PULSION Medical Systems SE | Hans-Riedl-Str. 21 | 85622 Feldkirchen | Germany

-Kunden Kontakt Details-

30th of June 2015

Urgent Field Safety Notice
PiCCO catheter, REF PV2014L08-A, LOT: 15AF12
PiCCO catheter, REF PV2015L50-A, LOT: 15AG12
FSCA-Identifier: CAPA-2015-010
Type of action: Removal

Dear Ladies and Gentlemen,

Unfortunately we have to inform you that PULSION Medical Systems SE reported to BfArM and other local authorities a product recall.

Within the scope of our quality insurance measures we have detected that the PiCCO catheter of the above mentioned article numbers and LOTs need to be recalled from the market. As you can see on the attached reply form your hospital or department of the hospital has received a certain amount of products from the affected LOTs. We therefore ask for your support of our field safety corrective action (FSCA).

Details of effected catheters

The PiCCO catheter is a specific disposable arterial catheter with thermodilution measurement function. It was developed for continuous advanced haemodynamic monitoring suitable with Pulsion Monitors or OEM partner modules (Dräger, GE, Philips, Mindray). PiCCO is mainly used in the intensive care or perioperative setting.

Description of the problem

Internal quality tests of the nitinol guidewires added to the PiCCO catheter revealed that the coating of the guidewire does not meet our quality criteria without doubts. It con not be discounted that the coating is partially delaminating from the guidewire.

Even though PULSION has not received any customer complaints, and is also not aware of any incidents in this regards, we have decided to take preventative measures. Herewith PULSION Medical Systems SE recalls the above listed batches of PiCCO catheters.

PULSION Medical Systems SE
Hans-Riedl-Str. 21, 85622 Feldkirchen, Germany
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Mikael Johansson, Dr. Sergej Kammerzell

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Phone: +49-89-459914-503
Fax: +49-89-459914-18

Immediate actions to be taken by the user / customer

- Please check your stock for any products from the above listed batches.
- Remove any listed batches from the above from use.
- Fill out and sign attached confirmation form and send all products of the above batches back to PULSION Medical Systems SE, Hans-Riedl-Str. 17, 85622 Feldkirchen, Germany
- We will provide a credit note for returned products

Transmission of this Field Safety Notice (if appropriate)

This notice needs to be passed on to all those who need to be made aware within your organisation or to any organisation / department where the potentially affected catheters have been transferred.

Contact reference person

PULSION Medical Systems SE
Dr. Volker Humbert
Hans-Riedl-Straße 21
85622 Feldkirchen
Phone: +49 89-459914-503
Email: recall@pulsion.com

The undersigned confirm that this notice has been notified the appropriate regulatory agency.

We kindly ask for your support on these matters. To confirm that all good relevant to this recall are sent back, please complete and return the attached form.

We sincerely apologise for any inconvenience caused.

With kindest regards

PULSION Medical Systems SE

i. V. Dr. Volker Humbert
Safety Officer

i. V. Rainer Bönigk
Head of Quality Management

Confirmation form for medical device recall
PiCCO catheter
PULSION REF : PV2014L08-A, LOT 15AF12&
PULSION REF : PV2014L50-A, LOT 15AG12

Customer Data	
Customer Name	
Hospital name / department	
Address	
State	

Please state in this table the quantity of unused PiCCO catheters in your local stock / organisation.

PiCCO REF | LOT	Received quantity	Remaining quantity in stock
PV2015L08-A | 15AF12		
PV2015L50-A | 15AG12		

If you have no PiCCO catheters of the affected LOT left on stock please fill in "0". In any case this document needs to be signed off and submitted.

We herewith declare that

- We do not have any PiCCO catheters of the recalled batches in stock with the exception of the listed above,
- All above listed quantities will be returned to Pulsion Medical Systems SE.

_____ _____

Date, City Signature

Please send a scan of this form to e-order@pulsion.com or +49 89 45 99 14 – 18 and attach the signed original document to your return shipment. The delivery address for the return shipment is:

PULSION Medical Systems SE
Christof Kunz
Hans-Riedl-Straße 17
85622 Feldkirchen
Germany