

7 June 2000

To: Consultant Plastic Surgeons
Consultant General Surgeons
General Practitioners
Directors of Public Health
Medical Directors of HSS Trusts
Directors of Nursing and Chief Nurses, HSS Boards
Directors of Nursing, HSS Trusts
Professors of Nursing, Queens & University of Ulster
In-Service Education Providers
Professional Organisations

Dear Colleague

TRILUCENT BREAST IMPLANTS

IMPORTANT: This information only applies to women who have had Trilucent breast implants inserted. These were used from 1995 to March 1999 when they were withdrawn from use.

This message is being issued to health professionals to help them provide advice to women who may approach them about Trilucent™ breast implants. These implants consist of a silicone elastomer shell containing a lipid filler derived from soybean oil and have been available since 1995. Previous advice was issued in March 1999 where these breast implants were withdrawn (ref HSS (MD) 4/99 and CNO letter 1/99).

MDA set up an Independent Advisory Group to evaluate the evidence available on the toxicity of the breakdown products of the filler material used in Trilucent™ breast implants.

The Advisory Group concluded that:

- there was an explicit risk from the potential release of genotoxic products as a result of the on-going diffusion of filler through the implant shell and possible rupture of the shell;
- although there were insufficient data to establish an increased risk of cancer or reproductive toxicity, these possible risks could not be excluded;
- all women with these implants should be informed that removal of Trilucent™ breast implants is now recommended because of these risks;
- there were no data on the safety or otherwise of implanting other breast implants subsequent to the removal of Trilucent™ implants.

The Advisory Group were unable to exclude the risk of reproductive effects on the basis of the data available, although there was no direct evidence for such effects. Neither MDA nor the manufacturer has received any reports of problems or abnormalities with babies born to

mothers with Trilucent™ breast implants. However the Group provided the following advice but stress that it is precautionary:

- The Advisory Group agreed that it was prudent to advise that pregnancy should be avoided (by use of contraception) until the implants were removed, but that this precaution would not be necessary after explantation as the breakdown products would be rapidly cleared by the body;
- In the Advisory Group's opinion, the possibility of genotoxic degradation products migrating from implants to breast tissue and milk could not be discounted. It was therefore prudent to recommend that breast-feeding should be avoided prior to removal of Trilucent™ breast implants.

The Advisory Group stressed that even if Trilucent breast implants were removed from women, additional studies would be needed to further characterise the risk and to form a basis for further advice to affected women.

Around 8000 women a year receive breast implants in the UK and in the order of 5000 women in total have received Trilucent™ breast implants. In Northern Ireland there has been approximately 100 Trilucent™ implants. From the information available to the Department of Health and Social Services and Public Safety it seems that all Trilucent™ implant operations have been carried out in the Private Sector in Northern Ireland. To date no adverse incidents have been reported in Northern Ireland.

Yours sincerely

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Chief Nursing Officer