



# 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

Stoney Road Dundonald Belfast  
Northern Ireland BT16 1US

Telephone 028 90 523714  
Facsimile 028 90 523900  
GTN Code 440

HN(NI) 2000/09

Date: 2 June 2000

Product	:	<b>ACRYFLEX SC60B-OUV &amp; SC600-2 AND ORION IFP3D6 INTRAOCULAR LENSES</b>
Manufacturer/	:	<b>- MEDICAL DEVELOPMENT RESEARCH (ACRYFLEX SC60B-OUV &amp; SC600-2) - EUROCRYSTAL (ORION IFP3D6)</b>
Supplier	:	<b>- KESTREL HEALTHCARE LTD (ACRYFLEX SC60B-OUV ONLY) - VISION NET (ACRYFLEX SC600-2 ONLY) - OPHTHALMIC INNOVATIONS INTERNATIONAL (SC60BOUV &amp; SC600-2)</b>
Problem	:	<b>LENS OPACIFICATION (CLOUDING)</b>
Action	:	<b>DO NOT IMPLANT</b>

# HAZARD

## 1. ATTENTION CHIEF EXECUTIVES/GENERAL MANAGERS

This 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 aside:

- Medical Directors
- Nurse Executive Directors
- Directors of Ophthalmic Departments
- Ophthalmic Outpatient Departments
- Ophthalmic Surgeons
- Ophthalmic Theatre Managers and Supply Departments
- Optometrists
- Ophthalmologists
- Dispensing Opticians
- Chairs of Primary Care Groups
- Private Hospitals
- General Medical Practitioners
- Practice Nurses
- Supplies Departments
- Risk Managers
- Safety Liaison Officers

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



An Executive Agency of the Department of Health and Social Services and Public Safety

## 2. IMMEDIATE ACTION

Do not implant Acryflex SC60B-OUV & SC600-2 or Orion IFP3D6 intraocular lenses.

Identify and isolate any remaining stocks and return them to the supplier.

Identify all patients implanted with these intraocular lenses and recall them for early review to identify any cases of lens opacification (clouding).

Thereafter consider periodic review of these patients if the lenses show signs of opacification (clouding).

If clouding does not clear consider lens replacement.

Inform patients with no lens clouding at follow up that they should contact their surgeon if they develop any signs of clouding if they experience reduced vision.

Report any problems associated with these lenses to the NIDIC.

## 3. BACKGROUND

Acryflex SC60B-OUV & SC600-2 and Orion IFP3D6 are hydrophilic acrylic intraocular lenses used in the treatment of cataracts. Acryflex SC60B-OUV and SC600-2 lens are made by Medical Development Research and are supplied in the UK by Kestrel Healthcare Ltd, Vision net and Ophthalmic Innovations International. Approximately 3200 Acryflex SC60B-OUV and SC600-2 lenses have been supplied in the UK.

Since March 1999, the same lenses have also been sold in Europe by Eurocrystal as the Orion IFP3D6. Eurocrystal has informed the department that they have not supplied Orion IFP3D6 lenses in the UK.

The Department has received reports from seven UK hospitals of opacification (clouding) of Acryflex SC60B-OUV lenses in 27 patients. Nine patients have had their lenses removed for this reason. Clouding has been reported at between 0 and 24 months post-implantation.

The manufacturer has been unable to establish the cause of the clouding; the cause remains unknown at this time. As a result Medical Development Research has decided to discontinue the distribution of Acryflex SC60B-OUV & SC600-2 lenses in the UK as a precautionary measure. The Department believes that this action should extend to those lenses already in the distribution chain and is advising that no more of these lenses should be implanted in the UK.

In France, the French Health Ministry has received reports of 4 cases of opacification (clouding) in Acryflex SC60B-OUV lenses, and a further 10 cases in Orion IFP3D6 lenses at between 3 and 24 months post-implantation. As a result, the French Health Ministry has halted the distribution and use of these lenses in France.

Other Medical Development Research intraocular lenses are not affected by this notice.

#### 4. ENQUIRIES

Enquiries to the suppliers should be addressed to:

Clare Freemantle  
Kestrel Healthcare  
Network House  
Basing View  
Hampshire  
RG21 4HG  
Tel: 01256 307580  
Fax: 01256 307590

Gary Holt  
Vision net  
Derwent House  
Washington  
NE38 7ST  
Tel: 0191 415 0667  
Fax: 0191 415 0684

David Rowswell  
Ophthalmic Innovations International  
5 Cope Haven  
Shenley Brook End  
Milton Keynes  
Buckinghamshire  
MK5 7HA  
Tel: 01908 506804  
Fax: 01908 506179

Enquiries 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 Brian Godfrey*

Tel: 028 90 523714  
Fax: 028 90 523900  
Email: [brian.godfrey@dhsspsni.gov.uk](mailto:brian.godfrey@dhsspsni.gov.uk)

Yours faithfully

BRIAN GODFREY  
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 and other medical and non medical equipment and supplies.



HN(NI)2000/09

# HAZARD

**Title:**

**ACRYFLEX SC60B-OUV & SC600-2 AND ORION IFP3D6  
INTRAOCULAR LENSES – INCREASED RATE OF LENS  
CLOUDING**

**ACTION BY:**

**(A) BOARD/TRUST**

Address/Address Stamp

This document was forwarded to the relevant Department/Personnel for action on \_\_\_\_\_(date)

**(B) RECIPIENT** [Please return to the Issuing Authority **at (A) above**, after completed action]

Receipt of the document is acknowledged and appropriate action completed on \_\_\_\_\_(date)

Signature \_\_\_\_\_ Position

Name (please print)

Address

**(C) COMMENTS ON ACTION TAKEN**