Aesculap Implant Systems, LLC.
Odontoid Fracture Fixation System Implant Instruction for Use (IFU)

Product Description
The AIS Odontoid Fracture Fixation System is a titanium alloy screw system that is implanted across the fracture site in the cervical spine through an anterior approach to affix the odontoid process. The AIS Odontoid Fracture Fixation System is indicated for fracture fixation of small bones and small bone fragments including odontoid fractures.

Indications
For fracture fixation of small bones and small bone fragments including odontoid fractures.

Materials
The materials used in the implant are listed on the packaging:
- Titanium forged alloy Ti6Al4V according to ISO5832-3

Warnings
- Ensure that all necessary implants and instruments are on hand and inspected prior to use.
- For implants and instruments that are supplied non-sterile, they must be sterilized prior to use.
- The screws should not be re-used under any circumstances.
- Patients should be advised of the possible limitations of their implant(s), including postoperative mobility and load bearing stress.
- Patient behavior can greatly affect surgical outcomes. Smokers and non-compliant patients should be advised of this fact and warned of the increased risk of potential complications.

Precautions
- The Odontoid Fracture Fixation System has not been evaluated for safety and compatibility in the MR environment, nor has it been tested for heating or migration in the MR environment.
- Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.
- Mixing of stainless steel implants with unalloyed titanium, titanium alloy, and other cobalt alloy implants should be avoided for implants that are in contact with each other.

Contraindications
Do not use in the presence of:
- Fever
- Infection: systemic or localized in the spine
- Pregnancy
- Medical or surgical conditions that could negatively affect the outcome of the implantation
- Foreign body sensitivity to the implant materials
- Acute osteopenia
- Severe osteoporosis or similar loss of bone density
- Severe damage to the osseous structures preventing fixation of the implant components
- Bone tumors in the region of implant fixation
- Anticipated overloading of the implant
- Systemic or metabolic diseases
- Dependency on pharmaceutical drugs, drug abuse, or alcoholism
- Morbid obesity (adiposity)
- Generally poor condition of the patient
- Inadequate patient compliance
- Cases not listed under indications
Side effects and interactions
Implant failure resulting from excessive load:
- Warping or bending
- Loosening
- Breakage
- Inadequate fixation
- Failed or delayed fusion
- Infection
- Spondylolisthesis
- Delayed healing, or non-union and development of pseudarthrosis
- Incorrect implant position
- Bone graft resorption
- Deterioration of the atlanto-occipital joints

Injuries to:
- Dura
- The vertebral arteries
- Nerve roots
- Spinal cord
- Blood vessels
- Organs
- Tissue reaction to the implant materials
- Reduced joint mobility and flexibility
- Arthralgia and reduced tolerance for exercise

Safety notes
Federal law restricts this device to sale by, or on order of a physician!
- It is the operating surgeon's responsibility to ensure that the surgical procedure is performed properly.
- General risk factors associated with surgical procedures are not described in the present instructions for use.
- The operating surgeon must have a thorough command of both the hands-on and conceptual aspects of the established operating techniques.
- The operating surgeon must be fully conversant with bone anatomy, including the pathways of nerves, blood vessels, muscles, and tendons.
- Aesculap is not responsible for any complications arising from wrong indication, wrong choice of implant, incorrect combination of implant components and operating technique, the limitations of the treatment method, or inadequate asepsis.
- The instructions for use for individual Aesculap implant components must be followed.
- The implant components were tested and approved in combination with Aesculap components. If other combinations are used, the responsibility for such action lies with the operating surgeon.
- Do not, under any circumstances, combine implant components from different manufacturers.
- Do not, under any circumstances, use damaged or surgically removed components.
- Implants that have been used before must not be reused.
- Delayed healing can cause implant breakage due to material fatigue.
- The attending physician shall make any decision with regard to the removal of implant components that have been used.
- Damage to the load-bearing structures of the implant can lead to loosening of components, dislocation, migration, and other severe complications.
- The implant components applied, along with their article numbers, the name of the implant, as well as the batch number and serial number (if available) must be documented in all patient records.
- Postoperatively, individual patient information, as well as mobility and muscle training, is of particular importance.
- Use Apfelbaum screws only with the instruments that are designed especially for the Apfelbaum system.
- Do not bend metal implants.
Application
The operating surgeon shall devise an operation plan that specifies and accurately documents the following:
- Selection of the implant components and their dimensions
- Positioning of the implant components in the bone
- Location of intraoperative landmarks

The following conditions must be fulfilled prior to application:
- All requisite implant components are ready to hand.
- Operating conditions are highly aseptic.
- All requisite implantation instruments must be available and in working order, including specialized Aesculap implantation systems.
- The operating surgeon and operating room team are thoroughly familiar with the operating technique and with the available range of implants and instruments; information materials on these subjects must be complete and ready to hand.
- The operating surgeon is fully conversant with the rules governing medical practice, the current state of scientific knowledge, and the contents of relevant scientific articles by medical authors.
- Information has been obtained from the manufacturer in the event of an ambiguous preoperative situation and if implants are present in the area to be treated

The surgical procedure and following information has been explained to the patient, and the patient's consent has been documented:
- In the case of delayed or incomplete fusion, the implants can break and loosen due to high loads.
- The life-span of the implant depends on the patient's body weight.
- The implant components must not be overloaded by extreme strains, hard physical labor or sports.
- Corrective surgery may be necessitated by implant loosening, fracture or loss of correction.
- Smokers present an increased risk of bone fusion failure.
- The patient must undergo medical check-ups of the implant components at regular intervals.

STERILITY
HOW SUPPLIED - IMPLANTS
Aesculap’s Odontoid Fracture Fixation implants are supplied non-sterile. Non sterile implants must be sterilized prior to each use according to the procedures outlined in this document.

Sterilization of non-sterile Implants
The Odontoid Screws are for single use only. Sterilization of implants is to be accomplished by steam autoclave in a standard prevacuum cycle. To achieve a sterility assurance level of 10⁻⁶, Aesculap recommends the following parameters:

Preconditioning Pulses: 3

<table>
<thead>
<tr>
<th>Sterilization Method</th>
<th>Temperature</th>
<th>Full Cycle Time SterilContainer™ System</th>
<th>Minimum Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Vacuum</td>
<td>270°F</td>
<td>4-minutes</td>
<td>20-30minutes</td>
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</tbody>
</table>

*The above parameters have been validated for sterility in an Aesculap STERILCONTAINER™ System. The cycle times for wrapped product are based on recommendations of the AAMI guidelines ST79 for steam sterilization.

*Aesculap has validated the above sterilization cycles and has the data on file. Other sterilization cycles may also be suitable; however individuals or hospitals not using the recommended methods are advised to validate any alternative method using proper laboratory techniques.
Note: Time and temperature parameters required for steam sterilization may vary according to the type of sterilizer, cycle, design, and packaging/containerization. The manufacturer’s instructions must be followed for each sterilization chamber.

If implant becomes contaminated, do not resterilize, reprocess, or reuse.

**STORAGE**
Once the product is sterilized, it can be stored in the SterilContainer™.

Refer to the system’s Surgical Technique for detailed implantation information. To obtain a Surgical Technique Guide, please contact Aesculap Implant Systems Customer Service Department at (866) 229-3002 or your Sales Representative.

**CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.**

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