"3M" 牙科骨內植體

"3M IMTEC" ENDURE CL Internal Hex Implants

衛署醫器輸字 020999 號

使用前請務必詳閱原廠之使用說明書並遵照指示使用

產品型號規格：

型號	產品說明	直徑	長度
3509	Endure CL Implant	3.5mm	9mm
3511	Endure CL Implant	3.5mm	11mm
3513	Endure CL Implant	3.5mm	13mm
3515	Endure CL Implant	3.5mm	15mm
3517	Endure CL Implant	3.5mm	17mm
4309	Endure CL Implant	4.3mm	9mm
4311	Endure CL Implant	4.3mm	11mm
4313	Endure CL Implant	4.3mm	13mm
4315	Endure CL Implant	4.3mm	15mm
4317	Endure CL Implant	4.3mm	17mm
5109	Endure CL Implant	5.1mm	9mm
5111	Endure CL Implant	5.1mm	11mm
5113	Endure CL Implant	5.1mm	13mm
5115	Endure CL Implant	5.1mm	15mm

產品敘述及用途：

本產品是設計給上下顎完全無牙或部分無牙的病人使用的，它也可以當作是固定或移除牙橋架構的終端或中間支柱。

所有 3.5mm 及 4.3mm ENDURE CL 植體皆有相同的 4.3mm 平台。所有 5.1mm ENDURE CL 植體皆有相同的 5.1mm 平台。所有 ENDURE CL 植體皆包含 0.8mm 覆蓋螺絲。所有 ENDURE CL 植體皆由第四級純鈦金屬製成。所有假體及組件皆由 Ti6Al4V 鈦合金製成。

禁忌症：

假如齒槽的寬度和高度不足以圍住植體，那麼最好不要使用此產品。

骨骼的可利用性不夠、骨質的缺乏、病人的口腔衛生習慣不佳、及全身性的疾病(例如糖尿病)，可能會造成骨整合不足與移植失敗。因此一套適當的病患選擇標準是必須的。

警告及注意事項：

植牙外科手術是非常專業且複雜的手術，因此強烈建議實行植牙手術的牙醫師需接受過專業訓練。執業者需參加完整的學習課程，促使他們具備口腔移植的技術。不適任的臨床醫師可能導致移植失敗和骨喪失。執行植牙的外科手術時，強烈建議您使用無粉醫療手套。使用不鋒利或損壞的器具可能導致植體斷裂。

請勿將本產品與其他廠牌之植入物或零組件搭配使用。

應以 X 光、觸診並徹底檢視預定植牙的部位，以確認有足夠的牙槽骨。在開始進行植牙程序前，先確認所有應避開的解剖學構造。

操作及滅菌

IMTEC 植體以無菌包裝方式提供。由於 ENDURE CL 植體表面處理性質，須以特別方式操作。（限穿戴無粉手套及利用鈦金屬器械操作 ENDURE CL 植體）

併發症

感染、移動及骨質流失都是骨整合不成功的現象。任何植入失敗的植體應盡速移除，並移除植牙部位的 granular 組織。

供應方式

每個 3M 骨內植體都裝在單一滅菌袋中，表面經過特殊的拋光處理。滅菌袋的標籤是易撕貼紙，可撕下貼在病歷上；標籤上包含了該植體的規格及其他重要的追蹤參考資訊。3M 骨內植體供應以下尺寸：

類型	直徑	長度
ENDURE CL 植體	3.5mm	9mm, 11mm, 13mm, 15mm and 17mm
ENDURE CL 植體	4.3mm	9mm, 11mm, 13mm, 15mm and 17mm
ENDURE CL 植體	5.1mm	9mm, 11mm, 13mm, and 15mm

製造廠名稱：3M IMTEC
製造廠地址：2401 North Commerce Ardmore, OK 73401, USA

藥商名稱：台灣明尼蘇達礦業製造股份有限公司
藥商地址：台北市大安區敦化南路二段 95 號 6 至 11、15 及 16 樓

ENDURE CL INTERNAL HEX SYSTEM™ INSTRUCTIONS FOR USE
PHASE 1: IMPLANT PLACEMENT

DESCRIPTION

The IMTEC® *ENDURE* CL Internal Hex System is designed for use in total or partial edentulous mandibles or maxillae or as a terminal or intermediary abutment for fixed or removable bridgework.

PATIENT SELECTION

Patient evaluation prior to implant surgery is extremely important, including determination of general health, oral hygiene habits and status, motivation toward good dental care, and anatomical acceptability. Thorough evaluation of the patient's medical status and health history is mandatory.

PREOPERATIVE TREATMENT PLANNING

Selection of proper implant size is crucial to the long-term success of the implant. It is desirable to utilize the maximum implant width and length possible for greater stability of the overlying prosthesis. Measurements can be made directly on panographic films using a millimeter ruler. Ridge contour should be adequately palpated to estimate an angle of insertion that will achieve parallelism with other implants and natural tooth abutments where indicated.

SURGICAL PROCEDURE

As in any surgery, it is important that the implantation procedure be aseptic. Instruments are provided nonsterile and must be sterilized via standard autoclave procedure prior to use. (See Handling and Sterilization)

SITE PREPARATION

Make a mesio-distal incision along the buccal side of the alveolar crest through the mucoperiosteum and attached gingiva to the bone. Using a periosteal elevator, carefully lift the periosteum to expose the alveolar bone only as necessary to provide an adequate surgical working area. Spinous ridge or other bone irregularities should be removed using a rosette bur or Rongeurs forceps. At least 4-6 mm (edge to edge) should be maintained between implants and/or adjacent natural dentition.

GENERAL INSTRUCTION FOR IMPLANT BED PREPARATION

It is mandatory that all bone-cutting procedures be performed with a low speed (60-1200 rpm), high-torque, internally-irrigated hand piece. Profuse irrigation is required.

All drilling, particularly with intermediate and final spade drills, must be accomplished with a straight, up-and-down motion in order to avoid the creation of an oval-shaped site.

To penetrate the dense ridge crest, a pilot hole should be prepared. (Step 1, below) Questions as to proper angularity and draw with respect to the ridge, existing dentition, or additional implants should be resolved prior to creation of each implant pilot hole.

STEP BY STEP PREPARATION OF THE IMPLANT BED

Implant bed preparation should be done in a clear field so that the operator can view the actual site at all times to properly prepare and fit the implant.

1. Keeping in mind the importance of the pilot hole, the pilot drill is used to create a well-defined, 8 mm deep pilot hole. Flush the pilot hole to remove bone debris, insert one parallel pin using the end, which corresponds in size to the pilot drill. Leave the parallel pin in the first hole and move on to the next preparation while referring to angularity and draw requirements established by the first implant bed preparation.
2. Use the internally-irrigated intermediate Trispade drill to make a channel of the proper depth. The intermediate Trispade drill is marked with concentric rings corresponding to various implant lengths.
3. Fixture type 3.5, 4.3 and 5.1mm diameter implants:
   Use the appropriate diameter IMTEC drill to complete the implant site preparation. The 2.0 and 3.5 mm drills are available for placement of the 3.5 mm fixture. Cortical, crestal bone is prepared for the flared collar of the 3.5 mm implant by using the counterbore. The same 2.0 and 3.5 mm drills are used for placement of the 4.3 mm fixture, and the additional 4.3 mm drill is ideally designed as the final drill. The 2.0, 3.5 and 4.3 mm drills are used for placement of the 5.1 mm fixture, and the additional 5.1 mm drill is ideally designed to be used as the final drill. The counterbore should always be used with the 3.5 mm implant but is not necessary for placement of the 4.3 or 5.1 mm implants. Bone Taps are available for each diameter and should always be utilized in D1 bone and at the discretion of the clinician in D2 or D3 bone.

HANDLING AND STERILIZATION

IMTEC implant bodies are provided in sterile packaging. Due to the nature of the treatment on the *ENDURE* CL Implant, special consideration is required for handling. **(Only powder-free gloved hands or titanium instruments should be used to handle the *ENDURE* CL Implant.)**

STERILIZATION: IMTEC instruments are not sterile and must be sterilized prior to use.

ENDURE CL IMPLANT PLACEMENT: FIXTURE TYPE

1. Irrigate the completed implant site with additional sterile water or sterile saline.

2. Carry the implant to the prepared site. The implant may be carried to surgical site without removing the implant from the vial cap. Appropriate caution must be exercised while handling the implant.
3. Using finger/thumb pressure on the head of the vial cap, partially seat the implant into the prepared site. Secure the implant using the ratchet wrench, hand piece driver or hand mount driver, rotating the implant in a clockwise direction until the implant is placed. The fixture implant is properly placed when the implant sits level with or 1 mm above the crest of the alveolar bone. A cover screw is included in the top of the vial cap to attach and secure to the implant prior to flap suturing.
4. A radiographic check of implant placement is advised prior to flap suturing.
5. The mucoperiosteal flap should be carefully repositioned for maximum tissue adaptation, and then sutured.

POSTOPERATIVE COURSE

The patient should be instructed to follow a routine post-surgery regimen, including cold packs for the initial twenty-four (24) hours. An antibiotic of choice may be prescribed. The sutures may be removed after one week. It is suggested that any removable prosthesis resting near the implant site be adequately relieved and relined using a soft tissue conditioner reline material.

Insufficient availability of bone, poor bone quality, poor patient oral hygiene, and generalized diseases (diabetes, etc.) may contribute to lack of osseointegration and subsequent implant failure.

HOW SUPPLIED

The IMTEC *ENDURE* CL Implant is available in single sterile pouches with a proprietary treated surface finish. Each pouch label provides a convenient peel off tab, which should be removed and placed in the patient's chart for future reference. The tab contains the specifics of implant placed and other important tracking reference data. The following *ENDURE* CL Implant sizes are available:

TYPE	DIAMETER	LENGTHS
ENDURE CL Implant	3.5mm	9mm, 11mm, 13mm, 15mm, and 17mm
ENDURE CL Implant	4.3mm	9mm, 11mm, 13mm, 15mm, and 17mm
ENDURE CL Implant	5.1mm	9mm, 11mm, 13mm, and 15mm

CONTRAINDICATIONS: IMTEC *ENDURE* CL Implants should not be placed if there is insufficient alveolar bone width and height to surround the implant.

Insufficient availability of bone, poor bone quality, poor patient oral hygiene habits, and generalized diseases (diabetes, etc) may contribute to lack of osseointegration and subsequent implant failure. An adequate patient selection criteria is therefore critical.

COMPLICATIONS: Unsuccessful osseointegration will be evidenced by infection, mobility or bone loss. Any failed implant should be removed as soon as possible and all granular tissue removed from the implant site.

WARNING: Surgical techniques required to place dental implants are highly specialized and complex procedures. Specialized training is therefore strongly recommended. Practitioners should attend and complete courses of study to prepare them in established techniques of oral implantology. Improper clinician technique can cause implant failure and loss of bone. Powder free gloves are recommended when placing implants. Using dull or worn tools may cause implants to fracture.
Do not use the IMTEC *ENDURE* CL Implant with implant or components that are not from 3M IMTEC.

PRECAUTION: The adequacy of bone should be determined by radiographs, palpations and thorough visual inspection of the proposed implant site. Establish the location of all anatomical features to be avoided prior to initiating any implant procedures.

CAUTION: Federal (U.S.A.) law restricts sale of the device to or on the order of a licensed dentist or physician, and use by any other person is strictly prohibited.

For technical assistance and more information or to order please call our toll free number (800) 879-9799.

Manufactured by:
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ENDURE™ CL
INTERNAL HEX IMPLANT

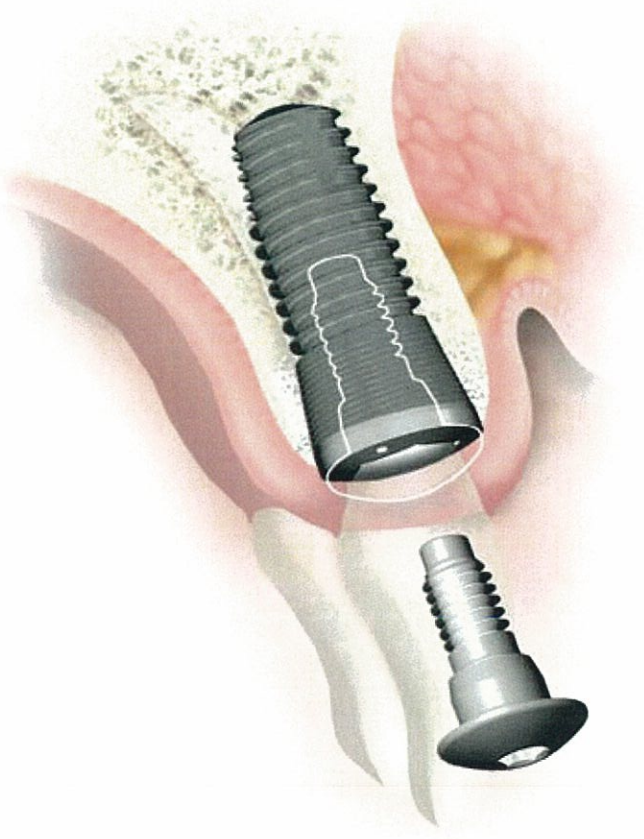
Product Catalog

IMTEC
a 3M Company

3M

ENDURE™ CL

Internal Hex Implant System



All 3.5mm and 4.3mm ENDURE CL Implants have the same 4.3mm platform. All 5.1mm ENDURE CL Implants have a 5.1mm platform. All ENDURE CL Implants include a 0.8mm Cover Screw. ENDURE CL Implants are manufactured from Grade IV commercially pure titanium. All prosthetic parts and components are manufactured from Ti6Al4V ELI.

ENDURE CL Implants

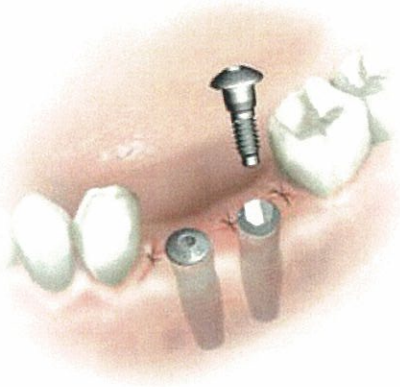
Lengths	3.5mm	4.3mm	5.1mm
9mm	**3509**	**4309**	**5109**
11mm	**3511**	**4311**	**5111**
13mm	**3513**	**4313**	**5113**
15mm	**3515**	**4315**	**5115**
17mm	**3517**	**4317**	

Cover Screw & Healing Abutments

0.8mm
4305

0.8mm Cover Screw included with each ENDURE Implant

3.0mm	4.5mm	6.5mm	8.5mm
4330	**4345**	**4365**	**4385**



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