



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
General Practitioners

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ADVICE NOTICE (NI) 99/01

Date: 8 March 1999

Product	:	TRILUCENT™ BREAST IMPLANTS:
Manufacturer/ Supplier	:	LIPOMATRIX INC/COLLAGEN AESTHETICS INTERNATIONAL INC
Issue	:	VOLUNTARY RECALL OF TRILUCENT™ BREAST IMPLANTS BECAUSE OF SAFETY CONCERNS
Action	:	DO NOT IMPLANT TRILUCENT™ BREAST IMPLANTS. IDENTIFY AND ISOLATE ALL STOCKS AND RETURN THEM TO THE MANUFACTURER

ADVICE NOTICE

1. ATTENTION CHIEF EXECUTIVES/GENERAL MANAGERS

This Advice 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:

- ◆ 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
- ◆ Private Hospitals and Clinics involved in cosmetic/plastic surgery



HEALTH ESTATES
ESTATE POLICY

An Executive Agency of the Department of Health
and Social Services

2. IMMEDIATE ACTION

Do not implant Trilucent™ breast implants.

Identify and isolate all stocks of Trilucent™ breast implants and return them to a Lipomatrix Inc/Collagen Aesthetics International Inc representative.

Identify all patients implanted with Trilucent™ breast implants (for further information, see Annex 1).

Inform the N.I Defect and Investigation Centre of problems relating to safety and performance of Trilucent™ breast implants.

3. BACKGROUND

The supplier estimates that since Trilucent™ breast implants were first marketed in 1995, over 9,000 have been sold in the UK, (approximately 120 of these in N Ireland) representing in the order of 5,000 women having these devices. From the information available to the Department of Health and Social Services in Northern Ireland, it seems that all implants have been carried out in the Private sector.

Trilucent™ breast implants consist of a silicone elastomer shell containing a lipid filler derived from soyabean oil. Chemical breakdown of the lipid filler occurs in the body following lipid leak through the intact implant shell or shell rupture. The extent of chemical breakdown of the filler in intact implants is not known.

The MDA has received 74 adverse incident reports (no reports in Northern Ireland) on Trilucent™ breast implants from clinicians and the supplier, including some reports of swelling generally associated with implant rupture.

The underlying aetiology of the swelling is unknown, but it may be due to a local inflammatory response. This local swelling is believed to resolve once the ruptured implant has been removed.

As a result of concerns arising from investigation of the reported adverse incidents, MDA requested relevant technical information from the supplier. Review of this information has revealed that the degree of chemical breakdown of the filler found in implants removed from women is in some cases significantly different than that predicted during pre-clinical testing.

This breakdown results in some biologically active substances the toxicology of which has not been adequately evaluated.

In the light of the MDA's concerns over long term safety of degraded filler to patients, the supplier has, as a precautionary measure, voluntarily withdrawn Trilucent™ breast implants from the UK market.

FUTURE INVESTIGATIONS

The Department of Health (DH) is working with the supplier to review the available clinical and toxicological data and to identify further testing which may be required. DH will provide the results of these investigations as soon as they are available.

4. ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Medical Director
Collagen Aesthetics
Freepost 438
Thame
Oxon OX9 3BR

Freephone 0800 216 613

CLINICAL ENQUIRIES in Northern Ireland should be directed to:-

Dr G Mock
Room C3.9
Castle Buildings
Upper Newtownards Road
Belfast BT4 3PP
Tel: 01232 520710
Fax: 01232 520718

Enquiries *in writing*: 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 Dominic Cafolla*
Fax 01232 523900

Yours faithfully

Dominic Cafolla
Deputising 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, medical devices and other medical and non medical equipment and supplies.

ANNEX 1

GUIDANCE ON CONSULTATION WITH WOMEN IMPLANTED WITH TRILUCENT™ BREAST IMPLANTS

The Medical Devices Agency and the Department of Health, give the following advice on which they have consulted with the relevant professional organisations

Need for consultation

Women who believe that they may have Trilucent™ breast implants should either make an appointment with their General Medical Practitioner or consult the surgeon who carried out the initial implantation or another suitably qualified clinician

General advice

The Department of Health is setting up a 24-hour Health Alert Line on 0800 004440 for women with Trilucent™ breast implants who are worried about the possible effects on their health.

Payment for consultation

Arrangements for reimbursement for further consultation are under discussion.

Points to be discussed during the consultation

The following points are listed as guidance to clinicians carrying out consultation with women implanted with Trilucent™ breast implants.

- the reason for the withdrawal of supplies of Trilucent™ breast implants
- that there are currently no safety data to suggest the removal of Trilucent™ breast implants is indicated
- that women should seek an immediate consultation if they notice unusual breast swelling or inflammation associated with a Trilucent™ breast implant
- the need for future clinical follow up
- any decision to remove Trilucent™ breast implants should be taken jointly by the woman and her clinician, based upon the individual clinical circumstances of each woman
- some women with Trilucent™ breast implants may be identified through the presence of a transponder
- MRI should not be carried out because this may cause damage from heating up the transponder