

“圖門” 牙齒骨內植入物附件(未滅菌)

“TruAbutment” Endosseous dental implant accessories (non-sterile)

衛部醫器輸壹字第 017781 號

使用前請務必詳閱原廠說明書並遵照指示使用

效能

本產品用於牙科植體手術，例如在每個植體系統的特定植入物部位開發、植體植入和植體修復。每個產品上的標籤都包含重要的產品信息，包括產品是無菌還是非無菌提供，以及產品是否僅供一次性使用。提供的非無菌器械和套件必須在首次使用前和之後的每次使用前進行清潔和消毒。

型號和規格

編號	型號	產品名稱
1	OTM-SSP08	TruScan Post GH1 compatible with Hiossen(Osstem) ET(TS) Mini Sirona
2	OTM-SSP18	TruScan Post GH2 compatible with Hiossen(Osstem) ET(TS) Mini Sirona
3	OTM-SSP28	TruScan Post GH3 compatible with Hiossen(Osstem) ET(TS) Mini Sirona
4	OTM-SSP38	TruScan Post GH4 compatible with Hiossen(Osstem) ET(TS) Mini Sirona
5	OTR-SSP08	TruScan Post GH1 compatible with Hiossen(Osstem) ET(TS) Regular Sirona
6	OTR-SSP18	TruScan Post GH2 compatible with Hiossen(Osstem) ET(TS) Regular Sirona
7	OTR-SSP28	TruScan Post GH3 compatible with Hiossen(Osstem) ET(TS) Regular Sirona
8	OTR-SSP38	TruScan Post GH4 compatible with Hiossen(Osstem) ET(TS) Regular Sirona
9	ZV3-SSP08	TruScan Post GH1 compatible with Zimmer TSV 3.5 Sirona
10	ZV3-SSP18	TruScan Post GH2 compatible with Zimmer TSV 3.5 Sirona
11	ZV3-SSP28	TruScan Post GH3 compatible with Zimmer TSV 3.5 Sirona
12	ZV3-SSP38	TruScan Post GH4 compatible with Zimmer TSV 3.5 Sirona
13	ZV4-SSP08	TruScan Post GH1 compatible with Zimmer TSV 4.5 Sirona
14	ZV4-SSP18	TruScan Post GH2 compatible with Zimmer TSV 4.5 Sirona
15	ZV4-SSP28	TruScan Post GH3 compatible with Zimmer TSV 4.5 Sirona

16	ZV4-SSP38	TruScan Post GH4 compatible with Zimmer TSV 4.5 Sirona
17	ZV5-SSP08	TruScan Post GH1 compatible with Zimmer TSV 5.7 Sirona
18	ZV5-SSP18	TruScan Post GH2 compatible with Zimmer TSV 5.7 Sirona
19	ZV5-SSP28	TruScan Post GH3 compatible with Zimmer TSV 5.7 Sirona
20	ZV5-SSP38	TruScan Post GH4 compatible with Zimmer TSV 5.7 Sirona
21	NAN-SSP08	TruScan Post GH1 compatible with NobelActive NP Sirona
22	NAN-SSP18	TruScan Post GH2 compatible with NobelActive NP Sirona
23	NAN-SSP28	TruScan Post GH3 compatible with NobelActive NP Sirona
24	NAN-SSP38	TruScan Post GH4 compatible with NobelActive NP Sirona
25	NAR-SSP08	TruScan Post GH1 compatible with NobelActive RP Sirona
26	NAR-SSP18	TruScan Post GH2 compatible with NobelActive RP Sirona
27	NAR-SSP28	TruScan Post GH3 compatible with NobelActive RP Sirona
28	NAR-SSP38	TruScan Post GH4 compatible with NobelActive RP Sirona
29	SBN-SSP08	TruScan Post GH1 compatible with Straumann Bone Level NC Sirona
30	SBN-SSP18	TruScan Post GH2 compatible with Straumann Bone Level NC Sirona
31	SBN-SSP28	TruScan Post GH3 compatible with Straumann Bone Level NC Sirona
32	SBN-SSP38	TruScan Post GH4 compatible with Straumann Bone Level NC Sirona
33	SBR-SSP08	TruScan Post GH1 compatible with Straumann Bone Level RC Sirona
34	SBR-SSP18	TruScan Post GH2 compatible with Straumann Bone Level RC Sirona
35	SBR-SSP28	TruScan Post GH3 compatible with Straumann Bone Level RC Sirona
36	SBR-SSP38	TruScan Post GH4 compatible with Straumann Bone Level RC Sirona
37	AE30-SSP08	TruScan Post GH1 compatible with Astra Tech OsseoSpeed EV 3.0 Sirona
38	AE30-SSP18	TruScan Post GH2 compatible with Astra Tech OsseoSpeed EV 3.0 Sirona
39	AE30-SSP28	TruScan Post GH3 compatible with Astra Tech OsseoSpeed EV 3.0 Sirona
40	AE30-SSP38	TruScan Post GH4 compatible with Astra Tech OsseoSpeed EV 3.0 Sirona
41	AE36-SSP08	TruScan Post GH1 compatible with Astra Tech OsseoSpeed EV 3.6 Sirona
42	AE36-SSP18	TruScan Post GH2 compatible with Astra Tech OsseoSpeed EV 3.6 Sirona
43	AE36-SSP28	TruScan Post GH3 compatible with Astra Tech OsseoSpeed EV 3.6 Sirona
44	AE36-SSP38	TruScan Post GH4 compatible with Astra Tech OsseoSpeed EV 3.6 Sirona
45	AE42-SSP08	TruScan Post GH1 compatible with Astra Tech OsseoSpeed EV 4.2 Sirona
46	AE42-SSP18	TruScan Post GH2 compatible with Astra Tech OsseoSpeed EV 4.2 Sirona
47	AE42-SSP28	TruScan Post GH3 compatible with Astra Tech OsseoSpeed EV 4.2 Sirona

48	AE42-SSP38	TruScan Post GH4 compatible with Astra Tech OsseoSpeed EV 4.2 Sirona
49	AE48-SSP08	TruScan Post GH1 compatible with Astra Tech OsseoSpeed EV 4.8 Sirona
50	AE48-SSP18	TruScan Post GH2 compatible with Astra Tech OsseoSpeed EV 4.8 Sirona
51	AE48-SSP28	TruScan Post GH3 compatible with Astra Tech OsseoSpeed EV 4.8 Sirona
52	AE48-SSP38	TruScan Post GH4 compatible with Astra Tech OsseoSpeed EV 4.8 Sirona
53	AE54-SSP08	TruScan Post GH1 compatible with Astra Tech OsseoSpeed EV 5.4 Sirona
54	AE54-SSP18	TruScan Post GH2 compatible with Astra Tech OsseoSpeed EV 5.4 Sirona
55	AE54-SSP28	TruScan Post GH3 compatible with Astra Tech OsseoSpeed EV 5.4 Sirona
56	AE54-SSP38	TruScan Post GH4 compatible with Astra Tech OsseoSpeed EV 5.4 Sirona
57	MRD-SSP08	TruScan Post GH1 compatible with MegaGen AnyRidge Sirona
58	MRD-SSP18	TruScan Post GH2 compatible with MegaGen AnyRidge Sirona
59	MRD-SSP28	TruScan Post GH3 compatible with MegaGen AnyRidge Sirona
60	MRD-SSP38	TruScan Post GH4 compatible with MegaGen AnyRidge Sirona
61	DSU-SSP08	TruScan Post GH1 compatible with Dentium SuperLine Sirona
62	DSU-SSP18	TruScan Post GH2 compatible with Dentium SuperLine Sirona
63	DSU-SSP28	TruScan Post GH3 compatible with Dentium SuperLine Sirona
64	DSU-SSP38	TruScan Post GH4 compatible with Dentium SuperLine Sirona
65	AS4-SSP08	TruScan Post GH1 compatible with Astra Tech OsseoSpeed TX 3.5-4.0 Sirona
66	AS4-SSP18	TruScan Post GH2 compatible with Astra Tech OsseoSpeed TX 3.5-4.0 Sirona
67	AS4-SSP28	TruScan Post GH3 compatible with Astra Tech OsseoSpeed TX 3.5-4.0 Sirona
68	AS4-SSP38	TruScan Post GH4 compatible with Astra Tech OsseoSpeed TX 3.5-4.0 Sirona
69	AS5-SSP08	TruScan Post GH1 compatible with Astra Tech OsseoSpeed TX 4.5-5.0 Sirona
70	AS5-SSP18	TruScan Post GH2 compatible with Astra Tech OsseoSpeed TX 4.5-5.0 Sirona
71	AS5-SSP28	TruScan Post GH3 compatible with Astra Tech OsseoSpeed TX 4.5-5.0 Sirona
72	AS5-SSP38	TruScan Post GH4 compatible with Astra Tech OsseoSpeed TX 4.5-5.0 Sirona
73	NRN-SSP08	TruScan Post GH1 compatible with NobelReplace NP Sirona
74	NRN-SSP18	TruScan Post GH2 compatible with NobelReplace NP Sirona
75	NRN-SSP28	TruScan Post GH3 compatible with NobelReplace NP Sirona
76	NRN-SSP38	TruScan Post GH4 compatible with NobelReplace NP Sirona
77	NRR-SSP08	TruScan Post GH1 compatible with NobelReplace RP Sirona
78	NRR-SSP18	TruScan Post GH2 compatible with NobelReplace RP Sirona
79	NRR-SSP28	TruScan Post GH3 compatible with NobelReplace RP Sirona

80	NRR-SSP38	TruScan Post GH4 compatible with NobelReplace RP Sirona
81	NRW-SSP08	TruScan Post GH1 compatible with NobelReplace WP Sirona
82	NRW-SSP18	TruScan Post GH2 compatible with NobelReplace WP Sirona
83	NRW-SSP28	TruScan Post GH3 compatible with NobelReplace WP Sirona
84	NRW-SSP38	TruScan Post GH4 compatible with NobelReplace WP Sirona
85	NR6-SSP08	TruScan Post GH1 compatible with NobelReplace 6.0 Sirona
86	NR6-SSP18	TruScan Post GH2 compatible with NobelReplace 6.0 Sirona
87	NR6-SSP28	TruScan Post GH3 compatible with NobelReplace 6.0 Sirona
88	NR6-SSP38	TruScan Post GH4 compatible with NobelReplace 6.0 Sirona
89	STR-SSP08	TruScan Post GH1 compatible with Straumann Tissue Level RN Sirona
90	STW-SSP08	TruScan Post GH1 compatible with Straumann Tissue Level WN Sirona
91	BC34-SSP08	TruScan post GH1 Compatible with Zimmer Biomet 3i Certain 3.4 Sirona
92	BC34-SSP18	TruScan post GH2 Compatible with Zimmer Biomet 3i Certain 3.4 Sirona
93	BC34-SSP28	TruScan post GH3 Compatible with Zimmer Biomet 3i Certain 3.4 Sirona
94	BC34-SSP38	TruScan post GH4 Compatible with Zimmer Biomet 3i Certain 3.4 Sirona
95	BC41-SSP08	TruScan post GH1 Compatible with Zimmer Biomet 3i Certain 4.1 Sirona
96	BC41-SSP18	TruScan post GH2 Compatible with Zimmer Biomet 3i Certain 4.1 Sirona
97	BC41-SSP28	TruScan post GH3 Compatible with Zimmer Biomet 3i Certain 4.1 Sirona
98	BC41-SSP38	TruScan post GH4 Compatible with Zimmer Biomet 3i Certain 4.1 Sirona
99	BC50-SSP08	TruScan post GH1 Compatible with Zimmer Biomet 3i Certain 5.0 Sirona
100	BC50-SSP18	TruScan post GH2 Compatible with Zimmer Biomet 3i Certain 5.0 Sirona
101	BC50-SSP28	TruScan post GH3 Compatible with Zimmer Biomet 3i Certain 5.0 Sirona
102	BHN-SSP08	TruScan Post GH1 compatible with Biohorizons Internal 3.0 Sirona
103	BHN-SSP18	TruScan Post GH2 compatible with Biohorizons Internal 3.0 Sirona
104	BHN-SSP28	TruScan Post GH3 compatible with Biohorizons Internal 3.0 Sirona
105	BHN-SSP38	TruScan Post GH4 compatible with Biohorizons Internal 3.0 Sirona
106	BH35-SSP08	TruScan Post GH1 compatible with Biohorizons Internal 3.5 Sirona
107	BH35-SSP18	TruScan Post GH2 compatible with Biohorizons Internal 3.5 Sirona
108	BH35-SSP28	TruScan Post GH3 compatible with Biohorizons Internal 3.5 Sirona
109	BH35-SSP38	TruScan Post GH4 compatible with Biohorizons Internal 3.5 Sirona
110	BH45-SSP08	TruScan Post GH1 compatible with Biohorizons Internal 4.5 Sirona
111	BH45-SSP18	TruScan Post GH2 compatible with Biohorizons Internal 4.5 Sirona

112	BH45-SSP28	TruScan Post GH3 compatible with Biohorizons Internal 4.5 Sirona
113	BH45-SSP38	TruScan Post GH4 compatible with Biohorizons Internal 4.5 Sirona
114	BH57-SSP08	TruScan Post GH1 compatible with Biohorizons Internal 5.7 Sirona
115	BH57-SSP18	TruScan Post GH2 compatible with Biohorizons Internal 5.7 Sirona
116	BH57-SSP28	TruScan Post GH3 compatible with Biohorizons Internal 5.7 Sirona
117	BH57-SSP38	TruScan Post GH4 compatible with Biohorizons Internal 5.7 Sirona
118	CMM-SSC4	TruScan Post Cap
119	TRUGKITCG2	TruGUIDE Kit
120	CG2-RM45	TruGUIDE Reamer
121	CG2-RM53	TruGUIDE Reamer
122	CG2-TP35	TruGUIDE Guide Tissue Punch
123	CG2-TDE15	TruGUIDE Drill Extension
124	CG2-SVPJ	TruGUIDE Guide Sleeve Pushing Jig
125	CG2-SVMS	TruGUIDE Guide Sleeve
126	CG2-SVMN	TruGUIDE Guide Sleeve

使用方式

使用前準備

1.由於所有手術工具均在非無菌狀態下提供，因此在使用前必須對其進行清潔和消毒。

注意：錯誤的清潔和消毒過程會導致工具腐蝕和損壞，如果直接使用，可能會導致二次感染。

2.根據骨骼狀況，建議使用鑽頭 20~30 次，如果刀片損壞或變形，必須更換。

注意：如果使用損壞的鑽頭，可能會發生熱壞死

3.在管理手術工具時，必須戴口罩和手套，以防止感染。

使用指引

1) TruScanPost: 為了在植牙操作過程中了解口腔內況，將其連接到固定裝置或基台以進行口腔掃描。

腔掃描完成後將其移除。

2) TruGuide Reamer: 磨出導引孔後，為(S)4.5 和(M)5.3 導引孔創建精確的鑽孔直徑尺寸。

3) TruGuide Tissue Punch: 用於在無翻瓣手術中去除組織。

4) TruGuide Drill Extension: 用於增加鑽桿的長度以進入齒間空間有限的區域。

5) TruGuide Sleeve Fitting Jig: 用於將金屬套管安裝到 CG2 導軌上。

警告

1. 器械清洗不徹底、殘留殘留物、乾燥不徹底等，滅菌過程可能會導致器械變色或腐蝕，必須重新進行整個過程。

2. 產品得接觸殺菌設備底部，殺菌必須低於 150 度。

• 未正確清潔或乾燥的產品可能會產生腐蝕。如果沒有清洗乾淨、沒有適當乾燥或已被腐蝕，請將它們與其餘部分分開或移除。(請勿將已腐蝕的器械與未腐蝕的產品一起消毒)

• 消毒時，溶液只能使用無鹽水或蒸餾水。(請勿使用自來水)

• 檢查器械是否完全乾燥，不要將它們放在潮濕的地方。

儲存

產品必須存放在乾燥清潔環境中的無菌容器中。如果包裝被打開或損壞，我們無法保證產品的滅菌狀態。

廢棄處理

1. 如果因誤用而造成產品缺陷，請立即丟棄
2. 對於廢棄物，應將其視為生物危險品，並根據當地政策處理受污染的物品。

***注意：任何與 TruAbutment 產品相關的嚴重事件都應報告給 TruAbutment 公司、使用者和/或患者所在地的主管機關。**

製造業者名稱/ 地址：

Manufactured by TruAbutment Korea Co., Ltd. (104-214~216, 101-1308~1309, 397, Seokcheon-ro, Bucheon-si, Gyeonggi-do, 14449, Korea) for TruAbutment Inc. (17666, Fitch, Irvine, CA 92614, USA)

醫療器材商名稱：國華牙材股份有限公司

醫療器材商地址：新北市中和區中山路二段 351 號 6 樓之 1