

STAR™ Ankle Instruments, Accessories, and Instrument Set

EN

INSTRUCTIONS FOR USE

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STAR™ Ankle Instruments, Accessories, and Instrument Set

INSTRUCTIONS FOR USE



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

CAUTION

This IFU is to be used only in the United States. The corresponding OUS version is V15159.

1 Contents

The package contains one or more STAR Ankle Instrument, Accessory, or Instrument Set. The instruments are provided non-sterile and should be cleaned and sterilized prior to use. Disposable saw blades packaged sterile are available to supplement the instrument set. Stryker may specify certain saw blades. **Saw blades and pins are single use items**

2 Overview

The STAR Ankle is intended for use as a non-cemented implant to replace a painful arthritic ankle joint due to osteoarthritis, post-traumatic arthritis or rheumatoid arthritis. For detailed information concerning the product(s), please refer to the dedicated operative technique.

3 Contraindications, warnings and precautions

3.1 Contraindications

- Active or prior deep infection in the ankle joint or adjacent bones.
- Skeletal immaturity.
- Bone stock inadequate to support the device including:
 - Severe osteoporotic or osteopenic condition or other conditions resulting in poor bone quality
 - Avascular necrosis of the talus
 - Prior surgery and/or injury that has adversely affected ankle bone quality.
- Malalignment or severe deformity of involved or adjacent anatomic structures including:
 - Hindfoot or forefoot malalignment precluding plantigrade foot
 - Significant malalignment of the knee joint
- Insufficient ligament support that cannot be repaired with soft tissue stabilization.
- Neuromuscular disease resulting in lack of normal muscle function in the affected ankle.

- Lower extremity vascular insufficiency demonstrated by Doppler arterial pressure.
- Charcot joint or peripheral neuropathy that may lead to Charcot joint of the affected ankle.
- Prior arthrodesis at the ankle joint.
- Poor skin and soft tissue quality at the surgical site.

3.2 Warnings and precautions

WARNING

- Only implant the STAR Ankle after adequate training and familiarity with the surgical technique manual, to avoid increased risk of device failure due to improper surgical technique.
- Do not use STAR Ankle components in combination with prosthesis components made by other manufacturers, because design, material, or tolerance differences may lead to premature device and/or functional failure. Components of the system have been specifically designed to work together.
- To ensure proper implantation of the STAR Ankle, use the instrumentation that is supplied with the system in accordance with the surgical technique manual.
- The trial prostheses shall not be implanted.
- Examine instruments for wear or damage before use. While rare, intra-operative instrument breakage may occur. Instruments that have experienced excessive use or force may be susceptible to breakage.
- The safety and efficacy of the STAR Ankle have not been studied in patients weighing > 250 lbs.
- Always confirm that the patient does not have a possible allergy to the implant/prosthesis material before selecting the STAR implant to minimize the risk of an allergic response.
- Discard all damaged or mishandled implants. Do not reuse implants and components. Although the implant may appear undamaged, it may have small defects and internal stress patterns which may lead to early failure of the device.
- Do not resterilize sterile packaged product. Do not use implants, components, or sterile packaged instruments if the package is damaged or has been opened prior to planned use.
- Always exercise care in selecting the proper type and size of implant. Size and shape of the human bone place restrictions on the size and shape of the implant, potentially limiting device function.
- Do not contour or bend an implant because it may reduce its fatigue strength and cause failure under load. Correct handling of the implant is extremely important.
- For a minimum of two weeks, a patient should not bear any weight on the implanted STAR Ankle. Certain vigorous physical activities (e.g., basketball, football) and trauma to the joint replacement may cause early failure of the STAR Ankle. Please refer to the section titled "Post-operative Management" for additional restrictions.
- Appropriate selection, placement and fixation of the STAR Ankle components are critical factors which affect implant service life.

- Improper selection, placement and fixation of the implant components may result in early implant failure. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanic and other extrinsic factors which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize service life.
- Single use is defined as use of one implant or instrument on a single patient in a single surgical procedure.
- Reuse of instruments designated as single use has been associated with necrosis of bone leading to implant failure. It may also lead to sepsis and/or communication of potentially lethal viruses.
- Reuse of implants designated as single use has been associated with sepsis and/or communication of potentially lethal viruses.

4 Post-operative management

For a minimum of two weeks after surgery, the patient should not bear weight on the operated ankle. The patient should keep the ankle elevated as much as possible while limiting all physical activities. Partial weight-bearing may begin at 2 to 3 weeks post-operation and gradually increase until the patient is fully weight bearing at 4 to 6 weeks postoperation. The ankle cast should typically be removed six weeks post-operation.

5 Precautions for products provided non-sterile

Instruments which are supplied in a non-sterile condition must be subjected to an appropriate cleaning and sterilization process before use. For adequate cleaning of multi-component instruments, these must be dismantled according to the assembly/disassembly instructions provided by Stryker. Please note that Stryker trays are intended for sterilization, transport and storage of medical devices. They are not designed for cleaning and disinfection in the fully equipped state. The devices must be removed from the tray for adequate cleaning results.

Effective sterilization requires surgical instruments to first be cleaned, disinfected, and inspected using a validated procedure after every use.

The following validated cleaning/disinfecting procedure is recommended:

- Prevent drying after use
- Manual pre-cleaning (brushing or ultrasonic) with cold water without any chemical additives.
- Disassemble whenever possible:
 - Remove the plastic connector from the alignment guide
 - Separate the rod from the remainder of the alignment guide
 - Remove the two set screws and disassemble the three remaining components of the guide block
 - Separate the adjustable twist drill from the stop
 - Separate the barrel from the remainder of the depth gauge.

- Machine cleaning, consisting of:
 - Cleaning at 50° C to 60° C, using demineralized water and a highly alkaline cleaning agent
 - Rinse with water without chemical additives
 - Acidic neutralization
 - Rinse with demineralized water without chemical additives
 - Approved thermal disinfection program at 90° C for at least 5 minutes with sufficient rinsing steps and filtered air for an active drying program
 - Final rinsing/ disinfection only with freshly prepared purified water/ highly purified water
 - Drying
 - Assembly and inspection/performance test of the instruments.
- Visually inspect each device for remaining soil and dryness. If soil remains repeat the cleaning process including the pre-cleaning stage. Remaining wetness may be removed with medical grade compressed air, clean and lint-free single use wipes or by heating in an oven below 110°C.
- Assure that all instruments necessary for the implantation procedure are available intact.

6 Sterilization/resterilization

Products not labelled as sterile are non-sterile.

In the event of contamination or 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.

The following process parameters are validated by Stryker and recommended for sterilization and/or resterilization: Moist-Heat Sterilization according to EN ISO 17665-1

Method (US):	Moist-Heat Sterilization
Cycle:	Pre-Vacuum (Pre-Vac)
Temperature:	270 °F (132 °C)
Exposure Time:	4 minutes
Dry-Time:	30 minutes (minimum, in chamber)
Cool-Time:	60 minutes (minimum, at room temperature)

NOTICE














Not for prion inactivation. It is the responsibility of the healthcare establishment to refer to the sterilizer manufacturer's instructions for use for load configurations and sterilization accessories.





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.

7 Additional precautions

- Assure that all instruments necessary for the implantation procedure are available intact.
- Do not implant the STAR implants with instruments other than those designed expressly for that purpose unless specified by Stryker.

8 Explanation of symbols and abbreviations used on product labels

	Catalogue Number
	Batch code
	Date of manufacture
	Manufacturer
	Use by date
	Sterilized using irradiation
	Do not re-use
	Do not re-sterilize
	Do not use if package is damaged
QTY	Quantity
	Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed physician
	Non-sterile
	Sterilized using ethylene oxide
	Keep dry

 or 	Consult instructions for use
	Fragile, handle with care
	Keep away from sunlight