

COOK®

Cook Ireland Limited
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Urgent Field Safety Notice

Commercial name of the affected product: Cholangioscopy Access Balloon
FSCA-identifier: 2010C0004
Type of action: Field Safety Corrective Action

Date: 7th – January - 2011

Attention: [REDACTED] (Germany)

Details on affected devices:

Cholangioscopy Access Balloon

Catalogue Numbers: DPOC-15

Lot Number: 1 X W2916501

Description of the problem:

Cook is conducting a Field Safety Corrective Action on Cholangioscopy Access Balloons.

During the initial commercialization phase, complications associated with the cholangioscopy procedure were reported.

The complications include: air embolism and gastrointestinal perforation. Difficulty with balloon deflation may have caused or contributed to the reports of perforation.

Advise on action to be taken by the user:

1. Please review the attached list and quarantine any affected product that remains in your stock.
2. Please complete the attached Reply Form, which lists the product and lot numbers affected and return by fax to Cook Ireland marked for contact persons as below as soon as possible to +353 61 334441 or alternatively via email to: European.Complaints@CookMedical.com.
3. Immediately collect all remaining unused products. The remaining unused products should be returned as soon as possible via DHL quoting Cook Ireland's account number: 960030813 to arrange pick up.

Send the removed devices to:
Cook Ireland Ltd.
O'Halloran Road
National Technology Park
Limerick
IRELAND

Please reference RA # 2010C0004 on the outside of the shipping carton.

Please be advised that the manufacturer will issue credit for all devices returned.

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

Please transfer this notice to other organisations on which this action has an impact.

Contact reference persons:

Emmett Devereux,
Director of Quality and Regulatory Affairs
COOK Ireland,
O'Halloran Road,
National Technology Park,
Limerick,
IRELAND.

Or

Mary Prunty,
Customer Quality Supervisor,
COOK Ireland,
O'Halloran Road,
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Should you have any questions, please feel free to contact us at Cook Ireland Ltd. for more information (+353 61 334440).

We regret the inconvenience this may cause you. Thank you again for your immediate assistance in this matter. We look forward to your response.