Azure Dental Implant System (C+E) / Azure 牙科植體系統 (C-system)

繁體中文

“牙王”天璽牙科植體系統
Azure
Dental Implant System (C-system)

※使用前請務必詳閱使用說明書並遵照指示使用

衛部醫器製字第006035號

產品敘述：
“牙王”天璽牙科植體系統由人工牙根(Dental Implant)、支柱(Abutment)、癒合帽(Healing Cap)及其它補綴配件組合而成，本產品不可與其它廠牌產品混合使用。人工牙根採用四級純鈦（CP Titanium Grade 4），支柱(Abutment)及其它配件產品使用鈦6鋁4釩(Ti6Al4V)材料，皆具備良好的生物相容性。全系列人工牙根(Dental Implant)產品採用
B.S.A(Bombardment with Soluble material and Acid etching)表面處理技術。本植體系統具備不同外型及規格，提供醫師治療時，依實際情況選用。

適應症：
本產品適用於牙科手術時，植入於上下齒槽骨內，做為替代原有單齒或多齒牙根之修復用。

禁忌症：
如有下列禁忌症患者，應由醫生評估是否適合植牙手術。
1. 糖尿病或血液相關疾病。
2. 齒槽骨病理性感染。
3. 精神病或藥物、酒精濫用情況。
4. 骨組織吸收、骨質短少、或骨質疏鬆。
5. 口腔衛生狀況惡劣。
6. 口內不正常咬合如磨牙或深咬等。

注意事項：
1. 本植體系統包裝方式，區分為滅菌與非滅菌二種包裝。人工牙根產品出廠前皆經過輻射滅菌，並於包裝上註明”STERILE”字樣。滅菌包裝產品不可重複使用或重複滅菌，若使用前發現產品包裝破損，應立即停止使用並更換新品。
2. 支台及其它配件為非滅菌產品，並於包裝上註明”NON-STERILE”字樣。使用前必須用高壓蒸氣鍋，以溫度135℃至少10分鐘，以達到完全滅菌效果。
3. 本產品應儲存於室內通風蔭涼處，並避免日光直接照射。使用前應先注意包裝上製造日期與保存期限，不可使用過期之產品。
4. 在使用本植體系統前，必須詳細閱讀手術說明書，並由合格的牙科醫師進行治療。
5. 本系列產品任何部份，不可與其它廠牌植體系統搭配使用，以避免產生搭配不良之情況。

潛在不良影響：
1. 可能會產生如化膿、膿瘡等發炎症狀症狀，或是特定部位腫大或出血之不良反應。
2. 手術部位持續疼痛或麻木或有異物感。
3. 因外力因素或骨整合不良造成植入失敗。

產品規格：詳見請參照型錄。

Azure™

藥商名稱：鐿鈦科技股份有限公司 總公司
藥商地址：40852台中市南屯區精科路9號
製造廠名稱：鐿鈦科技股份有限公司 總公司
製造廠地址：40852台中市南屯區精科路9號
TEL：+886-4-2359-5336
FAX：+886-4-3601-9772
www.intai.com.tw
www.ifu.biomet3i.com

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English

Instructions for use - Azure Dental Implant System (C+E)

1. Product description
Azure Dental Implant System processed with titanium is surgically inserted into the upper and/or lower jawbone and serves as a replacement for a patient’s tooth providing a stable foundation for restorations.
2. Purpose of product
Azure Dental Implant System is designed for use in dental implant surgery. It replaces the natural tooth root surgically inserted into the upper or lower alveolar bone. The Implant can restore the injured tooth by connecting abutment osseointegration with the alveolar bone.
3. Directions for use
The implantation procedure should be done under aseptic conditions with specifically designed sterile surgical instruments. Through the drilling a procedure, a gentle up and down pumping motion should be continued and external irrigation system should be to prevent bone heating. Implant placement should be executed by specific drilling sequences with pumping up and down motion during the drilling procedure. The insertion torque should be less than 45Ncm. Because too much insertion torque (over 45Ncm) may cause deformation of double hex in the implant. After completing the insertion procedure, place the cover screw into the implant. Close and suture the tissue flap.
4. Contraindications
Azure Dental Implant System should not be used in cases where the remaining alveolar bone is too diminished to provide adequate width or height to surround the implant. Lack of osseointegration or subsequent implant failure may occur in cases where there is insufficient available bone. poor bone quality, poor oral hygiene, heavy smoking, tobacco abuse, or medical conditions such as blood disorders or uncontrolled diabetes.
5. Warnings
For safe and effective use of Azure Dental Implant System, it is strongly suggested that specialized training be undertaken since the surgical required to place dental implants are highly specialized and complex procedures. Improper patient selection and technique can contribute to implant failure and/or loss of supporting bone. Azure Dental Implant System is intended for use only in the indicated applications. Dental implants must not be altered in any way. The use of electro-surgical instruments or lasers around metallic implants and their abutments is not recommended due to the risk of electric shock and/or bums. Implant
mobility, bone loss, chronic infection may indicate implant failure. If the implant becomes contaminated by the patient’s body fluids in any way, the implant cannot be used in any other patient.
6. Precautions
The surgical techniques required to place endosseous dental implants require specialized and complex procedures. Formal training for placement of implants is recommended.
Important: Determine local anatomy and suitability of the available bone for implant placement. Thorough screening of prospective implant candidates must be performed. Visual inspections as well as panoramic and per apical radiographs are essential to determine anatomical landmarks, occlusal conditions, periodontal status, and adequacy of bone. Lateral cephalometric radiographs, CT scans, and tomograms may also be beneficial. Adequate radiographs, direct palpation, and visual inspection of the implant site are necessary prior to treatment, planning, and use of Azure Dental Implant System . Although Azure Dental Implant System is made of nonmagnetic material, but the safety and compatibility in the magnetic resonance imaging (MRI) environment have not been evaluated. The distort images can be obtained via MRI. Intai Technology Corp. is not liable for damages resulting from treatment outside of our control. The responsibility rests with the MRI provider.
7. Adverse reactions
Some of the complications (loss of implant anchorage, prosthesis etc.) are possible occurrences after surgery. Lacks of quantity of remaining bone, infections, poor patient oral hygiene or cooperation, patient discomfort, implant mobility, local soft tissue degeneration, and unfavorable implant placement or alignment are causes for loss of anchorage.
8. Surgical complications
The implant procedure has risk, including localized swelling, dehiscence, tenderness of short duration, edema, hematoma, or bleeding. Numbness of the lower lip and chin region following lower jaw surgery, and of the tissue beside the nose following upper jaw surgery, is a possible side effect of the surgery. Though it would most probably be of a temporary nature, in very rare cases, the numbness has been permanent. Gingival-mucosal (gum tissue) ulceration, tissue reaction, or infection may occur, but generally responds to local care.
9. Sterilization and handling
The implant, implants mount and cover screw have been cleaned and sterilized by gamma irradiation and are ready to use. Sterile packages in which they are should be opened onto a sterile field and handled with sterilized tools only. Do not use if package is opened, damaged, or expired. Do not desterilize in any case. Discard any and all open, unused products.
10. Cautions
Sterility guaranteed only when the package is not opened or damaged.
The accompanying label for medical treatment should be used for care of patient.
11. Disposable sterilized medical device
This product is a disposable sterilized medical device.

STERILE R

Instructions for use - Azure Dental Implant System(C+E) Abutment & Prosthetic Components

1. Description:
Azure Dental Implant System abutment & prosthetic components consist of the following:

Classification	Materials
Abutment and prosthetic components	Ti6-Al4-V

Azure Dental Implant System abutment & prosthetic components are only compatible with the Azure Dental Implant System dental implant.
They cannot be used with other fixture systems.
Refer to product manual, catalogue of Azure Dental Implant System for details. For the product code, specification, manufacturing date, and expiration date see the product label.
2. Sterility :
Cover screw is cleaned and then sterilized by gamma irradiation. The sterilized product must be used in sterilized tools. If the package is damaged, or if the expiration date has passed, do not use the product. Expired or contaminated before must not be re-sterilized; they must be disposed of.
The unsterilized prosthetic components must be sterilized in an autoclave at 135° C or above for 10 minutes before use. After the steam sterilization, the abutments should be dried for 15 minutes before use.
3. Storage Conditions:
Keep in cool and dry place. Keep out of direct sunlight.
4. General Precaution:
The surgical procedure of dental implantation requires an expert; it is a complex procedure which requires formal training to perform implantation.
5. Important:
It is important to look at the anatomy and suitability of the available bone for implant placement.
Prepare the implant considering the expected situations and cautions. Visual Inspections as well as panoramic and periodical radiographs are essential to determine anatomical landmarks, occlusal conditions, periodontal status, and adequacy of bone. Lateral cephalometric radiographs, CT scans, and tomograms may also be beneficial. In particular, the exact implant fixture can be assembled to prepare the abutment and the prosthetic components.
6. Procedural Precautions(Surgery)
The implant operation requires high accuracy and careful attention, we must try to minimize damage to the cell tissue and pay special attention to the temperature, surgical trauma, and/or removal of the source of contamination and infection.
7. Procedural Precautions (Prosthetics)
The prosthetic structure is small; make sure it is neither swallowed nor inhaled by the patient. Stress distribution is especially important in implant operation as well as the fit of prosthesis and abutment on bridges, also the occlusal stability. Avoid using excessive force horizontally especially during immediate implantation. For the prosthesis whose substructure is made of gold alloy, gold should be used appropriately. Operate prosthesis after enough healing period.
8. Cautions for Patients
Keep the oral cavity thoroughly clean. Do not apply excessive stress on the teeth until the last prosthesis is placed.
9. Warning
Using Azure Dental Implant System dental implant safely and effectively requires special training, since the surgical techniques involved in the dental implant operation are highly specialized and very complex. The selection of inappropriate patients and operation methods can cause implant failures or loss of bone supporting the implant. Azure Dental Implant System dental implant must not be used for purposes other than the recommended use. Dental implants must never be remodeled. If implant is contaminated by the patient’s bodily fluids, it cannot be used in other patients. Although Azure Dental Implant System Abutment & Prosthetic Components are made of nonmagnetic material, but the safety and compatibility in the magnetic resonance imaging (MRI) environment have not been evaluated. The distort images can be obtained via MRI. Intai Technology Corp. is not liable for damages resulting from treatment outside of our control. The responsibility rests with the MRI provider.
10. Indication
Azure Dental Implant System was designed for dental implant surgery; it is placed on the maxillary or mandibular alveolar bone through a surgical operation to replace the dental root. The inserted implant can replace lost teeth by connecting the abutment post following osseointegration with the alveolar bone. The abutment system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over dentures.
11. Side Effect
These problems may occur after implantation (loss of implant stability, loss of prosthesis, etc.).
Deficient quality and quantity of remaining bone, inferior oral hygiene or uncooperativeness of patient, implant mobility, partial deterioration of tissue, and improper position and arrangement of implants can cause instability.
12. Contraindications
Contraindications include following, but are not limited to:
*Hemophilia Patient
*Patient experiencing difficulties related to bone and wound treatment
*Patient with uncontrollable diabetes, tissue disease influencing bone wound treatment; heavy smoker or alcoholic.
* Patient whose immunity system is inactivate due to chemical therapy and radiation therapy
* Patient with oral infection or inflammation (improper oval hygiene, bruxism)
* Patient with untreatable occlusion/joint disorder, insufficient dental arch space
* Patient with insufficient bone height or width
*Any patient who is not suitable for operation.
13. Use
Refer to Azure Dental Implant System general implant operation guide. For details, refer to our catalogue and prosthesis manual.

Azure™

Manufacturer:
INTAI TECHNOLOGY CORP.
Manufacturing Address:
9, Jingke Rd., Nantun District,Taichung City, Taiwan, 40852, R.O.C
TEL: 886-4-3601-5336
FAX: 886-4-3601-9772
www.intai.com.tw

EC REP

European Authorised Representative (E.A.R)
Lotus Global Co., Ltd.
West Drayton, Middlesex
London, UB7 9GG
United Kingdom

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