SMALL HEADED SCREW SYSTEM
PACKAGE INSERT

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

DESCRIPTION OF THE MEDICAL DEVICE:
The implants – delivered non-sterile – are:

- Screws existing in different diameters and lengths
- Screws having a recess for engaging a driver
- Screws designed to be implanted into bone
- Screws made out of Titanium alloy within the frame of the standard NF ISO 5832-3 and ASTM F136.

INDICATIONS FOR USE

These Small Headed Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. Screws are intended for single use only.

WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

MATERIAL
The implants are manufactured from a Titanium alloy (ISO 5832-3 and ASTM F136). The specialized instruments are made of surgical grade stainless steel (ISO 7153-1 and ASTM F899).

HOW SUPPLIED
The implants are delivered **non-sterile** as specified by the packaging.

The instruments are provided **non-sterile** and must be cleaned and sterilized prior to use according to the procedures outlined in this document.

CONTRAINDICATIONS
The implant should not be used in a patient who has current, or who has a history of:

- Local or systemic acute or chronic inflammation;
- Active infection or inflammation;
- Suspected or documented metal allergy or intolerance

WARNINGS and POTENTIAL RISKS
The implants are designed for **single patient use only and must never be reused.** As with all other orthopedic implants, these components should never be re-implanted under any circumstances.

The implants can become loose or break if subjected to increased loading. Factors such as the patient's weight, activity level, and adherence to weight-bearing or load-bearing instructions can affect the implant's longevity. Damage to the weight-bearing bone structures caused by infection can give rise to loosening of the components and/or fracture of the bone.

Serious post-operative complications may occur from the implant in a patient who; lacks good general physical conditions; has severe osteoporosis, demonstrates physiological or anatomical anomalies; has immunological responses, sensitization or hypersensitivity to foreign materials; systemic or metabolic disorders.

These warnings do not include all adverse effects which could occur with surgery, but are important considerations specific to metallic devices. The risks associated with orthopedic surgery, general surgery and the use of general anesthesia should be explained to the patient prior to surgery. See the PRECAUTIONS and POSSIBLE ADVERSE EFFECTS sections for additional warnings.

PRECAUTIONS
The implantation of screws should be performed only by experienced surgeons with specific training in the use of this screw system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Under no circumstances should damaged components or surgically excised components be used. Implants that have already been in contact with body fluids or body tissues must not be resterilized.

This Small Headed Screw System should never be used with dissimilar materials.

Pre-operative assessment of the suitability of the patient's anatomy for accepting implants is made on the basis of x-rays, CT scans, and other radiological studies.

Only patients that meet the criteria described in the INDICATIONS FOR USE section should be selected.

Correct selection of the implant is extremely important. The morbidity as well as patient weight height, occupation and/or degree of physical activity should be considered.

Proper implant handling before and during the operation is crucial. Handle the implant components properly. Ensure packaging integrity. Do not allow the implants surfaces to be damaged.

Adequately instruct the patient. The physician should inform the patient about orthopedic implant advantages and disadvantages, post-operative limitations, weight/load bearing stresses which could affect bone healing, implant limitations, and the fact that premature physical activity and full weight/load bearing stresses have been implicated in premature loosening, damage, and/or fracture of orthopedic prostheses.

IMPORTANT: The guidewires included in the Small Headed Screw System are not intended as implants. The guidewires are only intended for use as instruments to facilitate screw insertion.

POSSIBLE ADVERSE EFFECTS

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Pre-operatively, the patient should be made aware of the possible adverse effects of orthopedic surgery. Additional surgery may be necessary to correct some of these anticipated events including, but not limited to:

- Early or late loosening, disassembly and/or breakage of any or all implants;
- Metal sensitivity to a foreign body (implant material allergic reaction), including metallosis, staining, tumor formation, auto-immune disease, and/or scarring;
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown, penetration, pain, irritation, and/or wound complications;
- Tissue damage resulting from improper placement of implants or instruments;
- Infection;
- Hematoma;
- Allergy;
- Thrombosis;
- Nerve or vascular damage due to surgical trauma, including loss of neurological function, neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, appearance of radiculopathy, and paralysis (complete or incomplete);
- Bone loss due to resorption or stress shielding, decrease in bone density or bone fracture at operative site;
- Pain, discomfort, or wound healing complications at the surgical site;
- Misalignment of anatomical structures;
- Bone non-union or delayed union;
- Adverse effects may necessitate re-operation, revision, or removal surgery, arthrodesis of the involved joint, and/or amputation of the limb.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY

Non-clinical testing has demonstrated the Small Headed Screws are MR Conditional. A patient with these devices can be safely scanned in an MRI system meeting the following conditions:

- Static magnetic field of 3.0 T or 1.5 T
- Maximum spatial field gradient of 1900 gauss/cm (19 T/m)
- Maximum MRI system reported, whole body averaged specific absorption rate (SAR) of 1.0 W/kg

Under the scan conditions defined above, non-clinical testing results indicate the Small Headed Screws are expected to produce a maximum temperature rise of 8°C after 10 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 20mm from the Small Headed Screw when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

DIRECTIONS FOR USE
To implant the Small Headed Screw implants, use only the specialized instrumentation. Do not use implants or instruments from any other system or manufacturer.

These implants and instruments are provided non-sterile. Non-sterile implants and instruments must be cleaned and sterilized prior to use according to the procedures outlined in this document. All Small Headed Screw system components should be carefully inspected to ensure proper working condition. Critical areas, including joint surfaces, should be checked for wear, damage or irregularities. Damaged or broken Small Headed Screw devices must not be used or processed and should be returned to Zimmer for evaluation.

Before using the Small Headed Screw System for the first time, the surgeon should be thoroughly familiar with the Small Headed Screw Surgical Technique Manual as well as the functionality and assembly of the various components. Pre-operative planning by the surgeon should determine the type of implant required and an adequate supply of the implant sizes should be available prior to surgery, including larger and smaller sizes than those expected to be used.

For complete instructions regarding the proper use and application of all Small Headed Screw implants and instruments, please refer to the Small Headed Screw Surgical Technique Manual (available at no charge upon request).

CARE AND HANDLING
Implants and Instruments are provided non-sterile and should be stored in the original packaging until cleaned and sterilized. Prior to use, they must be cleaned and sterilized according to the standard hospital procedure. Refer to the CLEANING and STERILIZATION sections for recommended parameters.

Limitations on Processing
Repeated processing has minimal effect on these implant and instruments. End of life is normally determined by wear and damage due to use.

Point of Use
Before being used for the first time and each use thereafter, the instructions outlined below should be followed to ensure safe handling of biologically contaminated instruments.

Containment and Transportation
It is recommended that devices are reprocessed as soon as reasonably practical following use.

Preparation for Cleaning
Remove excess soil with a clean, lint-free, disposable, absorbent Kimwipe, cloth, or equivalent.

Cleaning (Automated)

Equipment: Automated washer, soft bristle brush, enzymatic detergent[1], and neutral pH detergent[2].

- Preclean the devices by placing under running water and scrubbing with a soft bristle brush to remove major debris. Rinse and scrub each devices for at least one minute.
- After precleaning, place in the automated washer, making sure the devices do not touch each other load devices in such a way that the parts can drain.
- At a minimum use a cycle meeting the following parameters:

Enzyme Wash	Hot (40 - 65º C) (104 - 149º F) for 3 minutes
Neutral pH Wash	60º C (140º F) for 3 minutes
Rinse	Ambient temperature for 1.5 minutes
Thermal Rinse	90º C (194º F) for 1 minute
Dry	82º C (180º F) for 6 minutes

- Determine if the devices are dry. If they are not dry, dry with a soft, clean, lint free cloth.
- After drying, check devices for complete removal of any debris. If necessary, repeat cycle or use manual cleaning. Replace any devices that cannot be cleaned

Cleaning (Manual)

Warning: Movable components and blind holes require particular attention during cleaning.

Preparation of Cleaning Agents (Recommended):

- Add 60 mL of Endozime® AW Plus to 3.8 L of water, (1:64 dilution).

Manual Cleaning Instructions:

- Preclean the devices by placing under running water and scrubbing with a soft bristle brush to remove major debris. Rinse and scrub each device for at least one minute.
- Bathe the devices in the enzymatic solution for 5 minutes; where appropriate, the devices shall be rotated and briskly moved in bath to promote flushing. Where appropriate, a large syringe or pulsating water jet may be used to thoroughly flush all channels and lumens with the solution.
- Scrub the devices with a soft bristle brush while submerged in the detergent.
- Rinse the devices in purified water at room temperature for 5 minutes.
- The rinse bath should be changed after each cleaning process.
- Pat dry with a soft, clean, lint free cloth.
- After drying, check instruments for complete removal of any debris. If necessary, repeat manual cleaning. Replace any devices that cannot be cleaned

Device Replacement

Warning: The use of damaged instruments may increase the risk of tissue trauma, infection, and length of operative procedures.

Warning: Do not attempt to repair any instrument.

If your device is defective or damaged, contact your local Zimmer Biomet Distributor. In your correspondence, please include at a minimum the following information:

- Device Lot Number
- Device Part Number
- Description of defect or damage
- Whether the device is available for return

Inspection and Function Testing

All instruments: Visually inspect for damage and wear. Where instruments interface with other devices, inspect to ensure that the interface is not damaged.

Check for staining, discoloration, corrosion, misalignment, burrs, bent or fractured tips. Mechanically test the working parts to verify that each instrument functions correctly. Replace any device that is not functioning.

Verify the legibility of all markings. Replace any device that is unreadable.

Repeat cleaning and/or replace the affected devices as needed to ensure proper operation before proceeding to sterilization.

Packaging

Instruments may be loaded into the specified instrument trays, or general-purpose trays. Wrap the trays using an appropriate method with no more than two layers of sterilization wrap that are FDA approved for pre-vacuum steam sterilization.

Sterilization

If not specifically labeled **STERILE**, or if labeled NON-STERILE, components are supplied non-sterile and must be cleaned and sterilized prior to surgery.

Warning: Tyber Medical does not recommend that the instruments be sterilized by Flash, EtO or Chemical sterilization. When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.

To achieve a sterility assurance level of SAL 10^{-6}, Tyber Medical recommends the following parameters:

Sterilizer Type	Gravity	Pre-Vacuum	
Minimum Temp.	132º C (270º F)	132º C (270º F)	135º C (275º F)
Exposure*	15 min	4 min	3 min
Dry Time	20 minutes		

**Tyber Medical has validated the above sterilization cycles and has the data on file. The validated sterilization parameters meet the minimum requirements per ISO 17665. Other sterilization cycles may also be suitable; however, individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques.*

Tyber Medical recommends following ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*, which includes: physical monitoring of the cycle, inclusion of a chemical indicator internal and external to the package, and monitoring of every load with a Biological Indicator and/or Class 5 Integrating Indicator.

Storage

The instruments must be completely dry before storing and must be handled with care to prevent damage. Store in designated trays and in areas which provide protection from dust, insects, chemical vapors and extreme changes in temperature and humidity.

RETRIEVAL AND ANALYSIS OF REMOVED IMPLANTS

The most important part of surgical implant retrieval is preventing damage that would render scientific examination useless. Special care should be given to protect the implant during handling and shipping. Follow internal hospital procedures for the retrieval and analysis of implants removed during surgery. When handling removed implants, use precautions to prevent the spread of bloodborne pathogens. Please contact Zimmer customer service for return of removed implants.

DISPOSAL

Observe internal hospital/institution procedures, practice guidelines, and/or government regulations for proper handling and disposal of the Small Headed Screw System.

CUSTOMER SERVICE

For further information regarding the Small Headed Screw System or a copy of the Small Headed Screw System Surgical Technique Manual, please contact Zimmer or your local Zimmer Distributor.

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SYMBOL	MEANING
℞	Caution: Federal (United States) law restricts this device to sale, distribution, and use by or on the order of a physician.
REF	Reference Number
LOT	Lot Number
MD	Medical Device
	Date of Manufacture/ Country of Manufacture
	Expiration Date
	Do Not Re-Use
	Consult Instructions for Use
	Caution
NON STERILE	Non-Sterile
	Distributor
	Manufacturer
CE 2797	CE Mark/ CE Mark with Notified Body
EC REP	Authorized Representative in the European Union
CH REP	Authorized Representative in Switzerland
UDI	Unique Device Identifier
MR	MR Conditional
	Patient Identification
	Patient Information Website
	Health Care Centre or Doctor

[1] ENZOL®, a trademark of Advanced Sterilization Products, was used in the cleaning validation

[2] Prolystica™ Ultra Concentrate neutral Detergent, a trademark of Steris Corporation, was used in the cleaning validation

SYMBOL	MEANING
	Date Information Was Entered or Procedure Took Place