The AOS External Fixation Systems are modular systems designed to provide options in frame construction, simplicity in frame components, and ease of use. The system is comprised of titanium (Ti-6Al-4V) and stainless steel (316L) clamps (rod-to-rod, pin-to-rod), aluminum (6061-T6) and stainless steel (316L) clamps (Multi-Pin), stainless steel fixation pins (316L), and carbon fiber connector rods.

**INDICATIONS FOR USE**

The AOS 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 External Fixation System is intended to be non-weight bearing.

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**

External fixation devices are contraindicated for the following:

1. Patients with an active superficial infection.
2. Disabled or non-compliant patients who cannot perform the necessary postoperative care.
3. Patients with fractures that will heal satisfactorily with conservative treatment.
4. Patients with known sensitivity and/or allergies to the materials in the external fixation device model to be used.
5. Patients with a history of frequent infections.
6. Patients with neuromuscular deficiencies in the affected limb.
7. Patients with significant deficiency in bone quantity and quality.
8. Patients with inadequate or impaired blood flow in the body site(s) to be treated.

**WARNINGS**

The AOS External Fixation Systems are 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.

The use of these devices requires a thorough understanding of the techniques and principles of orthopedic surgery procedures.

Preoperative frame assembly and adequate supply of components are recommended.

Intraoperative fracture or breakage of components can occur (e.g. due to excessive force, extensive use). Inspect all external fixation devices and components prior to surgery. Replace when necessary.

Avoid damage to nerves, muscles, tendons, and vessels by careful placement of pins.

Avoid heat necrosis of surrounding tissue and bone by drilling pins slowly through the bone.

Maintain meticulous daily pin site care management to prevent infection.

The AOS External Fixation Systems have 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 AOS External Fixation Systems in the MR environment is unknown.

Scanning a patient who has this device may result in patient injury. As the AOS External Fixation Systems are a non-weight bearing device special consideration should be taken before using this device on an overweight or obese patient.

**PRECAUTIONS**

Do not apply excessive force to external fixation devices. Use utmost care in handling and storing of devices to prevent cutting, bending or scratching of the device. Routinely check the security of pins and the overall integrity of frame components.

**Preoperative Care**

Preparation should include provision of a sufficient surplus supply of sterile components.

**Postoperative Care**

Assure daily cleansing of pin-skin interface. Assure that there is no weight bearing on the affected limb. Visualize and reevaluate the bone healing progress and arrange for adjustments accordingly.

The external fixation devices 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.

**CLEANING**

Warning: Follow the instructions and warning issued by the supplier of any cleaning disinfecting agents and equipment used. Do not exceed 285 °F during the cleaning process. Highly alkaline or acidic conditions can damage parts; keep the pH within the 6 to 8 range.

**Manual Cleaning**

1. Prepare a fresh neutral-pH, enzymatic cleaning solution (i.e. Enzol) to the cleaning solution’s specification using warm (30 to 43 °C/86 to 109 °F) tap water. Soak for 20 minutes.
2. Using a soft-bristled brush, remove all traces of soil, paying close attention to crevices, mating surfaces, actuating parts, and any hard-to-reach areas.
3. Thoroughly rinse for at least 1 minute using warm (30 to 43 °C/86 to 109 °F) tap water, actuating any moveable parts 5 times.
4. Prepare a fresh, neutral-pH, enzymatic cleaning solution (i.e. Enzol) to the cleaning solution’s specification using warm (30 to 43 °C/86 to 109 °F) tap water. Sonicate for 20 minutes.
5. Thoroughly rinse for at least 1 minute using warm (30 to 43 °C/86 to 109 °F) tap water, actuating any moveable parts 5 times.
6. Thoroughly dry with a soft cloth saturated in 70% Isopropyl Alcohol (IPA). Dry with compressed air at least 20 psi. Inspect each device for remaining debris (detergent or soil). If any is observed, repeat the cleaning procedure with freshly prepared cleaning solutions.
The above cleaning procedure has been validated in accordance with AAMI TIR30:2011.

STERILIZATION

All Advanced Orthopaedic Solutions External Fixation Devices are sold clean for single-use only. All Advanced Orthopaedic Solutions External Fixation Devices are sold non-sterile and may be sterilized by steam autoclaving in appropriate protective wrapping, after removal of all the original packaging and labeling. The pin caps supplied are for single use only and can be sterilized only once.

The External Fixation System fixation pins must be sterilized prior to use using the following sterilization cycle and drying times. In addition to the fixation pins the non-patient contact components in the system, pin clamps, connecting rods, pin caps, and instruments should also be sterilized using the cycle and drying time listed below.

The drying time for the AOS External Fixation Systems is 30 minutes.

<table>
<thead>
<tr>
<th>Method</th>
<th>Cycle</th>
<th>Temperature</th>
<th>Exposure Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>Pre-Vacuum</td>
<td>270 °F (132 ºC)</td>
<td>4 minutes</td>
</tr>
</tbody>
</table>

The above sterilization procedure has been validated to an SAL of $10^{-6}$ in accordance with AAMI TIR12:2010, ANSI/AAMI ST77:2013 and ISO 17665-1:2006 per the biological indicator overkill method per Annex D of ISO 17665-1:2006.

INFORMATION For further information please contact Advanced Orthopaedic Solutions at +1 310.533.9966.