Revision History

Fixture

Rev No.	Doc No.	Reason for revision
0	HNF-E01-R01 (19.10.11)	First enacted
1	HNF-E01-R01 (21.09.17)	Revision due to change of European representative address
2	HNF-E01-R02 (21.02.04)	Revision according to the addition of the Korean manual (using both English and Korean)
3	HNF-KE01-R03 (21.05.10)	Revision due to distribution of insert format

Abutment

Rev No.	Doc No.	Reason for revision
0	HNA-E01-R01 (19.10.11)	First enacted
1	HNA-E01-R01 (20.01.08)	Revision due to the addition of manufacturing sites
2	HNA-KE01-R02 (21.09.17)	Revision due to change of European representative address
3	HNA-KE01-R03 (21.05.10)	Revision due to distribution of insert format

Fixture

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1. Purpose

・Dental implant fixture : A lower structure of a dental implant inserted into the human body to support a prosthesis such as an artificial tooth used to restore the patient's mastication function.
・Cover Screw : Dental implant superstructure for restoration of mastication function and aesthetic restoration of damaged teeth

2. Preservation & Handling

・The product is sealed (gamma radiation sterilization) in a dry place at room temperature (4~30℃) Keep in.
・As this product is a sterilized product, it must be used immediately after opening, and reuse is prohibited.
・After opening, discard even if not used.

3. Instruction for use

1) Preparation before use

(1) Preparation for the patient

・Check the patient's oral condition.
・After preliminary examination and analysis are conducted for each patient, the oral condition is checked, and then an appropriate sized implant is selected.
・Thorough clinical evaluation is imperative prior to all implant surgeries.

(2) Preparation for the operator

・The operator's experience and surgical situation should be guaranteed.

· The operator should use the product after fully familiarizing himself with the operation method and precautions.
· Check the disinfection of surgical instruments and the preparation of instruments.
· Check if there are any biological or biological factors that may hinder the surgical outcome.
(3) Preparation for the product
· Check for damage to the packaging of the product and discard if any.
· Check if the expiration date has passed. (5 years from the date of manufacture)
· Even after opening, check the product for abnormalities such as foreign substances, stains, and dust before entering the procedure.

2) Using methods

(1) 1st surgery

① Check the implant placement position.
② Incise the gingiva at the desired location to expose the jaw.
③ Use a guide drill to pierce the cortical bone to determine the location where the implant will be placed. At this time, the procedure must be performed to prevent bone necrosis from occurring, and the drilling speed at the time of surgery is the patient's bone quality or procedure. It should be properly adjusted according to the range of use of the device. (Recommended: Guide Drill and 2.2mm first Drill-1200rpm/30-45 N.cm with irrigation)
④ Using a depth gauge, check whether the depth of the hole formed matches the length of the fixture and the occlusal relationship with the opposing teeth.
⑤ Using a parallel pin, check if the location and direction of the hole are correct as planned by the operator.
⑥ Using a pilot drill and a drill, expand the hole according to the diameter of the implant to be placed. (Recommended: Pilot Drill - 1200rpm/30-45 N.cm with irrigation)
⑦ The Final Drill finally decides the size and depth of the hole, so pay special attention. (Recommended: Final Drill- 1200rpm/30-45 N.cm with irrigation / Counter Sink Optional-1200rpm/ 30-45 N.cm with irrigation)

[Fixture installation]

⑧ Check the implant type, size, expiration date, and packaging condition indicated on the packaging label, and open the sterilized implant. When opening the fixture cap, hold the fixture container upright and engage the Implant Driver into the fixture and connect firmly together. Remove the fixture from the packaging.
⑨ Take care not to contaminate the implant with metal or saliva, Attaching fixture to the implant driver. Insert fixture into the bone, turning clockwise at 20rpm/35N.cm with irrigation using the Implant Driver. It is recommended that the top level of the fixture be located 0.5mm below the crestal bone.

[Cover Screw or Healing Abutment Application]

⑩ Thoroughly clean blood and fluid from the fixture interface prior to attaching cover screw or healing abutment, Failure to property clean the fixture can cause difficulty in removing the cover screw or healing abutment.

For two stage procedures, apply cover screw using the hex driver. For one stage procedures, apply healing abutment using the hex driver.

[Soft tissue suturing]

⑪ The healing period alter the first stage surgery is dependent on the patient's bone condition and quality. Radiographs are required prior to surgery to determine bone condition and again alter the second stage surgery. As well as prior to loading. To avoid movement at the fixture and possible loss the implant, prosthetic loading should not be done until there is evidence of implant osseointegration.

⚠caution

-Irrigate during drilling to avoid overheating the bone. Overheating can cause bone damage resulting in failure to ossify and loss 01 the fixture.

-Applying excessive torque (more than 80N.cm) may result in fracture or damage to the bone.

-Be careful as the rotation speed varies depending on the bone quality

(2) 2nd surgery

① Take measures to allow the patient to directly disinfect the oral cavity for a certain period after surgery.

② Pay attention to the patient so that excessive force is not applied to the implanted area until the upper prosthesis is installed after the implantation of the fixture.

③ After the alveolar mucosa is healed and bone fusion is achieved, incise the upper soft tissue of the implanted vice, remove the cover screw, and connect the healing abutment to the implant, and then suture the surrounding soft tissue.

⚠caution : During the 2nd surgery, it is performed with a sufficient healing period. (Depending on the nature of the bone, the healing period before connecting the abutment is different, so this should be considered, and if the bone is very soft, an additional healing period may be required.)

4. Care after use

· After the procedure is finished, the equipment is washed with alcohol, detergent, etc., and then stored after sterilization.

· Instruct the patient to take oral hygiene management to prevent side effects.

· Attach the identification tag (Lot No.) enclosed in the packaging box to the patient record to enable tracking management.

5. Precaution for use ⚠

(1) Precautions

· Bone disease (osteoporosis, osteomalacia) If there is a bone metabolic disorder, it should be carefully considered before the procedure.
· Pregnant women must consult a medical professional.
· Bone fusion may fail due to infection, bone loss, mobility, etc. The failed implant should be removed as soon as possible, and all granular tissue should be removed from the implant placement site.
· Follow the healing period after each meal and perform the following steps at the discretion of the practitioner after sufficient bone fusion, and make sure that pressure such as masticatory pressure is not applied to the fixture during the healing period.
· This product has not been evaluated for safety and suitability in magnetic resonance (MR) environments. Heat, movement, and image defects in a magnetic resonance environment were not tested. Therefore, the safety in magnetic resonance environment is unknown. In the case of scanning a patient with this medical device inserted, the patient may be damaged.

(2) side effects (adverse reactions)

· the patient by a dental professional, and any adverse reactions should be promptly addressed.
· Fracture of an implant or prosthesis. Poor fastening, pinching, deformation, and loosening of screws may occur.
· Bone loss around the implant, mucositis, etc. may occur.
· Complications such as malocclusion, paresthesia due to nerve damage, infection, edema, subcutaneous bleeding, pain, open sutures, and soft tissue ulcers may occur.
· Implant movement, local tissue deterioration, etc. may be caused.
· If the width and height of the alveolar bone surrounding the implant are insufficient, it may cause the implant to fail.
→Contraindications, side effects and preventive measures for changes in implant performance should be fully explained to the patient by a dental professional, and any adverse reactions should be promptly addressed.

(3) contraindications

The use is prohibited for the following patients.
· Patients with blood clotting or bone and wound healing disorders.
· Uncontrollable diabetics, excessive smoking or alcoholism.
· Patients with insufficient immune function due to chemotherapy and radiation therapy.
· Patients with oral infection or inflammation (inappropriate oral hygiene, tooth decay, dry section, etc.)
· In case of non-cooperative patient or mental or physical disability that may cause instability, fixation failure or complications of the prosthesis in postoperative management.
· Patients allergic to titanium.

· In case of a condition that affects aggregate remodeling, microcirculation, or blood.
· Patients whose periodontal or surgical operation is contraindicated

(4) Warning

· As improper procedures may damage the implant or damage to the surrounding bone tissue, it is forbidden to use it for purposes other than those specified.
· Implant surgery can only be performed by experienced dentists who can diagnose and plan surgery.
· If the implant location and fixation are unstable due to improper selection of the implant, the life of the implant may be shortened.
· Handle with care to prevent damage or deformation of the implant.
· This product is a disposable sterilization device, so do not re-sterilize or reuse.
The manufacturer does not assume liability for re-sterilized implants.
· Particular attention should be paid to the elimination of sources of contamination and infection.
· Do not use products with open or damaged packaging.

*** This product is disposable sterile medical device, So it must not be re-sterilization and re-used.**

CE	KR: CE적합성인증 US: CE conformity marking		KR: 제조일자 US: Date of Manufacture		KR: 재멸균 금지 US: Do not resterlize
LOT	KR: 제조번호 US: Batch code		KR: 제조업자 US: Manufacturer		KR: 사용설명서 참조 US: Consult instructions for use
REF	KR: 카탈로그번호 US: Catalogue number	EC REP	KR: 유럽대리인 US: Authorized representative in Europe		KR: 사용상 주의사항 US: Caution
	KR: 유효기간 US: Use by date		KR: 보관온도 US: Temperature limitation		KR: 포장 파손 시 사용 불가 US: Do not use if package damaged
	KR: 재사용금지 US: Do not re-use	STERILE R	KR: 방사선멸균 US: Sterilized using irradiation		KR: 습기 주의 US: Keep away from rain

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HNF-KE01-R03 (21.05.10)

Abutment

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1. Purpose

It is the implanted superstructure for supporting prosthesis that is used to recover chewing function.

2. Storage

It is supposed to store under the condition not expose to direct-sunlight, high and low temperature (4°C - 30°C) in a packaged condition.

3. Operating

(1) Before use

・X-ray films are decoded and the products tailored to the patient's characteristics should be selected.
・The deformation, discoloration, contaminants and damaged of the products need to be verified.
・All of the instruments must be sterilized before use. Before use, let the abutment steam sterilize at 121 °C for 30 minutes. But If the package is damaged or not tightly closed, abutments must not be used or re-sterilized.

・When abutments are combined on the oral of the patient, Clinical experts should surgery after verifying osseointegration of the implanted fixture by radiography picture and other methods.
・The clinical experts should clearly acquire the surgical methods, clinical symptom and cautions. used by surgical instrument.
・The oral condition of the patients is inspected and Biological factors that interfere with the surgical results are verified.
・The cover screw and Healing abutment is combine on it after implanting the fixture and Clinical

experts wait a certain periods for bone union.

· The cover screw is removed by surgical procedure after recovering, and the clinical experts should make the healing abutment combined on the upper of the fixture to select of the prothesis positions and let the gingiva recover because abutments are various.

· The clinical experts should determine the size and type of the abutment depending on the patient's oral conditions, The making prothesis should be planned.

(2) Using methods

The surgeries are only performed when the patients have the sufficient bone condition to implant fixtures.

All of the instrument needed for surgery should be perfectly disinfected, The clinical experts should perform the anesthesia on the implantation position and make it expose sufficiently after incising and implant artificial teeth.

Healing Abutment, Cover Screw

① The procedure is only performed when the clinical experts inspect adhesion condition with the implanted fixture and bone and judge them stable.
② The product that is appropriate on the patient's oral conditions is selected.
③ The product should not be touched on the contaminations.
④ The suggested union torque of this products is 10N·cm with the hand torque.

Abutment

① The procedures are only performed when the clinical experts inspect adhesion condition with the implanted fixture and bone and judge them stable.
② The abutment that is appropriate on the patient's oral conditions is selected.
③ The product should not be touched on the contaminations.
④ The healing abutment is removed by using prothesis equipments and the selected abutment is combined.
⑤ The impression of the oral is gotten by using Impression coping.
⑥ Based on the acquired impression, the mockup and prothesis are made.
⑦ Finally, the made prothesis are cleaned and polished.
⑧ The prothesis is fasten by using the adhesive material like a screw and cement.
⑨ The suggested union torque of this products is 30N·cm

4. Storage after using

It must not be reused because it is disposable.

5. Contraindications

Expert monitoring is required for the following:

(1) General contraindications

- Insufficient bone quantity or poor bone quality endangering the primary stability of the implant
- Acute or chronic infections
- Subacute chronic osteitis of the jaws
- Impairment of microvascular circulation
- Systemic disease
- Poor general health condition
- Recent myocardial infarction
- Immunosuppression
- Active treatment of malignancy / cancer / tumor
- Not completed maxillary or mandibular growth
- Allergies or hypersensitivity to chemical ingredients of materials used

(2) Relative contraindications

- Addictions (alcohol, tobacco, drugs)
- Inadequate oral hygiene, lack of motivation, lack of cooperation
- Diabetes mellitus head and neck radiation
- Postmenopausal and hormone replacement therapy
- Osteoporosis, e.g. intravenous bisphosphonate use
- Psychiatric illness
- Use of anticoagulation drugs / hemorrhagic diathesis
- Pre-term infants and neonates
- Pregnancy
- Infants and children: not before the jaw bones have stopped growing (in general 17-18 years).

(3) Local contraindications

- Uncontrolled parafunctional habits
- Insufficient height and/or width of bone
- Insufficient inter-arch space
- Intraoral infection
- Local root remnants

6. Adverse Effects

- Screw loosening
- Peri-implantitis
- Implant fractured

- Implant lost
- Inflammation/Hyperplasia
- Gingival recession
- Bone resorption
- Unidentified Device or Use Problem
- Fracture
- Osseointegration Problem

7. Precautions

- When abutments are combined on the oral of the patient, Clinical experts should surgery after verifying osseointegration of the implanted fixture by radiography picture and other methods.
- The plaster cast is made after obtaining the impression body considering the occlusal surface of the upper and lower.
- The temporary structures are combined on the oral cavity during making the final prothesis at the laboratory.
- When the investment agent solidifies, it must be cooled to avoid micro-shrinkage and expansion deformation.
- The products contaminated by clinical expert must not be used.
- All of the products that is used in the oral must be not re-used.
- The products opened must be discarded even if they are not in use.
- All personnel must wear the appropriate protective clothing and gloves.
- when the patients are in Contraindications and Caution matters, the implant surgery is re-considered.
- H-system are intended for use by adequately certified dentists with specifics implant training.
- If the clinical problems is founded on the implant site, the abutment are removed as soon as possible.
- Implant and abutment fractures can occur when applied loads exceed the normal functional design tolerances of the implant components. Potential overloading conditions may result from deficiencies in implant numbers, lengths and/or diameters to adequately support a restoration, excessive cantilever length, incomplete abutment seating, abutment angles greater than 25° degrees, occlusal interferences causing excessive lateral forces, patient parafunction (e.g., bruxing clenching), improper casting procedures, inadequate prosthesis fit, and physical trauma.

8 Cautions

- This product is disposable medical device, So it must not be re-used.
- Highness abutments are only intended for use with Highness fixtures, H-system Instruments and components.

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	KR: 유효기간 US: Use by date		KR: 보관온도 US: Temperature limitation
	KR: 재사용금지 US: Do not re-use	NON STERILE	KR : 비멸균제품 US : Non-sterile
	KR: 사용설명서 참조 US: Consult instructions for use		KR: 사용상 주의사항 US: Caution
	KR: 취급 주의 US: Fragile, handle with care		KR: 직사광선 노출 금지 US: Keep away from sunlight
	KR: 습기 주의 US: Keep away from rain		KR: 포장 파손 시 사용불가 US: Do not use if package damaged
℞ ONLY	KR: 처방 의료 장비 US : Prescription Device		

*For more information, please visit the website to download the user manual.
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HNA-KE01-R03 (21.05.10)

Detailed usage procedures are posted on the website.

Surgical KIT

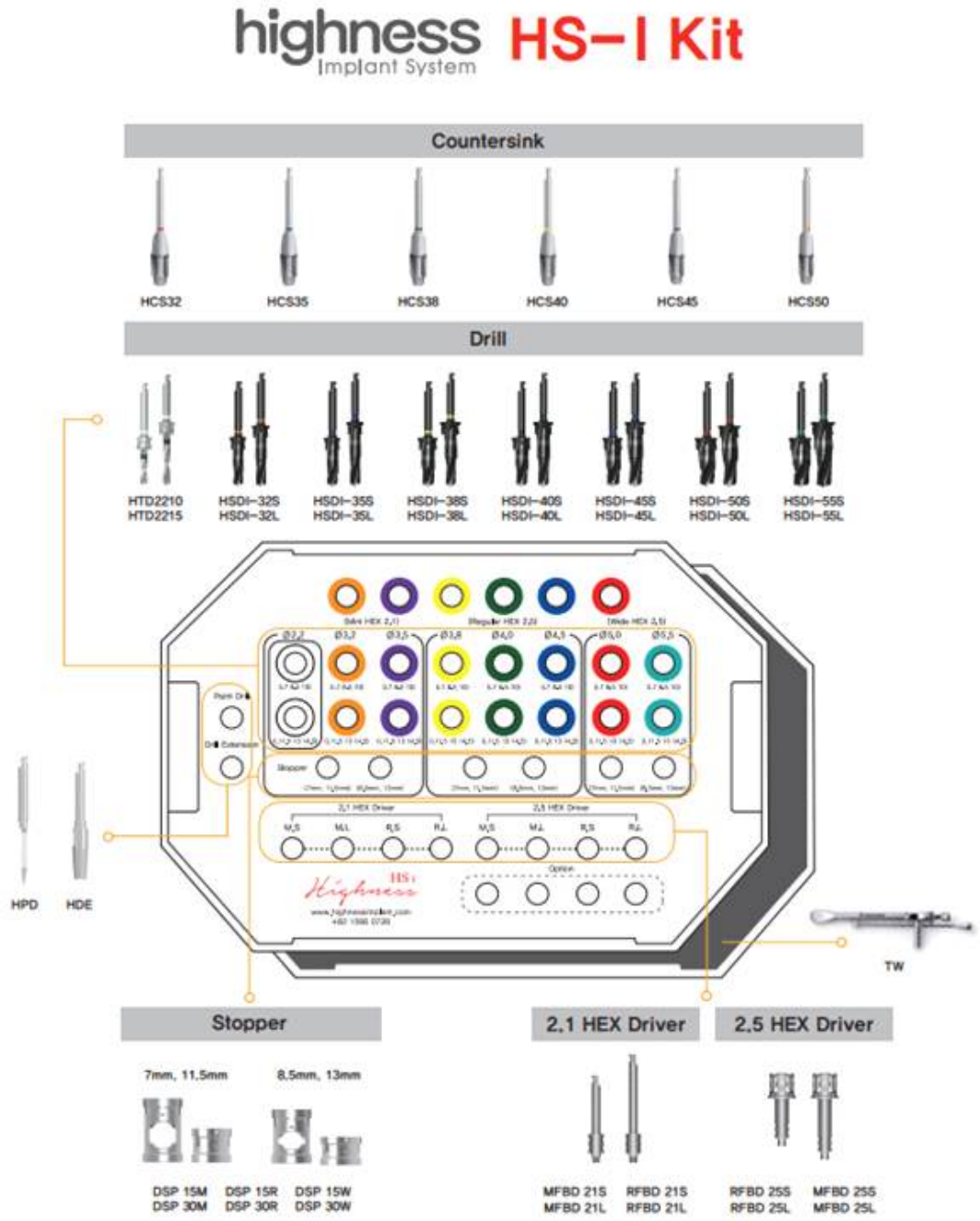
All components are color-coded and externally irrigated. They are designed to achieve maximum cutting efficiency while effectively removing bone from the osteotomy during drilling. The fixtures are applied differently according to the oral bone tissue condition of the patients. H-system has the drill tools of a various dimensions to be applied all specifications (Table 1)

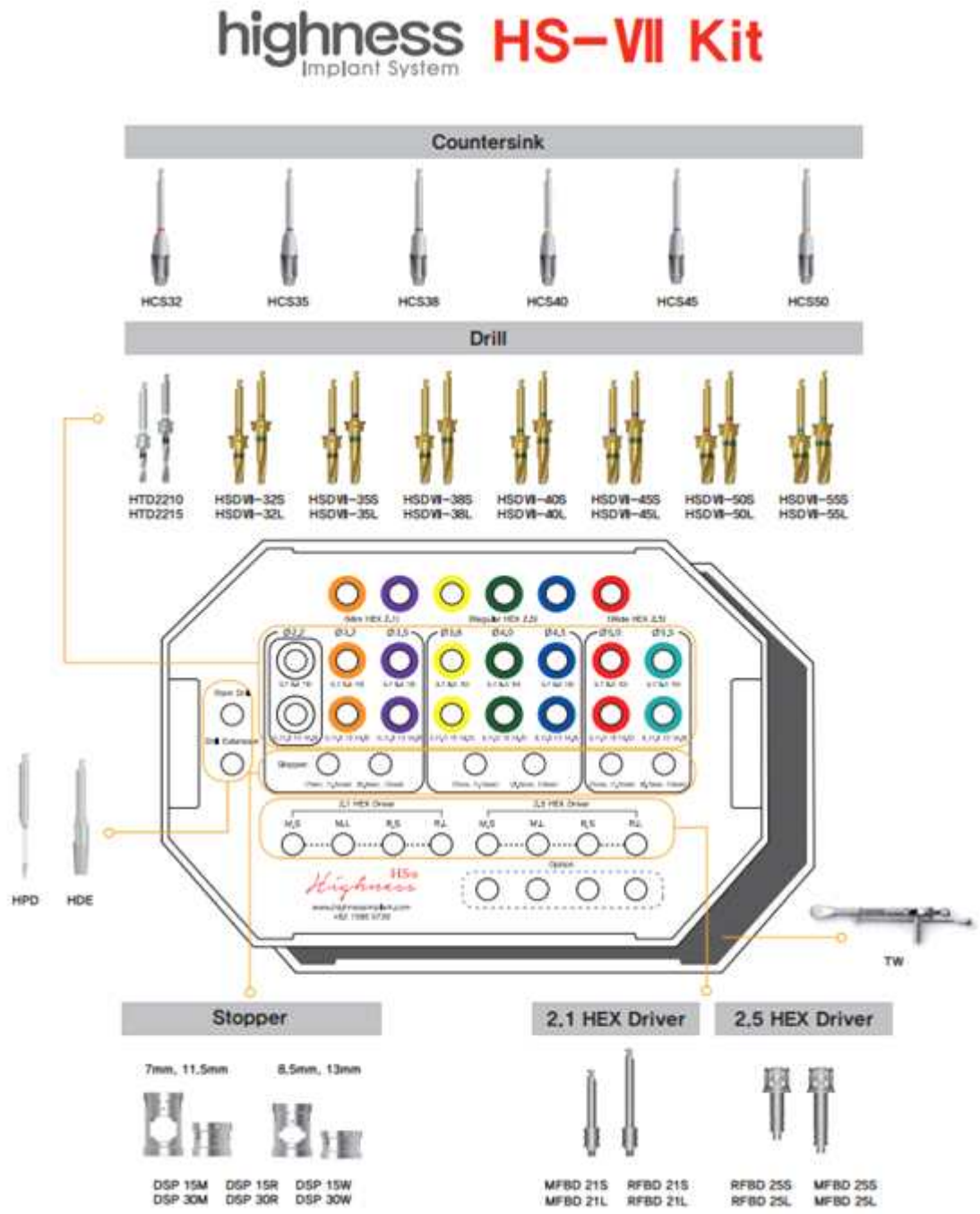
Table 1 Drills by dimension

Demension (ϕ)		3.2	3.5	3.8	4.0	4.5	5.0	5.5
Model.	HS-I	HSDI-32S	HSDI-35S	HSDI-38S	HSDI-40S	HSDI-45S	HSDI-50S	HSDI-55S
		HSDI-32L	HSDI-35L	HSDI-38L	HSDI-40L	HSDI-45L	HSDI-50L	HSDI-55L
	HS-VII	HSDVII-32S	HSDVII-35S	HSDVII-38S	HSDVII-40S	HSDVII-45S	HSDVII-50S	HSDVII-55S
		HSDVII-32L	HSDVII-35L	HSDVII-38L	HSDVII-40L	HSDVII-45L	HSDVII-50L	HSDVII-55L

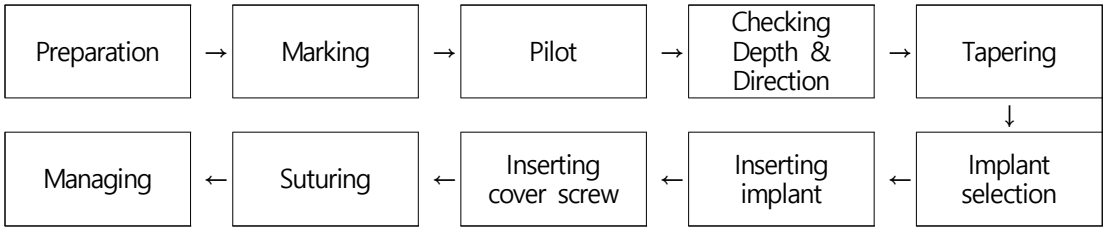
Additionally, More tools are used except for the drills when performing an implant.
The description is below (Table 2)

No.	Contents	Description
1	Ratchet	It is tools that us used to fix the abutments firmly. It has the screw to be tighten or loosen by moving the handle clockwise or counterclockwise.
2	Point Drill	It is used to mark position of the holes to be formed at the implant position.
3	Drill Extension	It operate by fastening with handpiece after connecting tools that needs the extension at the part.
4	Twist Drill	Drilling to a predetermined depth for placement of the dental implant fixture.
5	Step Drill	It is used to make hole for implant of the fixture
6	Drill Stopper	It is used to adjust the depth of drilling
7	ϕ 1.2 Hex Driver	It is the driver to be used for the implant procedure. It is used to tighten the abutment screw.
	ϕ 1.5 Hex Driver	
	ϕ 2.1 Hex Driver	
	ϕ 2.5 Hex Driver	


highness Implant System HS-I Kit
Countersink
HCS32
HCS35
HCS38
HCS40
HCS45
HCS50
Drill
HTD2210
HTD2215
HSDI-32S
HSDI-32L
HSDI-35S
HSDI-35L
HSDI-38S
HSDI-38L
HSDI-40S
HSDI-40L
HSDI-45S
HSDI-45L
HSDI-50S
HSDI-50L
HSDI-55S
HSDI-55L
HPD
HDE
TW
Stopper
7mm, 11.5mm
8.5mm, 13mm
DSP 15M
DSP 30M
DSP 15R
DSP 30R
DSP 15W
DSP 30W
2.1 HEX Driver
MFBD 21S
MFBD 21L
RFBD 21S
RFBD 21L
2.5 HEX Driver
RFBD 25S
RFBD 25L
MFBD 25S
MFBD 25L


highness Implant System HS-VII Kit
Countersink
HCS32
HCS35
HCS38
HCS40
HCS45
HCS50
Drill
HTD2210
HTD2215
HSDVII-32S
HSDVII-32L
HSDVII-35S
HSDVII-35L
HSDVII-38S
HSDVII-38L
HSDVII-40S
HSDVII-40L
HSDVII-45S
HSDVII-45L
HSDVII-50S
HSDVII-50L
HSDVII-55S
HSDVII-55L
HPD
HDE
TW
Stopper
7mm, 11.5mm
8.5mm, 13mm
DSP 15M
DSP 30M
DSP 15R
DSP 30R
DSP 15W
DSP 30W
2.1 HEX Driver
2.5 HEX Driver
MFBD 21S
MFBD 21L
RFBD 21S
RFBD 21L
RFBD 25S
RFBD 25L
MFBD 25S
MFBD 25L

Surgical Procedure



STEP 1 : Preparation

If traditional oral flap reflection type surgery is desired, dentists are supposed to proceed with administering local anesthesia.

STEP 2 : Preparation

For a better visualization, a periosteal elevator is used to expose the alveolar ridge after making a full-thickness crestal incision. When working with the anterior mandible, The surgeon is supposed to be aware to the mental foramen and where the inferior alveolar nerve exits. if it is needed to create a more even plane in which to place the implant, surgeons perform alveoloplasty on the crest of the ridge. Irrigation is supposed to be used for all modifications of the bone.

STEP 3 : Preparation

Surgeons select the appropriate implant (diameter and length).

STEP 4 : Marking

For optimal implant location, Surgeons are supposed to use marking drill. Drilling spot is marked on the alveolar crest using the surgical guide. When using the flapless technique, they are supposed to punch the soft tissue before using the marking drill. hole is drilled to the depth of 2-3mm with external irrigation until its penetrates in the cortical bone. When placing multiple implants, they are supposed to use the same drill for all the osteotomies before using the next drill in the sequence.
It is recommended to have 1.5-2 mm of buccal bone width after the implant placement to avoid bone dehiscence.

STEP 5 : Pilot

After selecting the 2.2mm drill, surgeons are supposed to drill directly through the alveolar crest using the surgical guide as a reference for proper positioning. To continue preparing the osteotomy, they

use the 2.2mm drill to make the hole of appropriate depth. The bone densith is determined with their technical sense. When using a flapless technique, they are supposed to add the soft tissue thickness to the drilling depth. If Placing more than one implant and parallelism is desired, they are supposed to insert the parallel 2.0mm pin. And then, they are supposed to begin drilling the next site and align.
(Recommended rotation speed: 1200rpm)

STEP 6 : Checking the depth

The surgeon are supposed to identify the drilling depth using the depth probe. The mark below show the drilling depth (7.0mm, 8.5mm, 10.0mm, 11.5mm, 13.0mm, 14.5mm)

STEP 7 : Checking the direction

To control the drilling direction, the surgeons decide that array with the adjacent teeth, other teeth and the opposite part using the guide pin. They are supposed to identify the correct direction by taking a CT. If the direction of teeth is wrong, the drilling direction must be adjusted.

STEP 8 : Tapering

The tapered drilling are commonly used to make holes for implant. It is used sequentially from small dimensions. This plan is set differently according to the bone density. The surgeons must be drilling with irrigating the oral tissue sufficiently.

STEP 9 : Implant selecting

The surgeons are supposed to choose the implant package to suit the surgical strategy. All implant is packaged in sterile double tubes.

STEP 10 : Inserting implant

The surgeons are supposed to place the sterile inner implant vial onto the sterile field after opening the outer vial. It enables a simple. The implant is manually removed from the vial and then it is placed directly at the osteotomy site.

STEP 11 : Inserting implant

After manually removing the implant from the vial, The implant is started using transfer mount until surgeons feel resistance and implant stops. When the implant has stopped, they are supposed to remove the transfer mount by simply pulling it out manually. They are supposed to insert the implant continually with the surgical driver, the ratchet or handle driver, and avoid contacting between the implant and other oral tissue or saliva.

with any insertion tool used, avoid tightening of the implant with more than 50 Ncm. Over 50N.cm, remove the abutment and continue insertion directly with the Implant. Over tightening may compromise the integrity of the abutment, internal connection and over compress the surrounding bone, compromising osseointegration. It is recommended to place the implants using a torque lower than 40 N.cm.

STEP 12 : Inserting implant

The surgeons are supposed to place the sterile inner implant vial onto the sterile field after opening the outer vial. The implant is picked up at titanum sleeve using the driver or motor mount after opening the inner vial. It is supposed to be carried to the osteotomy facing upward to prevent accidental dislodging.

STEP 13 : Implant Positioning

If the treatment plan includes using anatomically shaped abutments such as the angled or straight esthetic contour abutments, the rotational position of the implant can be adjusted at the placement time to ensure optimal positioning of the final abutment. The surgeons are supposed to allow to take full advantage of the anatomical abutment contours. If the clinical situation is allowed, they adjust the final position of the implant so that any one of the six internal Hexagon walls faces the buccal or facial aspect.

STEP 14 : Inserting cover screw

The surgeons are supposed to remove the cover screw from the package using a screwdriver after placing implant. They are supposed to carry the cover screw to the implant and have manually it to be combined.

STEP 14A : Healing Cap installation

When stabilization is adequate and the One Stage Protocol is desired, a trans-mucosal healing cap is supposed to be placed. Attaching a healing abutment immediately following implant placement eliminates the need for a second stage surgery.

STEP 15 : Closure and Suturing

The tissue flap must be closed and be sutured after completing previous steps. The surgeon is supposed to take a radiograph to use as a baseline of implant to bone height for later diagnosis.

STEP 16 : Post operative procedures

The patient must be instructed to follow a routine post-surgical regime that includes ice or cold packs

for 2-4 hours in intervals post-implantation and to consume a soft.
The patient is supposed to be examined periodically using radiographic evaluations to monitor healing of the soft tissues and bone.

STEP 17 : Immediated Loading

All implants are designed for immediate loading when good primary stability is achieved (35N.cm and more) and with appropriate occlusal loading. Use 30N.cm to tight the abutment screw.

STEP 18 : Tissue healing and Temporization procedures

STEP 18-1 : Healing Abutment

A titanium healing abutment can be placed at the time of implant placement (single-stage surgery) to help contour soft tissues during the healing phase. Healing abutments are available in a variety of sizes and diameters and are placed using the hex driver 1.2

STEP 18-2 : Removing the Abutment

To avoid unscrewing movements of the implant during the removal of the abutment immediatly after implantation in a soft bone.

STEP 19 : Managing

The patients are supposed to be instructed to cool it down 2 to 4 hours daily and to eat soft food only after the implant. The surgeons are supposed to inspect periodically the patients to monitor the bone healing.

Description of the implant (Technical specification & mechanical charateristics)

highness offers a complete range of products that adapt to many clinical situations thanks to a wide variety of titanium implants of several diameters and lengths, specially designed to be surgically implanted in the maxillary or mandibular bone. The system also includes prosthetic elements to be coupled to the implants, and auxiliary elements for surgical and prosthetic procedures. Dental implants, which are utilized for substituting missing teeth are appealed in clinical applications for decades. Moreover, they also are used for supporting craniofacial reconstructions and for orthodontic appliances. Besides having esthetically similar view to natural tooth, dental prostheses have no harmful effect to neighboring teeth and non-disturbing nature for the patient during mastication. From the beginning of this technic, a great evolution not only on implant design and surgical technologies of dental implants, but also on the classification of clinical success, failure and different surface treatments of dental implants is done. The failures are generally influenced on the mechanical properties of dental implants. Therefore, it is critical to estimate possible failures in a specific design of dental implant, which could protect the patients' health and comfort. For this purpose, the experimental methods for the dental implants provide precise data for clinicians and engineers. Maximum allowable stress and resistance to fracture are key parameters to determine long term durability of dental implants. Mechanical testing was performed to ensure that the strength of the highness is appropriate for its intended use. After determination of the worst-case construct, static and dynamic testing were performed according to ISO 14801 Dentistry - Implants - Dynamic loading test for endosseous dental implants.

Intended use

Fixtures of highness Dental Implant System are suitable for endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially edentulous patients (e.g., tooth loss due to falling, tooth decay, tooth loss due to untreated cavities, and etc.). Fixtures can be placed with immediate function on single-tooth, bar and bridge applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations are connected to the implants by the corresponding abutment components. The Abutment of highness Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic restorations, such as artificial teeth, crowns, bridges, or overdentures, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Cover screws and healing abutments are premanufactured prosthetic components directly connected to the endosseous dental implants and are indicated as temporary components to allow healing of the soft.

Name of disease of condition

People who need dental implant therapy to replace their missing teeth.

Target patient population

- Age: It can be used in adolescents, adults and old age group patients. For reference, the use of children (the jaw bones have completed growing; 17 to 18 years of age) depends on the decision of the dentist or oral surgeon and the benefit-loss relationship should be considered.
- Weight: not relevant
- Health: The patients that are used for the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients.
- Nationality: multiple

Target user group

Dentist or oral surgeon.

Organ/parts of the body/tissues or body fluids contacted by the device

These devices include dental implants and other dental devices that are partially or fully embedded in one or more of the soft tissues, bone, and transosteal implants.

Duration of use or contact with the body

Permanent contact (C) – devices whose cumulative single long-term use or contact exceeds 30d. (Fixture & Abutment)

Nature of body contact

Fixture : Tissue/bone implant devices used in dentistry.
Abutment/Healing cap/Cover screw : Mucosal tissue implant devices used in dentistry.

Contraindications

Customary observations should be made of the contraindications associated with implant materials used in oral surgery. First, the patient's general health and suitability for oral surgery must be assessed by the general practitioner by considering as follows:

<General contraindications>
- insufficient bone quantity or poor bone quality endangering the primary stability of the implant
- acute or chronic infections
- subacute chronic osteitis of the jaws
- impairment of microvascular circulation
- systemic disease
- poor general health condition
- recent myocardial infarction
- immunosuppression
- active treatment of malignancy / cancer / tumor
- not completed maxillary or mandibular growth
- allergies or hypersensitivity to chemical ingredients of materials used

<Relative contraindications>
- addictions (alcohol, tobacco, drugs)
- inadequate oral hygiene, lack of motivation, lack of cooperation
- diabetes mellitus head and neck radiation
- postmenopausal and hormone replacement therapy
- osteoporosis, e.g. intravenous bisphosphonate use
- psychiatric illness
- use of anticoagulation drugs / hemorrhagic diathesis
- pre-term infants and neonates
- pregnancy
- infants and children: not before the jaw bones have stopped growing (in general 17-18 years).

<Local contraindications>
- uncontrolled parafunctional habits
- insufficient height and/or width of bone
- insufficient inter-arch space
- intraoral infection
- local root remnants

Adverse effects

There were major perioperative complications in related literature(s) and/or equivalence device(s) as follows:

- Screw loosening

- Peri-implantitis
- Implant fractured
- Implant lost
- Inflammation/Hyperplasia
- Gingival recession
- Bone resorption

In addition, all the possible adverse effects associated with H-System, a listing of possible adverse events (FDA) includes16, but is not limited to:
- Unidentified Device or Use Problem
- Fracture
- Osseointegration Problem

General Precautions

Surgical technique for dental implant is necessary with professional and complicated process. The persons in charge need regular education and training for implant procedure. They are supposed to have the patients inform them of a patient history including hypertension, diabetes mellitus, osteoporosis. If the patients had bone disease(osteoporosis, osteomalacia), bone metabolism disorder, the additional treatments are supposed to be considered carefully before the dental procedure. The incorrected treatments can directly cause to fail osseointegration with infection, bone loss and so on. If the implant was failed, it is supposed to be removed as soon as possible. The persons in charge should clearly inform the patients of the healing periods after implantation. The persons in charge can decide the next step with looking at enough osseointegration, It must not have strong pressure and fracture on the fixture during the healing period.

Applicable Precautions

Healing periods need to be considered before combining the abutment on the fixture as the bone nature is different from people. The bone density of the implant placement is usually affect in healing periods. The persons in charge are supposed to advice the patient not to eat tough foods, not to smoke, to disinfect twice a day during a week to prevent pollution and infection after treatment. If

the problems happened on the implant placement during healing period, The persons in charge are supposed to do special care for removing pollution and infection.

Warning & Precautions

Federal law restricts this device to sale by or on the order of a dentist or oral surgeon.

Clinical use: Sterile handling is essential. highness implants and abutments are for single use only. A previously used, non-sterile or contaminated implant or cover screw must not be used under any circumstances. Re-use of single use devices may lead to infections, inflammations or loss of the implant.

Cleaning and Sterilization:
The implants are supplied after thorough cleaning and sterilization. Do not resterilize or reuse it. Clinically contaminated implants should NOT be cleaned and re-sterilized under any circumstances. Abutments are provided non-sterile and should be sterilized prior to placing them in the oral cavity. For sterilization, steam sterilize, 30 minutes at 121°C is recommended.

Re-sterilization: If the package is damaged or not tightly closed, abutments must not be used or re-sterilized. Same applies to expired implants. The manufacturer does not assume liability for re-sterilized implants.

Reprocessing and preparing medical devices / General requirements: Refer to the legal regulations and guidelines which are valid for medical office practices and hospitals in your country. This applies in particular to specifications for the effective denaturation of prions. Treatment always involves a risk of contamination and infection. Take preventive measures to actively eliminate the risk or to reduce it as much as possible. These measures include:

- Evaluation of the risks that accompany the medical intervention; decision on appropriate protective measures
- Development of systematic procedures for the workflow, in order to prevent contamination and injuries
- Careful recording of each patient's medical history to be aware of the individual contagion risk.

All medical devices that have been opened and laid out for use are to be considered contaminated and are to be reprocessed in the same way as used equipment. Organize the transport of contaminated devices in such a way that no staff members, co-workers or third parties are endangered. All personnel must wear the appropriate protective clothing and gloves. Medical products

may corrode if they are stored in a physiological
saline solution. Instruments are to be submerged fully in the sterilization trays, without air bubbles. The use of demineralized water to rinse instruments after disinfection is absolutely necessary to prevent water spots and the formation of crystals. These disrupt the subsequent sterilization process.
You are responsible for the sterility of the products you use. For this reason, you must use validated

procedures for the cleaning, disinfection, and sterilization of your medical devices and products. You must ensure regular maintenance of your equipment, and you must observe all process parameters in every cycle. Please note the shelf life of products in sterile packaging (manufacturer's data sheet). Reprocessing ends with the release for use. Sterilization indicator and sterilization date must be recorded on every sterile packing.

Important:

- Products that are delivered in non-sterile condition (e.g. drills and abutments) must be sterilized before they are used on a patient the first time.
- After use, all reusable medical devices must be reprocessed in accordance with the described procedure.

Proper case planning is essential to the long-term success of both the prosthesis and the implant. Overload is one of the key contributors to implant failure. One should ensure the implant size and abutment angulations are appropriate for the occlusal load. Highly angulated abutments (>25°) should be avoided and are not recommended. Splinting of off-axis loaded implants may be required to give better support.

Breakage

Implant and abutment fractures can occur when applied loads exceed the normal functional design tolerances of the implant components. Potential overloading conditions may result from deficiencies in implant numbers, lengths and/or diameters to adequately support a restoration, excessive cantilever length, incomplete abutment seating, abutment angles greater than 25 degrees, occlusal interferences causing excessive lateral forces, patient parafunction (e.g., bruxing clenching), improper casting procedures, inadequate prosthesis fit, and physical trauma.

Changes In Performance

It is the responsibility of the clinician to instruct the patient on all appropriate contraindications, side effects, and precautions as well as the need to seek the services of a trained dental professional if there are any changes in the performance of the implant (e.g., looseness of the prosthesis, infection or exudates around the implant, pain, or any other unusual symptoms that the patient has not been told to expect).

Hygiene & Maintenance

Long-term implant health is directly related to the maintenance of oral hygiene. Potential implant candidates should establish an adequate oral hygiene regimen prior to implant therapy. Following implant placement, the clinician should instruct the patient on proper tools and techniques to ensure longterm maintenance of the implant(s). The patient should also be instructed to maintain routinely

scheduled prophylaxis and evaluation appointments.

Treatment Planning

Appropriate imaging techniques should be used to determine if adequate bone is available, and to determine the location of important anatomical landmarks, such as the mandibular canal, maxillary sinuses and adjacent teeth. Thorough clinical evaluation is imperative prior to all implant surgeries.

General Considerations

Control of biomechanical stresses is the key factor to long-term success of the prosthesis. Even after implant integration, imbalances in occlusal forces can lead to implant failure. Implant patients should be monitored for signs of screw loosening, preimplant bone loss and tooth wear as signs of occlusal overloading.

Adverse Effects

The following complications may occur relative to implant placement: pain, discomfort, dehiscence, delayed healing, paresthesia, hyperesthesia, edema, hemorrhage, hematoma, infection, inflammation, local and generalized allergic reaction, lack of integration, damage to adjacent teeth, loss of bone or teeth, and loss of implant. Other adverse effects may also occur as a result of iatrogenic factors and host responses.

Sterility

The implants are supplied after thorough cleaning and sterilization. Do not resterilize or reuse it. Clinically contaminated implants should NOT be cleaned and re-sterilized under any circumstances. Abutments are delivered in unsterile condition, packed under Cleanroom condition. For sterilization, steam sterilize, 30 minutes at 121°C is recommended.

fixture : The implants are supplied after thorough sterilization as follows:
- Gamma Radiation (Radionuclide: 60 Co, Gamma-ray, Half-life: 5.27 year)
- Source Activity: Designed Capacity 5,000,000 Ci
- S.A.L: 10-6
- SIP: 1

<Abutment/Healing cap/Cover screw>
Abutments are provided non-sterile and should be sterilized prior to placing them in the oral cavity. For sterilization, steam sterilize, 30 minutes at 121°C is recommended.

Single use

Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure and transmission of infectious agents.

Shelf Life

The product expiration date is indicated by the hourglass symbol on the product label, followed by the year and month of expiration. Caution: Do not use sterile devices if the packaging providing the sterile barrier, including the outer cap, vial, or tray has been damaged or compromised in any manner (i.e. cracked or crushed).

Product Packaging

All implants have been cleaned, packaged in double tubes within an environmentally controlled room, and sterilized for convenience and immediate use. The implants are suspended on a carrier to titanium shaft for safe transfer to the prepared surgical site without risk of contact contamination. Both the implant and the inner tube packaging are sterile. The label on the outer blister packaging for each implant contains a lot number that should be recorded in the patient's file to ensure complete traceability of the product. Prosthetic components provided in sealed blister packages are also pre-cleaned for your convenience.

Storage and Management after Use

This is sterilized product and need to be used immediately after open and cannot be reused. It is supposed to be discarded even if it was not used after open. The surgical instruments are supposed to be kept as clean and sterilization after using it. It also be careful not to have over pressure on the procedure parts with chewing. Additionally, the persons in charge are supposed to manage disposal products by writing date and amount of used products when discarding it.

Warning

Surgical and restorative techniques required to place dental implants are highly specialized and complex procedures. Surgeons and all practitioners should be fully trained in such procedures and be competent in such implant practices. All practitioners should attend courses of study to familiarize themselves with implantology techniques. Improper technique can cause bone loss and implant failure. Ritter Dental implant systems are intended to be used only with Ritter Dental specially designed bone drills and prosthetics. Implants placed at severe angles relative to existing dentition or multiple implants placed at convergent/divergent manner can result in complex restorations that may overload implants. This overload may lead to the implant or it's prosthesis. A thorough diagnostic work-up and use of a surgical template is recommended to help ensure proper positioning of the implant or implants. Relative contraindications include the use of steroids, chemotherapeutic agents,

bisphosphonates and anticoagulants. These and other medicines which may effect the surgical site, surrounding tissue, or patient's healing function can impact the success of the implant. Careful patient selection including consultation with the attending dentist or oral surgeon is strongly recommended prior to implant treatment for patients on any such medication. Placement of an implant adjacent to an infected tooth or a failing root canal treated tooth may cause the implant to fail. Excessive mobility, bone loss, or infection may indicate the implant is failing. Any implant which appears to be failing should be treated or removed as soon as possible. If removal is necessary, curette any soft tissue from the implant site. One may either allow site to heal as though it were a traumatic extraction or perform guided tissue regenerative procedures as indicated. Due to the metal conductivity, electro surgery around the implants and intraoral abutment preparations without irrigation could result in tissue damage and implant failure. Patients should consult with their dentist or oral surgeon and imaging technician prior to undergoing an MRI procedure. The Straight and Angled Abutment have not been evaluated for safety and compatibility in the MR environment. The Straight Angled Abutment has not been tested for heating or migration in the MR environment. One hundred percent implant success cannot be guaranteed. Failure to observe the indicated limitations of use and working steps may result in failure. Products must be secured against aspiration when handled intraorally. Aspiration of products may lead to infection or unplanned physical injury. Despite the high success rates with highness implants, failures cannot be excluded. Reasons are casespecific and often not obvious. They should be documented and reported to the manufacturer. Excessive drilling depth can lead to permanent damage to the alveolar nerve of the patient. Make sure that the depth markings are clearly visible during the entire surgical process or use the highness
Surgical Technique Guide. The storage package is only to be opened shortly before implantation. The sterile package has to be checked for damages prior to opening. Any damage of the sterile package (blister) might affect sterility of the contained products. When taking the implant out of the package, please follow the valid instructions regarding aseptic conditions. highness products have to be stored in their original package and in a cool (ambient temperature) and dry environment and have to be protected against direct sunlight.

Caution

Through screening of implant candidates is critical to the success of the implant. Appropriate radiographic examination is supposed to be utilized to determine adequacy of bone, periodontal status, and the location of important anatomical landmarks. Post-implantation radiographs are also required to determine the progression of osseointegration. Exposure to magnetic resonance imaging, radiation, and chemotherapy may impact the health of the implant. The persons in charge are

supposed to instruct the patients to consult with their physicians prior to undergoing such treatment options. The use of electrosurgical instruments or lasers around the titanium implants and their abutments is not recommended due to the risk of electrical shock and/or burns.

H-system are intended for use by adequately certified dentists with specifics implant training

Side Effect

A few problems may occur after the operation (loss of implant stability, damage of prosthesis, etc.). it can occur the patients by as well as the persons in charge. Deficient quality and quantity of the remaining bone, infection, allergic reaction, inferior oral hygiene or uncooperative-ness of patient, implant mobility, partial deterioration of tissue, and improper position or arrangement of implants may cause the above mentioned problems. The person in charge are supposed to be able to control this factors.

Principle of operation

highness is support prosthetic restorations after fixtures are implanted into the maxillary and/or mandibular arch. The abutments are designed to be joined to the fixtures by tightening screws.

Mechanism of action

highness is support prosthetic restorations after fixtures are implanted into the maxillary and/or mandibular arch. The abutments are designed to be joined to the fixtures by tightening screws.

Storage Condition

The product is supposed to store under the condition not expose to direct-sunlight, high and low temperature (1°C – 30°C) in a packaged condition. If periods of usage was expired, it is supposed to be discarded.

Intended performance

As part of demonstrating the substantial equivalence of the proposed highness's implants and abutments, completed a number of non-clinical performance tests:

- Fatigue Testing – Mechanical testing of the proposed highness in accordance to ISO 14801 was conducted. The test articles were able to withstand 5,000,000 cycles without failure at a substantially equivalent load to the cited predicate and reference device.

No.	Property	Requirement
1	Adaption ccuracy	<3 <0

2	30 Compressive Loads	>500N
3	Fatigue Test	Product damage, crackng, deformation shall not occur above fatigue limit of 250N

- Corrosion testing - All tested dental metal alloys have very low corrosion rates, with the lowest corrosion rate achieved for the titanium, indicating that in physiological conditions the abutments presents low risk of corrosion when coupled with titanium. The test establishes the proposed abutments as having no risk for corrosion.
- Biocompatibility Testing - Biocompatibility testing (cytotoxicity) was conducted on the proposed highness's implants and abutments and results supported a conclusion non-cytotoxicity.
- Packaging configuration of the proposed dental implants, which are provided sterile. Validation of package integrity over the specified shelf life has been conducted according to methods described in ISO 11607-1 and ASTM F1929-12. Results of the shelf-life validation of the package configuration support the specified shelf-life.
- Sterilization validation has been conducted on the gamma irradiation sterilization process utilized to sterilize the proposed dental implants which are provided sterile to the end user and on the steam sterilization process for the proposed abutments which are provided non-sterile and are intended to be sterilized by the end user. Sterilization validations were conducted according to ISO 11137-1 and ISO 11137-2, for the irradiation process, as well as, ISO 17665-1 and ISO 17665-2 for the steam sterilization process. The results of the sterilization validations support a minimum sterility assurance level (SAL) of 10-6.

Planned changes

There are no changes related medical devices since initial product manufacture license in 2016.

Models

No.	Device	Type	Model
1	Fixture	General	HS3807 and 69 others
2		Cover Screw	SCS100 and 9 others
3		HS-I Fixture	HS-I 3207MS and 31 others
4		HS-Ⅱ Fixture	HS-Ⅱ 3207MS and 80 others
5		HS-Ⅶ Fixture	HS-Ⅶ 3207MS and 37 others
6		Cover Screw	SCS 100-17 and 2 others
7	Abutment	Internal Solid Abutment	ISA3540 and 17 others
8		Internal Excellent Solid Abutment	ISA34840 and 17 others
9		Internal Cemented Abutment (Octa)	ICAR4804O and 119 others
10		Internal Cement Abutment (Non-Octa)	ICNR4804O and 119 others

No.	Device	Type	Model
11		Internal Angled Abutment (Octa)	IAA38010O and 155 others
12		Internal Angled Abutment (Non-Octa)	IAN38010O and 155 others
13		Internal O-Ring Abutment	IOA3500 and 13 others
14		Internal Octa Abutment	IOA35 and 1 others
15		Internal Locator Abutment	ILA3500 and 11 others
16		Internal Ti-base Abutment	ITBA4802O and 215 others
17		Internal Ti-base Abutment (Non-octa)	ITBN4802O and 215 others
18		Internal highness Digital Link Abutment	IHDLA4802O and 179 others
19		Internal highness Digital Link Abutment (Non-octa)	IHDLN4802O and 179 others
20		Internal ComOcta Abutment (Octa)	ICOA3504O and 11 others
21		Internal ComOcta Abutment (Non-Octa)	ICON3504 and 5 others
22		Internal Abutment Screw	IAS100S and 2 others
23		Internal Cylinder Screw	ICS000
24		Cement Abutment (Type-A)	SCA4004AS and 329 others
25		Cement Abutment (Type-B)	SCA4004BS and 329 others
26		Cement Abutment (Non-Hex, Type-A)	SCN4004AS and 329 others
27		Cement Abutment (Non-Hex, Type-B)	SCN4004BS and 329 others
28		Round Cement Abutment	SMA40014S and 109 others
29		Round Cement Abutment (Non-Hex)	SMN40014S and 109 others
30		Solid Abutment (Type-A)	SSA4004A and 329 others
31		Solid Abutment (Type-B)	SSA4004B and 329 others
32		Loosening Zero Abutment	SLZA4004S and 109 others
33		Zero Screw	ZSS411 and 44 others
34		Angled Abutment (Type-A, EDGE)	SAAH45015AES and 395 others
35		Angled Abutment (Type-A, FLAT)	SAAH45015AFS and 395 others
36		Angled Abutment (Type-A, Non-Hex)	SAAH45015AS and 395 others
37		Round Angled Abutment (EDGE)	SMAH45015ES and 395 others
38		Round Angled Abutment (FLAT)	SMAH45015FS and 395 others
39		Round Angled Abutment (Non-Hex)	SMAN45015S and 395 others
40		Angled Abutment (Type-B, EDGE)	SAAH45015BES and 395 others
41		Angled Abutment (Type-B, FLAT)	SAAH45015BFS and 395 others
42		Angled Abutment (Type-B, Non-Hex)	SAAN45015BS and 395 others
43		O-Ring Abutment	SOA400 and 43 others
44		Milling Abutment	SMA4000S and 109 others

No.	Device	Type	Model
45		Milling Abutment (Non-Hex)	SMN4000S and 109 others
46		Locator Abutment	SLA3700 and 10 others
47		Link Abutment	SLA4004B and 1919 others
48		Link Abutment (Non-Hex)	SLN4004B and 1919 others
49		Highness Base Link Abutment	SBLA40005S and 2667 others
50		Highness Base Link Abutment (Non-Hex)	SBLN40005S and 2667 others
51		Highness Digital Link Abutment	HDL45005S and 629 others
52		Highness Digital Link Abutment (Non-Hex)	HDLN45005S and 629 others
53		Highness Digital Short Link Abutment (Hex)	HDLS4000S and 8 others
54		Highness Digital Short Link Abutment (Non-Hex)	HDLSN4000S and 8 others
55		Highness Digital Base Abutment	HDB4500 and 155 others
56		Highness Digital Angle Base Abutment	HDAB4500 and 129 others
57		Highness Digital Abutment (Hex)	HDA4530S and 107 others
58		Highness Digital Abutment (Non-Hex)	HDAN4530S and 107 others
59		Highness Digital Angle Base Cement Abutment	HDCA4510S and 155 others
60		Highness Digital Angle Post Abutment	HDAP4505S and 119 others
61		MULTI UNIT Abutment	SMU4500 and 119 others
62		MULTI UNIT ANGLED Abutment	SMUA45015S and 395 others
63		MULTI UNIT ANGLED Abutment (Non-Hex)	SMUAN45015S and 395 others
64		MULTI Cement Abutment	SMCA4510S and 129 others
65		MULTI ANGLED Abutment	SMA45015S and 395 others
66		FREE MARGIN Abutment	SFMA4004 and 329 others
67		Highness Base Milling Abutment (Hex)	HBMA4508S and 35 others
68		Highness Base Milling Abutment (Non-Hex)	HBMAN4508S and 35 others
69		Highness Base Cement Abutment (Hex)	HBCA5502S and 21 건 others
70		Highness Base Cement Abutment (Non-Hex)	HBCAN6507S and 21 others
71		Highness Digital Scanbody	HDS4520S and 65 others
72		Highness Digital Double Base	HDDB4500 and 155 others
73		Highness Digital Double Short Link (Hex)	HDDSL4000S and 8 others
74		Highness Digital Double Short Link (Non-Hex)	HDDSLN4000S and 8 others
75		Highness Digital Double Link (Hex)	HDDL45005S and 629 others
76		Highness Digital Double Link (Non-Hex)	HDDLN45005S and 629 others
77		Highness Digital Double Abutment (Hex)	HDDA4530S and 107 others
78		Highness Digital Double Abutment (Non-Hex)	HDDAN4530S and 107 others
79		Sub Abutment Screw	SAS100 and 4 others

No.	Device	Type	Model
80		Highness Digital Abutment Screw	HDAS100S and 2 others
81		Angle Base Cement Screw	SSA100S and 2 others
82		Base Digital Link Screw	SDLS100S and 1 others
83		Highness Digital Link Screw	SHDLS100S and 2 others
84		Highness Digital Short Link Screw	SHDLSS100
85		Internal Cover Screw	ICS400 and 3 others
86		Internal Closing Screw	ICS100 and 2 others
87		Internal Healing Abutment	IHA4801 and 39 others
88		Internal Cap Healing Abutment	ICHA4801 and 39 others
89		Cover Screw	SCS100 and 9 others
90		Base Cover Screw	SBCS100
91		Healing Abutment (Type-A)	SHA4001A and 189 others
92		Healing Abutment (Type-B)	SHA4001B and 189 others
93		Base Healing Cap (Type-A)	HBC453 and 49 others
94		Base Healing Cap (Type-B)	HBC453B and 49 others
95		Cement Abutment (Hex)	SCA 3505-17S and 161 others
96		Cement Abutment (Non-Hex)	SCN 3505-17S and 161 others
97		Angled Abutment (Hex)	SAAH 35015-17S and 107 others
98		Angled Abutment (Non-Hex)	SAAN 35015-17S and 107 others
99		Milling Abutment (Hex)	SMA 3005-17S and 96 others
100		Milling Abutment (Non-Hex)	SMN 3507-17S and 66 others
101		Solid Abutment	SSA 3509-17S and 42 others
102		O-ring	SOA 400-17S and 59 others
103		Locator Abutment	SLCA 3700-17S and 29 others
104		Abutment Screw	SAS 100-17 and 2 others

And #A2-3-4-1, Information of highness (model name, blueprints, photographs)
#A2-3-4-3, Information of Highness - Fixture Mini
#A2-3-4-4, Information of Highness - Abutment Mini

Description of the medical device

The highness is comprised of dental implants, superstructures, instruments for prosthetics. The highness is a dental implant made of titanium metal intended to be surgically placed in the bone of the upper or lower jaw arches. Fixture is made of pure titanium metal and supplied sterile (gamma radiation). The surface is SLA, Sand-blasted, Large grit, Acid-etched, treated. Abutment is device made of titanium

alloy and it is intended for use to make temporary prosthesis. The abutments and superstructures consist of Solid Abutment, Healing Abutment, Cemented Abutment, Abutment Screw, Angled Abutment, Multi Abutment, Cover Screw. All abutments are supplied non-sterile and autoclaved by the end user.

Drilling

Implant site is prepared in a sequential procedure using drills of increasing diameter with depth indication lines. The treatment that cuts bone tissue after preparing drills must be recommended outstanding drilling technique and carried out under ample irragation. Drilling instruments is required to be maintained consistently to run without errors next time. If their cutting efficiency is reduced, it must be replaced.

Caution

Refer to the Surgical and Prosthetic Manual for detailed instructions regarding surgical procedure. highness fixtures can be inserted using a one or two stage procedure. One stage implantation should only be considered for patients with good bone quality proper oral hygiene. Appropriate personal habits (non-smoker and no alcohol or drug abuse), and where there is the ability to obtain good initial stability of the implant (>35-45 N.cm). Prior to implantation a complete health evaluation oral examination, and radiological assessment should be conducted tor successful Implant treatment. All surgeries should be performed under aseptic conditions with sterile surgical instruments.

Drilling Sequence

First Stage Implant Surgery

- Incision and flap resection
- Drilling Sequence (Refer to Surgical and Prosthetic Manual for specific instructions)
  - Guide Drill and 2mm first Drill-1000rpm/30-45 N.cm with irrigation
  - Check drill path- Verity drilling path using the Parallel Pin and Depth Gauge
  - Pilot Drill and Final Drill- l000rpm/30-45 N.cm with irrigation
  - Counter Sink (Optionall-1000rpm/30-45 N.cm with irrigation

Warning: Irrigate during drilling to avoid overheating the bone. Overheating can cause bone damage resulting in failure to ossify and loss 01 the fixture.

Surgical KIT

All components are color-coded and externally irrigated. They are designed to achieve maximum cutting efficiency while effectively removing bone from the osteotomy during drilling. The fixtures are applied differently according to the oral bone tissue condition of the patients. H-system has the drill tools of a various dimensions to be applied all specifications (Table 2).

Table 2. Drills by dimension

Model	HSD2213	HSD3513	HSD4013	HSD4513	HSD5013
Demension	2.2	3.5	4.0	4.5	5.0

Additionally, More tools are used except for the drills when performing an implant. The description is below (Table 3).

Table 3. Tools in the kits

No.	Contents	Description
1	Ratchet	It is the tools that is used to fix the abutments firmly. It has the screw to be tighten or loosen by moving the handle clockwise or counterclockwise.
2	Point Drill	It is used to mark position of the holes to be formed at the implant position.
3	Drill Extension	It operate by fastening with handpiece after connecting tools that needs the extension at the part.
4	Drill	It is used to make hole for implant of the fixture.
5	Drill Stopper	It is used to adjust the depth of drilling.
6	Fixture Driver	It is the driver to be used for the implant procedure. It used to place the fixture in the oral cavity.
7	Φ1.2 Hex Driver	It is the driver to be used for the implant procedure. It is used to tighten the abutment screw.
8	Φ2.1 Hex Driver	
9	Φ2.5 Hex Driver	

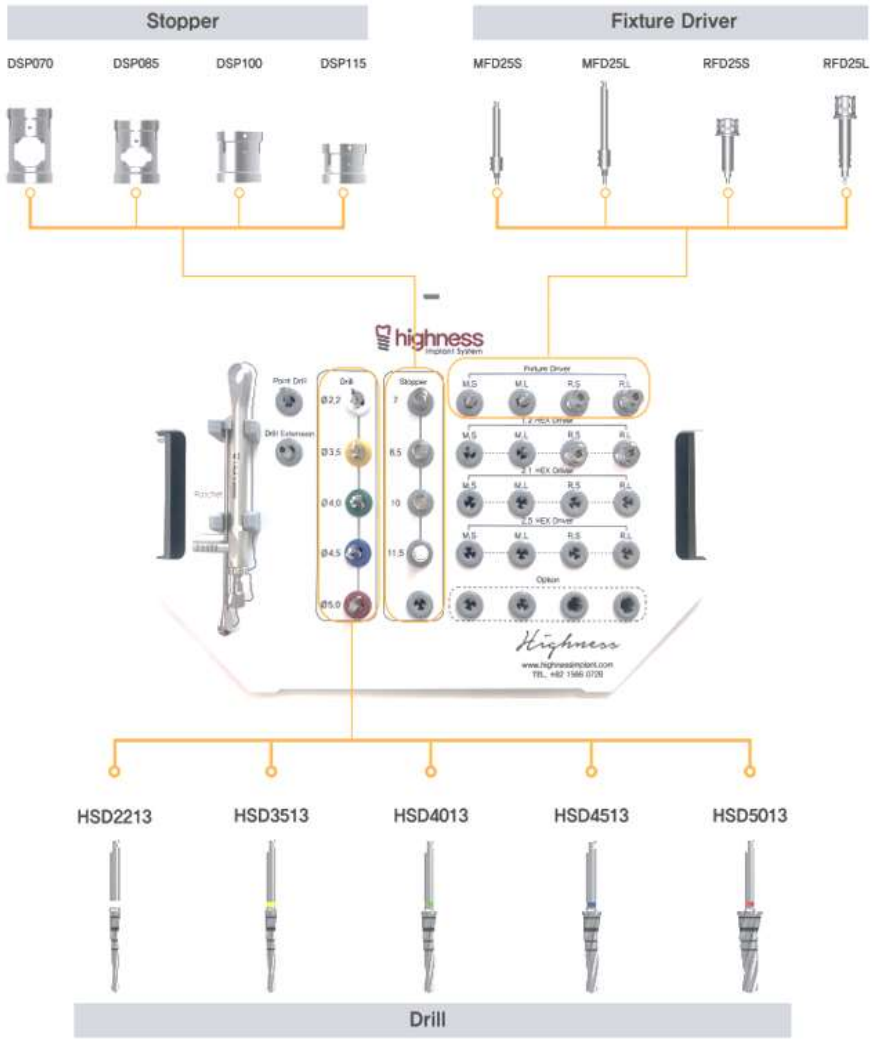


Image 1. H-system Kit

Cleaning procedure for surgical instruments

1. After using instruments, user places drills into a beaker of plain water, mail soap or specialized detergent solution to make it cleaned easily. Rinse the tray with water and dry thoroughly.
2. Place the instruments in a beaker of detergent solution and sonicate for approximately 10 minutes. Rinse thoroughly.
3. Then it is supposed to be rinsed with tap water for a minimum of two minutes while brushing with a soft bristled brush to remove visible debris. Users are supposed to inspect visually repeatably for any remaining bone fragments or debris and scrub until it is completely clean.

4. Rinse the instruments with ethyl alcohol (do not use IPA isopropyl alcohol) to remove soap residue and minerals. This is important to help prevent corrosion and spotting.
5. Blot the instruments with a towel and allow to air dry completely.
6. Return the instruments to the appropriate locations in the surgical tray.
7. Wrap the kit in a double-layer of autoclave-wrap.
8. Sterilize the kit according to the "Sterilization Table"

CAUTION

Do not remove the surgical kit from the autoclave until the dry cycle is complete

CAUTION

The use of hydrogen peroxide or other oxidizing agents will cause damage to the surface of the instruments. Towel or air-dry all instrumentation before sterilization. Drills and taps are supposed to be replaced when wear, a decrease in cutting performance, or signs of discoloration are noted. Cortex Dental Implants recommends replacement of drills after approximately 20 osteotomies, depending on bone density.

Sterilization (Surgical instruments)

The use of autoclaves is recommended for sterilization. The autoclave must be set at 30mins/121-124℃ (~250° F) and 30 minute dry time or 20mins/132-135℃ (~270°F) and 30 minute dry time. Sterilization temperature must not always exceed 140°C and always use dry cycles. Each dental office is responsible for the proper, routine sterilization of instruments. The surgical kit is set up in this manner. Follow the drilling sequence in this guide.

Surgical guide

The surgical guide is supposed to be made by cooperating with the implanting surgeons, the restoring dentists and the laboratory technicians. It is used to instruct practical boundaries for the placement of implants and may prevent implants from being placed too buccal/lingually or mesial/distally. This procedure helps to ensure functional placement of implants and esthetic restorative results. The implanting surgeon is supposed to communicate with the laboratory technician to identify any conditions that may affect guide with the laboratory technician.

Handling

Inspection procedure is required before the fixture can be applied appropriately to the patient's oral tissue. CT is mainly used to do it. if the patient's oral tissue is more soft than other one. A thin drill tool is used.
Then, perform the following procedure sequentially.

- open the fixture cab
- connect implant driver on the fixture
- operate the drills
- insert fixture in to the bone

During inserting fixture in to the bone. All treatment must be carried out under ample irrigation with saline solution. Especially, user has it to be turned clockwise at 20rpm/35N.cm.

Implant selection

Implant is chosen according to the measurements of the ridge width and vertical length on the CT Scan.

The anatomical structures like a mandibular canal are supposed to be secured and maintained the safety distance that is more than 2mm. The correct treatment planning methodology like it will provide maximum biomechanical stability by allowing better emergence profile utilizing an implant with a prosthetic platform slightly smaller in diameter than the emergence diameter of the tooth being replaced.

Implant selection is based on;
- The emerging dimension of the crown in relation to the diameter of the prosthetic platform of the implant
- The height and diameter of the intended restoration at the tissue exit point
- The bone volume at the implant site in relation to the diameter of the implant body

Table 4. Surgical Procedure

HS	FS
	

Diameter	Length(mm)	Product(Name)	Diameter	Length(mm)	Product(Name)
Φ3.8	7	HS 3807	Φ3.8	7	S 3807
	8.5	HS 3808		8.5	S 3808
	10	HS 3810		10	S 3810
	11.5	HS 3811		11.5	S 3811
	13	HS 3813		13	S 3813
Φ4.0	7	HS 4007	Φ4.0	7	S 4007
	8.5	HS 4008		8.5	S 4008
	10	HS 4010		10	S 4010
	11.5	HS 4011		11.5	S 4011
	13	HS 4013		13	S 4013
Φ4.5	7	HS 4507	Φ4.5	7	S 4507
	8.5	HS 4508		8.5	S 4508
	10	HS 4510		10	S 4510
	11.5	HS 4511		11.5	S 4511
	13	HS 4513		13	S 4513
Φ5.0	7	HS 5007	Φ5.0	7	S 5007
	8.5	HS 5008		8.5	S 5008
	10	HS 5010		10	S 5010
	11.5	HS 5011		11.5	S 5011
	13	HS 5013		13	S 5013
Φ5.5	7	HS 5507	Φ5.5	7	S 5507
	8.5	HS 5508		8.5	S 5508
	10	HS 5510		10	S 5510
	11.5	HS 5511		11.5	S 5511
	13	HS 5513		13	S 5513

Caution when Fixture is installed

When opening the fixture cap, hold the fixture container upright and engage the Implant Driver into the fixture and connect firmly together. Remove the fixture from the packaging. Attaching fixture to the implant driver. Insert fixture into the bone, turning clockwise at 20rpm/35N.cm with irrigation using the Implant Driver. It is recommended that the top level of the fixture be located 0.5mm below the crestal bone. Place label identifying the LOT number and REF number of the fixture in the patient's chart to ensure traceability to the implant used.

Warning

Applying excessive torque (more than 80N.cm) may result in fracture or damage to the bone.

Storage

First at all, user is supposed to arrange the tools in the kit back again. They are stored at the safety site that is not impaired physically.

Cover Screw or Healing Abutment Application

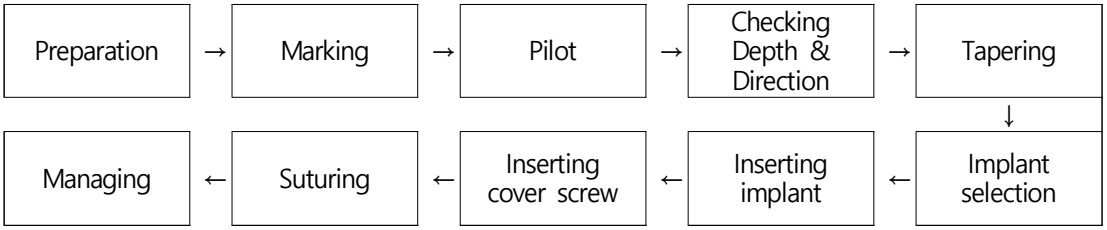
Thoroughly clean blood and fluid from the fixture interface prior to attaching cover screw or healing abutment, Failure to property clean the fixture can cause difficulty in removing the cover screw or healing abutment For two stage procedures, apply cover screw using the hex driver. For one stage procedures, apply healing abutment using the hex driver.

Soft tissue suturing

The healing period alter the first stage surgery is dependent on the patient's bone condition and quality. Radiographs are required prior to surgery to determine bone condition and again alter the second stage surgery. As well as prior to loading. To avoid movement at the fixture and possible loss 01 the implant, prosthetic loading should not be done until there is evidence of implant osseointegration.

Surgical procedure

Table 4. Surgical Procedure



STEP 1 : Preparation

If traditional oral flap reflection type surgery is desired, dentists are supposed to proceed with administering local anesthesia.

STEP 2 : Preparation

For a better visualization, a periosteal elevator is used to expose the alveolar ridge after making a full-thickness crestal incision. When working with the anterior mandible, The surgeon is supposed to be aware to the mental foramen and where the inferior alveolar nerve exits. if it is needed to create a more even plane in which to place the implant, surgeons perform alveoloplasty on the crest of the ridge. Irrigation is supposed to be used for all modifications of the bone.

STEP 3 : Preparation

Surgeons select the appropriate implant (diameter and length).

STEP 4 : Marking

For optimal implant location, Surgeons are supposed to use marking drill. Drilling spot is marked on the alveolar crest using the surgical guide. When using the flapless technique, they are supposed to punch the soft tissue before using the marking drill. hole is drilled to the depth of 2-3mm with external irrigation until its penetrates in the cortical bone. When placing multiple implants, they are supposed to use the same drill for all the osteotomies before using the next drill in the sequence.

It is recommended to have 1.5-2 mm of buccal bone width after the implant placement to avoid bone dehiscence.

STEP 5 : Pilot

After selecting the 2.2mm drill, surgeons are supposed to drill directly through the alveolar crest using the surgical guide as a reference for proper positioning. To continue preparing the osteotomy, they use the 2.2mm drill to make the hole of appropriate depth. The bone densith is determined with their technical sense. When using a flapless technique, they are supposed to add the soft tissue thickness

to the drilling depth. If Placing more than one implant and parallelism is desired, they are supposed to insert the parallel 2.0mm pin. And then, they are supposed to begin drilling the next site and align.

STEP 6 : Checking the depth

The surgeon are supposed to identify the drilling depth using the depth probe. The mark below show the drilling depth (6.0mm, 8.0mm, 10.0mm, 11.5mm, 13.0mm, 16.0mm)

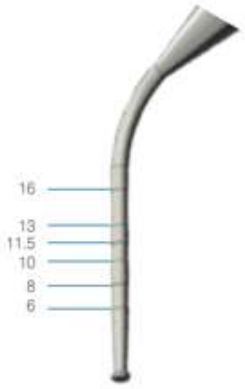


Image 2. The depth probe

STEP 7 : Checking the direction

To control the drilling direction, the surgeons decide that array with the adjacent teeth, other teeth and the opposite part using the guide pin. They are supposed to identify the correct direction by taking a CT. If the direction of teeth is wrong, the drilling direction must be adjusted.

STEP 8 : Tapering

The tapered drilling are commonly used to make holes for implant. It is used sequentially from small dimensions. This plan is set differently according to the bone density. The surgeons must be drilling with irrigating the oral tissue sufficiently.

Table 5. Tapered drills of H-system

Model	HSD2213	HSD3513	HSD4013	HSD4513	HSD5013
Diameter(mm)	2.2	3.5	4.0	4.5	5.0
Image					

STEP 9 : Implant selecting

The surgeons are supposed to choose the implant package to suit the surgical strategy. All implant is packaged in sterile double tubes.

STEP 10 : Inserting implant

The surgeons are supposed to place the sterile inner implant vial onto the sterile field after opening the outer vial. It enables a simple. The implant is manually removed from the vial and then it is placed directly at the osteotomy site.

STEP 11 : Inserting implant

After manually removing the implant from the vial, The implant is started using transfer mount until surgeons feel resistance and implant stops. When the implant has stopped, they are supposed to remove the transfer mount by simply pulling it out manually. They are supposed to insert the implant continually with the surgical driver, the ratchet or handle driver, and avoid contacting between the implant and other oral tissue or saliva.

with any insertion tool used, avoid tightening of the implant with more than 50 Ncm. Over 50N.cm, remove the abutment and continue insertion directly with the Implant. Over tightening may compromise the integrity of the abutment, internal connection and over compress the surrounding bone, compromising osseointegration. It is recommended to place the implants using a torque lower than 60 N.cm.

STEP 12 : Inserting implant

The surgeons are supposed to place the sterile inner implant vial onto the sterile field after opening the outer vial. The implant is picked up at titanum sleeve using the driver or motor mount after opening the inner vial. It is supposed to be carried to the osteotomy facing upward to prevent accidental dislodging.

STEP 13 : Implant Positioning

If the treatment plan includes using anatomically shaped abutments such as the angled or straight esthetic contour abutments, the rotational position of the implant can be adjusted at the placement time to ensure optimal positioning of the final abutment. The surgeons are supposed to allow to take full advantage of the anatomical abutment contours. If the clinical situation is allowed, they adjust the final position of the implant so that any one of the six internal Hexagon walls faces the buccal or facial aspect.

STEP 14 : Inserting cover screw

The surgeons are supposed to remove the cover screw from the package using a screwdriver after placing implant. They are supposed to carry the cover screw to the implant and have manually it to be combined.

STEP 14A : Healing Cap installation

When stabilization is adequate and the One Stage Protocol is desired, a trans-mucosal healing cap is supposed to be placed. Attaching a healing abutment immediately following implant placement eliminates the need for a second stage surgery.

STEP 15 : Closure and Suturing

The tissue flap must be closed and be sutured after completing previous steps. The surgeon is supposed to take a radiograph to use as a baseline of implant to bone height for later diagnosis.

STEP 16 : Post operative procedures

The patient must be instructed to follow a routine post-surgical regime that includes ice or cold packs for 2-4 hours in intervals post-implantation and to consume a soft, high-nutrient diet, if possible.

The patient is supposed to be examined periodically using radiographic evaluations to monitor healing of the soft tissues and bone.

STEP 17 : Immediated Loading

All implants are designed for immediate loading when good primary stability is achieved (35N.cm and more) and with appropriate occlusal loading. Use 30N.cm to tight the abutment screw.

STEP 18 : Tissue healing and Temporization procedures

STEP 18-1 : Healng Abutment

A titanium healing abutment can be placed at the time of implant placement (single-stage surgery) to help contour soft tissues during the healing phase. Healing abutments are available in a variety of sizes and diameters and are placed using the hex driver 1.25.

STEP 18-2 : Removing the Abutment

To avoid unscrewing movements of the implant during the removal of the abutment immediatly after implantation in a soft bone.

STEP 19 : Managing

The patients are supposed to be instructed to cool it down 2 to 4 hours daily and to eat soft food

only after the implant. They are better not to take a high-protein, high-vitamin or high-mineral supplement for a month. But they can be started a antibiotic therapy 1 day to 1 week after surgery. The surgeons are supposed to inspect periodically the patients to monitor the bone healing.

Second Stage Surgery

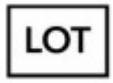
- Incision and removal of the cover screw (unscrew in a counterclockwise direction)
- Apply healing or combi abutment using the hex driver.
- Soft tissue suturing

Impression and restoration fabrication

Warning: Evidence of osseointegration should be confirmed radio graphically prior to loading a fixture to avoid movement of the fixture and possible loss of the implant.

Caution: highness fixtures are only intended for use with H- System Instruments, Abutments and Components.

Referent

	Catalog number
	Batch code
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	Do not re-use
	Sterilized using irradiation
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	Manufacturer

EC REP	Authorized representative in the European community
	Used by
Ø	Diameter
L	Length
	Manufacturing date

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