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**

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

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]
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 Albett

Contact reference person:

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

Email: ben.albutt@kimal.co.uk
Phone: +44(0)1527 572314
Fax: +44(0)1527 579936

Kimal reference: 11023