

MEDICAL DEVICE
SAFETY NOTICE

Avantgarde Wheelchair IMB Safety Notice: SN2006(06)

MANUFACTURER / SUPPLIER

Otto Bock

TARGET GROUPS

Occupational Therapists
Physiotherapists
Public Health Nurses
Risk Managers
Nursing Home Managers

ISSUE

Replacement of rear wheel camber washers on Avantgarde wheelchairs.

BACKGROUND

It was brought to the attention of the Irish Medicines Board (IMB), that camber washers on a number of wheelchairs with serial numbers below 45590 (distributed between April 2003 and October 2004) were replaced by the distributor Medifix Services Limited, leading the manufacturer Otto Bock to identify an issue with these washers.

The manufacturer has stated that at no time can the rear wheel come off the chair should a camber washer fail but the user would be aware of movement within the rear wheel mounting.

The manufacturer also states that there are parts of their products that will wear over time. These should be evident during annual maintenance inspections.

The manufacturer advises that all Avantgarde wheelchairs are serviced regularly as per the manufacturer's guidelines, annually for the average user and more frequently for heavier users.

Distributors in Ireland are Medifix Services Limited or Lifestyle Mobility, the latter has not distributed any Avantgarde wheelchairs.

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NOTICE

ACTION OR RECOMMENDATIONS

The following actions should be taken:

1. Ensure that prescribers / repair agents are made aware of this notice.
2. Ensure that users of these devices are reminded of the importance of annual maintenance or service intervals.

ENQUIRIES

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board
Medical Devices Department
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

If you have any enquiries, you may contact the Medical Devices Department at:

Telephone: +353-1-6764971
Fax: +353-1-6344033
Email: medicaldevices@imb.ie
Website: www.imb.ie

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