implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Germany
www.implantcast.de

January 07, 2022

URGENT SAFETY INFORMATION

Action: Product recall

Affected device: AGILON® glenoid components

Our reference no.: FSCA_22001

Dear Sir or Madam:

We are sending you this safety notice to inform you about a product recall which implantcast GmbH has decided to issue for the following AGILON® glenoid components:

Affected product	REF-No.
glenoid cementless size 3 round	38004001
AGILON® glenoid cementless anatomical sz. 3 short	38004009
AGILON® glenoid cementless anatomical sz. 3 long	38004010
AGILON® glenoid cementless anatomical sz. 2 short	38004028
AGILON® glenoid cementless anatomical sz. 2 long	38004029
AGILON® glenoid baseplate round sz. 3	38004075
AGILON® glenoid baseplate cementless anatomical short sz. 2	38004071
AGILON® glenoid baseplate cementless anatomical long sz. 2	38004072
AGILON® glenoid baseplate cementless anatomical short sz. 3	38004073
AGILON® glenoid baseplate cementless anatomical long sz. 3	38004074

We have ascertained that some individual screw holes in our AGILON® glenoids do not conform to the specification in the technical drawing and may be too large. If used with angle-stable screws, it is possible that the screw may pass through the hole, thus resulting in inadequate fixation of the AGILON® glenoid in the bone.

Our records show that you have been supplied with one or more of the affected devices, and therefore this product recall concerns you.

Risk Assessment / Patient Aftercare:

The production error affecting the screw hole has meant that, with the affected devices implanted to date, the angle-stable screws could pass through the holes during the surgery. As a result, the rotational and primary stability might be inadequate. Nevertheless, given adequate bone quality, sufficient stability should have been achieved with at least one additional screw, provided it was securely anchored in the bone.

If adequate rotational and primary stability of the glenoid is not achieved, micromovements may cause loosening and a change in the position of the glenoid component, with serious consequences. In the worst case, the glenoid component could become dislocated or break out. In addition, osteolysis in the neck of the scapula could lead to premature loosening of the glenoid, necessitating a revision, including replacement of the glenoid and possibly bone augmentation.

If the problem described above is encountered during surgery, it is recommended that the patient undergo regular clinical and radiological follow-up examinations.
To enable early detection and revision of any premature loosening or dislocation/rotational instability, the recommended post-op follow-up intervals are 6 weeks, 12 weeks, and 6 months.

If the operation was more than 6 months ago and the problems described did not occur, then no additional examination beyond the normal clinical routine is required.

Hazardous situations		
Description of the **immediate health consequences** which could result from using the affected device or being exposed to it.	**Most likely consequence**	**Most serious consequence**
	None - adequate primary and rotational stability achieved with a second screw, provided it has secure grip and is firmly tightened.	Revision operation - premature loosening of the glenoid, with possible osteolysis in the neck of the scapula and consequent need for revision and replacement of the glenoid, possibly with bone augmentation.
Description of the **long-term health consequences** which could result from using the affected device or device or being exposed to it.	**Most likely consequence**	**Most serious consequence**
	None - ingrowth of the implant into the bone (6-8 weeks) should provide adequate stability.	Revision operation, possibly multi-stage - major osteolysis in the region of the scapula neck with consequent bone augmentation and possibly use of special implants.

Course of action to be conducted:

1. Please read this safety notice carefully and make sure that all the relevant departments and operatives are informed about its contents.

2. The implantation of all **affected devices at your institution** must cease with immediate effect.

3. We are recalling all the affected **AGILON® glenoid components** with the REF numbers listed in the table below.

4. Please fill out the accompanying response form and return it to implantcast GmbH within **five working days** by email: FSCA@implantcast.de or fax: +49 4161 744 201.

Even if you no longer have any of the affected devices in stock because they have been used in an operation, please still complete the accompanying response form and return it to us.

We are aiming to complete this recall by **January 18, 2022.** Your prompt reply will enable us to keep to this deadline and make sure that all non-conforming devices are removed from the market as swiftly as possible.

We confirm that the responsible national authority in your country has been duly informed about this safety-relevant corrective action in compliance with the market surveillance guidelines (MEDDEV Vigilance Guidance Document, Reference 2.12/1).

On behalf of implantcast GmbH, we thank you for your assistance and support in implementing this recall, and we would like to apologize for any inconvenience caused.

We give you our assurance that implantcast GmbH does everything possible to make sure that all devices we supply meet your and our own high quality standards.

If you have any questions, please contact our Product Manager for the AGILON® system or our Head of Marketing and Sales.

Product Manager

[redacted]

Head of Marketing and Sales

[redacted]

Sincerely yours

implantcast

[redacted]

Head of Marketing and Sales

[redacted]

Person responsible according to
Article 15 MDR EU 2017/745

Please return by email to: FSCA@implantcast.de

or by fax to: +49 4161 744 201

Response form for urgent safety information

implantcast reference no.: FSCA_22001

Affected devices: AGILON® glenoid components

Customer number *(to be entered by implantcast)*:

Affected product – REF	Current stock held:	LOT number:
38004001 glenoid cementless size 3 round		
38004009 AGILON® glenoid cementless anatomical sz. 3 short		
38004010 AGILON® glenoid cementless anatomical sz. 3 long		
38004028 AGILON® glenoid cementless anatomical sz. 2 short		
38004029 AGILON® glenoid cementless anatomical sz. 2 long		
38004075 AGILON® glenoid baseplate round sz. 3		
38004071 AGILON® glenoid baseplate cementless anatomical short sz. 2		
38004072 AGILON® glenoid baseplate cementless anatomical long sz. 2		
38004073 AGILON® glenoid baseplate cementless anatomical short sz. 3		
38004074 AGILON® glenoid baseplate cementless anatomical long sz. 3		

PLEASE SIGN TO CONFIRM THE FOLLOWING:

1.) You have received and read the safety notice dated January 07, 2022.

2.) You have checked all your stocks and will return any affected devices that have not yet been implanted to the following address:

implantcast GmbH
AWS-Eingang
FSCA_22001
Alter Postweg 10b
21614 Buxtehude
Germany

3.) You have filled out the table above (please make a copy if you need more space for your entries).

Please complete the response form and return it by email to: FSCA@implantcast.de or by fax to: +49 4161 744 201.

Hospital / organization	
Address	
Name of contact	
Position of contact	
Tel. no. of contact	
Date	Signature