Instructions for use

GANNET® Implants and Instruments

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Caution: Federal law restricts this device to sale by or on the order of a physician

Device description

The GANNET® implant is a device for surgical fixation of femoral neck, trochanteric fractures and stable subtrochanteric fractures. The system is comprised of three main components: a blade for stable fixation within the femoral head, a barreled side-plate that facilitates controlled sliding and dynamization, and cortical bone screws for secure attachment to the femur. Together, these components are used for the extramedullary fracture stabilization, supporting both mechanical stability and bone healing. The implants are delivered sterile to the end-user. The implants are meant for single use.

The GANNET® is implanted with dedicated instruments. The instruments are stored in 2 trays for transport, cleaning and sterilization purposes: one for implantation and one for extraction. The instruments are delivered non-sterile to the end-user. The instruments are reusable. After every procedure the instruments need to be reprocessed and inspected on functionality. See recommended reprocessing procedure in this document.

Intended use

Fracture fixation in the proximal femur

Indications for use

The GANNET® implant is intended for use in fracture fixation in the proximal femur in adults.

The GANNET® implant is indicated for use in:

- Intracapsular and extracapsular fractures of the femoral neck
- Trochanteric fractures of the proximal femur
- Stable subtrochanteric fractures of the proximal femur

Contraindications

- Local infection or inflammation
- Unstable intertrochanteric femur fractures and/or fractures with multiple fragments, that cannot be classified as stable two (2) part intertrochanteric femur fractures
- Metastatic bone disease at the implant site
- Pathological fracture due to primary bone tumor
- 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 Surgical Technique available at the Manufacturer.

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.
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 anchors of the Gannet Blade are single use and should not be activated more than once after implantation.
INSTRUMENTS	Only use instruments and accessories listed in the surgical technique to avoid adversely affecting device performance or surgical outcome.
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 introducer and during 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 an 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

- Loosening, breakage, bending or cracking of the device
- Loss of fracture fixation
- Implant migration or cut-out
- Varus collapse
- Loss of reduction
- Non-union 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)

Material specification

The GANNET® implant components are all manufactured from medical grade stainless steel.

The GANNET® instruments components are all manufactured from medical grade stainless steel and polymers according ASTM F899.

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 the Distributor.

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.

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/sharp items.

Sterilization

The GANNET® implant components are packed individually and delivered in a sterile package. The sterile delivered devices have been exposed to a minimum of 25kGy of gamma radiation.

The GANNET® 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
- Thoroughly treat the outer surface under cold tap water with a nylon brush until visibly clean
- Thoroughly treat the inner surface/lumina under cold tap water with a bottle brush until visibly clean
- Rinse with cold critical 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 critical water
- Draining
- 2 min rinsing with cold critical water
- Draining
- 5 min thermal disinfection with 90 °C critical 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 inspected for any remaining soil or other contaminants. Repeat the cleaning process if any is found.
- 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 an FDA-cleared sterilization wrap according to 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 to ANSI/AAMI ST79 / ISO 17665
- Temperature: 132 °C (270 °F)
- Exposure time: 4 minutes
- Drying time: 20 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 products. Drying should be carried out in an environment in which particles and microbial contamination are controlled.

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.

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 device ever "malfunctioned" and/or may have caused or contributed to the death or serious injury of a patient, the manufacturer should be notified immediately by telephone or written correspondence. When filing a complaint, please provide the component(s) name and UDI(s), your name and address, the nature of the complaint and notification of whether a written report from the manufacturer is requested. Any 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

The most recent end-user information can be downloaded from the website of the Manufacturer, including:

- Instructions for use
- Surgical technique
- Instruments assembly and disassembly instructions

Further copies of end-user information can also be the requested at the Manufacturer.

MRI safety information

The GANNET implant has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the GANNET implant in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

Explanation symbols used in end-user information

The purpose of the symbols used is described below.

	Manufacturer		Quantity
	Catalogue number		Double sterile barrier system
	Batch code		Do not resterilize
	Unique Device Identifier		Do not use if package is damaged
	Use-by date		Do not re-use
	Consult instructions for use		Keep dry
	Caution		Rx only
	Country of manufacture		Sterilized using irradiation
	Date of manufacture		Non-sterile