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ADVANCED ORTHOPAEDIC SOLUTIONS

AOS 7.0mm CANNULATED BONE SCREW SYSTEM

INSTRUCTIONS FOR USE

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

DEVICE DESCRIPTION

The AOS 7.0mm CANNULATED BONE SCREW SYSTEM is an open reduction and internal fixation device. The set consists of 7.0mm diameter implantable titanium alloy self-tapping screws ranging in length from 30mm to 130mm. The system is provided in a dedicated sterilization tray and includes an accompanying set of instruments.

INDICATIONS FOR USE

The AOS 7.0mm CANNULATED BONE SCREW SYSTEM is intended for fracture fixation of small and long bones and of the pelvis. This system is not intended for spinal use.

CONTRAINDICATIONS

1. Patients with an active superficial infection.
2. Pediatric patients, or patients with skeletal immaturity.
3. Patients with a history of frequent infections.
4. Patients with known sensitivity or allergies to the implant materials.
5. Patients with neuromuscular deficiencies in the affected limb sufficient to render the procedure unwarranted.
6. Conditions that preclude cooperation with the rehabilitation regimen for postoperative care or impair the patient's ability to follow directions.
7. Physical conditions that would preclude adequate implant support or retard healing, such as blood supply impairment in the treated area, obliterated medullary canal, insufficient bone quality or quantity, previous infection, or obesity.

WARNINGS

The AOS 7.0mm CANNULATED BONE SCREW SYSTEM must be sterilized prior to use. Please refer to the section on STERILIZATION below.

The AOS 7.0mm CANNULATED BONE SCREW SYSTEM is intended for use by individuals with adequate training and familiarity with techniques associated with the orthopedic surgical procedure employed. For further information about techniques, complications, and hazards, consult the medical literature. Please refer to the AOS Cannulated Bone Screw System Surgical Technique (PN 9600) for additional information on the use of the AOS CANNULATED BONE SCREW SYSTEM.

The implants of the AOS 7.0mm CANNULATED BONE SCREW SYSTEM are for single use only. Reuse of the devices is associated with risks for the transmission of infectious diseases and loss of mechanical strength. While the device may appear undamaged, previous stress may have created imperfections and internal stress patterns which could lead to implant failure.

Use care in storage and handling of devices. While in storage, device components should be protected from corrosive environments such as salt air, moisture, etc. While handling device components, do not apply excessive force to implants, as cutting, bending, or scratching the surface of device components can reduce their strength and fatigue resistance. Inspect all device components for damage prior to surgery. Replace damaged or worn components, as necessary.

For proper care and handling of AOS REUSABLE INSTRUMENTS and AOS SINGLE USE INSTRUMENTS, please refer to their package insert (IFU-9000).

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that the AOS 7.0mm CANNULATED BONE SCREW SYSTEM implants are MR Conditional. A patient with a 7.0mm cannulated screw can be safely scanned in an MR system meeting the following conditions:

1. Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T).
2. Maximum spatial field gradient of 3,270 G/cm (32.7 T/m).
3. When scanning in a 1.5 T scanner, patients can be scanned with a whole-body averaged SAR of 2.0 W/kg (Normal Operating Mode) when landmarked superior to the elbow for a maximum scan time of 15 minutes. If scanning is performed between the elbow and distal femur, the whole-body SAR needs to be limited to 1.0 W/kg or less for a maximum scan time of 15 minutes. Scanning is not permitted at landmark locations inferior to the proximal femur in a 1.5 T scanner.
4. When scanning in a 3 T scanner, patients can be scanned with a whole-body averaged SAR of 2.0 W/kg (Normal Operating Mode) when landmarked superior to the elbow for a maximum scan time of 15 minutes. If scanning is performed below the elbow, the whole-body SAR needs to be limited to 1.0 W/kg or less for a maximum scan time of 15 minutes.

The scanner SAR restrictions above apply to a circularly polarized whole-body RF coil. For other RF coil types (e.g., extremity, head, neck), appropriate whole-body SAR restrictions should be considered to ensure similar levels of localized SAR are achieved.

RF HEATING

Under the scan conditions defined above, AOS 7.0mm CANNULATED BONE SCREW SYSTEM implants are expected to produce a maximum temperature rise less than or equal to 5.6 ºC after 15 minutes of continuous scanning.

MR ARTIFACT

In non-clinical testing, the image artifact caused by AOS 7.0mm CANNULATED BONE SCREW SYSTEM implants extend radially approximately 2.0 cm from the device.

POSSIBLE ADVERSE EVENTS

1. Nerve or soft tissue damage, necrosis of bone or bone resorption, necrosis of the tissue, or inadequate healing from surgical trauma or presence of implant.
2. Vascular disorders including thrombophlebitis, pulmonary emboli, wound hematomas, and avascular necrosis of the femoral head.
3. Metal sensitivity or histological or allergic reaction to device materials.
4. Irritation injury of soft tissues, including impingement syndrome.
5. Pain, discomfort, or abnormal sensations.
6. Infections, both deep and superficial.
7. Bone damage or refracture.

DIRECTIONS FOR USE

PREOPERATIVE

Inspect all AOS 7.0mm CANNULATED BONE SCREW SYSTEM implant components under adequate lighting prior to sterilization for wear or damage that would impact its performance. If wear or damage is identified, component parts should be discarded and replaced.

An image intensifier and an appropriate fracture table are required to perform this surgery.

Allergies and other reactions to device materials should be ruled out preoperatively.

INTEROPERATIVE

Select the most appropriate implant size suitable for the patient's age, weight, and bone quality. Use the largest implant suitable for the patient to prevent loosening, migration, bending, cracking, or fracture of the device or bone or both. A stable construct should be achieved and verified under image intensification.

POSTOPERATIVE
The AOS 7.0mm CANNULATED BONE SCREW SYSTEM is not designed to withstand the stress of weight-bearing, load-bearing, or excessive activity. Caution patients against unassisted activity that requires walking or lifting, to reduce the likeliness of weight-bearing on the affected limb during treatment. Device breakage or damage can occur when the implant is subjected early weight bearing or increased loading associated with delayed union, nonunion, or incomplete healing. Internal or external supports may be utilized to minimize internal stress loading of the implant and broken bone until solid bony union is evident by radiograph.

Periodic x-ray examinations for at least the first six (6) months postoperatively are recommended for close comparison with postoperative conditions to detect changes in position, nonunion, loosening, bending, or cracking of components.

The AOS 7.0mm CANNULATED BONE SCREW SYSTEM may be removed after treatment. In the absence of pain, removal of the implant in elderly or debilitated patients is not suggested.

STERILIZATION
Inspected devices should be placed into their trays as provided. The total weight of tray with devices should not exceed 11.4kg/25 lbs. (other local limits below 11.4kg/25 lbs. may apply). Packaging should be completed utilizing a pouch or wrap which conforms to the recommended specifications for steam sterilization as outlined below. The wrap should be completed following AAMI double-wrap or equivalent guidelines with an appropriate wrap (cleared by the FDA or the local governing body). Bracketed positions designated for specific devices shall contain only devices intended for those areas. Devices should not be stacked or placed in close contact. Only AOS devices should be included in the trays. These validated instructions are not applicable to trays or cases that include devices not intended to be used with AOS trays.

Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in the table below. Sterilizers vary in design and performance characteristics. Cycle parameters and the load configuration should always be verified against the sterilizer manufacturer's instructions.

RECOMMENDED STEAM STERILIZATION PARAMETERS

Prevacuum Cycle Type	Exposure Temperature	Exposure Time	Minimum Drying Time[1]	Minimum Cooling Time[2]
US Cycle[3]	132 °C/270 °F	4 minutes	30 minutes	30 minutes
UK Cycle[3]	134 °C/273 °F	3 minutes	30 minutes	30 minutes
Prion Cycle[4]	134 °C/273 °F	18 minutes	30 minutes	30 minutes

[1]Drying times vary according to load size and should be increased for larger loads.

[2]Cooling times vary according to the sterilizer used, device design, temperature and humidity of ambient environment, and type of packaging used. Cooling process should comply with ANSI/AAMI ST79.

[3]For markets outside of the US, the cycle parameters listed for exposure time and temperature can be considered as minimum values.

[4]For markets outside of the US, reprocessing parameters recommended by the World Health Organization (WHO) where there is concern regarding TSE/CJD contamination.

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

SYMBOL GLOSSARY

Part number (catalog number)

Lot number (batch code)

Quantity

Material


Caution


Consult instructions for use


Manufacturer


Date of manufacture


Expiration date


Do not reuse

Sterilized using irradiation

Do not resterilize

Non-sterile product

MR Conditional


Do not use if package is damaged

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