Surgical Technique

GANNET

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1. Introduction

1.1. Product 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 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.

1.2. Indications

The GANNET® implant is intended for use in fracture fixation in the adult population in:

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

1.3. 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.

1.4. Sterility

The implants are delivered sterile to the end-user. The implants are meant for single use. Do not re-use or resterilize the implants in this system, as adequate mechanical performance, biocompatibility, and sterility cannot be guaranteed.

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.

1.5. Material specification

The implants are manufactured from implant grade stainless steel AISI 316LVM (ASTM F138).

2. Surgical technique

Procedure overview

1. The patient is positioned on the fracture table. Gentle anatomical reduction of the fracture.
2. Make a ±8 cm lateral skin incision.
3. Insert the Guide Pin in the centre/centre position of the femoral head to a depth of 5 mm subchondrally, using the Aiming Device and the image intensifier.
4. Next, determine the length of the Blade by using the Measuring Gauge. After measuring it is advised to advance the guide pin further up to the subchondral cortex to stabilize de femoral head during insertion and also to prevent pulling out the guide pin on removal of the drill.
5. Insert the Stepped Drill over the Guide Pin and drill to a depth of 5 mm subchondrally using the image intensifier.
6. Insert the Positioning Device over the Guide Pin until the chisel is located on the lateral cortex. After releasing the chisel by turning the nut, tap on the Positioning Device to shape the hole for the implant. Remove the Guide Pin.
7. Insert the Bone Jack and turn the handle to prepare the space for the anchor placement.
8. Assemble the Blade and Plate. The wings of the Blade are single use. Do not activate using the Screw and Anchor Driver prior to implantation. Lock the Introducer onto the assembled Blade and Plate.
9. Place the mounted Blade and Plate in the pre-shaped hole and gently tap with a hammer. After the side plate is seated along the lateral cortex, the introducer is released and the locking blade further tapped in the femoral head up to 5 mm subchondrally using the image intensifier.
10. The Plate can be fully seated by using the Impactor with the correct tip on either the most proximal cortical screw hole or the Blade.
11. The Plate is fixed to the proximal femur with Self-Tapping Cortical Screws.
12. By turning the setscrew in the shaft of the Blade in clockwise direction, the impaction anchors are expanded and the Blade is locked within the femoral head.
13. Ensure the central positioning of the Blade by antero-posterior and axial views. Close the wound.

See the description of each individual step for more information.

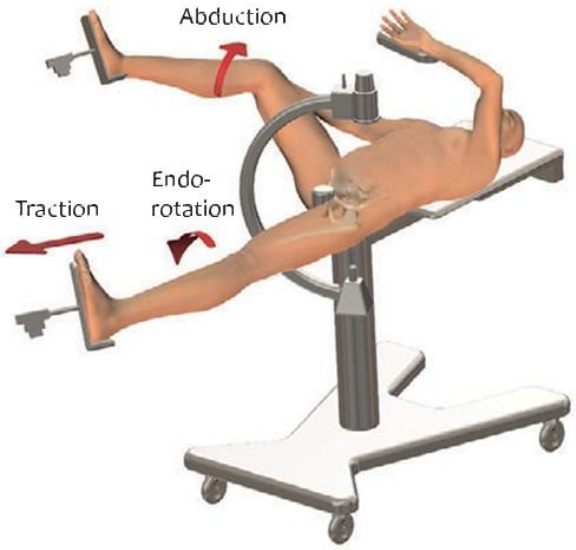
Overview of implants

Blade	Plate	Self-Tapping Cortical Screws
80 – 125 mm	2, 3 and 4 holes	Ø4,5x34 to 50mm
		

For detailed information and overview of the instruments see chapter *Catalogue*.

Step 1: Fracture Reduction

Anatomical reduction is the single most important step in this surgical procedure. No osteosynthesis will overcome any inadequate fracture reduction. Appropriate reduction is important for the fusion and vascularization of the fracture.



The patient is positioned supine on the fracture table with the fractured hip extended, adducted and slightly endorotated until the patella is in a position parallel to the floor.

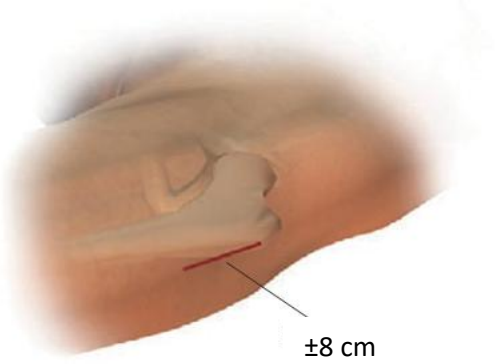
The contralateral leg is abducted. The fracture is then carefully reduced by gentle longitudinal traction using an image intensifier in the antero-posterior and axial planes.

An anatomical fracture is strived for. Distraction of the fracture by undue traction should be prevented at all costs.

After the fracture reduction, the anteversion angle of the femoral neck is assessed by axial imaging.

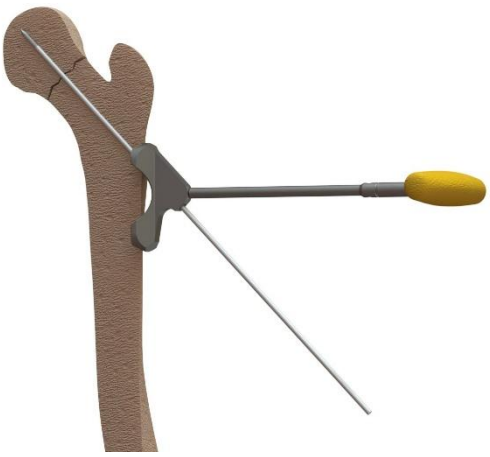
Step 2: Surgical exposure

A lateral skin incision of ±8 cm is made downwards from the lower end of the greater trochanter. The subcutis and the fascia lata are split in line with the skin incision. The vastus lateralis muscle is split longitudinally at its posterior border, and reflected upwards.



Step 3: Guide Pin insertion

To start with, the Guide Pin should be prechecked for its straightness. Roll the Guide Pin on a flat surface. Also check if the Guide Pin, including the threaded tip, slides smoothly through the cannulated Stepped Drill.



The Guide Pin should be positioned in the center/center position of the femoral head. The 3 mm Guide Pin is to be inserted using the Angled Guide. The Guide Pin must be inserted at the tip of lesser trochanter in the antero-posterior view.

The self-centering Angled Guide is positioned firmly on the lateral cortex in the anteversion plane, defined during the anatomical fracture.

The Guide Pin is inserted using an electric drill under image intensification. The Guide Pin should be positioned in the center of the femoral head in the antero-posterior and axial view; if not, the Guide Pin must be re-inserted.

After the Guide Pin has been positioned in the center of the femoral head, it is advanced until the tip is located at the planned depth in the femoral head: 5 mm subchondral.

NOTE: As the insertion of the Blade will not produce any rotational torque it is not necessary to introduce an extra 'anti-rotational' Guide Pin.

Step 4: Length determination

The reaming depth, as well as the length of the Blade, is determined by placing the Measuring Gauge over the protruding part of the Guide Pin all the way down to the lateral cortex.



The measured size is the actual length of the Blade. If the measured size is in between two implant sizes, always choose the longer Blade length.

After determining the implant size, it is advised to advance the Guide Pin further into the subchondral bone of the femoral head up to the subchondral cortex.

This is to prevent dislodgment of the Guide Pin during the later drilling procedure. Furthermore, this prevents tilting of the femoral head during the introduction of the Blade into the femoral head.

Step 5: Drilling

The cannulated Stepped Drill is set to the measured depth. The Stepped Drill is inserted over the Guide Pin, then the femoral neck and head are pre-drilled to the desired depth until the conical end-stop just touches the lateral cortex of the femur. The conical end-stop will prevent from drilling too deep.



It is strongly advised that at least the last part of the drilling is performed under image intensification. Remove the drill. The Guide Pin is left in place to assist the shaping of the hole.

Step 6: Shaping the pre-drilled hole with the Positioning Device



Make sure that the chisel is completely secured into the shaft by pulling the handle, before placing the Positioning Device over the Guide Pin. Secure this position by turning the locking ring. Then, place the Positioning Device over the Guide Pin until the chisel is located on the cortex and the base plate along the longitudinal axis of the femur.

Release the chisel by turning the locking ring. Tap on the Positioning Device to introduce the chisel into the femur and shape the predrilled hole to the implant. Continue until the chisel is fully inserted.

Retract the chisel and Positioning Device from the femur. Remove the Guide Pin.

Step 7: Preparing anchor space



If the cancellous bone is hard and it can be assumed that the anchors cannot be easily deployed, use the Bone Jack to prepare the bone. Insert the Bone Jack until the end of the predrilled hole.

To deploy the spacers turn the handle clockwise until the end point is reach. The Bone Jack may shift outward slightly. Verify the deployed anchors using image intensification. Retract the spacers by turning counter-clockwise and remove the Bone Jack.

Step 8: Introducer and Blade and Plate assembly



Based on the determined length the correct sized Blade is chosen. Place the Plate over the shaft of the Blade.

Position the Introducer onto the selected Blade. Screw the Introducer onto the Blade by turning it clockwise, do not over tighten.

The assembled Blade and Plate should now be locked on the Introducer.

Release the knob of the Introducer and slide it fully forward. The Introducer is now adjusted to the length of chosen Blade. Finally, lock the assembly again by turning the knob.

Step 9: Blade and Plate one-step insertion



Place the Introducer and the mounted Blade and Plate in the pre-drilled lateral cortex in the slots created by the Positioning Device. The Plate should be positioned parallel to the axis of the femur along the lateral cortex.

Gently tap on the Introducer until the Plate is seated along the lateral cortex. Release the Introducer by rotating the knob. Gently tap the Introducer until it reaches the end stop. The last part of the insertion is performed under image intensification.

Now, the Blade should be inserted 5 mm subchondral. Remove the Introducer by turning the thread counter clockwise.

Step 10: Plate and Blade impaction

If the Plate does not fully abuts the femur, the Impactor should be used. Place the correct black plastic tip of the Impactor in the upper cortical screw hole of the Plate and use a hammer to tap the implant in place.

The Impactor can also be used to gently tap the Blade as far as 5 mm subchondral. Use the correct tip for Blade impaction.



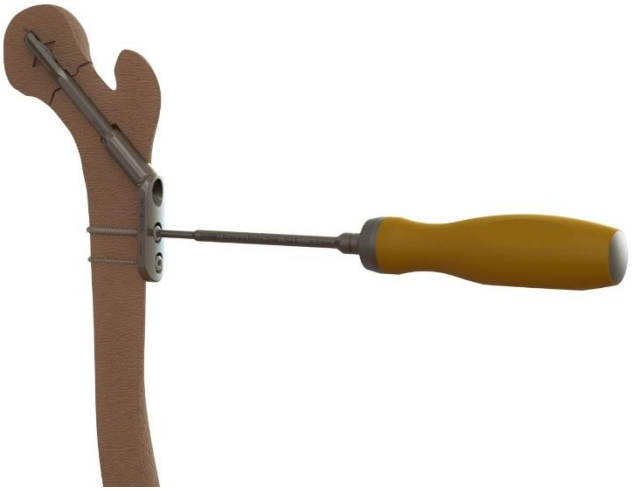


Step 11: Plate fixation

The Plate is fixed to the femur by using Self-Tapping Cortical Screws. Pre-drill bicortical by means of the 3.2 mm cortical Drill and Drill Guide.

Use the Depth Gauge Cortical Screws to determine the correct length of the Self-Tapping Cortical Screws. As an alternative to using a Screw and Anchor Driver, the Screw Driver Insert may be used in combination with an electric drill to place the Self-Tapping Cortical Screws.



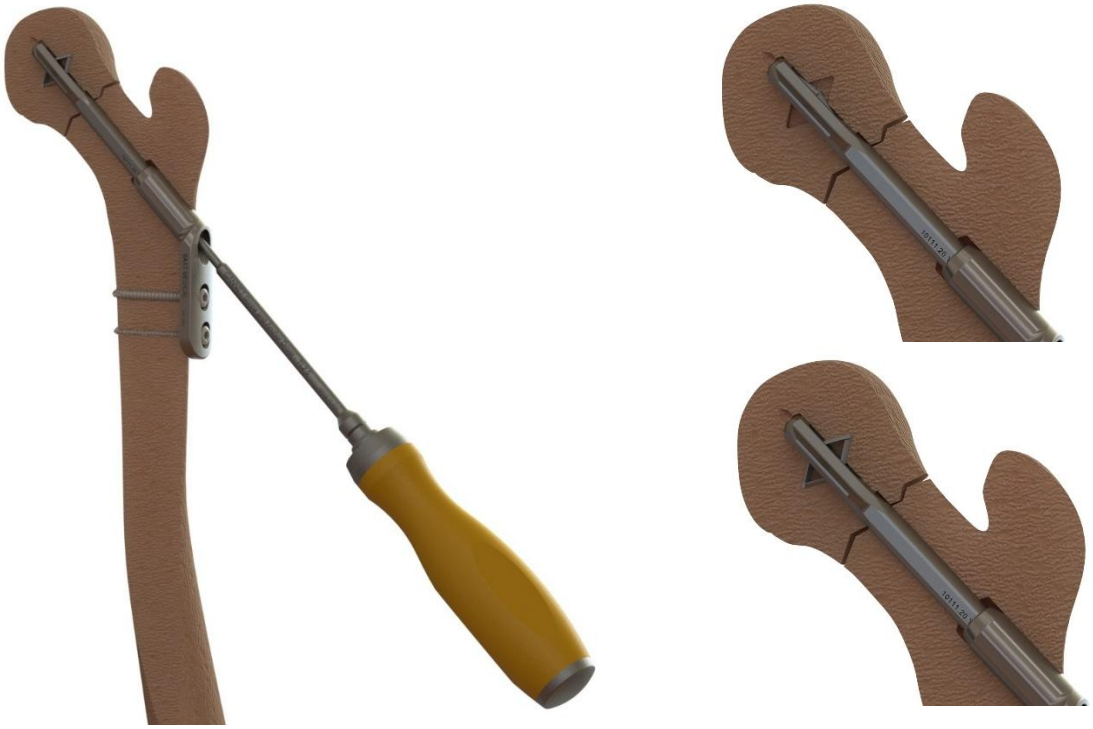


Step 12: Impaction Anchor deployment

Insert the Screw and Anchor Driver with torque limiter in the Blade shaft. Deploy the Impaction Anchors by turning the internal setscrew clockwise for about 9 full turns until the end stop is reached.

Make sure the Impaction Anchors are fully deployed with an antero-posterior view using image intensification. The anchors of the Gannet Blade are single use and should not be activated more than once after implantation.

NOTE: When the Impaction Anchors are not fully deployed because the torque limitation is reached, make sure to remove the implant with the Extractor as described in Chapter 3 and prepare the anchor space with the Bone Jack.



Step 13: Final check and wound closure

Ensure the central positioning of the Blade by antero-posterior and axial view. Store the representative X-ray views. Close the fascia lata, subcutaneous fascia and skin. Leave a drain if necessary.

3. Removal of implant (if necessary)

Procedure overview

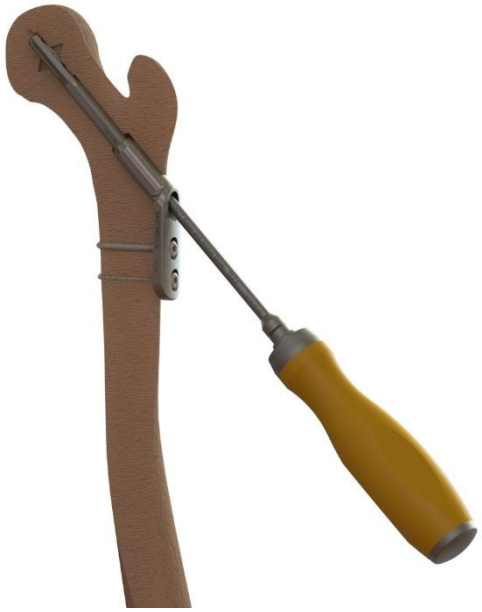
1. Approach - Make a ±8 cm lateral skin incision.
2. Retract the two Impaction Anchors using a Screw and Anchor Driver.
3. Remove the Self-Tapping Cortical Screws using a Screw and Anchor Driver.
4. Extract the Blade together with the mounted Plate by means of the Extractor mounted on the Blade.
5. Close the wound in three layers.

Step 1: Approach

A lateral skin incision of ±8 cm is made downwards from the lower end of the greater trochanter. The subcutis and the fascia lata are split in line with the skin incision. The vastus lateralis muscle is split longitudinally at its posterior border, and reflected upwards. Remove the tissue from the end of the Plate.

Step 2: Retraction of Impaction Anchors

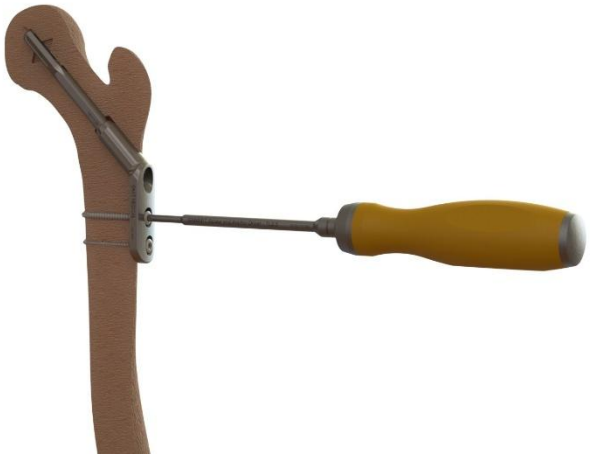
Using a Screw and Anchor Driver, retract the Impaction Anchors while exerting axial pressure on the instrument. Retraction may be checked by image intensifier to ensure that the Impaction Anchors are fully retracted.



Step 3: Removal of Self-Tapping Cortical Screws

Remove the Self-Tapping Cortical Screws with a Screw and Anchor Driver. As an alternative to using a Screw and Anchor Driver, the Screw Driver Insert may be used in combination with an electric drill to remove the Self-Tapping Cortical Screws.

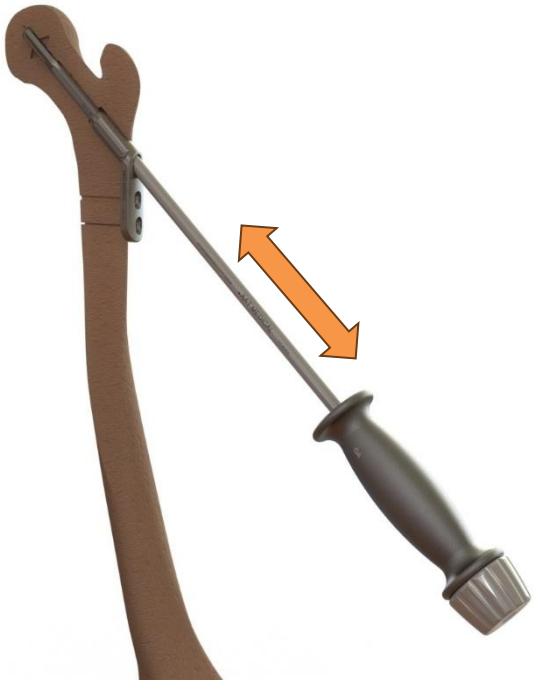
Free the Plate from overgrowing tissue/bone.



Step 4: Extraction of Blade and Plate

Slide the Extraction Slaphammer over the Extraction Slaphammer Rod. Subsequently, position the Extractor in the shaft of the Blade, facilitated by the tip of the Extractor. Screw the Extractor onto the Blade by turning it clockwise and do not over tighten.

Remove the Blade and mounted Plate by using the sliding handle of the Extractor to tap the implant out of the femur.



Step 5: Final check and wound closure

Wound closure in three layers

4. Catalogue

GANNET Blade

Part number	Description	Image
10111.20.080	GANNET Blade, length 80mm	
10111.20.085	GANNET Blade, length 85mm	
10111.20.090	GANNET Blade, length 90mm	
10111.20.095	GANNET Blade, length 95mm	
10111.20.100	GANNET Blade, length 100mm	
10111.20.105	GANNET Blade, length 105mm	
10111.20.110	GANNET Blade, length 110mm	
10111.20.115	GANNET Blade, length 115mm	
10111.20.120	GANNET Blade, length 120mm	
10111.20.125	GANNET Blade, length 125mm	

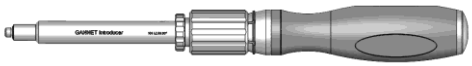
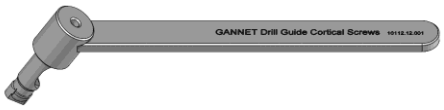
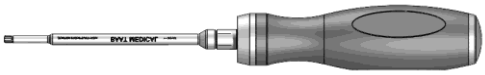
GANNET Plate

Part number	Description	Image
10111.30.002	GANNET 135° 2-holes Plate	
10111.30.003	GANNET 135° 3-holes Plate	
10111.30.004	GANNET 135° 4-holes Plate	

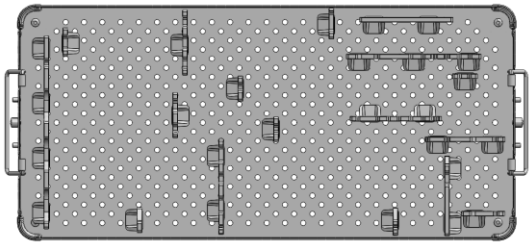
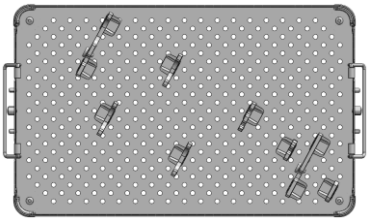
GANNET Self-Tapping Cortical Screw

Part number	Description	Image
10111.40.034	GANNET Self-Tapping Cortical Screw 4,5x34mm	
10111.40.036	GANNET Self-Tapping Cortical Screw 4,5x36mm	
10111.40.038	GANNET Self-Tapping Cortical Screw 4,5x38mm	
10111.40.040	GANNET Self-Tapping Cortical Screw 4,5x40mm	
10111.40.042	GANNET Self-Tapping Cortical Screw 4,5x42mm	
10111.40.044	GANNET Self-Tapping Cortical Screw 4,5x44mm	
10111.40.046	GANNET Self-Tapping Cortical Screw 4,5x46mm	
10111.40.048	GANNET Self-Tapping Cortical Screw 4,5x48mm	
10111.40.050	GANNET Self-Tapping Cortical Screw 4,5x50mm	

GANNET Instruments

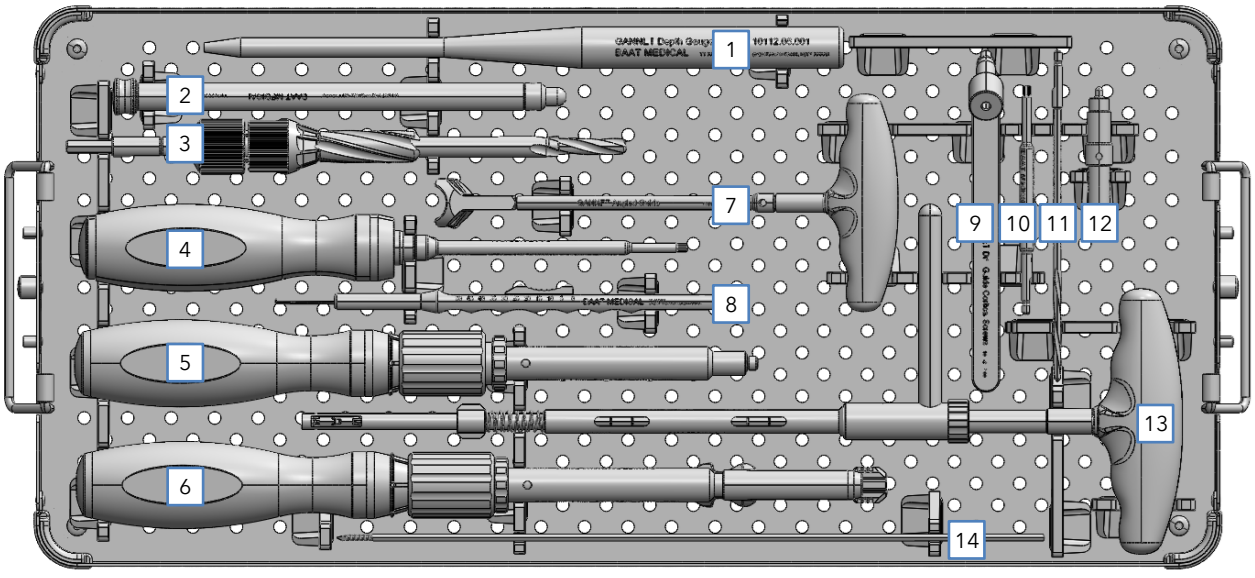
Part number	Description	Image
10112.01.001	GANNET Guide wire 3mm	
10112.02.001	GANNET Angled Guide	
10112.06.001	GANNET Depth Gauge Blade	
10112.07.001	GANNET Stepped Drill	
10112.08.001	GANNET Positioning Device	
10112.09.001	GANNET Introducer	
10112.10.001	GANNET Bone Jack	
10112.11.001	GANNET Plate Impactor	
10112.11.002	GANNET Plate Impactor Tip	
10112.11.003	GANNET Blade Impactor Tip	
10112.12.001	GANNET Drill Guide Cortical Screws	
10112.13.001	GANNET Drill Cortical Screws	
10112.14.001	GANNET Depth Gauge Cortical Screws	
10112.15.001	GANNET Screw and Anchor Driver – standard	
10112.15.002	GANNET Screw and Anchor Driver – ratchet	
10112.15.003	GANNET Screw and Anchor Driver - TL2,5	
10112.16.001	GANNET Screw Driver Bit T20	
10112.17.001	GANNET Extraction Slaphammer	
10112.18.001	GANNET Extraction Slaphammer Rod	

GANNET Trays

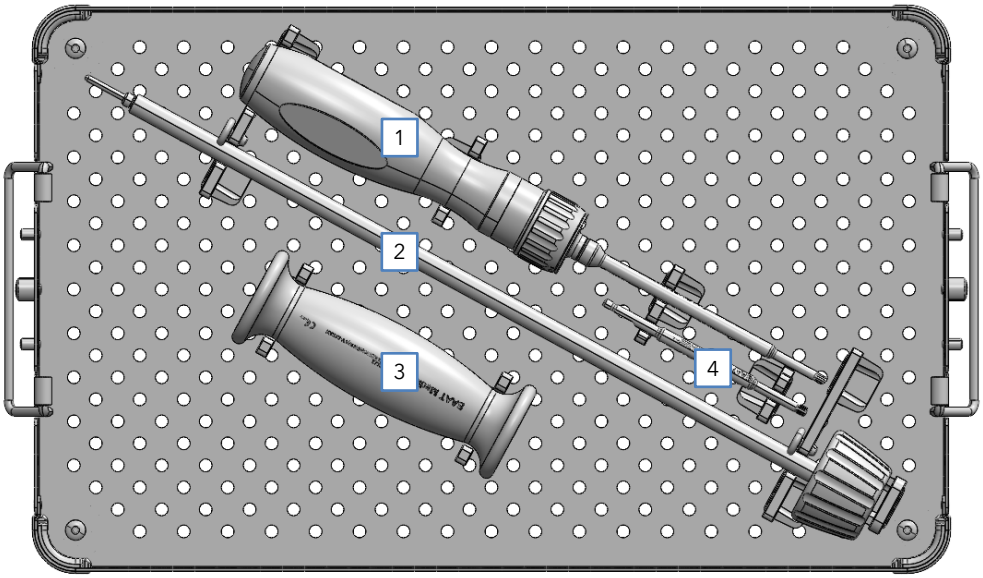
Part number	Description	Image
10112.19.001	GANNET Tray	
10112.20.001	GANNET Extraction Tray	

GANNET Tray Lay-out

GANNET Tray	
1. GANNET Depth Gauge Blade 2. GANNET Plate Impactor 3. GANNET Stepped Drill 4. GANNET Screw and Anchor Driver - TL2 5. GANNET Introducer 6. GANNET Positioning Device 7. GANNET Angled Guide	8. GANNET Depth Gauge Cortical Screws 9. GANNET Drill Guide Cortical Screws 10. GANNET Screw Driver Bit T20 11. GANNET Drill Cortical Screws 12. GANNET Blade Impactor Tip 13. GANNET Bone Jack 14. GANNET Guide wire 3mm



GANNET Extraction Tray	
1. GANNET Screw and Anchor Driver – ratchet 2. GANNET Extraction Slaphammer Rod	3. GANNET Extraction Slaphammer 4. GANNET Screw Driver Bit T20



5. Warnings

5.1. Warnings and precautions

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.

5.2. 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
- 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)



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