



TYBER MEDICAL
TYFIX™ 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 are:

- TyFix™ Screws exist in different diameters and lengths
- The screws have a recess for engaging a driver
- The screws are designed to be implanted into bone
- The implants are offered in Titanium alloy within the frame of the standard NF ISO 5832-3 and ASTM F136.
- The implants are also offered in Stainless Steel per ASTM F138.

The implants are shipped sterile and non-sterile.

INDICATIONS FOR USE

The Tyber Medical TyFix™ Screw is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion 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

Tyber Medical implants are manufactured from a Titanium alloy (ISO 5832-3) or Stainless Steel. The specialized instruments are made of surgical grade stainless steel (ISO 7153/1).

HOW SUPPLIED

The implants are shipped sterile or non-sterile as specified by the packaging.

All sterile implants are gamma radiation sterilized. The package should be inspected prior to use to ensure the sterile barrier has not been compromised. Do not resterilize.

Tyber Medical 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 Tyber Medical implants are designed for **single patient use only and must never be reused**. As with all other orthopedic implants, the Tyber Medical components should never be re-implanted under any circumstances.

The Tyber Medical 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 screw systems 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.

The Tyber Medical TyFix™ Screw Systems should never be used with dissimilar materials. Specifically, the titanium and stainless steel components offered with this system should not be used together.

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 Tyber Medical TyFix™ Screw Systems are not intended as implants. The Guide Wires 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

The Tyber Medical Implants have not been evaluated for safety and compatibility in the MR environment. The Tyber Medical TyFix™ Screw has not been tested for heating, migration or image artifact in the MR environment. The safety of Tyber Medical TyFix™ Screws in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

DIRECTIONS FOR USE

To implant the Tyber Medical TyFix™ Screw implants, use only the specialized Tyber Medical TyFix™ Screw instrumentation. Do not use implants or instruments from any other system or manufacturer.

The Tyber Medical TyFix™ Screw instruments are provided non-sterile. Non-sterile instruments must be cleaned and sterilized prior to use according to the procedures outlined in this document. All Tyber Medical TyFix™ Screw device 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 Tyber Medical TyFix™ Screw devices must not be used or processed and should be returned to Tyber Medical for evaluation.

Before using the Tyber Medical TyFix™ Screw System for the first time, the surgeon should be thoroughly familiar with the Tyber Medical TyFix™ 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 Tyber Medical TyFix™ Screw implants and instruments, please refer to the Tyber Medical TyFix™ Screw Surgical Technique Manuals (available at no charge upon request).

CARE AND HANDLING

Tyber Medical TyFix™ Screw Systems Implants are provided either sterile or non-sterile and instruments are provided non-sterile. Non-sterile instruments should be stored in the original packaging until cleaned and sterilized. Prior to use, they must be sterilized according to the standard hospital procedure. Refer to the STERILIZATION section 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 instruments are reprocessed as soon as reasonably practical following use.

Preparation for Cleaning

Where instruments interface with other devices, disassemble prior to cleaning.

Remove excess soil with a clean, disposable, absorbent Kimwipe or equivalent.

Cleaning (Automated)

Equipment: Automated washer, soft bristle brush, enzymatic detergent¹, and neutral pH detergent².

- Preclean the instruments by placing under running water and scrubbing with a soft bristle brush to remove major debris. Rinse and scrub each instrument for at least one minute.
- After precleaning, (precleaning is not required for implants) place in the automated washer, making sure the samples do not touch each other - load instruments in such a way that the parts can drain.
- Use a standard cycle with the following parameters (at a minimum) for non-sterile instruments:

Enzyme Wash	Hot (40 - 65 °C) (104 - 149 F) for 3 minutes
Neutral pH Wash	60 °C (140 °F) for 3 minutes
Rinse	Ambient temperature for 1.5 minutes
Thermal Rinse	90 °C (194 F) for 1 minute
Dry	82 °C (180 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 instruments for complete removal of any debris. If necessary, repeat cycle or use manual cleaning.
- Final Rinse shall be performed in purified water at room temperature for 5 minutes.
- The rinse bath should be changed after each cleaning process.

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 instruments (precleaning is not required for implants) by placing under running water and scrubbing with a soft bristle brush to remove major debris. Rinse and scrub each instrument for at least one minute.
- Bathe the instruments in the enzymatic solution for 5 minutes; where appropriate, the instrument 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 instruments 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.

After Cleaning

Where instruments have been disassembled prior to cleaning reassemble prior to use.

Maintenance and Repair

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 Tyber Medical instrument.

If your Tyber Medical instrument requires repair or maintenance, return the instrument in the Tyber Medical box or other sturdy box with adequate packaging material to protect the instrument. Send the packaged instrument to:

Tyber Medical, LLC
83 South Commerce Way, Ste 310
Bethlehem, PA 18017

Attn: Tyber Medical Technical Services

Note: Instruments returned to Tyber Medical must have a statement which testifies that each instrument has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.

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 misalignment, burrs, bent or fractured tips. Mechanically test the working parts to verify that each instrument functions correctly. Remove stained, discolored or damaged instruments.

Packaging

Instruments may be loaded into the specified Tyber Medical 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

For components provided Sterile, the sterilization method is noted on label. Sterile implant components are supplied sterile to a Sterility Assurance Level (SAL) of 10⁻⁶. Sterile packaged components are supplied in a protective sterile barrier packaging. Inspect package for punctures or other damage prior to surgery. If sterile barrier has been broken, return component to Tyber Medical.

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	Pre-Vacuum	Gravity Displacement
Minimum Temp.	132 °C (270 F)	132 °C (270 F)
Exposure*	4 minutes	15 minutes
Dry Time	20 minutes	30 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 17665-1. 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

Tyber Medical 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 Tyber Medical customer service for return of removed implants.

CUSTOMER SERVICE

For further information regarding the Tyber Medical TyFix™ Screw System or a copy of the Tyber Medical TyFix™ Screw Surgical Technique Manual, please contact Tyber Medical, LLC or your local Tyber Medical Distributor.



Tyber Medical, LLC
83 South Commerce Way, Ste 310
Bethlehem, PA 18017
Phone: +1 (866) 761-0933
Fax: +1 (866) 889-9914

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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.