

AN (NI) 2001/06

DATE: 27 September 2001

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



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TITLE:

**Hylamer Polyethylene Components Sterilised by
Gamma-Irradiation in Air:**

- 1. Duraloc Acetabular Liners,**
- 2. Hylamer Acetabular Cups**
- 3. Hylamer Global Shoulder Glenoid Components**

MANUFACTURER/SUPPLIER

DePuy International Ltd

PROBLEM

Poor clinical performance of some of the above joint replacement implant components, made from Hylamer polyethylene which has been sterilised by gamma-irradiation in air.

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
- Nursing Directors
- Trust Pharmacy Managers
- Supplies Staff
- Theatre Managers
- Orthopaedic Surgeons
- Directors of Orthopaedic Surgery
- Private Hospitals and Clinics
- General Medical Practitioners

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 and Private Hospitals and Clinics.

IMMEDIATE ACTION

On 26 September 2001 DePuy International Ltd sent a list of implant components incorporating Hylamer sterilised by gamma-irradiation in air to hospitals and clinics in England and Scotland who were supplied with these components. **We understand that none of these products were supplied to Northern Ireland**, but there is a possibility that patients who were fitted with these components may have moved away from their area of treatment in England or Scotland and may be living here. Additionally, patients will not know what type of implant they have and may be anxious. This Advice Notice provides information about the products should a patient approach their GP or hospital with enquiries about their implants.

The Medical Devices Agency have advised the NHS in England and Scotland to not implant any of the listed components.

- Identify all patients implanted with the listed components

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- Where the identified patients are already undergoing annual review, including radiographic examination, continue to monitor their progress. Look for evidence of accelerated wear, progressive osteolysis or fracture of the component.
- Where the identified patients are not currently undergoing annual review, recall them for clinical assessment, including radiographic examination, on an annual basis. Look for evidence of accelerated wear, progressive osteolysis or fracture of the component.
- Inform the Medical Devices Agency (MDA) of any cases that have been revised or are awaiting revision, with the reason for revision.
- Isolate any remaining stock of listed components and return them to the manufacturer.



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BACKGROUND

1. Hylamer was introduced by DePuy International Ltd in 1990 as a modified "implant grade" polyethylene developed to reduce wear in total joint replacement components. Initially all Hylamer components were sterilised by gamma-irradiation in air. Subsequently the Hylamer components were sterilised by different processing methods. In the late 1990s, a significant decrease in demand led to Hylamer being superseded by other materials.
2. No components incorporating Hylamer sterilised by gamma-irradiation in air have been supplied in Wales or Northern Ireland.
3. Hylamer Duraloc Acetabular Liners, sterilised by gamma-irradiation in air, were supplied in the UK between March 1990 and September 1997. The company's records show that 16 liners were supplied to 7 clinical centres in England.

Hylamer Ogee Acetabular Cups, sterilised by gamma-irradiation in air, were supplied in the UK between March 1994 and August 1999. The company's records show that 1715 cups were supplied to 90 clinical centres in England and Scotland.

Hylamer Global Glenoid shoulders, sterilised by gamma-irradiation in air, were supplied in the UK between April 1991 and December 1997. The company's records show that 290 components were supplied to 45 clinical centres in England and Scotland.

4. The presence of oxygen during gamma sterilisation and storage of sterilised components is known to cause progressive oxidative degeneration of "implant grade" polyethylene and is associated with decreased wear resistance and increased brittleness. Literature reports^{1,2,3,4} suggest that Hylamer is more susceptible to oxidative degradation than conventional "implant grade" polyethylene used in joint replacement implants.

Clinical experience - Duraloc Acetabular liners

5. DePuy International Ltd received a report of 7 cases of revision of Hylamer Duraloc Acetabular Liners within 5 years of implantation, in one centre in the UK. A radiographic review showed that, for components sterilised by gamma-irradiation in air which were stored for less than 3 years prior to implantation, the *in-vivo* wear rate was consistent with that usually seen with conventional "implant grade" polyethylene components. However, the wear rate in similar components that had been stored for more than 3 years prior to implantation was greater. Further clinical data, from an Australian clinic, showed 5 cases where the wear rate for Hylamer Duraloc Acetabular Liners sterilised by gamma-irradiation in air, which had been stored for more than 4 years prior to implantation, was greater than expected.

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Clinical experience - Ogee Acetabular Cups

6. DePuy International Ltd received a further report of a similar problem for Hylamer Ogee Acetabular Cups which had been sterilised by gamma-irradiation in air and used in conjunction with zirconia heads. In a 30 patient cohort, 10 patients had undergone or were awaiting revision. A partial review of the case notes by MDA showed that of 9 patients who had undergone or were awaiting revision, the average storage time of the components prior to implantation was 2.3 years, with a range from 1.1 to 3.9 years. A second centre has also reported 4 early revisions for wear of Hylamer Ogee Acetabular Cups, which had been sterilised by gamma-irradiation in air and used in conjunction with zirconia heads, with a storage time prior to implantation of less than 31 months.

However two other centres have reported excellent results with the same prosthesis in similar cohorts of patients. One centre, with 125 patients implanted with Hylamer Ogee Acetabular Cups that had been sterilised by gamma-irradiation in air and used in conjunction with zirconia heads, has had only one revision, which was unrelated to wear. In this series there is no radiographic evidence of loosening at five years follow up. In a second series, 47 patients with 58 hips have had no revisions (with no revisions pending) at a mean implantation time of 4.75 years.

Clinical experience - Global Shoulder Glenoid Component

7. DePuy International Ltd has advised MDA that recently available evidence shows that oxidation also occurs in Hylamer Global Shoulder Glenoid Components, when sterilised by gamma-irradiation in air. This may cause fixation peg fracture on insertion of the glenoid component during shoulder arthroplasty, due to decreased crack resistance. There is also a potential for increased wear or fracture after implantation in these components.

Patient management

8. It is possible that patients who have received affected Hylamer implant components that have been sterilised by gamma-irradiation in air may experience higher wear rates than normal and there may be a risk of premature implant failure, resulting in the need for clinical intervention or revision. MDA therefore considers it prudent to identify affected patients and review them.
9. As the effects of oxidation increase with the shelf age of the product at the time of implantation, patients having implants with the longest interval between sterilisation and implantation should be prioritised for review. The storage time can be established from the information supplied by the manufacturer to implanting centres (in the manufacturer's letter dated 26 September 2001) and the implantation date for each component (obtained from hospital records).
10. In all cases the benefit of radiographic examination should be weighed against the risks from radiation exposure on an individual patient basis, in line with the requirements of IR(ME)R 2000⁵.
11. The manufacturer and the Departments of Health in England and Scotland are finalising the arrangements for management of the patient reviews and details will be made available by DePuy International shortly.

Other Hylamer Components

12. There is no evidence of this problem occurring in Hylamer M components (used in knee implants), which use a different form of polyethylene, or with Hylamer products which have been subject to other sterilisation conditions or processes (such as gamma-irradiation in an inert atmosphere or gas plasma).



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Information for General Medical Practitioners

13. Patients in Northern Ireland may be concerned and may contact their doctor about this issue; so doctors may wish to be aware of the problem and the advice being given.

References

1. Collier J, Bargmann L, Currier B, Mayor M, Currier J and Bargmann B. An analysis of Hylamer and polyethylene bearings from retrieved acetabular components, Orthopaedics 1998, Vol 21 (8), 865-871.
2. Yamauchi K, Hasegawa Y, Isawada S, Sakano S, Kitamura S, Warashina H and Iwata H. Head penetration into Hylamer acetabular liners sterilised by gamma in air and in a nitrogen atmosphere, Journal of Arthroplasty 2001, Vol 16 (4), 463-470.
3. Yau S, Essner A, Schmidig G and Wang A. Effect of gamma sterilisation in air and shelf ageing on wear of enhanced an conventional UHMWPE acetabular cups, ORS 2000, 46th Annual Meeting, Orlando, USA>.
4. Schmalzreid T, Dorey F, McKellop H. The multi-factorial nature of polyethylene wear in-vivo. J Bone Joint Surg, 1998, 80A(8), 1234-1242.
5. The Ionising Radiation (Medical Exposure) Regulations 2000.

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Mr Paul Arnott
DePuy International Ltd
St Anthonys Road
Leeds
LS11 8DT
Tel: 0113 202 5948
Fax: 0113 387 6087

Enquires to the NIAIC should quote the reference number AN (NI) 2001/06 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

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) 2001/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided.

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



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