Sterile LeForte System **Bone Screw / Bone Plate**

INSTRUCTIONS FOR USE

JEILMEDICAL

Print Date

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한국어

- 구강악안면고정용나사(Bone Screw):
- 구강악안면부의 파손된 뼈를 고정하는 데 사용하는 나사
- 구강악안면고정용판(Bone Plate)
- 구강악안면부의 파손된 뼈를 고장할 때 사용하는 판

[사용방법]

1. 사용 전 준비 사항

- ① 시술자는 본 제품과 관련된 제품(Bone Screw, Bone Plate 및 시술기구 등)을 이용한 수술 방법과 임상적응증, 금기 사항 등에 관하여 숙지하고 있어야
- ② 사용 전 제품과 라벨의 사양이 일치하는지 확인한다.
- ③ 시술 시 사용되는 모든 시술기구는 세척 및 멸균하여 준비한다
- ④ 환자의 수술 결과에 영향을 미칠 수 있는 생물학적 및 생체 역학적 요인이 없는지 확인한다.
- ⑤ 본 제품은 멸균 상태로 공급되므로 제품의 외관 상태 및 유효기간이 경과 되었는지 반드시 확인해야 하며, 멸균 환경에서 제품을 개봉하도록 하여야
- ⑥ 포장이 파손되어 있거나 유효기간이 경과된 제품은 절대 사용해서는 안 된다.

2. 사용 방법

- ① $_{\mathrm{2}}$ 절제술이나 골절에 의해서 생성된 골절선 주위에 잔존해있는 조직과 응고된 혈액을 깨끗하게 제거한다.
- ② 골절 정복 겸자 등의 기구를 이용하여 골절 부위를 임시로 정복한다.
- ③ 골절선을 확인하고, 해부학 및 물리학적인 조건과 나사(Bone Screw)의 위치 등의 조건을 고려하여, 시술에 사용할 판(Bone Plate)의 형태 및 크기를 결정 한다
- ④ 시술기구나 손을 이용하여 판(Bone Plate)이 수술 부위에서 최대한 안착할 수 있도록 변형시킨다.
- ⑤ 시술 부위에 맞도록 변형시킨 판(Bone Plate)을 시술 부위에 위치시킨다.
- ⑥ 나사(Bone Screw)의 식립 위치에 맞게 드릴을 이용하여 구멍을 만든다.
- ⑦ 판(Bone Plate)을 나사(Bone Screw)로 고정시킨다.
- ※ 골절선을 기준으로 하여 가까운 쪽에서 먼 쪽으로 좌우 교대로 드릴링하는 것을 권장한다.

3. 사용 후의 보관 및 관리방법

① 본 제품은 일회용 의료기기이므로, 재사용 금지

[사용상 주의사항] 1. 경고

- 판(Bone Plate)과 나사(Bone Screw)의 형태 및 크기는 골 질, 골 형태, 기능 적인 부하력과 수술 후 환자의 적응성 등을 고려한 시술자의 판단에 의하여 선택되어야 한다.
- 본 제품을 효과적이고 안전하게 사용하기 위해서는, 시술자에게 본 제품과 관련한 수술 방법에 대한 충분한 훈련과 경험이 있어야 한다.
- 특별한 용도로 사용하기 위해서 판(Bone Plate)과 나사(Bone Screw) 형상을 결정할 때 합리적인 판단을 할 수 있어야 한다.
- 제품에 과도한 힘을 가하지 않도록 한다.
- 기능상 높은 부하가 예상되는 부위에 본 제품을 사용하는 것은 본 제품의 파쇄나 수술 실패를 야기할 수도 있다.
- 여타 금속으로 된 판(Bone Plate)과 나사(Bone Screw), 와이어 또는 다른 의료기기와 함께 또는 인접되게 사용해서는 안 된다.

- 제품을 불완전하게 고정하는 것은 본 제품의 손상이나 파쇄를 야기할 수도 있다.
- 시술자는 시술 시 발생할 수 있는 문제에 대한 적합한 예방 조치 등을 숙지하고 있어야 한다. • 제품을 이식하기 전 검사를 통하여 환자에게 적합한 판(Bone Plate)과 나사
- (Bone Screw)를 선택해야 한다. • 환자에 따른 적합한 제품, 수술 방법의 선택 및 제거 시기 등의 판단은 시술자에게
- 책임이 있다
- 본 제품은 일회용 의료기기이므로, 재사용하지 않아야 한다. • 유합의 지연, 비결합이나 부수적인 골 재흡수, 외상 등은 제품에 과도한 스트레스를
- 야기하여 제품의 파쇄나 헐거워짐을 야기할 수도 있다.

3. 예방 조치

- 시술자는 시술 전에 수술과 관련된 위험성에 대하여 환자에게 충분히 알려주어야
- 시술 전 제품의 손상 여부를 확인하고, 이상이 있는 제품은 사용하지 않는다.

- 골다공증이나 혈관 이식이 억제되어 골 형성이 부족한 환자에게 시술할 경우, 제품의 헐거워짐, 휘어짐, 부서짐, 파쇄 등이 일어날 수 있다
- 이식 후, 이른 제거수술은 골내 제품 고정의 실패를 야기하여 골절합이 불완전할 수도 있다
- 부적합한 정렬이나 배열은 절골 부위의 절합 지연과 절합 실패를 야기할 수도
- 티타늄 등의 금속 재질에 민감한 환자에게는 사용하지 말아야 한다.

5. 금기

- 활성 감염 또는 잠재적인 감염 • 골다공증
- 골 및 연조직의 결함 • 이식물에 대한 과민증
- (과민증이 의심된다면 이식 전에 테스트를 해보는 것이 좋다.)
- 패혈증
- 정신적, 신체적으로 수술 후 처치가 곤란한 환자 • 사용목적 이외의 용도로 사용해서는 안 된다.
- 기타 판(Bone Plate)과 나사(Bone Screw)의 고정력에 대해서 한계를 가지는
- 장애가 있는 환자에게는 사용하지 말아야 한다.
- 재멸균 하여 사용하지 않도록 하며, 재멸균에 대한 책임은 사용자에게 있다.

[유효기간] 제조일로부터 5년까지

[**보관조건 및 저장방법]** 실온의 건조한 곳에서 보관한다.

[본 제품은 일회용 멸균(감마) 의료기기임]

English

[DESCRIPTION]

The Sterile Leforte System Bone Screw & Bone Plate are comprised of a variety of shapes and sizes designed intended for use in selective trauma of the mid-face; reconstruction procedures; and selective orthognathic surgery of the maxilla and $\mbox{\it chin.}$

The plates includes straight, Y, Z, curved, square, L(Left/Right), T, X, H, mesh and etc. Plates are manufactured from titanium(ASTM F67) and Screw are manufactured from titanium alloy (ASTM F136). The Plate & Screw are provided a packaging as sterilized by gamma irradiation. The recommended plate & screw combination are as follows:

		Bone Screw	Bone Plate
	Micro	· 1.2/1.3/1.5mm Self-tapping Screws · 1.4mm Self-drilling Screws	Micro Plate series
	Mid	· 1.6/1.8/1.9mm Self-tapping Screws · 1.6mm Self-drilling Screws	Mid Plate series
	Mini	2.0/2.3mm Self-tapping Screws 2.0mm Self-drilling Screws 2.0/2.3mm Self-tapping Locking Screws	Mini Plate series, Mini Locking Plate series
	Maxi	· 2.4/2.7mm Self-tapping Screws · 2.4/2.7mm Self-tapping Locking Screws	Maxi Plate series, Maxi Locking Plate series

[DIRECTIONS FOR USE]

The Sterile Leforte System Bone Screw & Bone Plate offers the operating surgeon unique features and user friendly capabilities. A step by step explanation of how to use the system follows: Selecting Plate Configurations

1. Selecting Plate Configurations

The choice of which plate or screw size to use is at the discretion of the operating surgeon.

• MICRO/MID: The plates are 0.5mm thick and very malleable. Finger pressure is sufficient to bend these plates.

Whatever configuration fits the anatomy is usually selected. The outer segments of all the micro plates can also be bent and contoured on the bone using the bending forceps. Avoid bending across any of the screw holes. The hole to hole spans have been designed to allow the bending forceps to grip the plate between the inter-hole segments. By tweaking each segment, one can produce a gentle or tight radius bend along the length of any straight or pre-curved plate. To cut any of the plates, a plate cutter can be used.

• MINI: The most commonly used mini plates are the L and Z plates. These plates are used in the pyriform aperture and zygomatic buttress to secure maxillary osteotomies. The Z plates are used in the same region as an L plate, but unlike an L plate, the Z plate will not extend as high vertically.

With the L's, Z's and Y's, the outer screw hole segment can be moved using the bending forceps while the plate is partially secured to the

The Y plate was designed especially for fixating segmental maxillary osteotomies. A general rule of rigid fixation states that two screws should always be placed on each side of the osteotomy. Any of the mini plates can be cut using a plate cutter.

• MAXI: The BSSO plates (Being Sagittal-split osteotomy Plate) are specially designed to stabilize the proximal and distal segments resulting from sagittal split osteotomy of the mandible. These plates were designed to minimize overall plate length and to further improve bone segment fixation and stability. The BSSO plates can be bent using the forceps. The BSSO plates can also be used for fracture, especially in areas where a mini plate is not substantial enough. For instance, to further stabilize a mandibular fracture. The most common maxi fracture plates are the 4 hole straight plate and 6 hole straight plate. The angled 6 hole plate and reconstruction plate are often used. The thickness and overall dimensions of each of these plate types has been selected to optimize their applications. These plates (4, 6 hole straight plates and angled 6 hole plate) are strong enough to fixate and stabilize supported mandibular bone or for comminuted $\,$ fractures of supported mandible bone. The reconstruction plates are used without supporting bone. Each of the maxi plates is designed to be used with 2.4mm screws.

Plate Handling

The Sterile Leforte System Bone Plate is grasped, using the forceps supplied with the Sterile Leforte System.

3. Plate Bending

Micro, mid, mini plates can be bent and contoured using a plate bender or finger pressure. Exercised care to avoid distorting the screw hole. The Maxi plates are designed to be bent primarily in a transverse direction.

Very rarely are fracture plates or reconstruction plates bent about a radius longitudinally. The reason is, the mandibular and symphysis are usually of sufficient height to allow plate placement in a variety of

4. Plate Cutting Micro, mid and mini plates can be cut using plate cutters. Exercise care

while cutting plates to avoid producing flying plate fragments that can enter the surgical site. The maxi plates are much more difficult to cut. To cut maxi plates, the surgeon holds the plate in his hands, grab the end of the plate projecting beyond the bending his hand, and produce a very tight radius bend in the section of plate to be removed. By bending the plate section to be removed in the opposite direction, the plate snaps off. The edge made by breaking off a plate section can be easily smoothed using a round burr.

5. Drilling Pilot Holes Sterile Leforte System Bone Screws are self-tapping. The conical tip

design and sharp threads allow the screws to self-tap into bone. All selftapping screws require that a pilot hole be made in the bone prior to screw insertion. Drilling a pilot hole reduces the chance of fracturing bone and reduces the level of torque required to drive screws. To reduce the potential for thermal necrosis, all pilot drills should be used at minimal RPM. Proper pilot drilling technique indicates that the drill point do the cutting. Fault drilling causes that screws will not fit tightly into the bone or even strip in the bone. The surgeon must use drill fit

6. Plate and Screw fixation

To fixate plate and screw, the surgeon uses for driver shafts. Driver shaft types are comprised of micro, mid, mini and maxi. Insert the required driver shaft in the screwdriver body. Use it to pick up a screw then

rotate it to fixate the screw in the surgical site. Each driver shaft features a cruciform tip that friction fits into either the micro, mid, mini and maxi screw heads.

The driver shafts or other instruments are separated from the screwdriver body by pulling back on the collar at the distal end of the

Use a cannula/trocar system, to inserted the screw into the posterior regions of the mandible since it is almost impossible to reach with an intra- oral approach. Also, using a cannula allows screws to be inserted at right angles to the bone

[INDICATIONS]

This device is intended for use in selective trauma of the mid-face; reconstruction procedures; and selective orthognathic surgery of the

Bone Screw: Titanium Alloy (ASTM F 136) Bone Plate: Titanium (ASTM F 67)

[WARNING] • U.S. Federal Law restricts this device to the sale by or on the order of

- a licensed physician or other qualified medical professional. Selection of plate and screw size must be carefully considered by the operating surgeon and should take into consideration the quality of bone, bone type, functional loads exerted on bone(s), and postoperative patient compliance.
- For sale and effective use of [Sterile Leforte System Bone Screw & Bone Plate], the surgeon should have specific training, experience, and thorough familiarity with the use of rigid fixation and techniques.
- Multiple bending may weaken the plates and could result in implant fracture and failure.
- · The surgeon must exercise reasonable judgment when deciding which plate and screw type to use for specific indications. • Sterile Leforte System Bone Plate Screw are not intended to endure
- excessive abnormal functional stresses • Use of an undersized plate or screw in areas of high functional stress
- may lead to implant fracture and failure · Plates and screws, wires and other appliances of dissimilar metals should not be used together in or near the implant site.

- · Improper fixation of the plate and screw may result in the formation of a ridge
- Select the appropriately sized plate and screw for the patient. · Responsibility for proper selection of patients, adequate training, experience in the choice and placement of plate & screw and the decision to leave or remove plate and screw postoperatively, rests
- with the surgeon. · Once applied, never reuse this device.

Always follow appropriate safety precautions.

• Delayed healing, nonunion or subsequent bone resorption or trauma may cause excessive stress on this device and result in loosening or

[PRECAUTIONS]

- The physician should inform the patient of risks associated with surgery
- · Check the package if it is torn or damaged.
- Inspect each device to ensure they are not bent or damaged.

[POSSIBLE ADVERSE EFFECTS] • In many cases, adverse results may be clinically related rather than

- implant related. • Osteoporosis, inhibited revascularization and poor bone formation
- can cause loosening, bending, cracking and fracturing of this device or premature loss of fixation with the bone, leading to nonunion
- Delayed or nonunion of the osteotomy site or malunion resulting from improper alignment.
- Infection, early or late, both deep and/or superficial and/or superficial. • Metal sensitivity reactions following surgical implant have rarely been reported, and their significance awaits further clinical evaluation.

[CONTRAINDICATIONS]

- Not for use in cases of active or suspected infection or in patients
- previously sensitized to Titanium. · Not for use in patients exhibiting disorders which would cause the patient to ignore the limitations of rigid fixation plate and screw
- The manufacturer assumes no responsibility for attempted re-use.

[EXPIRATION DATE] 5 years from Manufacture date

[STERILE BY GAMMA IRRADIATION]

[PACKAGING]

All Sterile Leforte System Bone Screw / Bone Plate are packaged individually. This device is manufactured and sold by Jeil Medical

[SYMBOL DESCRIPTIONS]

LOT Batch code

REF Catalogue number



Do not re-use



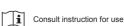
Do not resterilize Date of manufacture



Use-by Date



STERILE R Sterilized using irradiation





Do not use if package is damaged

