ATTENTION: OPERATING SURGEON PLEASE READ THE FOLLOWING INFORMATION PRIOR TO USE OF STAR PSI SYSTEM PLAN, GUIDES, AND MODELS.

STAR PSI SYSTEM GUIDES AND MODELS

℞ Only Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician

DESCRIPTION:
DJO Global's STAR PSI System is patient-specific guides created to fit the contours of the patient's distal tibial and proximal talar anatomy. The guides and models are designed and manufactured from patient computed tomography (CT) imaging data and are made from biocompatible nylon. The surgical guides in combination with STAR reusable instruments, facilitate the positioning of STAR Implants. DJO Global's STAR PSI System produces a variety of patient specific outputs including surgical guides, anatomic models, and case reports.

INDICATIONS FOR USE:
The STAR PSI System is intended to be used as patient specific surgical planning and instrumentation to assist in the positioning of total ankle replacement components intraoperatively, and in guiding bone cutting. The STAR PSI System is intended for use with DJO Global's STAR System and its approved indications for use as approved in P050050. The anatomical landmarks necessary for the design and creation of the STAR PSI System must be present and identifiable on computed tomography (CT) scan. The STAR PSI System is indicated for single use only and is generated from CT imaging data.

CONTRAINDICATIONS:
The guides and models from the STAR PSI System and the associated case report should not be used if any of the following occur:
1. Patient has an active infection.
2. Significant changes to patient's anatomy have occurred since the medical scan used for product definition was obtained.
3. The patient presents one of the contraindications for DJO Global's STAR System (refer to DJO Global's STAR System sterile implant instructions for use).

ADVERSE EFFECTS:
Potential device related adverse effects include:
1. Bone fracture
2. Allergic Reaction
3. Loss of anatomic positioning with rotation or angulation.
4. Damage to ligamentous, tendinous, and surrounding soft tissues
5. Pain and Nerve Injury
6. Surgical complications including, but not limited to: vascular disorders, thrombophlebitis, hematoma or damage to blood vessels resulting in blood loss, or death
7. Superficial or deep infection at any point in time post-operatively

MATERIALS:
Patient contact materials used in the guides and models have been tested and shown to be biocompatible in accordance with ISO 10993-1. The materials used to manufacture guides and models are nylon blends.

SHELF LIFE:
Refer to the expiration date listed on the part package label for product shelf life. Note that it is required to perform the surgery within 6 months of the CT scan date to ensure anatomic changes are minimized. If the patient's anatomy has changed significantly since the time of the CT scan, the patient specific guides and models should not be used, even if the time period of 6 months has not expired.

⚠ WARNINGS:
1. To avoid serious injury, patient identification on guides and models must be verified and confirmed against patient identification prior to use.
2. Guides and models are designed for a specific patient. To avoid the potential for serious injury, guides and models should not be modified in any way.
3. To avoid potentially serious allergic reactions, ensure that the patient is not allergic to the materials used in the guides and models prior to use.
4. Device(s) are single use only and designed for use with a specific patient only.
5. Prior to use of any STAR PSI guides and models, the user must thoroughly review this instruction for use and all other labeling provided with the devices.
6. The presence of any moisture on the wrap should be visually monitored. If any moisture is observed after 60 minutes, then the cycle is not considered sterile.
7. Adequate training and familiarity with the STAR implant system surgical technique is required, to avoid increased risk of device failure due to improper surgical technique.
8. Switch to standard STAR instrumentation if the device is dropped in the surgical suite.
9. Switch to standard STAR instrumentation if the device does not fit patient anatomy or pre-existing metal interferes with device use.

⚠ PRECAUTIONS:
1. STAR PSI guides and models are shipped in a non-sterilized state. To avoid possibility of infection, open, clean and sterilize per provided instructions before use.
2. To ensure that damage has not occurred during shipping and handling, inspect all guides and models for damage prior to use. Do not use if the guides or models are broken, cracked or otherwise damaged.
3. To ensure successful surgery in the event of device malfunction, have a tray of standard STAR instrumentation available at the time of surgery.

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4. Guides and models may be sterilized up to two times for the prescribed patient but may not be re-used for additional surgical procedures.
5. To avoid material toxicity reactions, contact time for each material should be limited to the time shown below:

MATERIAL APPLICABILITY TABLE:
The following table includes material information:

Material	Device	Contact Duration	Body Contact
DuraForm ProX PA®	Guides & Models	Limited (≤ 24 hours)	Tissue/Bone/ Mucosal Membrane

CLEANING & STERILIZATION:
Guides and models are provided in Non-Sterile condition. Cleaning and sterilization are required prior to use. The following table defines the basic methods that must be used for cleaning and sterilization of the STAR PSI guides and models:

Material	Cleaning	Sterilization
Duraform ProX PA®	Automatic or Manual	Steam

Manual Cleaning Method:
1. Prepare neutral pH enzymatic detergent solution following the manufacturer's recommendation.
2. Fully immerse the device into the prepared detergent and allow the device to soak for 5 minutes.
3. While immersed, use a soft bristle brush to brush this device, paying particular attention to crevices and other hard to reach areas.
4. Use a syringe to flush the holes or lumens and any difficult to reach areas.
5. Rinse the device under running reverse osmosis – deionized water (RO/DI) at ambient temperature.
6. While rinsing, use a syringe to flush the holes and difficult to reach areas.
7. Wipe dry with sterilized lint free cloths or wipes.

Automated Cleaning Method:
Manual Pre-Cleaning:
1. Prepare a neutral pH enzymatic detergent solution following the manufacturer's recommendation.
2. Fully immerse the device into the prepared detergent and allow the device to soak for 5 minutes.
3. While immersed, use a soft bristle brush to brush the device, paying particular attention to crevices and other hard to reach areas.
4. Use a syringe to flush the holes or lumens and any difficult to reach areas.
5. Rinse the device under running reverse osmosis – deionized water (RO/DI) at ambient temperature.
6. While rinsing, use a syringe to flush the holes and difficult to reach areas.
7. Transfer the test articles onto rack system contained inside the washer for processing.
8. Automatic Cleaning Parameters:

Phase	Recirculation Time (Min)	Temperature	Detergent Type and Concentration (If applicable)
Pre-wash 1	02:00	Cold tap water	N/A
Enzyme Wash	02:00	Hot tap water	Enzymatic cleaner 1 oz / gallon
Wash 1	02:00	65.0°C Set Point	Enzymatic cleaner 1 oz / gallon
Rinse 1	02:00	Hot tap water	N/A
Pure Water Rinse	00:10	43°C	N/A
Dry Time	07:00	115°C	N/A

Sterilization Method / Instructions:
1. **Packaging:** Double wrap parts using an FDA cleared sterilization wrap (e.g. Kimguard® Sterilization Wrap, P/N KC600)
2. **Cycle Type:** Dynamic-Air-Removal Sterilization (Pre-Vacuum / Steam)
3. **Cycle Temperature:** 132°C.
4. **Cycle Time:** 4 minutes
5. **Dry Time/Cool Time:** DuraForm ProX PA guides: 30 minute dry time, 30 minute cool down.
6. **Storage in Sterile State:** Product is intended for use immediately after sterilization only. Do Not Unwrap until ready for use.

Encore Medical L.P. d/b/a DJO Surgical
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Austin, Texas 78758

Comments or questions regarding the use of this device can be directed to Attn:

Customer Service
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Symbol Legend:

Warning
Symbol indicates a potentially hazardous situation, which if not avoided could result in death of serious injury to the user.

Precaution
Symbol indicates a situation that the user must take into consideration to ensure the safe and effective operation of equipment and associated accessories.

Manufacturer

Date of Manufacture

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Non-Sterile

Catalog Number

Prescription Only

Batch Code


Consult Instructions for Use


Do Not Use if Package is Damaged