

08.10.2019

URGENT SAFETY INFORMATION

Action: Safety-relevant Information

Products concerned: AGILON® screw M5

implantcast Reference No.: FSCA_19001

Dear Sir or Madam,

hereby, we would like to advise you about a safety information which is being voluntarily issued by implantcast GmbH for the following products:

Product Description	REF-No.
AGILON® trauma shoulder screw M5/25mm	38000525
AGILON® trauma shoulder screw M5/30mm	38000530
AGILON® trauma shoulder screw M5/35mm	38000535
AGILON® trauma shoulder screw M5/40mm	38000540
AGILON screw TiN M5/25mm	38000025
AGILON screw TiN M5/30mm	38000030
AGILON screw TiN M5/35mm	38000035
AGILON screw TiN M5/40mm	38000040

Problem:

Within our internal surveillance and reporting system it was ascertained that the AGILON® **M5** screw shows a greater risk of screw breakage compared to the AGILON® **M6** screw.

The AGILON® **M5** screw is no longer marketed on a regular basis. The AGILON® **M5** screw is employed **solely for revision operations**. The current AGILON® system is applied with an AGILON® **M6** screw.

Risk Assessment:

When planning a revision surgery of an AGILON® M5 system on a patient with a well sitting AGILON® stem, the following possible risks of the two procedures must be pondered:

- 1.) Keeping the AGILON® stem and re-implanting an M5 screw with the danger of a higher risk of an AGILON® M5 screw breaking, compared to an AGILON® M6 screw.
- 2.) The explantation of a tightly anchored stem: This constitutes a difficult operation where there is the danger of completely losing the proximal humeral bone material which can result in the change to a humerus mega prosthesis.

So, leaving in a tightly anchored and undamaged AGILON® stem and implanting an AGILON® M5 screw anew combined with the relevant proximal components will be preferable to a complete exchange of prosthesis in most cases.

Information Regarding Patient Aftercare:

Within the frame of a planned revision operation, the user must conduct an individual potential risk / use-of-potential analysis according to the above explained risk assessment.

Course of Action:

1. Read this safety information carefully and make sure all relevant departments and office-holders are informed about its content.
2. Please fill in the attached reply form and return it to implantcast GmbH within five working days via E-mail MDVS@implantcast.de or FAX +49 4161 744 201.



The envisaged deadline for completion of this course of action is **15.10.2019**. Your prompt response will enable us to meet this deadline and to ensure the received information has been taken note of.

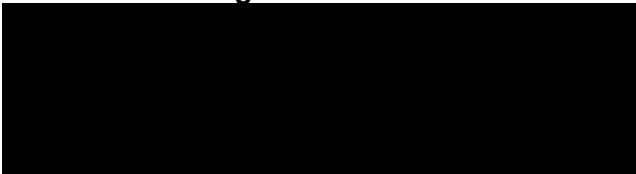
We confirm that the relevant national authority of your country has been notified about this safety information according to the guideline of market surveillance (MEDDEV Vigilance Guidance Document, Reference 2.12/1)

On behalf of implantcast GmbH we would like to sincerely thank you for your help and support with the implementation of this measurement and apologize for any inconvenience caused.

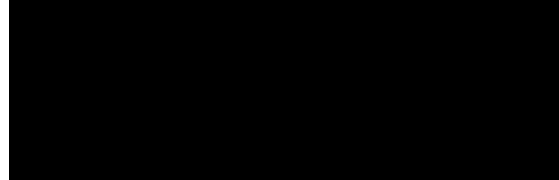
We would like to assure you that implantcast GmbH does all in its power to ensure that only such products are on the market that comply with your and our high standards of quality.

Should any questions arise, please contact our product manager or our director sales and marketing.

Product Manager

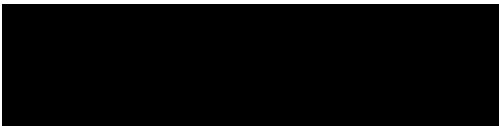


Director Sales and Marketing

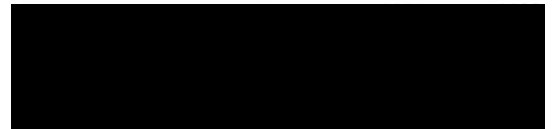


Yours sincerely,

implantcast



Director Quality Management



Safety Officer



Please send to Fax-No. +49 4161 744 201 or
E-Mail to MDVS@implantcast.de

Reply form urgent safety information

implantcast Reference-No.: FSCA_19001

- By signing you declare the receipt of the Safety Information dated 08.10.2019 as well as having taken note of the received information.
- Please, **sign** the form and return it to Fax-No.: +49 4161 744 201 or E-Mail: MDVS@implantcast.de.

Hospital and Address	
Name of Contact Person	
Function of Contact Person	
Phone No. of Contact Person:	
Date:	Signature: