

Company:

To:

Cc:

Hauptstrasse 26d  
CH-4437 Waldenburg, Switzerland  
Phone +41-(0)61 965 9020  
Fax +41-(0)61 965 9021

From: [REDACTED]

Date: May 29, 2008

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## URGENT FIELD NOTICE: IMMEDIATE ACTION REQUIRED

**Product Recall: Implants**

**REF #: see separate list**  
**LOT #: see separate list**

Dear ,

We have seen this morning that the implant mount can hardly be removed from some implant lots. It seems that lots are affected which have been packaged as of April 2008 and that a new lot of the O-ring on the implant mount plays a role. Therefore we have decided to recall all affected lots and to replace these implants. You will receive a list of the affected lots and the number of implants which you have received this afternoon or tomorrow morning at the latest.

We ask you to freeze your own stock of the affected lots, to inform me by e-mail until May 30, 2008 on the number of implants you have already delivered to customers, to recollect these implants from the stock of your customers warehouses (including consignment) and to return them immediately but not later than June 15 under separate cover and labelled with **Recall "implant mount" and "QUARANTINE, DO NOT USE"** to:

Thommen Medical AG  
Att. Mr. Reto Baumgartner  
Hauptstrasse 26d  
CH-4437 Waldenburg, Switzerland

**Please confirm immediate recollection as soon as possible.**

If you cannot return all recalled products, please inform in writing by the same date Mr. Reto Baumgartner about the reason therefore and the present location of the products.

[REDACTED] will send you a list with the availability of replacement implants as soon as possible.

We will also use the first part of Monday morning session of the Marketing & Sales Meeting to give you detailed and updated information on this recall.

We would like to apologise for any inconvenience caused by this product recall. Please do not hesitate to call us if you have any questions or concerns.

Yours faithfully,  
Thommen Medical AG

[REDACTED]  
[REDACTED]  
CEO

Cc: [REDACTED]

Article no.	Article	LOT	Expiration date
4.13.211	CONTACT Implantat, PF Ø4,5mm, E Ø3,5mm, L 9,5mm	5200	31.05.2013
4.13.214	CONTACT Implantat, PF Ø4,0mm, E Ø3,5mm, L 9,5mm	5200	31.05.2013
4.13.220	CONTACT Implantat, PF Ø3,5mm, E Ø2,7mm, L 11,0mm	5108	31.03.2013
4.13.221	CONTACT Implantat, PF Ø4,5mm, E Ø3,5mm, L 11,0mm	5200	30.04.2013
4.13.222	CONTACT Implantat, PF Ø5,0mm, E Ø4,2mm, L 11,0mm	5200	30.04.2013
4.13.240	CONTACT Implantat, PF Ø3,5mm, E Ø2,7mm, L 14,0mm	5200	30.04.2013
4.13.641	ONETIME Implantat, PF Ø5,0mm, E Ø4,2mm, L 8,0mm	5200	30.04.2013
4.13.900	ELEMENT Implantat, PF Ø3,5mm, E Ø3,5mm, L 8,0mm	5107	30.04.2013
4.13.901	ELEMENT Implantat, PF Ø4,5mm, E Ø4,2mm, L 8,0mm	5200	30.04.2013
4.13.911	ELEMENT Implantat, PF Ø4,5mm, E Ø4,2mm, L 11,0mm	5200	30.04.2013
4.13.911	ELEMENT Implantat, PF Ø4,5mm, E Ø4,2mm, L 11,0mm	5128	31.03.2013
4.13.914	ELEMENT Implantat, PF Ø4,0mm, E Ø4,0mm, L 9,5mm	5200	30.04.2013
4.13.924	ELEMENT Implantat, PF Ø4,0mm, E Ø4,0mm, L 11,0mm	5201	31.05.2013
4.13.924	ELEMENT Implantat, PF Ø4,0mm, E Ø4,0mm, L 11,0mm	5107	31.01.2013
4.13.941	ELEMENT Implantat, PF Ø4,mm, E Ø3,5mm, L 9,5mm	5200	30.04.2013
4.13.942	ELEMENT Implantat, PF Ø5,0mm, E Ø5,0mm, L 9,5mm	5200	31.05.2013
4.13.942	ELEMENT Implantat, PF Ø5,0mm, E Ø5,0mm, L 9,5mm	5114	31.03.2013
4.13.951	ELEMENT Implantat, PF Ø4,5mm, E Ø4,2mm, L 12,5mm	5122	31.03.2013