



ADVANCED ORTHOPAEDIC SOLUTIONS

## AOS STERILE SINGLE USE INSTRUMENTS



### INSTRUCTIONS FOR USE

Federal Law restricts this device to sale by or on the order of a physician

### DEVICE DESCRIPTION

AOS STERILE SINGLE USE INSTRUMENTS are a collection of sterile, single use instruments designed to assist in the surgical implantation of various AOS intramedullary nail systems. AOS STERILE SINGLE USE INSTRUMENTS such as drills, reamers, taps, guide pins and wires, drivers, sheaths, and extractors, have intricate design features that cannot withstand repeated use, and must therefore be discarded after use. They are manufactured out of stainless steel (17-4 PH SS, 316 SS per ASTM F138, and 455 SS per ASTM A564/A564M).

### INDICATIONS FOR USE

Drills and reamers are indicated for making holes in bone, by attachment to a surgical power drill. A tap is indicated to ease the insertion torque of screws through a pilot hole. A guide pin or wire is indicated for the temporary fixation of bone fractures during the implant process or planning the placement of a screw prior to use of a cannulated drill or cannulated screw. Drivers are indicated for tightening or loosening screws and bolts. A sheath is indicated for creating an unobstructed channel within the soft tissue through which a component may be inserted and/or implanted. An extractor is indicated for assisting with implant removal.

### CONTRAINDICATIONS

There are no contraindications for the use of the AOS STERILE SINGLE USE INSTRUMENTS.

### WARNINGS

AOS STERILE SINGLE USE INSTRUMENTS must not be resterilized.

AOS STERILE SINGLE USE INSTRUMENTS must be discarded appropriately after use. Soiled surgical instruments should be disposed of in proper biohazardous waste receptacles. Sharp items should be placed in an appropriate sharps container labeled for biohazardous waste.

AOS STERILE SINGLE USE INSTRUMENTS have been designed and evaluated for use with their corresponding AOS orthopedic implant systems only. Do not use the AOS STERILE SINGLE USE INSTRUMENTS with any other orthopedic implant system other than the AOS system for which they were designed. Use of the AOS STERILE SINGLE USE INSTRUMENTS with any orthopedic implant system other than the indicated AOS system is considered off-label use and could result in patient harm.

AOS STERILE SINGLE USE INSTRUMENTS are intended for use in an operating room for the surgical implantation of AOS implantable medical devices only. They are not intended to be used during diagnostic testing, and have not been validated for use in an MR environment.

Store AOS STERILE SINGLE USE STERILE INSTRUMENTS in their original protective packaging until immediately before use. Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use if package is damaged.

Preoperative and operative procedures, including knowledge of surgical techniques, are important considerations in the successful utilization of surgical instruments. The surgeon must be familiar with the surgical technique associated with the appropriate implant and instrumentation.

Care must be taken when using measuring instruments. Measuring instruments are calibrated for recommended implant length. When used to measure between two flat surfaces, measuring instruments are accurate to  $\pm 0.5$ mm of the reading. When measuring on a curved surface, care must be taken to ensure that the reading is accurate. Implant length should always be verified under C-Arm.

### ADVERSE EVENTS

There are no adverse events associated with the use of the AOS STERILE SINGLE USE INSTRUMENTS.

### INFORMATION

For further information please contact Advanced Orthopaedic Solutions at (310) 533-9966.

SYMBOL GLOSSARY

**REF** Part number (catalog number)

**LOT** Lot number (batch code)

**QTY** Quantity


**MATL** Material

 Caution

 Consult instructions for use

 Manufacturer

 Date of manufacture

 Expiration date


 Do not reuse

**STERILE R** Sterilized using irradiation

 Do not resterilize

 Non-sterile product

 MR Conditional

 Do not use if package is damaged

**EC REP** Authorized Representative in the European Community

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