Tyber Medical

Expand Your Brand

TYBER MEDICAL
HEADLESS TRAUMA SCREW SYSTEM
PACKAGE INSERT

DESCRIPTION OF THE MEDICAL DEVICE

The implants – delivered sterile or non-sterile – are:

- Trauma screws existing in different diameters and lengths
- Screws having a recess for engaging a driver
- Screws with the head of the trauma screw configured with threads to engage the proximal bone

The implants are manufactured from Titanium alloy within the frame of the standard ASTM F136. The Titanium alloy screw configurations are provided with and without modified surface treatment (MST).

The instruments – delivered sterile and non-sterile – are intended to support the implantation of the Tyber Medical Trauma Screws.

INDICATIONS FOR USE

The Tyber Medical Trauma Screw System is 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.

INTENDED USE

The Tyber Medical Trauma Screw System is designed to apply compression and fixation between two adjacent segments of cortical and/or cancellous bone.

LIMITATIONS

This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. Use of the implants in these anatomical locations can result in patient injury including vascular and central nervous system injury and longer surgery. With the exception of any limitations present in the Contraindications, Warnings and Potential Risks, and Precautions sections, there are no additional limitations of these devices when used as intended.

PATIENT TARGET GROUP

The Tyber Medical Trauma Screw System is for patients undergoing fixation of bones appropriate for the size of the screw.

INTENDED USER

The Tyber Medical Trauma Screw System is intended for use by experienced trauma and orthopaedic surgeons.

CLINICAL BENEFIT

The expected clinical benefit of the Tyber Medical Trauma Screw System when used as intended is to achieve bone union.

DEVICE LIFETIME

The Tyber Medical Trauma Screw System implants have completed their treatment lifetime and primary function of mechanical stabilization once the fusion mass has attained adequate strength to sustain the stability and integrity of the bone without necessitating external support (typically 6 weeks to 9 months depending on the bone(s) treated and the procedure(s) performed).

The expected treatment lifetime of the Tyber Medical Trauma Screw System single-use instruments is intended for short-term (transient) use defined by the time the instruments are functioning during the clinical procedure.

The expected lifetime of the Tyber Medical Trauma Screw System reusable instruments is dependent on many factors including the method and duration of each use and the handling between uses. Careful inspection and functional testing of the device before use, as described in the section below, is the best method for determining the reusable instrumentation end of life.

MATERIAL

Tyber Medical implants are manufactured from a Titanium alloy (ASTM F136). The specialized instruments are made of surgical grade stainless steel (ASTM F899 and ASTM F138). The guidewires are made of Cobalt Chromium Molybdenum Alloy, MP35N (ASTM F562). Refer to the following table for the quantitative composition of elements by % for the Titanium alloy.

Element	**Composition % (mass/mass)**
Nitrogen, max	0.05
Carbon, max	0.08
Hydrogen, max	0.012*
Iron, max	0.25
Oxygen, max	0.13
Aluminum	5.5 – 6.50
Vanadium	3.5 – 4.5
Titanium**	balance

*Material 0.032 in. (0.813mm) and under may have hydrogen content up to 0.0150%.

**The percentage of titanium is determined by difference and need not be determined/certified.

HOW SUPPLIED

Tyber Medical Implants and Instruments are delivered either **sterile or non-sterile** as specified by the packaging.

All implants and instruments labeled as **sterile** are exposed to a minimum dose of 25.0 kGy gamma radiation to obtain a minimum Sterility Assurance Level (SAL) of 10^{-6}. The package should be inspected prior to use to ensure the sterile barrier has not been compromised. Do not re-sterilize.

All **non-sterile** implants and instruments are provided clean and must be sterilized prior to use according to the procedures outlined in this document. The **non-sterile** implants and instruments may be cleaned before being sterilized, if desired.

Information on the status of sterilization (sterile or non-sterile) is contained on the product label.

CONTRAINDICATIONS

The Tyber Medical Trauma Screw System 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 surgeon should be aware of the following:

1. The Tyber Medical Trauma Screw System is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. Use of the implants in these anatomical locations can result in patient injury including vascular or central nervous system injury, pain, tissue damage, non-union and surgical delay.
2. The Tyber Medical Trauma Screw implants and sterile instruments are designed for **single patient use only and must never be reused** under any circumstances. Reuse may lead to infection, adverse tissue reaction, removal of hardware and/or implant revision.
3. All non-sterile instruments are provided clean and must be sterilized prior to surgery. Failure to do so may result in adverse tissue reaction, infection, and/or revision.
4. 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. Additional risks involved in overloading include tissue damage, malunion, hardware removal, and/or implant revision.
5. Serious post-operative complications, such as tissue damage, malunion, non-union, loosening, hardware removal, and/or implant revision 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.
6. 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

1. 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. Surgeons must be aware of the content of this IFU and the Surgical Technique Guide (STG) prior to device use.
2. Always verify that the sterile device is within its expiration date. 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 re-sterilized. The risks associated with not following these precautions are adverse tissue reaction, hardware removal, and/or implant revision.
3. The Tyber Medical Trauma Screw System should never be used with dissimilar materials, as this can cause corrosion, metal debris, and other negative outcomes including adverse tissue reaction, bone loss, non-union, infection, hardware removal and/or implant revision.
4. 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 INTENDED USE/INDICATIONS FOR USE section should be selected. Surgeons must be aware of the content of this IFU and STG prior to device use.
5. **Correct selection of the implant is extremely important**. The morbidity, as well as the patient's weight, height, occupation, and/or degree of physical activity should be considered. Surgeons must be aware of the content of this IFU and the STG prior to device use.
6. **Proper implant handling before and during the operation is crucial**. Handle the implant components properly, as improper handling can result in glove ripping, skin pinching, unintended cuts and/or pricks to the user, and/or surgical delay. Ensure packaging integrity. Do not allow the implants surfaces to be damaged.
7. **Adequately instruct the patient**. The physician should inform the patient about the 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.
8. **IMPORTANT:** The guidewires included in the Tyber Medical Trauma Screw System are not intended as implants. The guidewires are only intended for use as instruments to facilitate screw insertion. These misuses of the guidewires may result in adverse tissue reaction, infection and/or hardware removal.
9. The guidewires contain cobalt (CAS No. 7440-48-4; EC No. 231-158-0) defined as a CMR 1B in a concentration above 0.1% (w/w). Use of this product could lead to sensitization and/or allergic reaction. Current scientific evidence supports that medical devices manufactured from metal alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.
10. The drills and other cutting instruments are designed for single patient use only and should not be reprocessed or re-sterilized following use.
11. Guidewires, drills, and cutting instruments contain sharp features. Improper handling may result in injury.
12. To prevent damage or breakage of the drill, avoid contact of the drill tip or cutting flutes with other devices or striking, impacting, or bending the drill while in use.

POSSIBLE ADVERSE EFFECTS

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 or instrument 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, 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);
- 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

MRI Safety Information

A patient with any Tyber Medical standalone screw (i.e., screw on its own or with a washer, not with plates) may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Identification of device	Tyber Medical Standalone Screw Systems
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	20 T/m (2000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, no restriction on transmit-receive coils that the device is not within
Operating Mode	Normal Operating Mode
Maximum B_1^+RMS	See details below
Limits on B_1^+RMS and Scan Duration	**1.5 T MRI Systems** 2.80 µT for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
	3 T MRI Systems 0.8 µT for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of 20 mm.

If information about a specific parameter is not included, there are no conditions associated with that parameter.

DIRECTIONS FOR USE

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

The Tyber Medical Trauma Screw implants are provided in the option of either sterile or non-sterile. Non-sterile implants are supplied clean and must be sterilized prior to use but can be cleaned prior to sterilization if desired. The Tyber Medical Trauma Screw instruments are provided sterile or non-sterile. Non-sterile Instruments must be cleaned and sterilized prior to use. Perform all cleaning and sterilization according to the procedures outlined in this document. All Tyber Medical Trauma 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 Trauma Screw devices must not be used or processed and should be returned to Tyber Medical for evaluation.

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

CARE AND HANDLING

Certain Tyber Medical 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 sterilized according to the standard hospital procedure. Refer to the STERILIZATION section for recommended parameters.

LIMITATIONS ON REPROCESSING

All devices provided and labeled as sterile have undergone two reprocessing procedures: cleaning and gamma radiation sterilization. The sterile devices are not to be reprocessed under any circumstances. For non-sterile devices, repeated processing has minimal effect on these implants and instruments, as 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 not labeled as single use only 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 detergent[1], and neutral pH detergent[2].

- Preclean the instruments by placing them 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 instruments cycle with the following parameters (at a minimum):

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

- Determine if the instruments 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 by placing them 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. Visually inspect cleaned instruments to ensure cleaning was effective. Perform cleaning again on instruments that are not clean. Replace an instrument that cannot be cleaned Replace an

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

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

instrument that cannot be cleaned (see the Instrument Replacement section).

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.

Visually inspect all instruments under normal lighting to ensure cleaning was effective. Inspect instruments for surface damage such as:

- Nicks
- Scratches
- Cracks
- Burrs
- Staining/Discoloration

Replace any instrument affected.

Assess the instruments for proper use. Inspect instruments for:

- Wear
- Sharpness
- Straightness
- Corrosion
- Misalignment
- Proper interface with other devices (as applicable)

Inspect instruments with a cutting edge and/or tip cutting edge (i.e. drills) for a continuous cutting edge free from edge deformities such as:

- Dullness
- Chipping
- Cracking
- Rolling
- Other cutting edge deformities

Replace any instrument that does not perform as intended. If the resistance increases while using a cutting instrument, replace this instrument immediately.

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

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

INSTRUMENT 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 Tyber Medical instrument.

If your Tyber Medical instrument is defective or damaged, contact your local Tyber Medical Distributor. In your correspondence, please include, at minimum:

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

PACKAGING FOR STEAM STERILIZATION

For sterilizing **non-sterile** devices, the devices may be loaded into the specified Tyber Medical trays, or general-purpose caddies/trays. Wrap the trays using an appropriate method with no more than two layers of sterilization wrap that are intended for pre-vacuum steam sterilization.

STERILIZATION

For devices provided **sterile**, the sterilization method is noted on label. Sterile implant and instrument 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 the sterile barrier has been broken, return the component to Tyber Medical. Do not re-sterilize.

If not specifically labeled **STERILE**, or if labeled **NON-STERILE**, then the devices are non-sterile. Non-sterile devices are provided clean and must be sterilized prior to use but may be cleaned prior to sterilization if desired. Instruments 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.	132 °C (270 °F)	132 °C (270 °F)	135 °C (275 °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 17665-1. 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 Trauma Screw System or a copy of the Tyber Medical Trauma Screw System STG, please contact Tyber Medical, LLC or your local Tyber Medical Distributor.

DISPOSAL

Observe internal hospital/institution procedures, practice guidelines, and/or government regulations for proper handling and disposal of the Tyber Medical Trauma Screw System devices.

REPORTING OF SERIOUS ADVERSE EVENTS OR INCIDENTS:

Tyber Medical requests users and patients to report all Serious Events or Incidents to the manufacturer (see contact details before the symbol glossary) and to your local Competent Authority.

A copy of the current device Summary of Safety and Performance Characteristics (SSCP) can be accessed at the following link: (https://ec.europa.eu/tools/eudamed/#/screen/search-device).

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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
MATL	Material
	Country and Date of Manufacture
	Expiration Date
QTY	Quantity
STERILE R	Sterilized Using Irradiation
	Do Not Re-Use
	Do Not Use If Package Is Damaged
	Do Not Re-Sterilize
	Consult Instructions for Use
	Caution
NON STERILE	Non-Sterile
	Hazardous Substance
	Distributor
	Manufacturer
CE / 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
MD	Medical Device
	Double Sterile Barrier