Instruction for Use
Fixture

Product Description
URIS Implant System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function. The URIS Implant System is intended to be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability is achieved with appropriate occlusal loading. Below 3.3mm diameter impalnts are indicated only for replacement of central and lateral incisors in the maxilla and mandible

Instructions for operation and use
A. Preparation before use
1) Before clinical use, the dentist must be well acquainted with the surgical procedure and the product, and he has to inform the patient about the limitations of the implant. The patient should be well aware of the functional and aesthetic limits of the implant.
2) Because proper selection and fixation of the implant is closely related to the life-span of the implant, you must follow the indications, contraindication, cautions and recommendations strictly.
3) When handling the implant, without careful review of the patient's condition and establishment of proper diagnosis and therapeutic plans, you may damage the implant.
4) You should chose the appropriate product based on careful review of the patient's X-ray picture.
5) Check whether the product's expiration date hasn't expired, packaging is sound and the product isn't damaged.
6) As this product is supplied aseptically, you may not use it if the packaging is damaged or torn.
7) The contamination of surgical instruments may lead to loss of the implant so check the hygiene and preparatory state of the proper surgical instruments.
8) Check for foreign-body before use.

B. Instructions and procedural sequence
During the diagnostic and therapeutic planning, you must exclude any patient with local lesions or other contraindications and choose candidates who have proper bony condition to undergo implant surgery.
Before proceeding to operation you must sterilize operation room and patients oral cavity and perioral area thoroughly. After proper draping, perform local anesthesia and make an incision on the implant site and form a flap. Exposure the implant site sufficiently and proceed to implant surgery.

1) Implant site preparation
To implant the fixture, an adequate hole must be made in the recipient bone. To place the fixture accurately in the selected site, a hole must be made according to the size of the artificial dental prosthesis, using the respective instruments (drilling, tapping). Rotatory speed during these procedures must be adjusted taking the recipient bone condition and type of equipment used into consideration. The maximal permissible rotatory speed for the drill is generally 1,000~1,500rpm and 20~30 rpm for the tap drill. The procedure should be performed using adequate normal saline to prevent heat necrosis of the alveolar bone.

2) Placing the fixture
Remove the implant from the sterile vial by Fixture Driver and Adapter, transport the implant to the prepared site and insert into the osteotomy. Assemble it with the Handpiece or Hand Wrench, threading the implant into the osteotomy site using the preferred placement and rotate clockwise with applied torque threshold of 20~45Ncm and 20~30RPM until treatment plan.
NOTE: The final recommended torque at seating should be 20~40Ncm.

Applied manufacturer's recommended torque value during placement of URIS Implant. Excessively high insertion torque of Hand Wrench can cause deformation of the implant or connection may generate necrosis of the peri-implant bone in the receiving site and therefore the failure of the implant.

3) Inserting the cover screw
After the fixture has been placed, attach the cover screw using a driver below 10Ncm torque. Make sure there are no foreign bodies inside, and suture the operation site.

4) Connecting the abutment
Bony fusion of the fixture requires 3~4 months for the mandible and 6~8 months for the maxilla. During this period, expose the implant and connect the healing abutment to enhance mucosal healing.

5) Prosthesis attachment
After a healing period of between 2~4 weeks, connect the impression post to obtain an impression and manufacture a dental mockup. Attach the prosthesis produced in a dental-lab to the oral abutment.

Cautions for the usage
A. Cautions on use
1) The operation must be performed by well trained qualified dental specialist.
2) While drilling, you must follow the procedure written in the catalog and the fixation part should be sufficiently implanted.
3) Take care not to allow any soft tissues to come between the implant and prosthesis and disrupt the attachment.
4) If worn instruments are used during the operation, other components may be damaged. Therefore inspect the condition of the instruments before every operation.
5) The product is wrapped in aseptically via gama-ray sterilization so you should open the packaging just before use (and use it immediately after the packaging has been opened).
6) If the package has been damaged, you must discard the product because aseptic condition cannot be maintained. (unable to use)

B. Indications
1) Traumatic tooth loss without alveolar bone injury
2) Root treated tooth planned for extraction
3) Root-fracture
4) Tooth loss due to severe caries or periodontal disease without pyogenic exudate or acute inflammation.
5) Congenital permanent tooth deficit and remaining milk tooth with resorbed root
6) Internal and external root resorption
7) Root resorption after orthodontia
8) Sufficient and healthy soft tissue able to be sutured
9) If there is sufficient bony tissue proximal to the tooth extraction wound

C. Contraindications
In following conditions you should reconsider implant operation

1) Intraoral contraindications
>In cases with insufficient bony tissue so that severe bone resorption is predicted. Or if there is insufficient remaining bone for early-fusion in the proximal tooth extraction wound.
>Disorder in mastication or functional relation
>Pathologic condition of the alveolar bone
>Prior radiotherapy on jawbone
>Xerostomia
>Pathologic change of oral mucosa (vitiligo, lichen planus, stomatitis)
>Macroglossia
>If vital anatomical structures are nearby
>Cellulitis in surrounding soft tissues
>If there are not sufficient soft tissues or its condition is poor

2) Transient contraindications
>Acute inflammatory disease or infection
>Pregnancy
>Temporary effect of specific drugs (anticoagulant, immune-suppressant)
>Mental, physical fatigue

3) Psychological contraindications
>Poor compliance
>Alcohol or other substance abuse
>Neurosis, psychosis patient
>Troublesome patient

4) General medical contraindications
>General/nutritional condition - age (obesity, cachexia, 5yr survival rate)
>Current medications (corticosteroid, long-term antibiotic treatment)
>Metabolic disorder (pubertal diabetes, overt hyperglycemia (>300mg/dl))
>Hematologic disorder (disorder of RBC, WBC, coagulation)
>Cardiovascular diseases (artherosclerosis, overt hypertension (>300mmHg))
>Metabolic disorder of skeletal system (osteomalacia, Paget's disease, menopausal osteoporosis)
>Connective tissue disease (dermatosclerosis, rheumatoid arthritis)
>Implant as potential infection focus (prosthetic valve, bacterial endocarditis)

D. Warning
1) Implant operation should be performed by skilled dental surgeon because mishandled procedure may damage the implant or recipient bone
2) Implant is not to be recycled and it should be used for its original purpose
3) Damaged or mishandled implant should be removed
4) Inappropriate implant selection and improper implantation site or unstable fixation may shorten the life-span of the implant
5) Defective product should be withdrawn
6) Handle the implant carefully to prevent any damage or deformation

E. POTENTIAL ADVERSE EFFECTS AND COMPLICATIONS
General complications after intraoral implant surgery include local hemorrhage, edema and hematoma. Transient loss of taste sense and masticatory function may occur. Additionally following complications may develop

1) Iatrogenic trauma of surrounding tissues
(lower alveolar nerve injury or sensory change, injury or hemorrhage in maxillary sinus or nasal cavity)
2) Insufficient or failed bony fusion
3) Wound dehiscence on sutured site
4) Delayed recovery, edema due to anesthesia
5) Mucositis around implant due to insufficient adhesive soft tissue
6) Incomplete implant placement due to insufficient bone removal or overt compression
7) General hypersensitivity reaction

MRI
URIS Implants have not been evaluated for safety, compatibility, heating, or migration in the magnetic resonance(MR) environment

Sterility
All dental implants are supplied sterile and are labeled "STERILE". All products sold sterile are for single-use before the expiration date printed on the product label. Do not use sterile products if the packaging has been damaged or previously opened. Do not re-sterilize.

Storage
The product has to be stored in its original package in a dry place at room temperature.

Handling
>This product is a disposable sterilized medical instrument and should therefore not be reused.
>Packing must be opened prior to surgery in clean area.
>Discard if wrapping has been opened even if product is unused.
>Do not use the product, if the valid date (shelf life) were expired.
>Unpacked products cannot be returned to the manufacturer or distributor.
>Manufacturer or distributor has no responsibility for the products re-sterilized by users.

Labeling Symbols

Do Not Reuse	
Use By Date	
Batch Code	LOT
Date Of Manufacture	
Sterilized Using Irradiation	STERILE R
Catalogue Number	REF
Caution, consult accompanying documents	
Manufacturer	
Consult Instructions For Use	
Do Not Use If Package Is Damaged	
Prescription Only	Rx Only

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