

Instructions for use

Gannet® Instruments

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Manufacturer website: www.baatmedical.com



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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® instruments must only be used in combination with the Gannet® implants. The operating procedure is described in detail in the Gannet® 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.

In case of fragments of the Gannet® instruments, localization of fragments can be performed using imaging techniques.

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.
- 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 packaging can lead to an untraceable product or infection.
- 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 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. 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

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.
- For maintenance 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.

serious incident that has occurred in relation to the device should also be reported to the competent authority of the Member State in which the user and/or patient is established.

End-user information

Surgical techniques

Copies of the surgical technique can be requested at BAAT Medical Products BV.

Instructions for use

Further copies of the Instruction for use can be requested BAAT Medical Products BV.

Explanation of non-harmonized symbols used in end-user information

The following symbols are not described in harmonized standards or Common Specifications and therefore their purpose is described below.



Manufacturer



Date of manufacture



Catalogue Number



Do not use if package is damaged



Batch Code



Keep dry



Quantity



Consult instructions for use



Non-sterile



Caution

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 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. Any