



DEFECT & INVESTIGATION CENTRE



FOR ACTION BY:

Chief Executive of each HSS Trust
General Manager/Chief Executive of each HSS Board
General Manager/Chief Executive of each Agency

**Stoney Road Dundonald
Belfast
Northern Ireland BT16 0US**

HN(NI) 97/09

Date: 12 May 1997

**Telephone 01232 523714
Facsimile 01232 523900
GTN Code 440**

Product	:	SHELF PESSARY (ALSO KNOWN AS SIMPSON PESSARY) ALL SIZES
Manufacturer/ Supplier	:	SUPPLIED BY SOUTHERN SYRINGE SERVICES LTD MADE BY GTS (UK)
Problem	:	The coating of these shelf pessaries is liable to disintegrate or peel with the potential for local irritation and erosion. Additionally the packaging and labelling are inadequate. There is no way of identifying the product or manufacturer and no sterilization information or instructions for use are supplied.
Action	:	The pessaries should not be used and devices in use should be replaced with an alternative product as soon as possible.

HAZARD

1. ATTENTION CHIEF EXECUTIVES/GENERAL MANAGERS

This notice should be brought to the immediate attention of all who need to know, or be aware of it including those listed below, in accordance with local procedures, and immediate action should be taken as detailed overleaf:

- ◆ Directors of gynaecology units
- ◆ Directors of obstetric units
- ◆ Directors of surgical units
- ◆ Gynaecologists
- ◆ Family Planning Clinics
- ◆ General Practitioners
- ◆ Safety Liaison Officers
- ◆ Supplies Officers
- ◆ Sterile Service Departments

Boards/Trusts should ensure that if appropriate, this information is passed to **ALL** persons having the responsibility for premises registered under "THE REGISTERED HOMES (NI) ORDER 1992".

2. IMMEDIATE ACTION

- ◆ *Do not use these products.*
- ◆ *Purchasing records should be checked to identify whether these pessaries have been ordered and supplied. If this is the case they should notify the relevant clinical units.*
- ◆ *Identify and isolate all existing stocks of these shelf pessaries.*
- ◆ *Return all unused shelf pessaries to Southern Syringe Supplies Ltd. Full credit will be given.*
- ◆ *Ensure that all patients using these shelf pessaries have been identified and that devices in use are replaced with an alternative product as soon as possible.*

3. BACKGROUND

Shelf pessaries are inserted into the vagina to treat prolapse, they are kidney shaped plates with a protuberance from their underside. These are made of metal with a black coating and have two holes in the plate.

The Department has received two reports where the coating of these devices have disintegrated and peeled while in use; in one of these cases the patient required a general anaesthetic during device removal. The coating on two further devices were found to be chipped prior to use.

These devices are inadequately packaged and are not labelled. There is no batch numbering system or other means of product identification.

There are no sterilization instructions or instructions for use supplied with this device. Neither the design of the product nor suitable sterilization methods have been validated.

The material used in the pessary coating is currently being analysed. Should there be clinical consequences associated with the coating a further advisory notice will be issued.

4. ENQUIRIES

Company Contact

Mr Ian Paul
Southern Syringe Services Ltd
New Universal House
303 Chase Road
Southgate
London
N14 6JB

Tel: 0181 882 1951
Fax: 0181 886 7757

Enquiries *in writing*: regarding this notice should be addressed as follows:

DEFECT & INVESTIGATION CENTRE (NIDIC)
Health Estates
Estate Policy
Stoney Road
Dundonald
Belfast BT16 0US *marked for the attention of Mr E K Devenney*

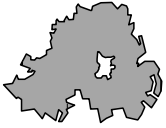
Yours faithfully

E K DEVENNEY
Defect Centre Manager

HOW TO REPORT DEFECTS

Professional Estate Letter PEL(93)36 issued by Estate Services Directorate, on 27th July 1994 advises Health and Social Services Boards, HSS Trusts and agencies how to notify HPSS about accidents with and defects in medicinal products, buildings and plant and other medical and non medical equipment and supplies.

NORTHERN



IRELAND

HN(NI)97/09

HAZARD

Title:

SHELF PESSARY (ALSO KNOWN AS SIMPSON PESSARY)

ALL SIZES

ACTION BY:

(A) BOARD/TRUST

Address/Address Stamp

This document was forwarded to the relevant Department/Personnel for action on _____(date)

(B) RECIPIENT [Please return to the issuing Authority at (A) above, after completed action]

Receipt of the document is acknowledged and appropriate action completed on _____(date)

Signature _____ Position _____

Name (please print) _____

Address _____

(C) COMMENTS ON ACTION TAKEN