

Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/54

Issued: 28 September 2004

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	✓
INFORMATION REQUEST	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
Medical Device/Equipment: Trilucent (soya bean oil filled) breast implants.	▶ ①
Problem: Previously identified risk from Trilucent breast implants; actions following conclusion of research and update of HN(NI)2000/10	▶ ②
Action by: Plastic, reconstructive and oncological surgeons.	▶ ③
Action: See actions on page 2.	▶ ④
Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers General Medical Practitioners	▶ ⑤
Contacts Details of the company with product liability (AEI Inc) and Trilucent Care Centre, NIAIC contacts for technical and clinical aspects.	▶ ⑥
Feedback Requirements to NIAIC Inform the Trilucent Care Centre, AEI Inc and NIAIC of any incidents associated with the use of Trilucent breast implants.	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

Trilucent (soya bean oil filled) breast implants manufactured by Lipomatrix Inc. Subsequently the product liability was taken on by Collagen Aesthetics International and then by AEI Inc. These implants were withdrawn from use in the UK in March 1999.

2. PROBLEM:

NIAIC issued two notices about this device:

- An Advice Notice about the voluntary recall of Trilucent breast implants (Advice Notice (NI)99/01). This was in response to the Agency identifying concerns about the long-term safety, particularly in relation to the breakdown of the filler material.
- A Hazard Notice advising that removal of Trilucent breast implants is recommended (HN(NI)2000/10). This advice was issued because the preliminary results of toxicological testing indicated that the breakdown products of the soya bean oil filler material were potentially genotoxic.

Approximately 4,500 women were implanted with Trilucent breast implants in the UK. As of July 2004, over 3,700 women in the UK have had their Trilucent breast implants removed.

In 2000, a programme of research was initiated to investigate any potential risks to women implanted with Trilucent breast implants. This programme was directed, on behalf of AEI Inc, by a panel of independent experts. The programme has recently been completed. The results and conclusions of the research are summarised in Annex 1. A more detailed report of the research programme is available on the Trilucent website (<http://www.trilucentinfo.com>) and full details of investigations and results will be published in peer reviewed journals in due course.

The independent experts concluded that:

- the recommendation that Trilucent breast implants should be removed remains appropriate because exposure of local tissue to toxic compounds has been confirmed
- there is no evidence for local or systemic disease risk once the implants have been removed
- no further studies are needed to assess the potential risk of Trilucent breast implants.

The results of the recently completed research programme suggest that there is no significant systemic risk from Trilucent breast implants, whether they are left in place or removed. Therefore, there is no significant risk to the fetus or children of implanted women and there is no evidence to suggest that breastfeeding should be avoided.

Although the research programme has been completed, MHRA continues to record and investigate reports of adverse events associated with Trilucent breast implants. If further problems are identified, NIAIC will issue advice.

3. ACTION BY:

Plastic, reconstructive and oncological surgeons.

4. ACTION:

- Be aware that this Alert supersedes HN(NI)2000/10
- Be aware of the conclusions of the Trilucent research programme (see Annex 1)
- Identify women who were implanted with Trilucent breast implants
- For women who still have these devices implanted:
 - Arrange for a consultation
 - Inform them of the conclusions of the research programme (see Annex 2)
 - Advise them to consider having their Trilucent breast implant removed
 - Inform the Trilucent Care Centre
- For women who have already had these devices removed:
 - Reassure them that neither they nor their children are at an increased risk of disease (see Annex 2)

Be aware that the Trilucent Care Centre will close on 31 December 2004.

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Medical Directors
- Nursing Directors
- Medical, Nursing and Care Staff
- Oncological Surgeons
- Plastic Surgeons
- Practice Nurses
- Directors of Public Health
- Independent Health and Social Care Providers – Private Clinics including Cosmetic Surgery Clinics through HSS Board R&I Units
- Operating Theatre Staff
- Specialist Nurses involved in Breast Cancer Care

6. CONTACTS:

Enquiries to AEI Inc or Trilucent Care Centre should be addressed to:

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

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

Tel: 0118 9469 100

Fax: 0118 9461 010

Tel: 0845 608 0808

*Note:

E-mail: Annricha@aol.com

1. The Trilucent Care Centre was set up in 2000 for the care of women with Trilucent breast implants, including arranging payment of any incurred costs.
2. The Trilucent Care Centre will close on 31 December 2004, after which date AEI Inc will take responsibility for these functions.

Enquires to NIAIC should quote reference number MDEA(NI)2004/54 and be addressed to:
Northern Ireland Adverse Incident Centre (NIAIC), Health Estates, Estate Policy Directorate
Stoney Road, Dundonald, Belfast BT16 1US

Tel: 028 9052 3868 Fax: 028 9052 3900 Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

Inform the Trilucent Care Centre, AEI Inc and NIAIC of any incidents associated with the use of Trilucent breast implants.

Brian Godfrey
NIAIC Manager



HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2004/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety

Results and conclusions of the Trilucent research programme

Background

Degradation of lipids, such as the soya bean oil filler used in Trilucent breast implants, can give rise to genotoxic breakdown products. However, the body is capable of dealing with low levels of exposure to such compounds without any significant risk of harmful effects. In 1999, the Medical Devices Agency (MDA, now part of the MHRA) became concerned about reports of swelling and inflammation of the breast, associated with the rupture of Trilucent breast implants. These implants were removed from use as a precautionary measure when it was found that the rate of degradation of the filler material was higher than expected.

In 2000, MDA advised explantation of Trilucent breast implants when it was confirmed that potentially genotoxic breakdown products were present in explanted filler material and a programme of research was initiated to investigate the risks to women implanted with Trilucent breast implants. This programme has now been completed. The research programme was designed and carried out by a panel of independent experts from the UK and the USA, who are experts in the fields of toxicology, medicine and chemistry. They obtained the following results:

Studies on implants and filler material:

- While the risk of breast implant rupture is low, the soya bean oil filler may weaken the shell of Trilucent breast implants over time, possibly increasing the risk of rupture with length of time implanted.
- Recently completed studies have confirmed the presence of a compound known to be genotoxic in samples of filler material taken from women with Trilucent breast implants. There was a correlation between the concentration of this breakdown product in the explanted filler material and genotoxicity in an in vitro test.

Studies using clinical samples:

- Plasma and urine taken from patients implanted with Trilucent breast implants were compared with control samples taken from patients who had been implanted with silicone gel breast implants. The concentration of breakdown products was higher in some samples taken from women with Trilucent breast implants than in the controls. However, they were within the range expected for healthy individuals and did not alter following explantation. It was concluded that the differences seen could not be attributed to the presence of Trilucent breast implants.
- Analysis of tissue taken from the fibrous capsule surrounding Trilucent breast implants provided evidence that breakdown products had reacted with DNA in the fibroblasts and inflammatory cells of the capsule. No such reactions were detected in white blood cells from the systemic circulation. These findings provide confirmation of local, but not systemic, exposure to genotoxic breakdown products, but do not amount to evidence of a toxic response.
- A histological study of capsules surrounding Trilucent breast implants revealed no atypical features and found that the tissue exhibited changes typical of capsules surrounding other types of breast implant.
- It was noted that the cell types found in the capsule are not progenitors of mammary epithelial carcinoma and the location of the implant would preclude the possibility of breakdown products reaching the mammary ductal system, which is the site of mammary carcinoma.

The independent experts and MHRA agree that the results summarised above are sufficient to characterise the toxicological risk to women who received Trilucent breast implants. Additional research, such as an epidemiology study, would be unlikely to provide worthwhile additional information. It is therefore unlikely that further significant information on the risks of Trilucent breast implants will become available in the future.

Conclusions

The independent panel of experts concluded that:

- the risk of breast implant rupture is low but the shell of Trilucent breast implants may deteriorate more quickly than that of other types of breast implant and the risk of rupture increases with length of time implanted
- the filler material undergoes degradation leading to the production of genotoxic breakdown products
- there is no evidence of any adverse health effects arising from genotoxic breakdown products
- breakdown products were found to bind to DNA in the periprosthetic capsule, confirming exposure of local tissue to genotoxic compounds. However, exposure of mammary tissue or the rest of the body to breakdown products is unlikely and there is no evidence for systemic exposure
- any breakdown products would be rapidly metabolised and removed from the body, thus eliminating the risk once the implants have been removed.

In summary, the research programme confirmed that women with implants in place can be exposed to genotoxic breakdown products arising from the filler material. However, such exposure is localised to the periprosthetic capsule. There is minimal risk of exposure of breast tissue, other parts of the body, a fetus or breast-fed baby, to genotoxic compounds arising from the filler material.

On the basis of these conclusions, it is clear that the recommendation that Trilucent breast implants should be removed remains appropriate. However, there is no significant systemic risk to women who were implanted with Trilucent breast implants, or to their children.

Annex 2 to MDEA(NI)2004/54

Information for women who were implanted with Trilucent breast implants

NIAIC has provided this information sheet. It is intended to give you information about Trilucent breast implants.

Trilucent breast implants are filled with soya bean oil and were sold in the UK between 1995 and 1999, when the Agency identified that Trilucent breast implants might be unsafe. In 2000:

- the Agency recommended that women should consider having these implants removed
- the Trilucent Care Centre was set up by AEI Inc. (the company that assumed liability for Trilucent breast implants) to co-ordinate the care of women who had received Trilucent breast implants
- an independent study was set up to investigate the potential risks associated with this implant .

The study has recently been completed. It confirmed that there is a risk of exposure to harmful breakdown products that can react with tissue surrounding the implant. Therefore, NIAIC continues to recommend that women should have their Trilucent breast implants removed. However, the study found no evidence that Trilucent breast implants caused health problems in implanted women and it is clear that removal of the implants removes any risk.

The arrangements that were put in place in 2000 for the care of women with these implants, including payment of any incurred costs, will close on 31 December 2004. After that date, the point of contact will be AEI Inc and there is no guarantee that incurred costs will be reimbursed.

Advice to women

If you still have Trilucent breast implants:

You should contact your surgeon immediately to arrange a consultation to discuss:

- the risks associated with Trilucent breast implants
- whether you should have your Trilucent breast implants removed
- implications for pregnancy and breastfeeding
- arrangements for future clinical follow-up.

Whether or not you decide to have your Trilucent breast implants removed, you should get in contact with the Trilucent Care Centre so that you can be informed if any further advice or information becomes available.

If you had Trilucent breast implants in the past but have already had them removed:

You can be reassured that, once the implants are removed, there appear to be no long-term risks to you or your children. Furthermore there is no evidence that breastfeeding could harm your baby.

If you want further advice:

You should contact your surgeon.

Useful telephone numbers

Trilucent Care Centre (operational until 31 December 2004)

Contact: Mrs Sue Warburton 0845 608 0808

AEI Inc (company with product liability and manager of Trilucent Care Centre after 31 December 2004)

Contact: Mrs Ann Richardson 0118 9469 100

Northern Ireland Adverse Incident Centre (NIAIC)

Contact: Tel: 028 9052 3868

Email: NIAIC@dhsspsni.gov.uk