ANSER Clavicle Pin Set

BAAT Medical Products B.V.
F. Hazemeijerstraat 800
7555 RJ Hengelo
The Netherlands
+31 (0)88 565 66 00
www.baatmedical.com

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INSTRUCTIONS FOR USE

Device description
The ANSER Clavicle Pin is a device intended to be used for intramedullary fixation of mid-shaft clavicle fractures. The device consists of three parts. The main component is a nail, that is placed within the medullary canal of the fractured clavicle. It has a threaded medial end for fixation into the bone. At the lateral end an endcap is placed after insertion for lateral fixation of the pin. In this way the pin is secured both medially and laterally.

Intended purpose
Intramedullary fixation of mid-shaft clavicle fractures in order to restore and maintain the anatomical position of the clavicle and facilitate osteosynthesis.

Indications for use
Indications for the ANSER clavicle pin include skeletally mature patients suffering from mid-shaft clavicular fractures.

Relative contra-indications [1]
- Patients suffering from (severe) osteoporosis
- Patients who are not fit for surgery
- Patients with non-union or mal-union
- Patients who are not skeletally mature
- Possible non-compliant patients (e.g. due to alcohol and drug addiction, dementia)
- Additional neurovascular injury
- Pathologic fractures

[1] *Relative contraindications are contraindications for circumstances in which the patient is at higher risk of complications from treatment, but these risks may be outweighed by other considerations or mitigated by other measures. For example, a pregnant woman should normally avoid getting X-rays, but the risk may be outweighed by the benefit of diagnosing (and then treating) a serious condition such as tuberculosis. Relative contraindications may also be referred to as cautions, such as in the British National Formulary.*

Warnings and pre-cautions

Warnings
- Avoid, if possible, using multiple insertion attempts during placement of the ANSER Clavicle Pin medial fixation in the medial fragment and placement of the ANSER Lateral Fixation Device in order to prevent weakening/destruction of the (self-) tapped threaded interfaces.
- Be aware that if the ANSER Clavicle Pin section protruding from the clavicle is severely bent the resulting friction may rotate the Pin further into the bone while applying the ANSER Tap. Adjust or replace the ANSER Clavicle Pin if necessary.
- If placing the End Cap is hard or impossible to do, the ANSER Lateral Fixation Device may be damaged or incorrectly positioned. Check that the "legs" are straight and correctly placed in the grooves of the ANSER Lateral Pin. Adjust or replace the ANSER Lateral Fixation Device if necessary.
- Equivalent intramedullary implants have a reported risk of hardware failure. The risk exists that the pin may plastically deform or break due to peak loading. The risk exists also during surgery. Do not exceed in forcing (pushing or rotation) during surgery.
- Proper alignment of the fracture parts before traversing the fracture site with the ANSER Clavicle Pin is of utmost importance. Failure to align the fragments may lead to disastrous complications such as penetration of the subclavian artery or the lung.

Pre-operative pre-cautions
- Please consult the applicable surgical technique for intended use, indications, contraindications, selection and use of a device and check the full labeling for other necessary information.
- Surgical technique brochures may be by requested from the distributor or from BAAT Medical Products B.V. directly.
- Those using brochures published more than two years before the surgical intervention are advised to obtain an updated version.
- BAAT Medical Products B.V. devices can only be used by surgeons who are fully familiar with the surgical technique required and who have been trained to this end.
- The operating surgeon must take care not to use the specialized instruments to exert inappropriate stress on the patient or the implants and must scrupulously comply with any operating procedure described in the surgical technique provided. For example, the forces exerted when repositioning an instrument in-situ must not be excessive as this is likely to cause injury to the patient.
- To reduce the risks of breakage, care must be taken not to distort the implants or nick, hit or score them with when the devices are used near vital organs, nerves or vessels.
- In the presence of flaws on the packaging or expiration of shelf life, the device is considered non-sterile, and must be discarded and disposed.

In-operative pre-cautions
Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-06e1 and ASTM F2119-07. Non-clinical testing of worst case scenario in a 3 Tesla (T) MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

Radio-Frequency-(RF-)induced heating according to ASTM F2182-11a. Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]).

MRI conditioned relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. It is recommended to pay particular attention to the following points:
- It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
- Patients with impaired thermoregulation or temperature sensation should be excluded from MRI scanning procedures.
- Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.
- Using the ventilation system may further contribute to reduce temperature increase in the body.

Potential adverse effects
As with any major surgical procedure, there are risks involved in orthopedic surgery. Potential risks identified with the use of this system include, but are not limited to:

General / procedure related
- Infection (superficial or deep infection)
- Neurological complications (e.g. brachial plexus palsy, nerve palsy, (temporary) paresthesia)
- Cardio/vascular complications (e.g. thromboembolic events)
- Skin / wound related complications (e.g. skin irritation, skin perforation, keloid formation)
- (persistent) Pain
- Poor cosmetic appearance

Device related
- Hardware irritation
- Hardware failure (e.g. plastic deformation, breakage)
- Hardware migration (migration, protrusion, telescoping)
- Loss of fixation
- Delayed union
- Nonunion / malunion
- Refracture
- Reoperation / revision

Disposal
The disposal of this medical product requires no special measures. Be sure to observe all national/local regulations and guidelines when disposing of the packaging material and potentially infectious items.

Material specification
The ANSER Clavicle Pin Set design is fabricated from a titanium alloy (Ti-6Al-4V).

Packaging
Packages for each of the components should be intact upon receipt. To reduce the risk of infection the packaging of all sterile devices must be inspected for flaws in the sterile barrier or expiration of shelf life before opening. In the presence of such a flaw or expiration of shelf life, the device is considered non-sterile, and must be discarded and disposed.

Recommended storage and handling conditions
The products shall be stored and handled with care. The primary, secondary and eventual tertiary packaging shall remain intact at all times.

Sterilization
The ANSER Clavicle Pin Set components are packed and delivered together in one sterile package. Devices which are delivered sterile have been exposed to a minimum of 22.5kGy of gamma radiation. Only sterile products should be placed in the operative field.

Product complaints
Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or BAAT Medical Products B.V. Further, if any of the implanted devices ever malfunctions, (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any ANSER product ever "malfunctioned" and/or may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

End-user information
Further copies of the surgical technique and instruction for use can be requested at BAAT Medical Products B.V.