stryker

T2 Alpha™ Humerus Nailing System

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INSTRUCTIONS FOR USE

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THIS DOCUMENT IS APPLICABLE TO USA AND CANADA

CONTENTS

T2 Alpha™ Humerus Nailing System

ALL OF THESE INSTRUCTIONS FOR USE MUST BE READ CAREFULLY PRIOR TO CLINICAL USE

⚠ CAUTION

Federal law in the USA restricts this device to sale by or on the order of a physician. See product label for information regarding the specific product referenced in this package insert.

Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets.

1 Description

The T2 Alpha Humerus Nailing System is an IM humerus fracture nailing system consisting of implants (Humeral Nails, End Caps, Compression Screw and Washer) as well as instrumentation to allow the use and application of the T2 Alpha Humerus implants.

The T2 Alpha Humerus Nailing System is intended to be used in surgical procedures involving the associated screws of the IMN Screws System and the associated instruments. The T2 Alpha Humerus Nailing System does not alter the intended use and indications for use of compatible systems; for specific information, refer to the intended use and indications for these.

This instruction for use applies to the implants and instruments of the T2 Alpha Humerus Nailing System.

For detailed information concerning the identification of the product (such as system association, catalog number (REF), material, shelf life) please refer to the marking on the product and/or the labeling of the package. For specific intended use and indications for use please refer to the corresponding sections below or the specific operative technique.

2 Intended Use and Indications

The T2 Alpha Humerus Nailing System is indicated for the treatment of humerus fractures. Fractures can include, but are not limited to, non-unions, malunions, malalignments, pathological fractures, and impending pathological fractures.

3 Contraindications

The physician's education, training and professional judgement must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

- Any active or suspected latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.

- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation of the devices.
- Material sensitivity, documented or suspected.
- Patients having inadequate tissue coverage over the operative site.
- Implant utilization that would interfere with anatomical structures or physiological performance.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

4 Warnings and Precautions

Always consult the relevant operative techniques for additional information regarding each operative step.

⚠WARNING

- The licensed healthcare professional and operating room team must be thoroughly familiar with the operating technique, the instruments, as well as the range of implants to be applied. Complete information and labeling on these subjects must be readily available at the workplace.
- Only use a device for its intended purpose. Improper use of devices may lead to loss in function or usage.

⚠CAUTION

- Before and during the surgical procedure, ensure that all components, including implant to instrument and/or instrument to instrument connections, prepared for the procedure function correctly with each other.
- Avoid surface damage of implants
- The implants should be clean and dry for assembly.
- Under no circumstances should an instrument be implanted.
- The design of the devices must not be modified in any way.

4.1 Pre-Operative

⚠WARNING

Surgical devices should be handled with care and stored in an appropriate location, away from heat and moisture, in order to avoid damage, minimize time before cleaning and avoid drying of soil prior to cleaning. Devices should not be exposed to direct sunlight, ionizing radiation or particulate contamination. It is recommended to remove devices from plastic bags before storing them to avoid condensation. Devices must not be stored in contact with or near products that may have a corrosive effect.

⚠ CAUTION

Always exercise care in selecting the proper type and size of implant. Implants can be available in different versions, varying for example in length, diameter, angle. Failure to use the appropriate appliance for the fracture condition may result in early implant failure. Failure to use the proper component to maintain adequate blood supply and provide rigid fixation may result in loosening, bending, cracking or fracture of the device and/or bone. The correct implant size for a given patient can be determined by evaluating the patient's height, weight, functional demands and anatomy. Every implant must be used in the correct anatomic location, consistent with accepted standards of internal fixation.

4.2 Intra-Operative

⚠ WARNING

- Discard all damaged or mishandled implants.
- During the course of the operation, repeatedly check to ensure that the connection between the implant and the instrument, or between the instruments, required for precise positioning and fixing is secure.
- After the procedure, check that all implants are positioned correctly using an image intensifier.
- After implantation, the secure anchoring and correct positioning must be verified.
- When using drilling instrumentation or during the placement of implants, it is important to regularly screan with an image intensifier. In all cases, the benefit of fluoroscopy should be weighed against the risk from radiation exposure on an individual patient basis, in line with the requirements of SI2000 N°1059 (The ionising Radiation Regulations – Medical Exposure).

⚠ CAUTION

- Ensure that all components needed for the operation are available in the operation theatre.
- Visually inspect devices prior to use for damage, debris, dirt, flaws, or if the device was stored past the shelf life expiration date. Do not use them.
- Careful handling and storage of the product is required. Scratching or damage to the implants can significantly reduce the strength and fatigue resistance of the product.
- The implant must not be modified in any way.
- While rare, intra-operative breakage of instruments may occur. Instruments which have experienced excessive use or excessive force are susceptible to breakage. Instruments should be examined for wear or damage prior to surgery.
- Discard all damaged or mishandled instruments
- Do not use components of Stryker product systems in conjunction with components from any other manufacturer's system unless otherwise specified (see operative technique).

4.3 Post-Operative

⚠WARNING

- The implant is for single use only.
- Products which have already been used in a surgically invasive manner, even if implanted only partly or temporarily during the surgical procedure, must not be reprocessed for reuse.
- Single use devices shall not be reused, as they are not designed to perform as intended after the first use. Changes in mechanical, physical or chemical characteristics introduced under conditions of repeated use, cleaning and re-sterilization may compromise the integrity of the design and/or materials leading to diminished safety, performance and/or compliance with relevant specifications. Please refer to the device label and/or cleaning and re-seterilzation release to identify single or multiple use.
- After the procedure, check that all implants are positioned correctly using an image intensifier.
- The implant is intended for temporary bone fixation. In the event of a delay in bone consolidation, or if such consolidation does not take place, or if explantation is not carried out, complications may occur, for example, breakage or loosening of the implant or instability of the implant system. The surgeon must advise the patient to attend all follow-up examinations as directed.
- The risk of post-operative complications (e.g. failure of an implant) is higher if patients are obese, have a mental or neuromuscular disorder and are unable to follow the post-operative care plan. For this reason, for these patients the HCP may consider additional post operative follow up.

⚠CAUTION

Implant removal should be followed by adequate postoperative management to avoid fracture or refracture of the bone.

5 MRI Safety Information

The T2 Alpha Humerus Nailing System and compatible IMN Screws System is MR conditional. A patient implanted with the T2 Alpha Humerus Nailing System and compatible IMN Screws System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Device name	T2 Alpha Humerus Nailing System and compatible IMN Screws System
Static magnetic field strength (T)	1.5 T and 3.0 T
Maximum spatial field gradient	30 T/m (3000 Gauss/cm)
RF excitation	Circularly Polarized (CP)
RF transmit Coil Type	Integrated Whole Body Transmit Coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR (W/kg)	1 W/kg
Scan Duration	For imaging landmarks when the edge of the implant is < 35 cm from the isocenter, a scan time of 5 minutes of continuous RF (a sequence or back to back series/scan without breaks) followed by a wait time of 15 minutes if this limit is reached, for the total scanning session duration of up to 1 hour (or 60 minutes). For imaging landmarks when the edge of the implant is > 35 cm from the isocenter, 60 minutes of scan time without the need for a cooling pause.
MR Image Artifact	The presence of this implant produced an image artifact of approximately 27 mm from the T2 Alpha Humerus Nailing System and compatible IMN Screws System when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

⚠ CAUTION

The MRI safety information provided is based on testing which did not include supplementary devices. If there are supplementary devices (i.e. plates, screws, wires, etc.) present in proximity to the system, this could result in additional MRI effects and the information provided above may not apply.

6 Informing the Patient

⚠WARNING

- Post-operative patient activity: These implants are neither intended to carry the full load of the patient acutely, nor intended to carry a significant portion of the load for extended periods of time. For this reason, post-operative instructions and warnings to patients are extremely important. External immobilization (e.g., bracing or casting) may be employed until X-rays or other procedures confirm adequate bone consolidation.
- During the postoperative phase, in addition to mobility and muscle training, it is of particular importance that the physician keeps the patient well informed about postsurgical behavioral requirements.
- Explain the need to report unusual changes in the surgical site as well as falls or accidents, even if the device or the site of operation did not appear to be harmed.

⚠CAUTION

The patient should be advised that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity or trauma and that the device has a finite expected service life. Removal or revision of the device may be required sometime in the future due to medical reasons.

The surgeon must advise patient of surgical risks, and make them aware of of adverse effects and/or alternative treaments.
Explain the need to appear for the postoperative examinations (e.g. X-ray checks) and for the possible explantation of the implant.

The healthcare professional is responsible for filling out the Medical Device Card, providing the Medical Device Card to the patient, as well as informing the patient about the availability of the Medical Device Card on the website www.patientinfo.stryker.com.

- Print a copy Medical Device Card which is available on www.patientinfo.stryker.com.
- To retrieve the Medical Device Card, follow the instructions on the website.
- Copy the catalogue number(s) (REF) of the implanted device(s) on the dedicated empty lines of the Medical Device Card.
- You can find the catalogue number(s) (REF) on the package label(s) of the implanted device(s).
- Inform the patient to store the Medical Device Card in a safe place.
- Instruct the patient to consult the healthcare professional prior to an MR exam and to provide a copy of the Medical Device Card to the MRI site personnel before an MR exam.

7 Adverse Events and Adverse Effects

Complications that can occur as a consequence of osteosynthesis of bones and bone fragments using humeral nailing implants may include the following clinical signs and symptoms:

Arthritis, Abdominal complications, Bone Fracture(s), Cardiovascular Complications, Central Nervous system complications, Delayed Union, Embolism/Embolus, Hemorrhage/Bleeding, Hypersensitivity/Allergic Reaction, Implant Pain/Pain, Infection, Inflammation, Loss of Range of Motion, Malunion of Bone, Muscle/Tendon Damage, Nerve Damage, Non-union Bone Fracture, Other Bone/Joint Damage, Other Soft Tissue Damage, Respiratory complications, Thrombosis/Thrombus, Urinary tract complications and Wound Complication/Wound Dehiscence.

Device failure modes for humeral nailing implants may include implant breakage, loosening, migration, malpositioning, and material deformation/bending. Failure modes could be related to improper procedures or methods.

Adverse effects associated with the use of humeral nailing implants may result in the need to change the surgical method, or additional or revision surgery.

8 Sterility, Cleaning and Sterilization

Products delivered sterile have either been exposed to a minimum of 25 kGy of gamma radiation from a cobalt 60 source or have been sterilized by vacuum steam sterilization (please see product label for sterilization method applied).

⚠WARNING

- Products not labelled as sterile are non-sterile.
- In the event of contamination, expiration of shelf life, or in the case of products supplied non-sterile, the product must be subjected to an appropriate cleaning process and sterilized by means of a validated sterilization procedure before use, unless specified otherwise in the product labeling or respective product technical guides.
- All packaging layers of the sterile barrier system should be visually inspected before opening.
- In the presence of flaws, if the packaging was unintentionally opened before use, or expired of shelf life, the product must be assumed non-sterile. Do not use them.
- Do not re-sterilize single use devices.
- Reusable Instruments must be cleaned directly after use.
- If any of these conditions occur, contact the manufacturer.
- Follow the instructions provided in our cleaning and sterilization guide (OT-RG-1).
- All non-sterile devices must be cleaned and sterilized before use.
- Multicomponent instruments must be disassembled for cleaning. Please refer to the corresponding assembly/ disassembly instructions.

The following process parameters are validated by Stryker and recommended for sterilization and/or resterilization, but not suitable for prion inactivation though:

Method:	Moist heat sterilization according to EN ISO 17665 and ANSI/AAMI ST79
Cycle:	Pre-Vacuum (Pre-Vac)
Temperature:	270°F (132 °C)
Exposure Time:	4 minutes
Drying Time:	30 minutes (minimum, in chamber)
Cool Time:	60 minutes (minimum, at room temperature)

NOTICE

Not for prion inactivation. Proceed according to local or national guidelines.

For more information regarding the cleaning and sterilization of these instruments please refer to the Stryker “Instructions for Cleaning, Sterilization, Inspection and Maintenance” (OT-RG-1) which may be requested online at www.ifu.stryker.com.

Where appropriate, reusable devices shall be placed in the compatible tray for sterilization according the process parameters provided below.

Where appropriate the cleaned, disinfected, and checked medical devices should be assembled into the dedicated trays provided. Stryker Trauma & Extremities cases/trays should be double wrapped. In the USA, Stryker Trauma & Extremities recommends compliance with ANSI/AAMI ST79 and the use of FDA cleared sterilization wrap. Please use a suitable instrument spray on articulating surfaces and moving parts.

Any cycle should be validated for different sterilization chambers, wrapping methods and/or various load configurations. The Instructions for Cleaning, Sterilization, Inspection and Maintenance (OT-RG-1) may be requested online at www.stryker.com or www.ifu.stryker.com.

9 Notification

Please inform the manufacturer, if a product related incident has occurred while using this device.

10 Transport and Storage Information

The device is individually packed in protective packaging that is labelled according to its contents. Store and transport the device in the original protective packaging or the appropriately marked storage module/tray. Do not remove the device from the packaging until it is planned to be used or it is ready to be placed in the storage module/tray. Store the devices in standard hospital environmental conditions (cool and dry) unless specific requirements are defined and described on the product label.

11 Special Training

The healthcare professional must be licensed to perform surgery in the respective field of medicine and must be familiar with the principles of the surgical procedure. No mandatory training is required for the intended user group before using the devices of the T2 Alpha Humerus Nailing System.

12 For Further Information

Ensure that you are familiar with the intended purposes, indications/contraindications, compatibility and correct handling of the implants which are described in the operative technique manual for the product system. Please remember that product systems may be subject to alterations that affect the compatibility of the implant with other implants or with instruments. For your information, avail yourself of the publications offered (e.g. operative techniques).

Important information for doctors and operating room (OR) staff: This package insert does not include all of the information necessary for selection and use of a device. Please see full labeling for complete information!

- Instructions for Use, Operative Techniques, “Instructions for Cleaning, Sterilization, Inspection and Maintenance” (OT-RG-1) and other associated labeling may be requested online at www.ifu.stryker.com.
- The use of the system is described and/or illustrated in the operative technique of the product system. The applicable Operative Techniques for the T2 Humerus Nailing System can be found on www.ifu.stryker.com.
- For a symbol explanation please refer to the glossary OT-IFU-210 on www.ifu.stryker.com.
- Please contact Stryker or your authorized representative if further information on this product is needed.
- If the product does not function satisfactorily, please contact your local Stryker representative or call Stryker Customer Service.

13 Disposal

The hospitals should follow the national regulations in force for medical waste disposal.

Contaminated units should be decontaminated before they are discarded.

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