**CAUTION (if applicable): Federal law (USA) restricts this device to sale by or on the order of a physician.**

## DESCRIPTION OF THE DEVICE

*Archer$^{R}$ PSI System* is an instrument set containing a glenoid guide and its bone model and/or an humeral guide and its bone model. This patient-specific medical device is designed to fit the patient's anatomy to transfer a patient-specific pre-operative plan to the operating room. It is intended for surgical interventions in orthopaedic procedures for total shoulder arthroplasty.

## INDICATION FOR USE

*Archer$^{R}$ PSI System* is indicated as an orthopedic instrument to assist the physician in the intra-operative positioning of total shoulder replacement components and in guiding the drill and the cut of the bone.

*Archer$^{R}$ PSI System* must only be used conjointly with Archer™ CSR Total Shoulder (K152825, K173812, K181287, K182500, K191811), Catalyst EA Convertible Stemmed Shoulder (K222317) and Archer™ R1 Reverse (K202611, K211991, K213349, K223655, K232583) components in the context of primary total shoulder replacement and following a delto-pectoral approach only.

*Archer$^{R}$ PSI System* is manufactured from a pre-operative planning validated by the surgeon in the 'Archer™ 3D Targeting' platform (K213779). *Archer$^{R}$ PSI System* is indicated for patient population fulfilling the Archer™ CSR Total Shoulder, Catalyst EA Convertible Stemmed Shoulder and Archer™ R1 Reverse indications and for which CT images are available with identifiable placement anatomical landmarks and compliant with imaging protocol provided by Archer 3D Targeting.

The device is intended for single use only.

The device is intended for adult patients.

The device has to be used by a physician trained in the performance of surgery.

## PACKAGE COMPOSITION

The surgeon can request to order the glenoid and bone model, the humeral guide and bone model or both glenoid and humeral guides and bone models together. Please check the package label, the surgical reports and the parts available in the package to ensure the package is complete. Contact the legal manufacturer if the references do not correspond to the ones mentioned in the surgical report.

## RAW MATERIALS AND COMPONENTS

The device is made by additive manufacturing with a laser sintering method – Polyamide/Nylon. The device contains stainless-steel cylinder(s) inside inside the device pin cylinders.

## EXPIRATION OF THE DEVICE

There is no expiration date of the raw materials of the device. However, it is advised to use the device within 6 months from the scan acquisition date available on the package label. If the patient's anatomy has changed significantly since the time of the CT-scan, the device should not be used, even if the time period of 6 months has not expired. *It is the responsibility of the final user to determine if the patient's condition or anatomy is sufficiently similar to use the device with required performances.*

## CONTRAINDICATIONS

*Archer$^{R}$ PSI System* should not be used if any of the following occur.

- Ensure the accurate positioning of the device using its shape AND in comparison to the pictures available in the surgical report. Do not use in case of bad fit of the guides or if this positioning is not similar or seems not relevant for the medical practitioner.
- Do not use in case of active infection in the shoulder joint area.
- Do not use in case significant changes to patient's anatomy have occurred since the medical scan used for product definition was obtained.
- Do not use if the patient presents one of the contraindications for the Archer™CSR Total Shoulder, Catalyst EA Convertible Stemmed Shoulder and Archer™ R1 Reverse replacement instructions for use.

## WARNINGS

- The device has particular contact surfaces with the patient's bone and should only be used with the patient mentioned in the surgical report attached in the package. Compare the patient ID on the surgical report and devices before use.
- The surgeon should not remove any of the contact surfaces of the device. Do not use the device in case it would not fit in the surgical incision. It is the responsibility of the surgeon to make sure the device is stable prior to use it. Please refer to the surgical report for complete instructions.
- Metallic cylinders are inserted in the cylinders of the device. Make sure to inspect the device prior to use. Do not use if any doubt about the integrity of those parts.
- The device is a single use, disposable device. Do not attempt to recondition or reuse the device.
- The device must be handled by a qualified medical staff in the practice of orthopaedic surgeries and the use of the device. It is the surgeon's obligation to evaluate whether to follow or not follow the pre-operative planning result and/or associated guides regarding the real situation during the surgery.
- The physician in charge must be able to operate without the device.
- The device is made for a maximum contact duration of 60 minutes. An extended contact is the responsibility of the surgeon. Ensure that the patient is not allergic to the materials used in the guides prior to use.
- The quality and the accuracy of *Archer$^{R}$ PSI System* depends on the quality of the patient CT scan data received. Presence of metallic implants at the shoulder area of interest may decrease the quality of the patient bone reconstruction due to imaging artifacts. The device should not be used if no exploitable CT scans should be obtained for manufacturing of this patient specific instrumentation.
- The device should be properly cleaned prior to sterilization. Do not use if the devices are broken, deteriorated or in presence of loose powder.
- The device in the package is provided non-sterile and must be cleaned and sterilized prior to use.
- If the internal cardboard box is damaged, carefully check the integrity of the parts inside the box and call your local representative in case of doubt.
- Do not attempt a surgical procedure with damaged or suspect instruments or case reports. Inspect all components preoperatively. Inspect holes/slots to ensure no debris is present.
- Either the applicable Archer™ CSR Total Shoulder, Catalyst EA Convertible Stemmed Shoulder or Archer™ R1 Reverse tray is

mandatory for the *Archer[R] PSI System* surgical procedure and must be available at the time of surgery. Consult the prosthesis labeling and instructions for use for specific patient indications, contraindications, associated risks, information for use, warnings, and precautions.

**PRECAUTIONS**

- Do not apply mechanical stress to the instruments.
- Use proper tooling and instrument motorization to remove the pins from the metallic cylinders. Make sure to inspect the device after use to ensure no metallic cylinder popped out from the device.
- If cutslots are available on the device, use proper surgical blades compatible with the surgical procedure of the implant manufacturer to perfom the cuts through the device. Make sure to inspect the device after use to check the integrity of the cutslots.
- Excessive friction induced heat can alter the polyamide of the device.
- Do not re-use the devices after accidental dropping.
- The medical device cannot be burnt before destruction without preventing any risk of toxic release (CO, NO et CO2).

**ARCHER[R] PSI SYSTEM IDENTIFIERS**

The guides and bone models are labelled with the reference of the patient. Those identifiers should be checked for readability and confirmed by the surgeon before use. Contact the legal manufacturer if the reference does not correspond to the one mentioned in the surgical report.

**ADVERSE EVENTS**

The use of medical devices presents a risk of infection at the same level as any other surgery. An allergic reaction may be observed.

**DESTRUCTION**

At the end of the surgery, the device should be considered postoperative waste, and follow the same destruction route. In case of secondary use of the device in a non-surgical use (e.g. educational), it should be re-sterilized following the method described in this document.

**CLEANING AND STERILIZATION**

PREPARATION

- Only handle the parts while wearing gloves.
- Get the guides and bone models out of the package. Do not sterilize them in the protective bag or packaging supplied with them.
- Verify that the number of instruments matches with the information on the label.
- Place them in an appropriate basket (not supplied), **without mechanical stress**.

STEP 1: CLEANING

Compatible detergents and rinse aids may be used as recommended by the manufacturer of the washer-disinfection unit.

A. Visual inspection & manual cleaning

Inspect the parts visually. Remove visible soil under running water using a mechanical aid such as a brush with soft nylon bristles until visible clean.

B. Automated cleaning

Clean the parts automatically using an automatic washer-disinfection unit utilizing thermal disinfection (continuous tunnel process type or cabinet type). The following table outlines the recommended automated cleaning method for use.

| Step | Minimum Duration | Cleaning Instructions |
|---|---|---|
| Pre-Wash | 2 minutes | Cold-45°C (cold-113F°) tap water |
| Detergent Wash | 10 minutes | 40°C-80°C (104°F-176°F) tap water; 0.2%-1% alkaline detergent (e.g. Neodisher Mediclean Forte) |
| Wash | 2 minutes | 70°C-80°C (158°F-176°F) tap water |
| Rinse | 2 minutes | 70°C-95°C (158°F-203°F) critical water |
| Drying | 20 minutes | 115°C-120°C (239°F-248°F) |

Before the cleaned products are packaged and sterilized, carefully examine them to verify whether they are dry, clean, and undamaged. Only handle the parts while wearing gloves.

STEP 2: RECOMMENDED STERILIZATION SPECIFICATIONS

During sterilization of single-use devices, pouches may be used. Single pouch the devices. Only legally marketed, FDA cleared and validated sterilization pouches or wraps should be used. Ensure to pack elements in order to avoid shocks or potential damage resulting from stacking the baskets.

Ensure to place the pouches in the center of the tray and avoid contact with the edge of the tray to allow efficient drying during the 70-minutes time.

In case a surgery is re-scheduled or for any other reason, the device can not be re-cleaned and re-sterilized since they could have been contaminated. Please contact support@3dside.eu for any questions.

Sterilize the guides and bone models using pre-vacuum steam sterilization before use. Use the following standard steam sterilization settings:

| Type | Temperature | Exposure Time | Minimum vacuum drying time |
|---|---|---|---|
| Pre-vacuum steam sterilization | 132°C (270°F) | 4 minutes | 70 minutes |

Allow the device to cool with the sterilizer door open for 30 min and to cool down in a rack outside the sterilizer for 60 minutes prior the use in the surgery room.

**Please contact company for product inquiries, cleaning instructions and surgical techniques, or to report any adverse event.**

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