

“凱石” 牙科用植體基柱  
“KEYSTONE” PrimaConnex Abutment

衛部醫器輸字第 029647 號

使用前請務必詳閱原廠之使用說明書並遵照指示使用。

■ 產品用途

本產品是與Keystone PrimaConnex牙科植體搭配使用，用於上下顎的單顆、多顆或覆蓋假牙膺復的支撐。本產品包括黏著固位、螺絲固位及覆蓋式固位。

■ 產品敘述

Healing Abutment

可在初始手術時或在第二階段手術(手術以露出植體)之後附接到牙科植體，同時軟組織癒合以防止組織在植體上再生長。

材質：鈦合金  
為已滅菌產品

Temporary Abutment (包含Temporary Cyrex Sleeve、Abutment Screw、Occlusal Plug)

可用於單元(鎖定)或多元(非鎖定)臨時修復體的基底。

材質：Temporary Sleeve：鈦合金及PMMA、Abutment Screw：鈦合金、Occlusal Plug：Acetal  
為已滅菌產品

Temporary Sleeve (包含Temporary Sleeve、Abutment Screw、Occlusal Plug)

用於部分或全口假牙臨時修復。可塑造臨時基柱。

材質：Temporary Sleeve 及 Abutment Screw：鈦合金、Occlusal Plug：Acetal  
為已滅菌產品

\* Temporary Abutment 與 Temporary Sleeve皆含M1.8 Abutment Screw，且無獨立型號。

黏著固位式膺復

Temporary/Healing Cap

在軟組織癒合過程中放置Temporary/Healing Cap以保護基柱，或可當作暫時牙冠的基底。

材質：PMMA  
為已滅菌產品

螺絲固位式膺復

Multi-Unit Abutment (本系列包含Gold Sleeve、Coping Screw、Plastic Sleeve、Impression Post、Prosthetic Screw、Abutment Screw、Analog、Healing Cap、Temporary Sleeve)

用於多顆牙冠和牙橋的膺復，及球體附接覆蓋式膺復。不可用於單顆的膺復。

材質：皆為鈦合金，除了Gold Sleeve：金合金、Plastic Sleeve：Acetal

所有產品皆已滅菌，除了：Gold Sleeve, Plastic Sleeve, Temporary Sleeve, Coping Screw, Prosthetic Screw, and Analog。

覆蓋式膺復

ZEST Locator Abutment (包含Locator Abutment、Denture Cap、Replacement Male、Replacement Male Pink、White Block Out Spacer)

用於兩個以上牙科植體的附接覆蓋式膺復。Locator Abutment螺紋直接鎖入PrimaConnex牙科植

體。

材質：Locator Abutment及Denture Cap：鈦合金、Replacement Male及Replacement Male Pink：尼龍、White Block Out Spacer：矽膠  
為已滅菌產品

### ■ 禁忌症

- 一般外科手術必須注意的禁忌症。
- 可能禁忌症：慢性出血問題、心理障礙、骨代謝或結締組織疾病、皮質類固醇的治療、某些心臟與血管疾病、抽菸、糖尿病（未受控制）、化學藥物治療、慢性腎臟疾病、口腔衛生不良患者、夜間磨牙、酗酒。
- 暫時性禁忌症：全身性感染、局部口腔或呼吸道感染。
- 解剖或病理上的禁忌症：牙槽骨的寬度及高度少於1mm以至無法包覆植體。

### ■ 滅菌

本產品經確效之方法滅菌（除了部分配件）。請參考各產品包裝盒標籤的滅菌資訊；所有滅菌產品皆標示有“STERILE”。滅菌產品限單次使用並於保存期限前使用。勿使用外包裝有破損或包裝已被打開之滅菌產品。

- 建議滅菌方式(未滅菌產品)：  
高壓蒸氣滅菌121°C 20分鐘。

### ■ 警告及注意事項

當植體或本產品負荷超過其功能可能發生過度的骨損失或植體或膺復設備的斷裂。生理和解剖的條件可能會對植體的功能有負面影響。當植入牙科植體時應考慮下列情況：

- 不好的骨質
- 不好的口腔衛生
- 醫療條件如血液疾病或未受控制的賀爾蒙分泌

本產品只能銷售給有證照的牙醫師。本產品不可與其他製造廠的牙科植體一起使用。

### ■ 患者的評估與選擇

成功的植牙手術必須有植牙醫師、膺復牙醫師和牙科實驗室技術人員的協調努力。對牙科植體長期功能適當的患者選擇是非常重要的。在做植牙手術時要先考慮下列情況：

- 患者病史
- 口腔衛生
- 患者的期望
- 一般牙科和產品的用途及禁忌症
- 植體位置的解剖標記
- 咬合間隙（牙槽脊和對應牙列間空間）
- 相應於植體直徑的牙橋寬度

■ 產品型號及規格

**Healing Abutment**

型號	敘述
15301K	Straight Healing Abutment, SD For SD PrimaConnex Implants / 3mm Cuff
15302K	Straight Healing Abutment, SD For SD PrimaConnex Implants / 5mm Cuff
15303K	Straight Healing Abutment, SD For SD PrimaConnex Implants / 7mm Cuff
15304K	Contoured Healing Abutment, SD For SD PrimaConnex Implants / 5.0mm Dia 3mm Cuff
15305K	Contoured Healing Abutment, SD For SD PrimaConnex Implants / 5.0mm Dia 5mm Cuff
15307K	Straight Healing Abutment, RD For RD PrimaConnex Implants / 3mm Cuff
15308K	Straight Healing Abutment, RD For RD PrimaConnex Implants / 5mm Cuff
15309K	Straight Healing Abutment, RD For RD PrimaConnex Implants / 7mm Cuff
15310K	Contoured Healing Abutment, RD For RD PrimaConnex Implants / 6.0mm Dia 3mm Cuff
15311K	Contoured Healing Abutment, RD For RD PrimaConnex Implants / 6.0mm Dia 5mm Cuff
15313K	Straight Healing Abutment, WD For WD PrimaConnex Implants / 3mm Cuff
15314K	Straight Healing Abutment, WD For WD PrimaConnex Implants / 5mm Cuff
15315K	Contoured Healing Abutment, WD For WD PrimaConnex Implants / 6.0mm Dia 3mm Cuff
15316K	Contoured Healing Abutment, WD For WD PrimaConnex Implants / 6.0mm Dia 5mm Cuff
15317K	Contoured Healing Abutment, SD For SD PrimaConnex Implants / 4.0mm Dia 3mm Cuff
15318K	Contoured Healing Abutment, SD For SD PrimaConnex Implants / 4.0mm Dia 5mm Cuff
15319K	Contoured Healing Abutment, RD For RD PrimaConnex Implants / 5.0mm Dia 3mm Cuff
15320K	Contoured Healing Abutment, RD For RD PrimaConnex Implants / 5.0mm Dia 5mm Cuff
15321K	Contoured Healing Abutment, WD For WD PrimaConnex Implants / 5.0mm Dia 3mm Cuff
15322K	Contoured Healing Abutment, WD For WD PrimaConnex Implants / 5.0mm Dia 5mm Cuff

**Temporary Abutment**

45112K	Temporary Abutment, SD For SD PrimaConnex Implants / Locking 5.0mm Diameter
45113K	Temporary Abutment, SD For SD PrimaConnex Implants / Non-Locking 5.0mm Diameter
45114K	Temporary Abutment, RD For RD PrimaConnex Implants / Locking 6.0mm Diameter
45115K	Temporary Abutment, RD For RD PrimaConnex Implants / Non-Locking 6.0mm Diameter
45116K	Temporary Abutment, WD For WD PrimaConnex Implants / Locking 6.0mm Diameter
45117K	Temporary Abutment, WD For WD PrimaConnex Implants / Non-Locking 6.0mm Diameter
45118K	Temporary Abutment, SD For SD PrimaConnex Implants / Locking 4.0mm Diameter
45119K	Temporary Abutment, SD For SD PrimaConnex Implants / Non-Locking 4.0mm Diameter

45120K	Temporary Abutment, RD For RD PrimaConnex Implants / Locking 5.0mm Diameter
45121K	Temporary Abutment, RD For RD PrimaConnex Implants / Non-Locking 5.0mm Diameter
45122K	Temporary Abutment, WD For WD PrimaConnex Implants / Locking 5.0mm Diameter
45123K	Temporary Abutment, WD For WD PrimaConnex Implants / Non-Locking 5.0mm Diameter

### Temporary Sleeve

45075K	Temporary Sleeve, SD For SD PrimaConnex Implants/Locking Titanium
45076K	Temporary Sleeve, SD For SD PrimaConnex Implants/Non-Locking Titanium
45077K	Temporary Sleeve, RD For RD PrimaConnex Implants/Locking Titanium
45078K	Temporary Sleeve, RD For RD PrimaConnex Implants/Non-Locking Titanium
45079K	Temporary Sleeve, WD For WD PrimaConnex Implants/Locking Titanium
45080K	Temporary Sleeve, WD For WD PrimaConnex Implants/Non-Locking Titanium

### Temporary/Healing Cap

45209K	Temporary/Healing Cap, SD For SD Quick-Abutments / 5.0mm Diameter
45210K	Temporary/Healing Cap, RD For RD Quick-Abutments / 6.0mm Diameter
45211K	Temporary/Healing Cap, WD For WD Quick-Abutments / 6.0mm Diameter
45236K	Temporary/Healing Cap, RD For RD Quick-Abutments / 5.0mm Diameter
45237K	Temporary/Healing Cap, WD For WD Quick-Abutments / 5.0mm Diameter

### Zest Locator Abutment Assembly

45258K	Zest Locator Abutment Assembly, SD For SD PrimaConnex Implants / 2mm Cuff
45259K	Zest Locator Abutment Assembly, SD For SD PrimaConnex Implants / 3mm Cuff
45260K	Zest Locator Abutment Assembly, SD For SD PrimaConnex Implants / 4mm Cuff
45261K	Zest Locator Abutment Assembly, RD For RD PrimaConnex Implants / 2mm Cuff
45262K	Zest Locator Abutment Assembly, RD For RD PrimaConnex Implants / 3mm Cuff
45263K	Zest Locator Abutment Assembly, RD For RD PrimaConnex Implants / 4mm Cuff
45264K	Zest Locator Abutment Assembly, WD For WD PrimaConnex Implants / 2mm Cuff
45265K	Zest Locator Abutment Assembly, WD For WD PrimaConnex Implants / 3mm Cuff

### Multi-Unit

45161K	Multi-Unit Gold Sleeve, SD/RD For SD/RD PrimaConnex Multi-Unit Abutments
45168K	Multi-Unit Gold Sleeve, WD for WD PrimaConnex Multi-Unit Abutments
45164K	Multi-Unit Coping Screw For PrimaConnex Multi-Unit Abutments
45162K	Multi-Unit Plastic Sleeve, SD/RD For SD/RD PrimaConnex Multi-Unit Abutments
45169K	Multi-Unit Plastic Sleeve, WD For WD PrimaConnex Multi-Unit Abutments
45159K	Multi-Unit Impression Post, SD/RD For SD/RD PrimaConnex Multi-Unit Abutments
45166K	Multi-Unit Impression Post, WD For WD PrimaConnex Multi-Unit Abutments
45333K	Multi-Unit Prosthetic Screw TiLobe Implants
45334K	Multi-Unit Abutment Screw, Angled TiLobe Implants
45327K	Multi-Unit Abut. Imp. Post, Open Tray Tilobe Implants
45328K	Multi-Unit Abut. Imp. Post, Closed Tray Tilobe Implants
45329K	Multi-Unit Abutment Analog Tilobe Implants
45330K	Multi-Unit Abut. Healing Cap, 4.0mm Height For Tilobe Implants
45331K	Multi-Unit Abut. Ti Temporary Sleeve TiLobe Implants
45332K	Multi-Unit Abut. Plastic Sleeve TiLobe Implants

\* SD: Small Diameter; WD: Wide Diameter; RD: Regular Diameter

\* Locking: for single tooth restorations; Non-Locking: for multi-unit, splinted restorations.

製造廠名稱：Keystone Dental, Inc.

製造廠地址：5 Holland Building 209 Irvine, CA USA 92618

藥商名稱：杏昌生技股份有限公司

藥商地址：請依所轄衛生局核定內容刊載