Distributor
Name
street
Zip / City

Date: 08. March 2013

URGENT PRODUCT SAFETY INFORMATION/PRODUCT RECALL

Concerns product: MUTARS® tibial plateau MUTARS® M-O-M and tibial plateau modular

Our reference-no.: 003-13

Dear Roberto,

By means of this PRODUCT SAFETY INFORMATION we would like to notify you about an URGENT CORRECTIVE MEASURE WITH THE USERS OF MEDICAL DEVICES.
This has been initiated for all products listed below.

According to our files at least one of the involved products listed below was delivered to you and is therefore involved in this action.

Reference-No.:

Tibial plateau M-O-M cementless	
REF 57510203	xsmall
REF 57510200	small
REF 57510205	standard
REF 57510210	large
REF 57510203N	xsmall
REF 57510200N	small
REF 57510205N	standard
REF 57510210N	large

Tibial plateau M-O-M cemented	
REF 57510303	xsmall
REF 57510300	small
REF 57510305	standard
REF 57510310	large
REF 57510303N	xsmall
REF 57510300N	small
REF 57510305N	standard
REF 57510310N	large
REF 57510300S	small
REF 57510305S	standard
REF 57510310S	large

Tibial plateau modular, cementless *N	
REF 57550005	small
REF 57550010	standard
REF 57550005N	small
REF 57550010N	standard

Tibial plateau modular, cemented *N	
REF 57550105	small
REF 57550110	standard
REF 57550105N	small
REF 57550110N	standard

Lot-/Serial-No.: all implants

Problem:
Two incidents have been reported on the market where the MUTARS® tibial plateau M-O-M could not be screw-fastened to the appropriate stem implant.

The initiated inspection has shown that it cannot be excluded that further implant components could possibly be affected by an ascertained dimensional deviation.

Risk assessment:
It is feasible that the MUTARS® tibial plateau M-O-M or modular cannot be screw-fastened to the tibial stem during operation leaving proper care of the patient not warranted.

Patients who have successfully been operated on with implants of the same type are not subjected to any greater risk, as in these cases the MUTARS® tibial plateau M-O-M or modular was screw-fastened correctly.

Course of Action:

1. With effect from now any MUTARS® tibial plateaus M-O-M and modular which you, your dealers and their hospitals might have, must not be implanted.
2. All implant components are being called back to implantcast Germany.
3. You are responsible for:
    a. Make sure the goods are barred at once
    b. Notifying your dealers and hospitals
    c. Supervising the implementation of the call back action
4. Please fill in the attached fax-form and fax it to implantcast within five working days.
    - FAX: 0049 4161/744-200

Possibly these products are no longer on stock with you if they have been used up in operations.

Please return the filled-in customer's answer form within five working days as from the date of receipt so we can update our files.

This way, you will not receive any further information about this subject unnecessarily. We appeal to you to fill in and return the form to us even if you presently have none of the above listed products on stock.

The envisaged deadline for this course of action is March 15, 2013. Your prompt response will render keeping this date possible and will ensure that all non-conform products are being removed from the market as soon as ever possible.

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

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

Should any questions arise, please contact your export manager.

[redacted]

Yours sincerely

[redacted]
Head of Quality Management

[redacted]
Safety officer

Please return to Fax No. +494161 744 200

FAX-ANSWER FORM
URGENT CORRECTIVE MEASUREMENT

Product concerned*: MUTARS® tibial plateau M-O-M and tibial plateau modular*

Reference-No.:

Tibial plateau M-O-M cementless		**Tibial plateau M-O-M cemented**	
REF 57510203	xsmall	REF 57510303	xsmall
REF 57510200	small	REF 57510300	small
REF 57510205	standard	REF 57510305	standard
REF 57510210	large	REF 57510310	large
REF 57510203N	xsmall	REF 57510303N	xsmall
REF 57510200N	small	REF 57510300N	small
REF 57510205N	standard	REF 57510305N	standard
REF 57510210N	large	REF 57510310N	large
		REF 57510300S	small
		REF 57510305S	standard
		REF 57510310S	large

Tibial plateau modular, cementless *N		**Tibial plateau modular, cemented *N**	
REF 57550005	small	REF 57550105	small
REF 57550010	standard	REF 57550110	standard
REF 57550005N	small	REF 57550105N	small
REF 57550010N	standard	REF 57550110N	standard

LOT / SN - No.: all implants

implantcast Reference-No.: **003-13**

PLEASE TICK THE APPROPRIATE PARPAGRAPH:

☐ WE STATE THAT ALL RELEVANT STOCK HAS BEEN CHECKED AND THAT NONE OF THE PRODUCTS CONCERNED ARE ON STOCK.

☐ WE STATE THAT ALL DEALERS AND HOSPITALS ARE INFORMED AND THAT ORDERS FOR THE CORRECTIVE ACTION HAVE BEEN GIVEN

☐ WE STATE THAT ALL RELEVANT STOCK HAS BEEN CHECKED. WE HAVE IDENTIFIED SOME OF THE PRODUCTS CONCERNED ON OUR STOCK AND WOULD LIKE TO HAND BACK THE PRODUCTS LISTED BELOW FOR EXCHANGE.

Own stock / Dealer / Hospital	Ref. No	Qty	Own stock / Dealer / Hospital	Ref. No	Qty

Should this list not be large enough, please fax the form as often as necessary.

Please sign the form and send it back to us *(FAX: +494161/744-200)* in order to inform us as to the receipt of the notification of product safety.

Distributor:	
Name of Contact Person:	
Tel. No. of Contact Person:	
Date:	**Signature:**

Please return this form to us within five days!