Instructions for use ENGLISH

Gannet implants

Doc. Nr.: 02019BR191021_IFU_GANNET_Implants_EN
Rev. nr.: 4
Date of issue: 28-02-2022

CE 0344

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Device description

The Gannet® is a single use, class IIb implant, that consists out of a blade, a SHS barrel plate and two cortical bone screws. Fixation of the fracture is done by centrally positioning the blade in the femoral head under an angle of 135 degrees. The blade can slide within the plate. The plate is fixated on the lateral side of the femur with two bone screws. The blade is a pin with two lateral “wings” at the end for rotational stable fixation of the femur head. The blade will be secured in the femur head by two impaction anchors, which are located at the end of the pin. Dynamization of the fracture is obtained by the sliding fixation from the blade in the plate.
The GANNET implants are implanted with the dedicated GANNET instrument set and standard surgical instruments available in the OR such as X-ray screening, as described in the surgical technique.

Clinical Benefits

- Surgical treatment of hip fractures compared to conservative management: In general, 30-day and 1-year mortalities are higher in conservatively treated patients compared to surgical treatment (van de Ree et al., 2017)
- SHS compared to other surgical treatments lowers the amount of blood loss during surgery, has a shorter operating time and a low infection rate (Liang, Yang, Lin, & Fan, 2015)
- The Gannet provides the stability necessary for the revascularisation and union of the femoral neck fracture.

Intended purpose

Treat stable extracapsular intertrochanteric (pertrochanteric) femur fractures and intracapsular femoral neck fractures by trained surgeons in a hospital environment.

Indications for use

- Stable adult intertrochanteric (pertrochanteric) femur fractures; classified as 31-A1 and 31-A2.1 by the AO/OTA system
- Displaced and un-displaced adult femoral neck fractures

(Relative) Contra-indications

- Local infection or inflammation
- Compromised bone stock
- Unstable intertrochanteric (pertrochanteric) femur fractures and/or fractures with multiple fragments, that cannot be classified as stable adult two (2) part intertrochanteric (pertrochanteric) femur fractures
- Material sensitivity
- Morbid obesity
- Inadequate local tissue coverage
- Any mental or neuromuscular disorder, which would create an unacceptable risk of fixation failure or complications in postoperative care
- Other medical or surgical conditions, which would preclude the potential benefit of surgery

Instructions for use

The operating procedure is described step by step in the GANNET Surgical Technique available 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 the femoral neck fracture fixation technique to avoid adversely affecting device performance or surgical outcome.
- Patient selection: Appropriate patient selection is critical to the surgical outcome. Only patients who satisfy the indications AND who do not have any of the contraindications should be considered for trauma surgery using the Gannet implants and instruments to avoid adversely affecting device performance or surgical outcome.
- Patient education: Preoperative instructions to the patient are essential. The patient should be made aware of the limitations and potential adverse effects of the surgery. The patient should be instructed to limit the postoperative activity as this will reduce the risk of bent, broken and/or loose implant components. The patient must be made aware that implant components may bend, break and/or loosen, even though restrictions in activity are followed.
- Single use only: The Gannet implants are provided as single use implants only, and are not to be reused, resterilized or reimplanted in any situation as this might adversely affect device performance and/or increase risk of infection.
- Single activation only: The wings of the Gannet Blade are single use and should not be activated prior to implantation.
- 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.

- Use-by date and sterility: Before using the Gannet implants check the use-by date (YYYY/MM/DD) and sterility marker on the packaging. Do not use the implant after its expiration date or if the marker does not indicate it is irradiated, this can lead to infection.
- 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.
- Fracture reduction: Appropriate reduction is important for the fusion and vascularization of the fracture.
- Size selection: The Gannet implant is available in a wide variety of sizes to ensure appropriate sizing of the implanted components. Correct size selection is critical to the surgical outcome. An under- or oversized implant can lead to premature failure of the implant.
- Implant placement: The Gannet has wings and anchors to maximize primary stability. Adequate implant positioning is critical; an improperly placed implant can adversely affect device performance or surgical outcome.
- Implant handling: The implants should be handled appropriately to protect them from unintentional damage. Avoid scratching or damaging the implant at any time (specifically during attachment of the implant to the inserter and implant placement), as this may lead to premature failure of the implant. Do not use damaged implants.
- Imaging: Confirm by means of the appropriate imaging technique (e.g., fluoroscopy) the correct position and/or direction of the instrument or implant. This is important for correct and safe application of the instrument or implant and prevent harm to patient and/or user.
- Powered instruments: The use of a powered instrument for drilling or driving a bone screw in position can damage the anatomical structures or damage the implant or instruments.
- MR safety: The effects of MR on Gannet implant have not been tested. Based upon study of scientific literature it can be concluded that a majority of patients with orthopedic implants have been imaged with MR without incident with respect to implant displacement and heating. The Gannet implant will distort (imaging artifacts) the image in vicinity of the implant.

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:

- Loosening, breakage, bending or cracking of the device
- Loss of fracture fixation
- Implant migration or cut-out
- Varus collapse
- Loss of reduction
- Nonunion or delayed union
- Femoral head necrosis (avascular necrosis)
- Shortening of the effected bone/fracture site
- Early or late, superficial or deep infections
- Inflammatory reactions
- Intra-operative or periprosthetic femur fractures
- Metal sensitivity or allergic reactions to foreign body

- Neurological problems as a result of surgical trauma
- Vascular problems as a result of surgery (including hemorrhage, hematoma, thrombosis, pulmonary embolism)

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 Gannet® implant 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. 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 Gannet® implant components are each packed individually and delivered in a sterile package. The sterile delivered devices have been exposed to a minimum of 25kGy of gamma radiation from a cobalt 60 source. Only sterile products should be placed in the operative field.

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..