

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.

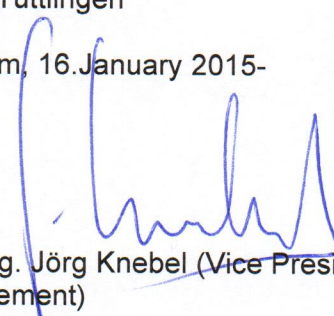
Should the application of a defect spring be confirmed against our expectations, the shunt patient should be observed medically for a period of at least three weeks, if the patient has any shunt disfunction symptoms (overdrainage). Should there be any of these symptoms, the valve needs to be revised.

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	Zentralklinik Bad Robert-Koch-All Bad Berka
						N11508CG0146	Alder Hey Child Eaton Road Liverpool
						N11510CG0101	Alder Hey Child Eaton Road Liverpool
20025329	94D/4506413408, 02.12.2014	FX410T	2 Stück	23.12.14	Tutlingen	N11428	UCL Hospital Tr Hampstead Road London
						N11481	Klinikum Mannheim Theodor-Kutzer-Mannheim
							UCL Hospital Tr Hampstead Road London
							UCL Hospital Tr Hampstead Road London
20025318	4D/4506410763, 01.12.2014, 1.T	FX414T	4 Stück	22.12.14	Tutlingen	N11430CS9945	UCL Hospital Tr Hampstead Road London
						N11470CG0052	UCL Hospital Tr Hampstead Road London
						N11501CS9679	UCL Hospital Tr Hampstead Road London
						N11513CG0023	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	UCL Hospital Tr Hampstead Road London
						N11512CS9578	Norrbrogade Århus Universitetshospil NOA-GS OP 44, DK 8000
						L15365N11494	Neurokir. afdeling Århus C Norrbrogade Århus Universitetshospil NOA-GS OP 44, DK 8000
20025322	B. Braun Danmark	FX993T	2 Stück	22.12.14	Dänemark	L15520N11514	Universitetsklini Josef-Schneider Würzburg
						N11425CS9327	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	Streckergeschäft 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	FX441T	2 Stück	08.01.15	Sankt Augustin	N11571CG0109 N11615CG0103	Asklepiusklinik St. Augustin	Janssenstraße 29 St. Augustin	53757
20025357	94D/4506428338, 08.12.2014, 1 FX414T	FX414T	3 Stück	06.01.15	an Charité	N11523CS9895	Charité	Angustenburg	
						N11541CS9573 N11575CS9510	Neurochirurgisch e OP	Angustenburg Platz 1	13353 Berlin

6 Stück

komte bei Asc. Abgefangen werden  
komte bei Asc. Abgefangen werden  
komte bei Asc. Abgefangen werden

15.01.15  
F. Gumbel