

We,

Christoph Miethke GmbH & Co. KG
Ulanenweg 2

D – 14469 Potsdam / Germany

want to inform you about a recall / field safety corrective action of the products listed in the attachment.

This Field safety corrective action is a precautionary corrective action. There has been neither any incidence nor any near incidence.

During production the mounting personnel stated that some of the pressure adjustment springs to be mounted in the valve for pressure control were outside specification. These springs were scrapped and not assembled.

However all finished products passed the 100% final control without any deviations.

There is a very low suspicion that the adjustments springs of a very few products might not stand the average stress forces put on the spring during lifetime thus negatively affecting the pressure control of the valve.

Because of this suspicion, however improbable it may be, the safety officer has decided to recall the affected products (23pieces) to have them additionally tested. Lots on stock were already tested successfully and 46 pieces passed without any objection.

We intend to test all products in the field in order to prove an correct function of the products.

We would like to stress that there is only a low suspicion for a defect product and that we want to assure 100% medical device safety.

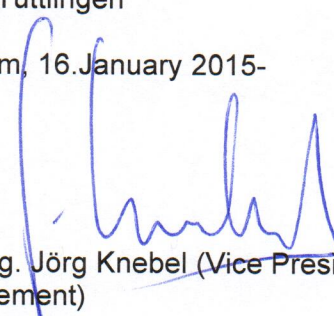
Should the application of a defect spring be confirmed against our expectations, the shunt patient should be observed medically for a period of at least three weeks, if the patient has any shunt disfunction symptoms (overdrainage). Should there be any of these symptoms, the valve needs to be revised.

Please send concerned products back to

Aescualp AG,
Abteilung QMV,
Am Aescualap Platz
78532 Tuttlingen

Potsdam, 16. January 2015-

Christoph Miethke GmbH & Co. KG
Regulatory Affairs


Dipl.-Ing. Jörg Knebel (Vice President Quality
Management)

Attachment: List of affected lots

Rückrufprodukte

Lot:	Bestell-Nr.	Art-No	Amount	Dispatch date	Via	Serial No	Aufenthaltsort /Address
20025343	94D/4506420975, 04.12.2014	FX413T	5 Stück	05.01.15	Tutlingen	N11419CG0121 N11487CG0072 N11467CG0165 N11508CG0146 N11510CG00101	Zentralklinik Bad Robert-Koch-All Bad Berka Alder Hey Child Eaton Road Liverpool Alder Hey Child Eaton Road Liverpool
20025329	94D/4506413408, 02.12.2014	FX410T	2 Stück	23.12.14	Tutlingen	N11428 N11481	UCL Hospital Tr Hampstead Road London Klinikum Mannheim Theodor-Kutzer-Mannheim
20025318	4D/4506410763, 01.12.2014, 1.T	FX414T	4 Stück	22.12.14	Tutlingen	N11430CS9945 N11470CG0052 N11501CS9679 N11513CG0023	UCL Hospital Tr Hampstead Road London UCL Hospital Tr Hampstead Road London UCL Hospital Tr Hampstead Road London UCL Hospital Tr Hampstead Road London
20025330	4D/4506410763, 01.12.2014, 2.T	FX414T	2 Stück	23.12.14	Tutlingen	N11444CS9724 N11512CS9578	UCL Hospital Tr Hampstead Road London Nørrebrogade
20025322	B. Braun Denmark	FX993T	2 Stück	22.12.14	Dänemark	L15365N11494 L15520N1514 N11425CS9327	Århus Universitetshospi NOA-GS OP 44, DK 8000 Neurokir. afdeling Århus C Nørrebrogade Universitetshospi NOA-GS OP 44, DK 8000 Neurokir. afdeling Århus C Universitetsklini Josef-Schneider Würzburg
20025328	94D/4506364213, 12.11.2014	FX420T	2 Stück	23.12.14	Tutlingen	N11437CS9335	Universitetsklini Josef-Schneider Würzburg

17 Stück

Produkte, die direkt an Kliniken versendet waren

20025361	Streckengeschäft Gera	FX419T	1 Stück	07.01.15	an Gera	N11568CS9383	SRH Walldklinikum, OA Dr. Walter	Dr. Semmelweisweg	07548 Gera
20025367	94D/4506387636 21.11.2014, 1. FX441T	2 Stück	2 Stück	08.01.15	Sankt Augustin	N11571CG0109 N11615CG0103 N11523CS9895 N11541CS9573 N11575CS9510	Asklepiusklinik St. Augustin Charité Neurochirurgisch	Janssenstraße 29 St. Augustin Augustenburger e OP	53757 St. Augustin Augustenburger Platz 1
20025357	94D/4506428338, 08.12.2014, 1. FX414T	3 Stück	6 Stück	06.01.15	an Charité				13353 Berlin

15.01.15


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