

AN (NI) 2000/09

DATE: 11 December 2000

**For Attention and Action by:
Chief Executive of each HSS Trust
General Manager/Chief Executive of each HSS Board
Chief Executive of each Agency**



HEALTH ESTATES
ESTATE POLICY

**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

TITLE:

Breast Implants: Novagold™

MANUFACTURER/SUPPLIER

Novamedical/Somatech Medical Ltd

PROBLEM

Recall of NovaGold™ breast implants.

DISTRIBUTION

This notice should be brought to the attention of all who need to know or be aware of it, including those listed below, in accordance with local procedures. This will include:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Medical Directors
- Clinical Directors
- Nursing Directors
- Medical, Nursing and Care Staff
- Plastic and Cosmetic Surgeons and all Surgeons involved in breast reconstruction
- Directors of surgical units involved in breast reconstruction
- Specialist Nurses involved in breast cancer care
- Private Hospitals and Clinics involved in plastic, cosmetic and breast reconstructive surgery
- General Medical Practitioners – for information in case women contact you
- Practice Nurses - in case women contact you

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

ACTION

1. Do not implant NovaGold™ breast implants.
2. Identify and isolate all stocks of NovaGold™ breast implants and return them to Supplier.
3. Report any adverse incidents concerning implanted devices to NIAIC.

ADVICE

NOTICE

BACKGROUND

NovaGold™ breast implants are made in Germany and supplied by Somatech Medical Ltd in the UK. Approximately 250 women in the UK have been implanted with these implants since they were first introduced in 1996. In formation available to the Department of Health, Social Services and Public Safety would indicate that no women in Northern Ireland have these implants, but this Advice Notice is being issued to ensure that healthcare professionals have information concerning this product.

NovaGold™ breast implants have a silicone elastomer shell and filled with a polyvinylpyrrolidone (PVP) hydrogel and guar gum gel. PVP was previously used in the filler of another breast implant (MistiGold) manufactured by Bioplasty Inc. which was supplied until the mid 90's.

Hydrogels are polymeric materials that have the ability to swell in water without dissolving and to retain water within their structures. There are many different types of hydrogels which are used in a wide variety of products including, pharmaceuticals, foods and medical devices such as contact lenses and surgical dressings. The information given in this Advice Notice applies only to NovaGold™ breast implants and not to other uses of hydrogel.

CONCERNS

Because of concerns received in relation to breast implants, MDA has been undertaking a series of planned investigations into the safety of breast implant filler materials. Only one adverse incident (an implant rupture) has been reported involving NovaGold™ breast implants. However, MDA's investigation has identified that the manufacturer's biological safety assessment of this product is inadequate, due to the lack of long-term toxicity data or clinical follow-up, together with methodological flaws in some of the pre-clinical tests. The particular concerns are:

- Uncertainty over the metabolic fate of the filling material.
- Pathological changes suggesting a systemic effect in rabbits following implantation of the filling material for 28 days. No long-term toxicity data are available to allow an assessment of the significance or reversibility of these effects.
- Lack of data to assess risks arising from the implantation of guar gum.

In light of this, MDA has concluded that, as a precautionary measure, no more NovaGold™ breast implants should be implanted until these concerns have been addressed.

ADVICE FOR IMPLANTED WOMEN

Women who are worried should be offered a consultation. It should be emphasised that a definite health risk has not been identified. The concern lies only with the adequacy of the safety assessment for NovaGold™ breast implants. **There is no evidence at present to recommend explantation of NovaGold™ breast implants.** Any decision to explant NovaGold™ breast implants should be taken jointly by the woman and her clinician/surgeon, based upon the individual clinical circumstances, balancing the potential risk arising from the lack of safety data against the known risks associated with any surgical procedure.

At present, there is no information to indicate that there is any specific risks to women or any effects on children, either prior to or during pregnancy or from breast feeding.

There is no indication from the scientific studies currently available to suggest that pregnancy should be postponed. Women who are concerned about the inadequacy of the safety assessment may wish to consider waiting until further safety tests have been performed and evaluated, before planning a pregnancy.

Annex 1 has been written to provide information to women. In addition they can ring the Health Information Service on 0800 66 55 44.

PAYMENT FOR CONSULTATION

The Department is currently pursuing reimbursement for clinical consultations with the manufacturer.



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FUTURE INVESTIGATION/ADVICE

The manufacturer has been asked to carry out further testing and to provide the results to MDA for review. MDA's analysis of the test results will be made available along with clear recommendations if appropriate.



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ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Dr Aydin Dogan
NOVAMEDICAL Products GmbH
Heinestr. 3
D-40789 Monheim
Germany

Tel: + 49 21 73 95 38 0
Fax: + 49 21 73 95 38 55

Clinical Aspects:

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

Tel: 02890 520710
Fax: 02890 520718

Enquires to the NIAIC should quote the reference number AN (NI) 2000/09 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US
Marked for the attention of Mr Brian Godfrey

Tel: 02890 523714
Fax: 02890 523900
Email: brian.godfrey@dhsspsni.gov.uk

Brian Godfrey
NIAIC Manager

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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 Safety Notice SN (NI) 2000/NIAIC. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided.

*Health Estates is an Executive Agency of the Department of Health, Social Services and Public Safety
Áisíneacht Feidhmeannach don Roinn Sláinte. Serbhísí Sóisialta agus Sábháilteacht Phoiblí*

INFORMATION FOR WOMEN ABOUT NovaGold™ HYDROGEL BREAST IMPLANTS

The Department of Health, Social Services and Public Safety (DHSSPS) in co-operation with the Medical Devices Agency (MDA) has provided this information sheet. It is designed to give you information about NovaGold™ breast implants.



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Background

NovaGold™ breast implants are filled with a hydrogel. Hydrogels consist mainly of water with a substance to give them a “jelly-like” consistency.

There are many different types of hydrogels used in a wide range of products including foods, medicines and contact lenses. MDA’s advice relates only to the hydrogels used in the NovaGold™ breast implants on sale in the UK and not to hydrogels used in other products.

Reason for removing NovaGold™ breast implants from the UK market

It should be emphasised that a definite risk has not been identified. There are no known cases of harm caused by NovaGold™ breast implants. The concern is only with the way the safety of the hydrogel filler has been assessed.

MDA has looked at the breast implants filled with hydrogel on the UK market. The information provided by the makers of NovaGold™ breast implants was looked at and MDA found that there is not enough information to fully assess the filler material.

Because of their concerns, MDA has decided that no more NovaGold™ breast implants should be used until more information is available.

MDA is not recommending the removal of NovaGold™ breast implants.

If new information comes to light which changes MDA’s advice, the DHSSPS will immediately inform doctors and women about this.

General Advice

If you think you have NovaGold™ breast implants and you are worried you may wish to:

- contact your Surgeon or your Doctor.
- get advice from the Health Information Service on tel. 0800 665 544.

Removal – At present there is no information to suggest that you should have your NovaGold™ breast implants removed. If you have concerns discuss these with your Surgeon or Doctor.

Rupture - If your NovaGold™ breast implants have ruptured, you should discuss this with your surgeon.

Having a Baby or Breast Feeding – At present there is no information to indicate there is any actual risk of effect on children, either prior to or during pregnancy or from breast feeding.

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