EN

ADVANCED ORTHOPAEDIC SOLUTIONS

AOS TEMPORARY EXTERNAL FIXATION SYSTEM

INSTRUCTIONS FOR USE

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

DEVICE DESCRIPTION

The AOS TEMPORARY EXTERNAL FIXATION SYSTEM is an external fixation device comprised of rods, rod-to-rod clamps, pin-to-rod clamps, multi-pin clamps and pins used for the management of bone fractures and reconstructive orthopedic surgery. The AOS TEMPORARY EXTERNAL FIXATION SYSTEM is a modular system designed to provide options in frame construction, simplicity in frame components, and ease of use. The system is comprised of titanium alloy, stainless steel clamps, and carbon fiber. The system is provided in a dedicated sterilization tray and includes an accompanying set of instruments.

INDICATIONS FOR USE

The AOS TEMPORARY EXTERNAL FIXATION SYSTEM is indicated for external fixation of open or closed long bone fractures where soft tissue injury precludes the use of other fracture treatment. The AOS TEMPORARY EXTERNAL FIXATION SYSTEM is intended to be non-weight bearing.

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 TEMPORARY EXTERNAL FIXATION SYSTEM must be sterilized prior to use. Please refer to the section on STERILIZATION below.

The AOS TEMPORARY EXTERNAL FIXATION 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 External Fixation Systems Surgical Technique (PN 9051) for additional information on the use of the AOS TEMPORARY EXTERNAL FIXATION SYSTEM.

The implants of the AOS TEMPORARY EXTERNAL FIXATION 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.

The AOS TEMPORARY EXTERNAL FIXATION SYSTEM has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the AOS TEMPORARY EXTERNAL FIXATION SYSTEM in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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

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 TEMPORARY EXTERNAL FIXATION 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. Avoid heat necrosis of surrounding tissue and bone by drilling pins slowly through the bone. A stable construct should be achieved and verified under image intensification.

POSTOPERATIVE

The AOS TEMPORARY EXTERNAL FIXATION 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, non-union, loosening, bending, or cracking of components.

Assure daily cleansing of pin-skin interface. Maintain meticulous daily pin site care management to prevent infection. Routinely check the security of pins and the overall integrity of frame components.

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

Authorized Representative in the European Community

Advanced Orthopaedic Solutions
3203 Kashiwa Street
Torrance, CA 90505
USA

Phone: (310) 533-9966
Email: ATI_Regulatory@arthrex.com

Arthrex GmbH
Erwin-Hielscher-Straße 9
81249 Munich
Germany

Phone: +49 89 90 90 05-0
Email: info@arthrex.de

EN

ADVANCED ORTHOPAEDIC SOLUTIONS

AOS SMALL BONE EXTERNAL FIXATION SYSTEM

INSTRUCTIONS FOR USE

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

The AOS SMALL BONE EXTERNAL FIXATION SYSTEM is an external fixation device comprised of rods, rod-to-rod clamps, pin-to-rod clamps, multi-pin clamps and pins used for the management of bone fractures and reconstructive orthopedic surgery. The AOS SMALL BONE EXTERNAL FIXATION SYSTEM is a modular system designed to provide options in frame construction, simplicity in frame components, and ease of use. The system is comprised of titanium alloy, stainless steel clamps, and carbon fiber. The system is provided in a dedicated sterilization tray and includes an accompanying set of instruments.

INDICATIONS FOR USE

The AOS SMALL BONE EXTERNAL FIXATION SYSTEM is intended to be used with the AOS EXTERNAL FIXATION SYSTEM. It is intended to be used in the stabilization of open and/or unstable fractures in anatomies such as the hand, wrist, forearm, foot, and ankle where soft tissue injury may preclude the use of other fracture treatments. The AOS SMALL BONE EXTERNAL FIXATION SYSTEM is intended to be non-weight bearing.

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 SMALL BONE EXTERNAL FIXATION SYSTEM must be sterilized prior to use. Please refer to the section on STERILIZATION below.

The AOS SMALL BONE EXTERNAL FIXATION 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 External Fixation Systems Surgical Technique (PN 9092) for additional information on the use of the AOS SMALL BONE EXTERNAL FIXATION SYSTEM.

The implants of the AOS SMALL BONE EXTERNAL FIXATION 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.

The AOS SMALL BONE EXTERNAL FIXATION SYSTEM has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the AOS SMALL BONE EXTERNAL FIXATION SYSTEM in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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 SMALL BONE EXTERNAL FIXATION 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 quantity. Use the largest implant suitable for the patient to prevent loosening, migration, bending, cracking, or fracture of the device or bone or both. Avoid heat necrosis of surrounding tissue and bone by drilling pins slowly through the bone. A stable construct should be achieved and verified under image intensification.

POSTOPERATIVE

The AOS SMALL BONE EXTERNAL FIXATION 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, non-union, loosening, bending, or cracking of components.

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Advanced Orthopaedic Solutions
3203 Kashiwa Street
Torrance, CA 90505
USA

Phone: (310) 533-9966
Email: ATI_Regulatory@arthrex.com

Arthrex GmbH
Erwin-Hielscher-Straße 9
81249 Munich
Germany

Phone: +49 89 90 90 05-0
Email: info@arthrex.de