩的骨骨上制作交叉咬合时, 作为种植体结构的辅助。

2. 禁忌症
下列情况的患者不应进行植入:
a. 口腔外科手术禁忌症(皮肤手术、或抗凝血剂或双联凝血剂)
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forward rotation.

9. **Side-effects and complications post procedure**
As with any dental implantation, certain complications may occur following procedure. These possible complications are:

1. Pain, swelling, phonic difficulties, gingivitis
2. More persistent symptoms:
Chronic pain in connection with the dental implant, permanent paresthesia, dyesthesia, loss of maxillary/mandibular ridge bone, localized or systemic infection, orofacial or oronasal fistula, unvaryably does not relieve the use of Cortex products of the responsibility of determining whether or not any product is suitable for the intended purpose, indications and procedures. Use of this product is not within the control of Cortex Dental Implants Industries, it is the responsibility of the host/dry for loss or damage attributable to the use of this product is excluded.

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RF 运行模式 正常速度运行

最大全身 SAR 2 W/kg
扫描时间 在连续或重复序列/扫描时

MR成像伪影 在非重复序列中, 重复序列重复顺序列表 3.0 T MR 系统或伪影。由 Cortex 牙种植体产生的伪影的伪影可能达每序列约 15 mm。

6. 植入 当所施加的负荷超过种植体的正常设计使用范围时, 可能导致种植体和基台骨折。

7. 切勿将植入物用于非设计用途: 种植体长度、长度或高度的不足可能导致系统不稳定, 不可逆的损伤或 adjacent teeth fractures of implant, jaw bone or prosthesis, esthetic problems, nerve damage, edema/infection, hyperplasia.

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a. 口腔外科手术禁忌症(皮肤手术、或抗凝血剂或双联凝血剂)
b. 患有其他免疫抑制剂治疗的患者。

3.0直径种植牙的专门适应症
Cortex 6 mm种植牙的专门适应症

因在牙槽骨植入区表面积不足, 此类种植体只能在以下情况使用:
b. 在严重萎缩的骨骨上制作交叉咬合时, 作为种植体结构的辅助。

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9. Электроиригурия. Зубные имплантаты изготовлены из металлического сплава, поэтому они обладают высокой электропроводностью. Избегайте использования электроиригаторических вмешательств зубных имплантатов строго противопоказано.

4. **Возможные дополнительные противопоказания**
Не рекомендуется использовать изделие, если у пациента наблюдаются одна или несколько из следующих проблем: хронические нарушения слуха/зрения/слуха, психологические нарушения, лечение химиотерапевтическими препаратами, метаболические заболевания эндокринной или нервной системы, неконтролируемый сахарный диабет, некоторые заболевания сердца и сосудов, сахарный диабет (неконтролируемый), употребление табака, хроническое заболевание почек, недостаточная глубина полости рта, бруксизм, алкогольизм.

5. **Временные противопоказания**
1. Системная инфекция, местная инфекция полости рта или инфекция путей.
2. Анатомические или патологические изменения, в том числе следующие:
a. недостаточная ширина и высота кости альвеолярного отростка для окружения имплантата как минимум 1,5 миллиметров кост;
d. недостаточная высота кости, для нормальной установки имплантата (включая случаи атрофии костной ткани, микроциркуляторного синуса и т. д.

5. **Contraindications**
It is contraindicated placing dental implants in the following patients:

1. Medically unfit for oral surgery procedure on corticosteroids, or anticoagulants or bisphosphonates, and those receiving radiation or other immunosuppressive therapy.

2. Lactating or pregnant women are not candidates, nor are patients with abnormal laboratory results.

3. Patients with diabetes, cardiovascular disease and Hypertension above 170/110 mm Hg.

4. Osteoporotic crush fractures, respiratory disease, thyroid or parathyroid as well as patients with osteoporosis and unexplained lump or masses in the head or neck.

5. Patients with uncontrolled disease such as; Hemophilia, Granulocytopenia or other bleeding problems, steroid use, Prophylactic antibiotics use, Brittle Diabetes, Osteoporosis, Osteoarthritis, Osteoradionecrosis, Renal failure, organ transplantation, Anticoagulation therapy, unexplained hypers

