

31<sup>st</sup> May 2011

**Urgent Field Safety Notice:**  
**Instructions to End User**

**Product Range: Pelispec Vaginal Speculum including Smoke Extractor and those in the Light Source Packs and IUD Procedure Packs**

**Lot No: Week 18/2006 (Expiry 18/2011) to Week 17/2011 (Expiry 17/2016) inclusive**

**Type of action: Return of Product to Supplier**

**Description of the problem:**

Pelican Feminine Healthcare Limited would like to inform you of a potential manufacturing irregularity during the production of the Pelispec Vaginal Speculum, with and without nut and threaded runner. During the transportation there is the potential that the peel pouch may be pierced. If this were to occur sterility of the product would be compromised.

To address any potential risk of harm, the affected product is being recalled. This recall covers the Pelispec range of products, including Smoke Extractor and those in the Light Source and IUD procedure packs, please see the attached product list. Please note the decision has been made to recall products with lot numbers 18/2006 to 17/2011, with expiry dates from 18/2011 to 17/2016 inclusive.

**Instruction on action to be taken by the End User:**

Our records show that you have taken delivery of the affected products. Please take the following steps:

1. Please immediately isolate the products.
2. Complete the enclosed form which should be returned to your distributor by 30<sup>th</sup> June 2011, **even if you no longer have any of the affected products in your possession.**
3. Return all affected products to your distributor for credit by the 30<sup>th</sup> June 2011.
4. Please mark all returned product clearly with 'Recalled Products from Your Name, Company Name and Address, and Distributed by (your distributors name)'.

**Communication**

Pelican Feminine Healthcare Limited apologise for any inconvenience this may cause and request that you share this Notice with all relevant customers/users. If you have any questions then please contact your Distributor or Pelican Feminine Healthcare's Customer Services Department immediately on 029 2074 7400.

The relevant National Authorities have been advised about this Field Safety Corrective Action.

Thank you for your assistance in this matter.

Yours sincerely,



C. Cochlin  
Senior Manager