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Incident no.: INT-00008 **02.06.2014**

Urgent Safety Information

Recall
for
Automatic tourniquet „kariba“ UT 1210-00

Dear Sirs,

During our technical safety check of your tourniquet we have made a mistake which can possibly cause a risk for the patient.

With this letter we would like to inform you of the following:

- Details about the problem
- The actions our customers / operators have to take in order to avoid risks for patients
- ulrich medical’s planned corrective actions.

By mistake we have put the quality mark “technical safety check” on the tourniquet which normally confirms a complete technical safety check. In these cases the control was incomplete.

Our Urgent Safety Information contains details to identify the concerned devices as well as all necessary actions. Please follow especially the instructions “Which actions must be taken by the addressee?”

This voluntary corrective action has also been reported to the responsible authorities.

We are very sorry for all inconvenience caused by this problem.
Your cooperation in this matter is highly appreciated.

Best regards

ulrich GmbH & Co. KG

[redacted]
Chief Executive Officer

[redacted]
Safety Officer

Identification of concerned medical device: kariba, UT 1210-00

Technical safety check executed by ulrich GmbH & CO. KG within the following period: 06.05.2013 – 21.05.2014.

For the following serial numbers:

0.219769	0.217448	0.216407	0.214325	0.213354	0.212373	0.210981	1.2112912	1.2111511	1.2110640
0.218868	0.217378	0.216347	0.214195	0.213234	0.211992	0.210701	1.2112822	1.2111481	1.2110460
0.218558	0.217207	0.215987	0.214175	0.212933	0.211982	0.210671	1.2112812	1.2111330	1.2110450
0.218538	0.216937	0.215496	0.214125	0.212883	0.211912	0.210611	1.2112562	1.2111300	1.2110290
0.218498	0.216837	0.215486	0.214065	0.212873	0.211862	0.210351	1.2112342	1.2111290	1.2110280
0.218038	0.216797	0.215466	0.213744	0.212863	0.211842	0.210090	1.2112211	1.2111260	1.2110220
0.217868	0.216767	0.215086	0.213734	0.212743	0.211782		1.2112151	1.2111060	
0.217838	0.216597	0.214465	0.213554	0.212693	0.211422		1.2112091	1.2111010	
0.217748	0.216517	0.214395	0.213514	0.212473	0.211372		1.2111971	1.2110860	
0.217598	0.216417	0.214345	0.213364	0.212413	0.211212		1.2111941	1.2110770	

Description of the problem and root cause:

Description of the problem:
During the annual technical safety check the following checks were not executed due to missing of the AC power line and the external power supply: Control of the AC power line and external power supply as well as control of the electrical safety acc. to. DIN EN 62353 [C1 – C3]. The technical safety check was therefore not executed completely.

By mistake we have put the quality mark “technical safety check” on the tourniquet which normally confirms a complete technical safety check. In these cases the check was incomplete.

The electrical safety was not checked. Therefore we cannot confirm it.

Potential risk:
We cannot exclude the risk of an electric strike for patients, operators or third persons

Which actions must be taken by the addressee?
Please put the device out of operation and return the tourniquet incl. AC power line and external power supply to ulrich medical (freight collect). For return shipment please use the original packaging. Return delivery documents as well as further details you will get from the contact person mentioned below.
ulrich medical has initiated this corrective action for the concerned device voluntarily and will execute the technical safety check free of charge.

Will you please confirm receipt of this document with the enclosed Acknowledgement of receipt immediately.

For reference use the following incident number: **INT-00008**.

Forwarding of the information described in this document

Please make sure that within your organization all operators of the above mentioned products and all other persons this may concern will get the Urgent Safety Information without delay.

If the tourniquets were delivered to third parties, we ask to forward this information accordingly or inform our contact person.

Please keep this information in your files at least until the corrective actions are finished.

Our German authority „Bundesinstitut für Arzneimittel und Medizinprodukte has received a copy of this „Urgent Safety Information".

Contact persons:

For questions please contact:

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