ANSER Instruments

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INSTRUCTIONS FOR USE

Device description
ANSER Instruments are re-usable surgical instruments dedicated for inserting and extracting the ANSER Clavicle Pin Set, consisting of ANSER Clavicle pin, Lateral Fixation Device and End Cap. The instruments are:

- ANSER Lateral Fixation Device Inserter
- ANSER Tap
- ANSER End Cap Inserter
- ANSER Manual Pin Driver
- ANSER Drill Bit
- ANSER Drill Guide
- ANSER Tray

After every procedure the instruments need to be reprocessed and controlled on functionality. See also reprocessing specifications in this document. The implant is available in one size.

The ANSER instruments must only be used in combination with the ANSER Clavicle implants. The operation procedure is described in detail in the ANSER Clavicle Pin Set surgical technique.

Intended purpose
The ANSER instrument set is intended to facilitate placing and retrieval of the ANSER Clavicle Pin Set.

Indications for use
There are no indications and contra-indications defined for the ANSER instruments. The indications and contra-indications of the related device, the ANSER Clavicle Pin Set, are described in the IFU for the ANSER Clavicle Pin Set.

Instructions for use
The end-user information consists of the instructions for use and surgical technique. The operating procedure is described step by step in the ANSER Clavicle Pin Set surgical technique. Further copies of the instructions for use and surgical technique can be requested at BAAT Medical Products B.V.

Warnings and precautions

INSTRUCTIONS FOR USE The surgeon should strictly follow the recommendations in the surgical technique. All staff involved should be familiar with the surgical procedures associated with intramedullary fixation of mid-shaft clavicle fractures to avoid adversely affecting device performance or surgical outcome.
INSTRUMENTS Only use instruments and accessories listed in the surgical technique to avoid adversely affecting device performance or surgical outcome. The surgical team must verify that the instruments are in good condition and in operating order prior to use during surgery.
POWERED INSTRUMENTS The use of a powered instrument for drilling or driving the clavicle pin in position can damage the anatomical structures or damage the implant or instruments.

Material specification
The ANSER Instrument components are all manufactured from medical grade stainless steel and plastics.

Packaging
Packages for each of the components should be intact upon receipt. Damaged or unintentionally opened sterile packages and products should not be used and should be returned to BAAT Medical Products B.V.

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 reusable instruments are delivered non-sterile. Instruments must be sterilized before use. For specific sterilization instructions, see Recommended reprocessing procedure.

Recommended reprocessing procedure
LIMITATIONS ON REPROCESSING
Repeated processing has minimal effect on the products. End of life is normally determined by wear and damage due to use.

CLEANING AND DISINFECTION
Preparation at point of use
It is recommended that products are reprocessed as soon as is reasonably practical following use.

- Remove excess soil at point of use

Manual pre-cleaning

- Rinse under cold tap water (approx. 18 ˚C) for 10 s
- Sonicate in cleaning solution 0.5% Neodisher MediClean Forte (Dr. Weigert) at 40 ˚C for 5 min
- Treat the outer surface under cold tap water with a nylon brush until visibly clean
- Treat the inner surface/lumina under cold tap water with a bottle brush until visibly clean
- Rinse with cold desalinated water for 10 s

Automated cleaning and disinfection
Use a washer-disinfector according ISO 15883-1/2. Load products so that cannulations and holes can drain. Connect cannulated products to an MIS-rack. Load products so that cannulations and holes can drain. The trays must not be overloaded to guarantee an optimal rinsing. Use the following program:

- 2 min pre-cleaning with cold tap water
- Draining
- 5 min cleaning with 55 ˚C tap water and 0.5% Neodisher MediClean Forte
- Draining
- 3 min rinsing with cold desalinated water
- Draining
- 2 min rinsing with cold desalinated water
- Draining
- 5 min thermal disinfection with 90 ˚C desalinated water (A0-value > 3000).
  Other parameters are acceptable when an A0-value of 3000 is achieved.
- Draining
- Drying, do not exceed 120 °C

MAINTENANCE AND INSPECTION

- The product must be examined for visible damage such as cracks, deformations, wear and corrosion.
  Cutting edges should be free of nicks and present a continuous edge. Discard blunt or damaged instruments.
- Apply a small quantity of surgical grade lubrication oil to hinges and threaded sections.
- Hinged instruments: Check for smooth movement of hinge without excessive “play”.
  Locking (ratchet) mechanisms should be checked for action.
- Check instruments with long slender features (particularly rotating instruments) for distortion.
  Where instruments form part of a larger assembly, check assembly with mating components.

STERILIZATION
Packaging

- Products may be loaded into the dedicated tray or a general-purpose sterilization tray
- Double wrap in sterilization paper according ISO 11607-1, EN 868-2

Steam sterilization
When sterilizing multiple products in one autoclave cycle ensure that the sterilizer’s maximum load is not exceeded.

- Method: Pre-vacuum dynamic-air-removal according EN 13060 / EN 285 / ISO 17665
- Temperature: 132 °C
- Exposure time: 4 minutes

or

- Method: Pre-vacuum dynamic-air-removal according EN 13060 / EN 285 / ISO 17665
- Temperature: 134 °C
- Exposure time: 3 minutes

Drying
The integrity of packaging and containers should be visually checked after removal from the sterilizer. Damaged packaging and containers should be treated as non-conforming product. Drying should be carried out in an environment in which particles and microbial contamination are controlled.

- Drying time: 20 minutes

STORAGE
Products must be stored in a controlled environment.

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.

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
Surgical technique
Copies of the surgical technique can be requested at BAAT Medical Products B.V.

Instructions for use
Copies of the instructions for use can be requested at BAAT Medical Products B.V.