Instructions for use
GANNET Instruments

Doc. n.: 02019BR191030_IFU_GANNET_Instruments_EN

Rev. n.: 2; Date of issue: 28-02-2020

Manufacturer website: www.baatmedical.com

CE 0344

BAAT MEDICAL Products B.V.
F. Hazemeijerstraat 800
7555 RJ Hengelo, The Netherlands
Telephone: +31 (0)88 565 66 00

Device description

GANNET are re-usable surgical instruments dedicated for inserting and extracting GANNET implants; nail, blade and screws.

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 different sizes. To decide on the correct length the instrument set contains dedicated measurement instruments, the GANNET measuring guide and the GANNET introducer are included in the set.

The GANNET instruments must only be used in combination with the GANNET implants. The operating procedure is described in detail the implants and instruments in the surgical technique.

Intended purpose

The GANNET® instrument set is intended to facilitate placing and retrieval of the Gannet implant.

There are no indications and contra indications defined for the Gannet instruments. The indications and contra-indications of the related device: The GANNET® implants are described in the IFU for the GANNET Implants.

Instructions for use

The operating procedure is described step by step in the Surgical Technique available at BAAT Medical Products B.V.

Warnings and pre-cautions

- 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 the femoral neck fracture fixation technique 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.
- Packaging integrity: Before use of the Gannet implants and instruments check the secondary packaging, labelling and sterile primary packaging are intact. The sterile packaging should be free of cracks, holes, tears and any other damage. Use of an Implant or instrument from a damaged
- Powered instruments: The use of an powered instrument for drilling or driving a bone screw in position can damage the anatomical structures or damage the implant or instruments.

Material specification

The GANNET instruments components are all manufactured from medical grade stainless steel and plastics according ISO16061

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 (A_0-value > 3000). Other parameters are acceptable when an A_0-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.
- For maintanance of the Stepped drill and introducer see assembly and disassembly instructions

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
The products shall be stored and handled with care. The products shall be stored and handled in an environment that is:
dry and clean, protected from direct sunlight, not in close proximity of heat sources.

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.

The above-mentioned instructions are validated by the legal manufacturer as being CAPABLE of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the reprocessing as actually performed, using equipment, materials, and personnel in the reprocessing facility, achieves the desired result. This normally requires validation and routine monitoring of the process. Any deviation by the re-processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

Product complaints

If the GANNET implant 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, instruction for use, assembly and disassembly instructions can be requested at BAAT Medical Products B.V.