ORA
Implant Abutments

Instructions for Use

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Order online at **www.sterngold.com**

ENGLISH

Before using the ORA Implant Abutments, the clinician in charge should carefully study the indications, contraindications, recommendations, warnings and instructions, as well as all other product-specific information (technical product description, description of the surgical and restorative technique, catalogue sheet, etc.) and fully comply with them. Detailed instructions over and above those contained in these instructions for use can be found in the technical user's guide. It is also recommended to attend the appropriate user-training courses. The aforementioned documents and details of the training courses may be obtained from the appropriate representatives in the various countries. The manufacturer, the importer and the suppliers of the ORA Implant Abutments are not liable for complications, other negative effects or damages that might occur for reasons such as incorrect indications, unsuitable choice of material or handling thereof, unsuitable use or handling of the instruments, asepsis and so on. The clinician is responsible for any such complications or other consequences. It is also the clinician's responsibility to properly instruct and inform the patient on the functions, handling and necessary care of the product and on all known product risks.

INDICATIONS/INTENDED USE
The ORA Implant Abutment System is indicated for use with dental implants to support and/or retain removable dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The abutment screws directly into endosseous implants or they screw into SFI Abutments which are screwed into endosseous implants.

CONTRAINDICATIONS
The ORA Implant Abutments can only be screwed into compatible Implants. They should not be used by anyone with allergies or hypersensitivity to titanium alloy, Ti 6Al 4V.

WARNINGS
The ORA Implant Abutments should not be used unless the dental implants are stable and there are no signs of infection or severe bone loss. Poor bone quality, poor patient oral hygiene, heavy tobacco use, uncontrolled systemic diseases (diabetes, etc.), reduced immunity, alcoholism, drug addiction, and psychological instability may contribute to lack of integration and/or subsequent implant failure. Severe bruxism, clenching, and overloading may cause bone loss, screw loosening, component fracture, and/or implant failure. Exposure to radiation and chemotherapy may impact health of the implant. Dental implant patients should be instructed to consult with their physician prior to undergoing such treatment options.

Restorative techniques required to place and restore dental implants are highly specialized and complex procedures. Practitioners should attend courses of study to familiarize themselves with implantology techniques. Improper technique can cause bone loss and implant failure.

Other relative contraindications include steroid and anticoagulant treatment which may affect the surgical site, surrounding tissue, or patient's healing function. Exposure to long-term use of bisphosphonate drugs especially with chemotherapy may impact implant survival. Careful patient selection including consultation with the attending physician is strongly recommended prior to implant treatment. 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 and allow site to heal as though it were an atraumatic extraction. Due to the metal conductivity, electrosurgery around the implants and intraoral abutment preparations without irrigation could result in tissue damage and implant failure. Patients should consult with their physician and imaging technician prior to undergoing an MRI procedure.

The ORA Implant Abutments are only provided straight and are not intended to be modified to an angle.

PRECAUTIONS
Proper case planning is essential to the long-term success of both the prostheses and the implants. Overload is one of the key contributors to implant failure. Ensure the implant angle corrections are appropriate for the occlusal load.

Breakage
Implant and tooth fractures can occur when applied loads exceed the normal functional design tolerances of the components. Potential overloading conditions may result from deficiencies in implant or tooth numbers, lengths and/or diameters to adequately support a restoration, excessive cantilever length, incomplete abutment seating, abutment angles greater than 30 degrees, occlusal interferences causing excessive lateral forces, patient parafunction (e.g. bruxing, clenching), improper denture manufacture procedures, inadequate denture 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 exudate around the implant, pain, or any other unusual symptoms that the patient has not been told to expect).

Hygiene & Maintenance
Long-term health is directly related to the maintenance of oral hygiene. Potential candidates should establish an adequate oral hygiene regimen prior to implant therapy. Following placement, the clinician should instruct the patient on proper tools and techniques to ensure long-term maintenance of the prosthesis. The patient should also be instructed to maintain routinely scheduled prophylaxis and evaluation appointments.

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 peri-implant bone loss and excessive attachment 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, loss of bone, and loss of implant. Other adverse effects may also occur as a result of iatrogenic factors and host responses.

STERILITY
ORA Implant Abutments and ancillary components are sold non-sterile. Refer to the specific packaging for sterilization and disinfection procedures. Sterilize and disinfect according to these procedures for non-sterile product prior to use in patients.

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.

Product Packaging
ORA Implant Abutments are packaged in a sealed chevron pouch. These pouches are not autoclavable. Parts need to be removed from pouch prior to autoclaving and placed in an autoclavable pouch or tray.

Caution: Federal (USA) law restricts this device to the sale by or on the order of a dentist (or other licensed practitioner).

Devices are for Single Use only and are not to be re-used or re-sterilized.

Shelf Life
The ORA Implant Abutments have no expiration date.

CLEANING, DISINFECTION AND STERILIZATION
ORA Implant Abutments and ancillary components are sold non-sterile. Sterilize and/or disinfect according to the procedures below prior to use in patients.

The autoclave is to be used according to manufacturer instructions. The health care facility should monitor the sterilizer for the facility according to an FDA recognized sterility assurance standard such as ANSI/AAMI ST79. Disinfection and sterilization procedures should conform to OSHA or local guidelines for blood borne pathogens.
Caution: It is the responsibility of the user to establish whether or not their sterilizer has been cleared by the FDA to meet these recommended parameters, and to use accessories (BIs, CIs, and wraps/pouches/containers) cleared by FDA and labeled for use.

Cleaning/Disinfection Prior to Use
Use the following guidelines for cleaning/disinfecting products:

Rinse with cool-to-lukewarm water for two-and-one-half minutes. For all parts place in an ultrasonic cleaner with an enzymatic detergent diluted with tap water per the manufacture's guidelines. Sonicate for 10 minutes. Rinse with tap water for three minutes.

Transport
Remove device from package and bring it to cleaning/disinfection area for processing.

Inspection and assembly
Before sterilization, inspect devices visually, unmagnified, under good lighting conditions. Check for any damage on devices after cleaning. Devices should be inspected for visible soil and/or corrosion.

Sterilization
Individual parts shall be sterilized in autoclaving pouches using steam sterilization and a gravity placement autoclave. The following sterilization parameters (method, time, and temperature) are required to achieve a 10-6 sterility assurance level (SAL). To ensure autoclave is performing effectively, periodic use of biologic indicators should be considered.

Cycle Type: Steam Sterilization
Temperature: 121˚C / 250˚F
Exposure Time: 30 minutes
Dry Time: 15 - 30 minutes

Operation Mechanism
Choose the abutment with the proper cuff height that fits the existing implant. Screw an abutment into each implant. The abutments are tightened to 20 Ncm, using a hex tool which engages the hex at the base of the ball.

Once the O-Ring Abutments are in place, an impression is taken using a light impression material. Impression is sent to the laboratory so that the denture can be created. The O-Ring Abutments can remain in place while the denture is being created.

The laboratory will incorporate the O-Ring Retainers into the denture. Any exposed areas of the abutment are blocked out so that only the metal housing is exposed. The retaining ring (metal housing) is then processed into the denture. The denture is then snapped onto the ball abutment in the patient's mouth.

MR Safety
The ORA Implant Abutments have not been evaluated for safety and compatibility in the MR environment. The ORA Implant Abutments have not been tested for heating or migration, or image artifact in the MR environment. The safety of ORA Implant Abutments in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

EMC and Electrical Safety
The ORA Implant Abutments do not require EMC and Electrical Safety Evaluation.

Software
The ORA Implant Abutments do not contain or utilize software.

Storage
Place devices in a dry place to prevent damage and/or deterioration.

	Do not reuse		Used by YYYY-MM-DD or YYYY-MM
LOT	Batch code		Manufacturer
EC REP	Authorized representative in the European Community	NON STERILE	Symbol for Non-Sterile
Rx only	Symbol for "Use by Prescription only"		Caution, consult accompanying documents
CE	Symbol for "European Conformity"	REF	Catalog number
	Do not use if package is damaged		

Manufactured and distributed in the U.S.A. by:

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EC REP

ORA Implant Abutments are compatible with the following implant systems.	
Implant Brand	**Model**
Nobel Biocare Brånemark System	3.3 Fixture, 3.75 Fixture, 4.0 Fixture, 5.0 Fixture (Old Version), 3.75 MkII Self-tapping Fixture, 4.0 MkII Self-tapping Fixture
Sterngold-ImplaMed	3.3 Hex Cylinder, 4.0 Hex Cylinder, 3.75 Standard Hex Screw, 3.75 Self-tapping Hex Screw, 3.75 Self-tapping "SST" Hex Screw, 4.0 Standard Hex Screw, 4.0 Self-tapping Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 5.0 RP "SST" Hex Screw, 3.75 RP Acid Etched, 4.0 RP Acid Etched,5.0 RP Acid Etched, 4.1 Stern IC (4.8 head), 3.3 Stern IC (4.8 head)
Nobel Biocare (Steri-Oss®)	3.8 HL Cylinder, 3.8 HL Threaded, 4.5 HL Threaded, 3.5 Nobel Replace™, Replace® Select (NP), 4.0 Nobel Replace Straight, (RP), 4.3 Replace® Select & Nobel Replace™ (RP)

ORA Implant Abutments are compatible with the following implant systems.	
Implant Brand	**Model**
Keystone (Lifecore)	3.75 Restore® Self-tapping Screw, 4.0 Restore® Self-tapping Screw, 3.75 Restore® External Hex Screw, 4.0 Restore® External Hex Screw, 4.0 Restore® External Hex Cylinder, 4.2 Sustain® External Hex Cylinder, 3.75 Sustain® External Hex Screw, 4.0 Sustain® External Hex Screw, 4.2 Sustain® External Hex MC Cylinder, Stage-1™ (3.3 and 4.0 fixtures)
3i Implant Inovations	3.25 External Hex Miniplant®, 3.25 ICETM Miniplant®, 3.25 OSSEOTITE® Miniplant®, 3.3 Cylinder Miniplant®, 3.3 External Hex Cylinder, 3.75 ICETM Self-tapping, 3.75 OSSEOTITE®, 3.75 Self-tapping Threaded, 3.75 Standard Threaded, 4.0 External Hex Cylinder, 4.0 ICE™ Self-tapping, 4.0 OSSEOTITE®, 4.0 Standard Threaded, 4.25 External Hex Cylinder, TG OSSEOTITE® (4.8 Platform), 4.0 OSSEOTITE® Certain™, 4.0 OSSEOTITE® NTCertain™, 4.0 OSSEOTITE® CERTAIN PREVAIL, 5.0 Osseotite® Certain, 5.0 Osseotite® NT Certain, 5.0 Osseotite® Certain Prevail
IMTEC Corp.®	3.3 Universal Flare Cylinder, 3.75 Universal Self-tapping, 3.75 Universal Self-tapping Coated, 4.0 Spike Cylinder, 4.0 Universal Cylinder
Interpore IMZTM	3.3 Hex Cylinder, 3.75 Self-tapping Threaded, 4.0 Hex Cylinder, 4.0 Self-tapping Threaded, 4.25 Hex Cylinder
Osstem	4.1 US II, III, II Plus, III Plus, SS II, III (4.8 head)
Zimmer Dental	3.5 Bio-Vent® X™, 3.75 Swede-VentT™ Conical Neck CST, 3.75 Swede-Vent™ Standard, 4.0 Swede-Vent™ Standard, 4.0 Bio-Vent® X™, 3.25 Micro-Vent® (3.5 head), 3.3 Screw-Vent® (3.5 head), 3.5 Bio-Vent® (3.5 head), 3.7 Screw-Vent® (3.5 head), 3.75 Screw-Vent® (3.5 head), 4.3 Core-Vent® (3.5 head),4.25 Micro-Vent® (4.5 head), 4.5 Bio-Vent® (4.5 head), 4.7 Screw-Vent® (4.5 head), 5.3 Core-Vent® (4.5 head), 3.7 Tapered Swiss Plus™ (4.8 platform), 4.8 Tapered Swiss Plus™ 4.1 Straight Swiss Plus™ , 4.8 Straight Swiss Plus™, 3.75 ThreadLoc™ , TSV 5.7mm
Straumann	ITI TE™ 3.3 (4.8 head), ITI 3.3 Std & Std Plus (4.8 head), ITI TE™ 4.1 (4.8 head), ITI 4.1 Std. & Std. Plus (4.8 head), ITI, 4.8 Std. & Std. Plus (4.8 head), Bone Level RC, Bone Level NC
Biolok International	4.5 Silhouette Screw, 4.0 Micro-Lok Screw, 4.0 Micro-Lok Cylinder, 3.75 Micro-Lok Screw, 3.3 Micro-Lok Cylinder
Bud	3.25 Bud Screwvent, 3.75 Bud Screwvent
INNOVA	4.1 ENDOPORE® External Connection, 4.0 ENTEGRA™ External Connection
OIC	3.0 Osteo Standard ST, 3.25 Osteo Standard ST, 3.75 Osteo Standard ST
MIS IMPLANTS	3.3mm Internal Hex, 3.75mm Internal Hex, 4.20mm Internal Hex, 5.0mm Internal Hex
BioHorizons®	3.5 Internal, 4.0 Internal, 4.5 Internal, 3.5 Single Stage, 4.5 Single Stage, BioHorizon 5.7
Implant Direct	Legacy 3.5mm, Legacy 4.5mm, RePlant™ 4.3mm, RePlant™ 3.5mm, 3.7mm ScrewPlant, 4.7mm ScrewPlant, Legacy 5.7, Implant Direct 5.0 RePlant
Minimatic/ Stryker	3.3 External Hex Cylinder, 3.75 External Hex Screw, 4.0 External Hex Cylinder, 4.0 External Hex Screw, 4.75 External Hex Screw, 5.0 External Hex Cylinder
Ankylos	Ankylos
Nobel Biocare	Nobel Replace WP, Nobel Replace Select WP, NobelSpeedy Replace WP, Nobel Conical Connection RP, Nobel Conical Connection NP
Blue Sky Bio	Blue Sky Bio Max, Conus 12 4.5 / 5.0, Conus 12 3.5 / 4.0, Square Taper NC, Square Taper RC, Bio 5.0 Trilobe
Astra Dental	Astra 4.5 / 5.0, Astra 3.5 / 4.0