Tyber Medical

Expand Your Brand

TYBER MEDICAL DISTAL RADIUS PLATING SYSTEM PACKAGE INSERT

DESCRIPTION OF THE MEDICAL DEVICE

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

- Various bone plates of different shapes and hole configurations.
- Variable angle locking and non-locking screws in various lengths and diameters.

The plate and screw implants are manufactured from Stainless Steel per ASTM F138, or from Titanium alloy per ASTM F136.

The instruments – delivered sterile and non-sterile – are intended to support the implantation of the Tyber Medical Distal Radius Plating System implants.

INTENDED USE

The Tyber Medical Distal Radius Plating System is intended to bridge or otherwise stabilize bone fragments to facilitate healing.

INDICATIONS FOR USE

The Tyber Medical Distal Radius Plating System is indicated for fixation of fractures, fusions, non-unions and malunions, or osteotomies of the radius, ulna, and hand. The Tyber Medical Plating System is not for spinal use.

LIMITATIONS

This device is not approved for plate and/or 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 Distal Radius Plating System is for skeletally mature patients undergoing fixation of bones appropriate for the size of the implants. The application of all implants is according to the judgment of the experienced trauma or orthopedic surgeon with utilization at the appropriate anatomical locations as defined in the indications.

INTENDED USER

The Tyber Medical Distal Radius Plating System is intended for use by experienced trauma and orthopaedic surgeons.

INTENDED USE ENVIRONMENT

The Tyber Medical Distal Radius Plating System is intended to be used in an operating room or surgical setting.

CLINICAL BENEFIT

The expected clinical benefit of the Tyber Medical Distal Radius Plating System when used as intended is to achieve bone union.

DEVICE LIFETIME

The Tyber Medical Distal Radius Plating 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 19 weeks depending on the bone(s) treated and the procedure(s) performed).

The expected treatment lifetime of the Tyber Medical Distal Radius Plating 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 Distal Radius Medical Plating 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.

MATERIALS

The Tyber Medical Distal Radius Plating System implants are manufactured from Titanium alloy (ASTM F136) or Stainless Steel (ASTM F138). The specialized instruments are made of surgical grade stainless steel (ASTM F899), radel (ASTM D6394) and PEEK (ASTM 2026). Refer to the following tables for the quantitative composition of elements by % for the Titanium alloy and Stainless Steel.

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.

Stainless Steel:

Element	Composition % (mass/mass)
Carbon, max	0.030
Manganese, max	2.00
Phosphorous, max	0.025
Sulfur, max	0.010
Silicon, max	0.75
Chromium	17.00 to 19.00
Nickel	13.00 to 15.00
Molybdenum	2.25 to 3.00
Nitrogen, max	0.10
Copper, max	0.50
Cobalt	<0.10
Iron^, max	balance

*The percentage of iron content by difference is not required to be determined or certified.

HOW SUPPLIED

Tyber Medical Plating System 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 Distal Radius Plating System should not be used in a patient who has current, or who has a history of:

- Active infection or inflammation.
- Patient conditions including blood supply limitations, obesity, and insufficient quality or quantity of bone.
- Patients with mental or neurological conditions who are unwilling or are incapable of following postoperative care instructions.
- Foreign body sensitivity. If material sensitivity is suspected, testing is required prior to implanting the device.

WARNINGS and POTENTIAL RISKS

The surgeon should be aware of the following:

1. Use of the Tyber Medical Distal Radius Plating System could lead to re-operation to remove or replace implants at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
2. The Tyber Medical Distal Radius Plating System is not approved for implant 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.
3. The Tyber Medical Distal Radius Plating System implants and sterile instruments are designed for **single patient use only and must never be reused** under any circumstances. Reuse may lead to adverse tissue reaction, tissue damage and/or minor surgical delay.
4. 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.
5. The Tyber Medical Distal Radius Plating System 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 device and/or fracture of the bone. Additional risks involved in overloading include tissue damage, malunion, hardware removal, and/or implant revision.
6. 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 condition, has severe osteoporosis, demonstrates physiological or anatomical anomalies; has immunological responses, sensitization or hypersensitivity to foreign materials; systemic or metabolic disorders.
7. These warnings do not include all possible 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 plates and screws should be performed only by experienced surgeons with specific training in the use of this plating 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 devices or surgically excised implants 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 Distal Radius Plating System should never be used with dissimilar materials, as this can cause electrolytic action, 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. The proper selection and placement 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. The decision to leave or remove implants postoperatively, rests with the surgeon and the surgeon must be aware of the content of this IFU and the STG prior to device use.
6. Improper insertion of the device during implantation may result in implant loosening or implant migration.
7. 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.
8. 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.
9. Loosening or migration and loss of fixation due to incorrect implantation, delayed union, non-union, and incomplete healing may occur.
10. Bending or fracturing of the implants due to applied excessive stress may occur.
11. **IMPORTANT:** The guidewires included in the Tyber Medical Plating System are not intended as implants. The guidewires are only intended for use as instruments to facilitate implant fixation. These misuses of the guidewires may result in adverse tissue reaction, infection and/or hardware removal.
12. The plate sizing templates and drills are designed for single patient use only and should not be reprocessed or re-sterilized.
13. Guidewires and drills, and cutting instruments contain sharp features. Improper handling may result in injury.
14. 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.
15. Failure to follow postoperative care instructions may result in procedure complications or failure.

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:

- Fracture of the implant due to excessive loading
- Incomplete or inadequate healing
- Implant migration and / or loosening
- Infection
- Pain, discomfort, wound healing complications, or abnormal sensations due to the presence of an implant
- Nerve or vascular damage resulting from surgical trauma
- Bone necrosis or bone resorption
- Delayed healing or nonunion of bone fragments
- Allergic reaction to the implant and / or instrument materials
- 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 Distal Radius Plating System is MR Conditional and may only be used in an MR environment under specific conditions.

The patient should consult with their healthcare providers prior to an MR exam and inform the MRI site personnel that they have an MR Conditional device prior to the MR exam.

The following tables provide the MR conditions for which the Tyber Medical Distal Radius Plating System may be safely scanned in the MR environment. Failure to adhere to these conditions may result in injury or device malfunction.

MRI Safety Information

MR

A patient with the Tyber Medical Plating System (plate/screw construct) 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 Plating System
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	**Body Coil:** See scan limitations below. **Local Coils**: No restrictions on local transmit-receive coils that the device is not within.
Operating Mode	Normal Operating Mode
Maximum Whole Body SAR	See details below
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
RF Conditions	**1.5 T MRI Systems** B_1 RMS ≤ 3.40 μT for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks) or Whole body average SAR ≤ 1.0 W/kg for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
	3 T MRI Systems B_1 RMS ≤ 1.45 μT for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks) or Whole body average SAR ≤ 0.8 W/kg 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 68 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 Plating System implants, use only the specialized Tyber Medical Plating System instrumentation. Do not use implants or instruments from any other system or manufacturer.
The Tyber Medical Distal Radius Plating System 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 Distal Radius Plating System 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 Distal Radius Plating System device system should be carefully inspected to ensure proper working conditions. Critical areas, including joint surfaces, should be checked for wear, damage, or irregularities. Damaged or broken Tyber Medical Distal Radius Plating System devices must not be used or processed and should be returned to Tyber Medical customer service for evaluation.

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

POSTOPERATIVE MANAGEMENT

The patient is allowed to ambulate with weightbearing to tolerance on the operated fracture site within limits imposed by postoperative discomfort. The progression to normal use of the digit or limb is limited only by the persistence of postoperative swelling and discomfort.

CARE AND HANDLING

Certain Tyber Medical Distal Radius Plating System devices 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 and device 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 used thereafter, if reusable, the instructions outlined below should be followed to ensure safe handling of biologically contaminated devices.

CONTAINMENT AND TRANSPORTATION

It is recommended that Tyber Medical Distal Radius Plating System devices not labeled as single use only, are cleaned as soon as reasonably practical following use.

PREPARATION FOR CLEANING

Note: Non-sterile implants are supplied cleaned from the manufacturer and do not require cleaning prior to initial use.
Where instruments interface with other devices, disassemble prior to cleaning. Remove excess soil with a clean, disposable, absorbent Kimwipe or equivalent.

Disassembling of Depth Indicator
1. Unthread proximal cap counterclockwise until cap disengages from outer cannula of instrument.
2. Remove cap and inner cannulas from outer cannula.
3. Proceed to cleaning steps below.

Automated CLEANING

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

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

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 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

[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..

debris. If necessary, repeat cycle or use manual cleaning. Replace devices that cannot be cleaned.

MANUAL CLEANING

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 them 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 device 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 soft, clean, lint free cloth.

AFTER CLEANING

Where instruments have been disassembled prior to cleaning, reassemble prior to use. Visually inspect cleaned devices to ensure cleaning was effective. Perform cleaning again on any devices that are not clean. Replace a device that cannot be cleaned (see the Device Replacement section).

INSPECTION AND FUNCTION TESTING

Visually inspect all devices under normal lighting prior to use for damage and/or wear and to ensure cleaning was effective. For instruments that interface with other devices, inspect to ensure there is no visible interface damage prior to use.

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

Prior to use, inspect devices for surface damage such as:
• Nicks
• Scratches
• Cracks
• Burrs
• Staining/Discoloration

Replace any device affected.
Assess the instruments for prior 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 (i.e. drills) for 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 resistance increases while using a cutting instrument, replace this instrument immediately.
Prior to use, verify the legibility of all markings. Replace any device that is unreadable.
Repeat cleaning and/or replace affected instruments as needed to ensure proper operation before proceeding with sterilization.

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 Tyber Medical Distal Radius Plating System instrument.

If your Tyber Medical Distal Radius Plating System device is defective or damaged, contact Tyber Medical customer service. 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 Plating System trays, or general- purpose caddies/trays. Visually inspect the tray before loading the implants and/or instruments. Wrap the trays using an appropriate method with no more than two layers of sterilization wrap that are FDA cleared 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 devices are supplied in protective sterile barrier packaging. Inspect device package for punctures or other damage prior to surgery. If the sterile barrier has been broken, return the component to Tyber Medical customer service. 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)	134˚C (273.2˚F)	135˚C (275˚F)
Exposure*	15 min.	4 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 Integrated Indicator.

STORAGE

The Tyber Medical Distal Radius System devices 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 changed 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 Distal Radius Plating System or a copy of the Tyber Medical Distal Radius Plating System STG, please contact Tyber Medical customer service.

DISPOSAL

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

REPORTING OF SERIOUS ADVERSE EVENTS OR INCIDENTS:

Tyber Medical requests users and patients to report all Serious Events or Incidents to the distributor (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 GLOSSARY

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
	Distributor
	Manufacturer
EC REP 2797	CE Mark / CE Mark with Notified Body
XX REP	Authorized Representative in the identified country or jurisdiction
UDI	Unique Device Identifier
	MR Conditional
MD	Medical Device
	Double Sterile Barrier