Sterngold Prosthetic System

Instructions for Use

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

Prosthetic and Ancillary Components, Abutments and Attachments

ENGLISH

Before using the Sterngold Prosthetic Components, 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 Sterngold Prosthetic Components 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 Sterngold Dental prosthetic components are devices used to connect Sterngold Implants to dental prostheses, designed to be used in single and multiple implant fixed and removable restorations.

The ERA® Implant Abutments are a resilient retention device for dental prostheses, designed to be used in the restoration of removable dentures.

NOTE: To improve the cement bond, air abrade the inside of the cup shaped area of the base of the Angle Correction ERA® Implant Abutments, and ERA Implants. 50 micron aluminum oxide blasting for 3 seconds is recommended.

The ERA® Micro 23˚ and 30˚ females are intended to be used as a retention device in conjunction with the Sterngold Acid Etched Dental Implant System in the maxillary and/or the mandibular arch to provide support for overdentures for partially and fully edentulous patients.

CONTRAINDICATIONS
The ERA® Implant Abutments are not appropriate for case designs requiring rigidity in function.

WARNINGS
The Sterngold Prosthetic Components 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.

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
Sterngold Dental prosthetic and ancillary components are sold non-sterile. Refer to the specific packaging for sterilization or 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
Sterngold Prosthetic Components and associated products are packaged in a plastic case or non-autoclavable pouches. The abutments may also be packaged with a plastic "Gripper" attached to each abutment. This Gripper acts as a carrying handle and as hand tool to begin screwing the abutment into the implant.

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

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

Shelf Life
The Sterngold Prosthetic Components have no expiration date.

CLEANING, DISINFECTION AND STERILIZATION
Disinfection and sterilization procedures should conform to OSHA or local guidelines for blood borne pathogens.

Cleaning Disinfection Prior to Use
Devices are to be cleaned, disinfected and sterilized by user priot to use.

Use the following guidelines for cleaning/disinfecting products: Instruments, Abutments and Nylon parts - Disassemble multi-piece components, if applicable. 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 should be placed in appropriate autoclave for moist heat sterilization or in a dry heat pouch for dry heat sterilization. The following sterilization parameters (method, time and temperature) are required to achieve a 10-6 sterility assurance level (SAL). Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in the table. Exceeding these sterilization parameters may result in damage to plastic components. Verify the calibration of your unit to ensure recommended temperatures are not being exceeded. To ensure autoclave is performing effectively, periodic use of biologic indicators should be considered.

	Cycle Type	Temp-erature	Exposure Time	Dry Time (only for kits)
Parts individually pouched	Gravity (steam)	121˚C 250˚F	40 minutes	n/a
Parts in a kit	Gravity (steam)	132˚C 270˚F	15 minutes	30 minutes
	Pre-vacuum (steam)	134˚C 273˚F	5 minutes	30 minutes

Symbol	Used For	Symbol	Used For
2	Do not reuse		Do not use if package is damaged
LOT	Batch code		Manufac-turer
EC REP	Authorized representa-tive in the European Community	NON STERILE	Symbol for Non-Sterile
Rx only	Symbol for "Use by Prescription only"	!	Caution, consult ac-companying documents
CE	Symbol for "European Conformity"	REF	Catalog number
2 STERILIZE	Do not re-sterilize		

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

EMC and Electrical Safety
The Sterngold prosthetic devices do not require EMC and Electrical Safety Evaluation.

Software
The Sterngold prosthetic devices do not contain or utilize software.

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

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

Sterngold Dental, LLC
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EC REP

Dental Implants Compatible with Abutment Bases	
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

Dental Implants Compatible with Abutment Bases	
Implant Brand	**Model**
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), 3.5 TRU, 4.3 TRU, 5.0 TRU, 6.0 TRU, 3.5 PUR, 4.3 PUR, 5.0 PUR, 6.0 PUR
Nobel Biocare® (Steri-Oss®)	3.8 HL Cylinder, 3.8 HL Threaded, 4.5 HL Threaded, 3.5 NobelReplace™, Replace® Select (NP), 4.0 NobelReplace Straight, (RP), 4.3 Replace® Select &NobelReplace™ (RP)
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)
Biomet 3i™ Implant Inovations	3.25 External Hex Miniplant®, 3.25 ICE™ Miniplant®, 3.25 OSSEOTITE® Miniplant®, 3.3 Cylinder Miniplant®, 3.3 External Hex Cylinder, 3.75 ICE™ 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 Corporation®	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 IMZ™	3.3 Hex Cylinder, 3.75 Self-tapping Threaded, 4.0 Hex Cylinder, 4.0 Self-tapping Threaded, 4.25 Hex Cylinder
Osstem Hoissen	4.1 US II, III, II Plus, III Plus, SS II, III (4.8 head)
Zimmer Dental Paragon, Calcitek®, Centerpulse	3.5 Bio-Vent® X™, 3.75 Swede-Vent™ 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™
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), 4.1 Regular Crossfit (Bone level), 4.8 Regular Crossfit (Bone level), 3.3 Narrow Crossfit (Bone level)
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 ENTEGRATM 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

Dental Implants Compatible with Abutment Bases	
Implant Brand	**Model**
Implant Direct	Legacy 3.5mm, Legacy 4.5mm, RePlant™ 4.3mm, RePlant™ 3.5mm, 3.7mm ScrewPlant, 4.7mm ScrewPlant
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