14/10/2014

KIMAL
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Kimal plc: URGENT FIELD SAFETY NOTICE

MEDICAL DEVICE SAFETY ADVISORY NOTICE

Kimal plc 30cc Inflation Device

Product code	Product Description	Batch / Lot number affected	
K68/97	INFLATION DEVICE 30CC	14D0095	14F0509
CZ-K20222	FIFEJDY PACK	14F0362	
SPR/9911/44217	IMAM HUSSAIN HOSPITAL KARBLA ANGIOG	14E0430	
SPR/9976/44331	PTCA PROCEDURE PACK - AL SALAM HOSP	14F0392	

Dear Customer,

Our supplier, Perouse Medical, has issued a Product Advisory Notice concerning their Inflation Device with Mid Pressure 3 Way Stopcock. These particular devices are supplied to Kimal and included within finished products, which are supplied to you.

From the information provided by Perouse Medical, their affected batch numbers have been included in the above mentioned Kimal product codes. It has been brought to our attention that Kimal plc has supplied you with either, or all, of the above mentioned products.

As the legal manufacturer, Kimal plc are circulating this Product Advisory Notice to all customers whom have received these products, and request that the actions mentioned below are taken by our distributors and end users.

Yours Sincerely,
KIMAL PLC

*KIMAL MANUFACTURING DIVISION **
SHERWOOD ROAD
ASTON FIELDS
BROMSGROVE B60 3DR
ROYAUME-UNI

For the attention of: REGULATORY AFFAIRS DEPARTMENT

Ivry le Temple, October 6th 2014

Registered letter with receipt acknowledgment

URGENT SAFETY NOTICE FOR MEDICAL DEVICE

Commercial name of the product	Dolphin Inflation device- Caliber Inflation Device	Inflation device
Reference	0185NA/0185ND/0185NF/0185NR/0185PD/0185QL 0185TG/0185TR/0185TS	0252NA/0252NB
Batch Numbers	All batch numbers beginning with : 1403, 1404, 1405, 1406, 1407	4041354/4062650/4072586
Type of action	SAFETY NOTICE	SAFETY NOTICE

Dear Sir or Madam,

DETAILED CONCERNED PRODUCT INFORMATION

PEROUSE MEDICAL has issued a voluntary corrective action notice regarding the above mentioned products.
The product is a one-piece disposable inflation system including a syringe barrel of 30 cc with a mechanical clutchable piston on a thread, a rotatable handle, a pressure gauge, and a high-pressure connection line with a rotating luer lock

Devices with references 0185 are used during angioplasty procedures. Devices with references 0252 are used during Kypho-plasty and other interventional procedures.

PROBLEM DESCRIPTION

Several cases of inability to raise the pressure beyond 10 atm have been reported to us. The reported cases have not generated, to our knowledge, any consequences for the patient, except a longer-lasting procedure.

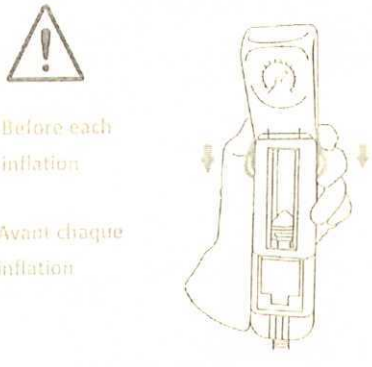
These difficulties may occur when increasing the pressure above 10 atm with no manual locking by the practitioner before inflation. In case of multiple inflations, the automatic return to the lock position after inflation may be incomplete due to excessive friction between the device components. Therefore, if the practitioner does not manually lock the buttons before inflation, the system can be unlocked if the pressure goes higher than 10 atm. In that case, the pressure would drop and it would be necessary to lock the device manually to carry on a new cycle of pressure rise.

SAFETY ACTION DESCRIPTION

PEROUSE MEDICAL carries out a safety notification to provide additional clarification on the use of the inflation device.

PEROUSE MEDICAL adds the following clarification: it is necessary BEFORE EACH INFLATION to manually lock the buttons by pulling them toward the user as shown in the picture below, and check the lock. This information will be included as an additional label on each primary packaging from today

TEMPLATE LABEL



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Medical Device Safety Advisory Notice

Action to be taken by the user:

- Please carefully read the Medical Device Safety Advisory Notice.
- Transmit the Advisory Notice on to relevant personnel within your organisation or any organisation where the potentially affected products were transferred.
- Complete the confirmation of receipt of the Field Safety Notice and return to the contact reference person at Kimal.

Additional Information:

This notice has been communicated to the relevant Competent Authorities.

We sincerely apologise for the inconvenience caused and thank you in advance for your understanding and cooperation.

Kind regards,
Ben Albutt

Contact reference person:

Mr Ben Albutt
Compliance / Vigilance Co-ordinator
Kimal plc
Sherwood Road
Aston Fields
Bromsgrove
B60 3DR
United Kingdom

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Kimal reference: 11023