



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 1US

Telephone 028 90 523714
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HN(NI) 2000/10

Date: 6 June 2000

Product	:	TRILUCENT™ BREAST IMPLANTS: Recommendation to Remove
Manufacturer/ Supplier	:	LIPOMATRIX INC/AE1 INC (FORMERLY COLLAGEN AESTHETICS INTERNATIONAL INC)
Problem	:	PRODUCTION OF POTENTIALLY GENOTOXIC COMPONENTS FROM THE BREAKDOWN OF SOYA BEAN OIL FILLER.
Action	:	IDENTIFY ALL WOMEN WHO HAVE BEEN IMPLANTED WITH TRILUCENT™ BREAST IMPLANTS AND ARRANGE FOR THEM TO HAVE A CONSULTATION WITH A PLASTIC SURGEON TO DISCUSS THE ATTACHED RECOMMENDATIONS FROM AN INDEPENDENT ADVISORY GROUP AND THE OPTIONS FOR CLINICAL MANAGEMENT.

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 aside:

- ◆ Chief Executives, Medical Directors and Nurse Executive Directors
- ◆ All Medical and Nursing Staff in Hospitals and in the Community
- ◆ Plastic and Cosmetic Surgeons and all surgeons involved in breast reconstruction
- ◆ Directors of surgical units involved in breast reconstruction
- ◆ Cancer Centres and Cancer Units
- ◆ General Medical Practitioners
- ◆ All Theatre Staff
- ◆ Supplies Departments
- ◆ Safety Liaison Officers
- ◆ MRI Departments
- ◆ Registration and Inspection Units

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".



HEALTH ESTATES

ESTATE POLICY
ESTATE POLICY

An Executive Agency of the Department of Health
and Social Services and Public Safety

2. IMMEDIATE ACTION

1. Identify all women who have been implanted with Trilucent™ breast implants and arrange for them to have a consultation (see Annex 2) with a plastic surgeon to discuss the attached recommendations from an Independent Advisory Group (see Annex 1) and the options for clinical management.
2. Advise women to consider having their Trilucent™ breast implants removed. Priority should be given to those women who have already shown a reaction to the implants (such as local swelling) and to those considering pregnancy.
3. Prior to removal of the implants, give advice regarding contraception, breast-feeding and replacement with other implants (see Annex 1).
4. During consultation, stress that all the above advice is precautionary. Although there have been reports of breast swelling and discomfort in some women with these implants, there has been no clinical evidence of any serious health problems, so far.
5. As part of her consultation, ensure the woman is given a copy of Annex 3 “Information for Women about Trilucent™ Breast Implants”.

3. BACKGROUND

Trilucent™ (soya bean oil filled) breast implants obtained CE marking in 1995. Over 9000 implants have been implanted into almost 5,000 women in the UK.

In 1999 the Medical Devices Agency (MDA) raised concerns relating to the long-term safety of Trilucent™ breast implants particularly in relation to the breakdown of the filler. As a result of MDA's concerns the company voluntarily withdrew the product from the market in March 1999 as a precautionary measure. At this time MDA issued advice to the Health Service¹. The Advice Notice stated that there were no data to suggest that removal of Trilucent™ breast implants was indicated. However, women were advised to seek an immediate consultation if they noticed unusual breast swelling or inflammation associated with their Trilucent™ breast implants.

The company agreed to MDA's request to carry out further toxicological testing. The results of these preliminary tests, suggest that genotoxic products may be created when the soya bean oil breaks down.

Future Investigation

MDA is working with AEI Inc in the continuing investigation of the nature and amount of breakdown products arising from the filler. In addition, further clinical monitoring is proposed. MDA will provide further advice as necessary.

Reference

1. AN1999(01) - Trilucent™ breast implants: voluntary withdrawal. Copies can be obtained from Northern Ireland Defects and Investigation Centre.

REIMBURSEMENT AND CLINICAL MANAGEMENT

Arrangements for reimbursement have been made with AEI Inc, under which the company has undertaken to pay certain agreed expenses for consultation, implant removal, replacement with other implants (where indicated) and follow-up care.

AEI Inc has established the Trilucent Care Centre to manage the programme of activities arising from this Notice. Women with Trilucent™ implants, plastic surgeons, GPs, and all other interested parties are encouraged to contact the Centre at the address/telephone number given below. The centre will be open 24 hours a day, seven days a week.

4. ENQUIRIES

Trilucent™ breast implants were manufactured by Lipomatrix Inc. Product liability now rests with AEI Inc which has confirmed its willingness to act in the best interests of affected women and has taken on responsibility for the current healthcare management and explanation programme.

Enquiries to the company should be addressed to:

Ann Richardson
AEI Inc
Chiltern Court
37 St Peters Avenue
Caversham
Berkshire
RG4 7DH

Tel: 0118 9469 100
Fax: 0118 9461 010

Mrs Sue Warburton
Trilucent Care Centre
Freepost
Anchorage 3
Anchorage Quay
Salford Quays
M5 2XL

Tel for Clinicians: 0845 608 0808
Tel for Women: 0800 028 6622

Clinical Aspects

Dr G Mock
Room C3.8
Castle Buildings
Upper Newtownards Road
Belfast BT4 3PP

Tel: 028 90 520710
Fax: 028 90 520718

Enquiries regarding this notice should be addressed as follows:

NORTHERN IRELAND DEFECT & INVESTIGATION CENTRE (NIDIC)

Health Estates
Estate Policy
Stoney Road
Dundonald

Belfast BT16 1US

marked for the attention of Mr Brian Godfrey

Tel: 028 90 523714
Fax: 028 90 523900

Email: brian.godfrey@dhsspsni.gov.uk

Yours faithfully

BRIAN GODFREY
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.



HAZARD

HN(NI)2000/10

Title:

TRILUCENT™ BREAST IMPLANTS

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