Sterile Humeral Cut Guide Fixation Kit
Instructions for Use.

Description

The Sterile Humeral Cut Guide Fixation Kit is intended for use with Catalyst OrthoScience implant systems to aid in the bone preparation and implant insertion. It is the responsibility of the surgical team to determine which instruments are required for each case.

Indications for Use

The instruments within the Sterile Humeral Cut Guide Fixation Kit are intended to supplement the Catalyst OrthoScience re-usable instrumentation in bone preparation for total or hemi shoulder replacement. The instruments are designed to drill holes in the bone and stabilize instrumentation during use.

Contraindications

Use of the Sterile Humeral Cut Guide Fixation Kit is contraindicated for patients with known sensitivity to stainless steel.

Materials

The patient contacting material of the Sterile Humeral Cut Guide Fixation Kit instruments is stainless steel. The material is listed on the product labeling.

Handling/Inspection

- Thoroughly inspect all packaging materials for damage which can compromise sterility. Do not use and discard any instruments that are packaged in open or damaged packaging.
- Dispose of all instruments in accordance with all applicable federal, state and local medical and hazardous waste practices.
- Use caution when handling instruments as they may incorporate sharp tips/edges that can cause injury.

Warnings

- Do not reuse instruments without appropriate re-processing, as this may result in product contamination, patient infections and/or failure of the instrument to perform as intended.
- Instruments should not be used for purposes other than their intended use.
- Use appropriate personal protection equipment when handling contaminated instruments.

Sterility

The sterile single use instruments are sterilized by exposure to a minimum dose of 25 kGy of gamma irradiation.
Do not use devices after expiration date has passed.

Reprocessing

Following use, the instruments included in the Sterile Humeral Cut Guide Fixation Kit may be placed back into their designation locations within the Catalyst CSR instrument tray and re-processed in accordance with Catalyst Document 1226-6201 (Care, Handling, Cleaning and Sterilization of Instruments).

Questions or comments regarding the use of these devices should be directed to Catalyst OrthoScience Customer Service.

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