BAAT MEDICAL Products BV
F. Hazemeijerstraat 800
7555 RJ Hengelo
The Netherlands

Field Safety Notice

GANNET implants incorrect IFU/ST

Type of action: rework of device regarding IFU

02019BR220301
GANNET Implants
Revision 1
02 March 2022

Dear health care professional,

The purpose of this Field Safety Notice is to inform you of an issue with the following product:

Commercial name of the affected product: GANNET Implants
FSCA-identifier: 02019BR220301_FSCA Gannet_rev1

Details on affected devices

Manufacturer: BAAT Medical B.V. (EU Single Registration Number NL-MF-000001569)
GANNET Implants
Variants, lot nrs. March 2020 – current:

REF	UDI-DI (GTIN)	Description	Relevant lot nrs.
2019.GA.080S	08719324251006	GANNET Blade 80mm	-
2019.GA.085S	08719324251013	GANNET Blade 85mm	A9921-01-S2, B4230-01-S2, B9448-01-S2, B9448-02-S2, B9448-03, C3793-02-S2, C3793-05, C4488-02, C4488-04, C4700-04, C5282-04
2019.GA.090S	08719324251020	GANNET Blade 90mm	A9897-01-S2, B4231-01-S2, B9454-01-S2, B9454-02-S2, B9454-03, C3794-02-S2, C3794-05, C3795-02-S2, C4489-02, C4489-04, C4701-02, C4701-04
2019.GA.095S	08719324251037	GANNET Blade 95mm	B4240-01-S2, B4240-02, B9451-01-S2, B9451-02-S2, B9451-03, C3801-02-S2, C3801-05, C3802-02-S2, C4491-02, C4491-04, C4702, C4702-02, C4702-04
2019.GA.100S	08719324251044	GANNET Blade 100mm	B4239-01-S2, B8712-01-S2, B8712-02, B9455-01-S2, B9455-02, C3803-02-S2, C3804-02-S2, C4492, C4492-02, C4492-04, C4703, C4703-02, D3341
2019.GA.105S	08719324251051	GANNET Blade 105mm	B4241-01-S2, B4241-02, B9449-01-S2, B9449-02-S2, B9449-05, C3805-02-S2, C3805-03, C3810-02-S2, C4493-02, C4493-04, C4704, C4704-02, C4704-04, D3332
2019.GA.110S	08719324251068	GANNET Blade 110mm	B4244-01-S2, B9452-01-S2, B9452-02-S2, C3808-02-S2, C3809-02-S2, C4494-04, C4714-02, C4714-04
2019.GA.115S	08719324251075	GANNET Blade 115mm	B4235-01-S2, B9456-01-S2, C3807-02-S2, C3807-05, C4496-04, C4716-04
2019.GA.120S	08719324251082	GANNET Blade 120mm	B4233-01-S2, B9453-01-S2, B9453-02-S2, B9453-05-S2, C3806-02-S2, C4705-04
2019.GA.125S	08719324251099	GANNET Blade 125mm	-

2019.GP.135S	08719324251105	GANNET 135° 2-hole Plate	00924121, 18-00005-02, 18-00005-05, 18-00005-S2, 18-00023-S2, 18-00051-02, 18-00051-05, 18-00128-02, 18-00128-04, 19-00066-01, 19-00087, 19-00087-02
2019.TP.135S	08719324251112	GANNET 135° 3-hole Plate	18-00020-01
2019.FP.135S	08719324251129	GANNET 135° 4-hole Plate	-
2019.SC.034S	08719425464961	GANNET Self-Tapping Cortical screw 4,5x34mm	02019AAO-34-S2, 02019BAL-34-S2, 02019BAV-34-S2, 02019BBA-34-S2, 18-00006-01-S2, 18-00006-05, 18-00006-06-S2, 18-00039-01-S2, 18-00039-04-S2, 18-00039-05, 18-00039-06-S2, 18-00053-03-S2, 18-00053-04-S2, 18-00053-05
2019.SC.036S	08719425464978	GANNET Self-Tapping Cortical screw 4,5x36mm	02019BAL-36-S2, 02019BBA-36-S2, 18-00007-05, 18-00007-06-S2, 18-00040-05, 18-00040-06-S2, 18-00054-04, 18-00054-05, 19-00137-01
2019.SC.038S	08719425464985	GANNET Self-Tapping Cortical screw 4,5x38mm	02019BAL-38-S2, 02019BBA-38-S2, 18-00008-02, 18-00008-05, 18-00041-03, 18-00041-04-S2, 18-00041-05, 18-00055-04-S2, 18-00055-05, 18-00055-06, 19-00138-01, 19-00138-02, 21-00070
2019.SC.040S	08719425464992	GANNET Self-Tapping Cortical screw 4,5x40mm	02019BAL-40-S2, 02019BBA-40-S2, 18-00009-01-S2, 18-00009-06-S2, 18-00042-01-S2, 18-00042-02, 18-00042-05, 18-00056-04, 18-00056-04-S2, 18-00056-05, 18-00056-06, 19-00139-01, 21-00015
2019.SC.042S	08719425465005	GANNET Self-Tapping Cortical screw 4,5x42mm	02019BAL-42-S2, 02019BAV-42-S2, 02019BBA-42-S2, 18-00010-01-S2, 18-00010-06-S2, 18-00043-03, 18-00043-04-S2, 18-00043-05, 18-00057-04-S2, 18-00057-05, 18-00057-06, 19-00140-01, 19-00140-02, 21-00072
2019.SC.044S	08719425465012	GANNET Self-Tapping Cortical screw 4,5x44mm	02019BAL-44-S2, 18-00011-01-S2, 18-00011-05, 18-00011-06-S2, 18-00044-01-S2, 18-00044-03, 18-00044-04-S2, 18-00044-05, 18-00058-04-S2, 18-00058-05, 18-00058-06, 19-00141-01, 21-00073
2019.SC.046S	08719425465029	GANNET Self-Tapping Cortical screw 4,5x46mm	02019BAL-46-S2, 02019BAV-46-S2, 02019BBA-46-S2, 18-00012-01-S2, 18-00012-05, 18-00045-01-S2, 18-00045-04-S2, 18-00045-05, 18-00059-04-S2, 18-00059-05
2019.SC.048S	08719425465036	GANNET Self-Tapping Cortical screw 4,5x48mm	02019BAL-48-S2, 02019BAV-48-S2, 18-00013-01-S2, 18-00013-06-S2, 18-00046-01-S2, 18-00046-04-S2, 18-00046-05, 18-00060-04, 18-00060-04-S2, 18-00060-05

Description of the problem

A review of the technical documentation of the GANNET Implant has shown incorrect warnings displayed on the Instructions for Use (IFU) and the Surgical Technique (ST), and a textual discrepancy in the indications of the Surgical Technique compared to the Instructions for Use. The deviations are listed below:

Current:	Occurring in:	correct text:
Implant placement: 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.	IFU/ST	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 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.	IFU/ST	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.
(Indications) Stable adult intertrochanteric (pertrochanteric) femur fractures; classified as 31- A1 by the AO/OTA system.	ST	Stable adult intertrochanteric (pertrochanteric) femur fractures; classified as 31-A1 and 31-A2.1 by the AO/OTA system.

BAAT has reviewed all complaints related to GANNET Implants from the issuing of the current Instructions for Use and Surgical Technique (March 2020 until current) to check if the incorrect Instructions for Use and Surgical Technique may have led to serious incidents. No complaints have been received related to the incorrect Instructions for Use and Surgical Technique.

The risk for incorrect warnings for implant placement and handling was evaluated against the risks associated with implant placement. The highest risk concerning implant placement is indicated as: *product is inoperable with loss of primary function with possible transient injury to patient or user (possibility of further surgical procedures)*. The description of the surgical technique additionally guides in the correct implant placement. Assessment concerning the indications in the surgical technique concluded that the indications on the current surgical technique describe a narrower wording compared to the wording in the Instructions for Use. The severity on this particular aspect is considered negligible. The overall severity is considered moderate and a rework of the current device with corrected Instruction for Use and Surgical Technique as part of the Field Safety Corrective Action is considered appropriate. The corrected Instructions for Use and Surgical Technique are attached as part of this Field Safety Notice.

Advise on action to be taken by Distributors

- Confirm the receipt of this Field Safety Notice (see confirmation below);
- Acceptance of the Field Safety Notice allows surgical procedures to continue, please read the attached Instructions for Use and Surgical Technique;
- Identify and quarantine the devices in your warehouse;
- Train on rework procedure (02019BR0302_training form reprocessing_rev1), return the signed form (contact details below);
- Rework according to the corresponding rework procedure (02019BR030122_Rework IFU current stock Gannet implants_rev1);
- Return signed rework forms;
- Accepted and reworked devices can be released from quarantine;

Advise on action to be taken by Hospitals

- Confirm the receipt of this Field Safety Notice (see confirmation below);
- Acceptance of the Field Safety Notice allows surgical procedures to continue, please read the attached Instructions for Use and Surgical Technique;

Transmission of this Field Safety Notice: (if appropriate)

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (If appropriate)

Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

Name : K. van Abbema
Organisation : BAAT Medical BV
Address : F. Hazemeijerstraat 800 - Building A04
7555 RJ Hengelo
The Netherlands
Contact details : +31-(0)88-565 6625, regulatory@baatmedical.com

BAAT, the undersign confirms that this notice has been notified to the appropriate Regulatory Agency

Confirmation of receipt:
Please confirm the receipt of this FSN by returning a signed and dated version of this document (see bottom page) to **regulatory@baatmedical.com**. It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN. Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

Contact for Additional Information
Should you have questions regarding this notice, please contact BAAT Medical: **0031-8856 56 625** or mail us at **regulatory@baatmedical.com**. We apologize for any difficulties this may cause you and your patients and are committed to support you as good as possible to execute this action.

Yours sincerely,

R&D, Annex III of the Quality Manual (SOP-001, revision 11)

Attachments:

- 02019BR191021_IFU_GANNET_Implants_print_rev4
- 02019BR081128_GANNET_Surgical_Technique_EN_rev19
- 02019BR081128_GANNET_Surgical_Technique_IT_rev19
- 02019BR081128_GANNET_Surgical_Technique_NL_rev19
- 02019BR030122_Rework IFU current stock Gannet implants_rev1
- 02019BR0302_training form reprocessing_rev1

1. Confirmation of receipt (FSN 02019BR220301_FSN Gannet_rev1) **(Tick all that apply)**		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	To complete
☐	I have identified hospitals that received or may have received this device	If applicable
☐	I have informed the identified hospitals of this FSN	If applicable, date of communication:
Print Name*		Print name here
Signature*		Sign here
Date *		

Mandatory fields are marked with *