Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2020/021 Issued: 20 July 2020 at 13:00 Valid until July 2021

Masks: type IIR from Cardinal Health – destroy affected lots

Summary

Foam strip on the mask can flake and enter the wearer's airway or mouth; ties and/or stitching may detach from the mask.

Action

- Identify, stop using and immediately dispose of all lots relating to BWM028 of the Cardinal Type IIR masks. See below for lot numbers.
- If you have a shortage of Type IIR masks, please notify National Supply Distribution Response (NSDR) on 0800 915 9964 who will arrange an emergency delivery if required.
- For all general enquiries for the PPE Dedicated Channel, call their customer services on 0800 876 6802.

Action by
Anyone who uses these masks.

Deadlines for actions
Actions underway: 27 July 2020
Actions complete: 03 August 2020

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Device details

There is one affected product:

- Mask, Type IIR
- Supplier: Cardinal Health
- NPC: BWM028
- MPC: AT74535UK

Applies to all lots of AT74535UK

0120GLP09	0516KLP09
0302FLP09	0516MLP09
0305HLP09	0517CLP10
0310GLP09	0517JLP09
0321FLP09	0518CLP10
0321FLP09	0518LLP09
0327FLP09	0518LLP09
0402HLP09	0519ALP10
0408HLP09	0519KLP09
0411FLP09	0519MLP09
0411HLP09	0520CLP10
0413HLP09	0520JLP09
0416HLP09	0520LLP09
0419HLP09	0521KLP09
0422HLP09	0521MLP09
0425HLP09	0522ALP10
0428HLP09	0522LLP09
0431HLP09	0523CLP10
0501ALP10	0523JLP09
0502BLP10	0523MLP09
0502CLP10	0524KLP09
0502LLP09	0524LLP09
0503DLP10	0525ALP10
0503JLP09	0525JLP09
0503KLP09	0526CLP10
0504ALP10	0526LLP09
0504LLP09	0526MLP09
0505BLP10	0527KLP09
0506ALP10	0528JLP09
0506JLP09	0528LLP09
0506KLP09	0529CLP10
0506LLP09	0529KLP09
0508DLP10	0529MLP09
0508KLP09	0530JLP09
0508MLP09	0531CLP10
0509JLP09	0531KLP09
0510KLP09	
0511ALP10	
0511JLP09	
0511MLP09	
0513ALP10	
0513KLP09	
0513MLP09	
0514JLP09	
0516ALP10	

Problem / background

The PPE dedicated supply channel sent their customers an Important Customer Alert on 26 June 2020 (ICA: 003).

MHRA is publishing this Medical Device Alert to help broadcast the actions in the ICA.

Although these masks meet the breathability, filtration and splash resistance requirements of BS EN 14683, in light of ongoing monitoring, further complaints reported and testing from the manufacturer on the masks, the MHRA recommends that all lots of this product are disposed of locally**.**

Safety details

- You will see that boxes have been labelled with a new expiry date.
  This is because they were subject to shelf life extension testing by the manufacturer in 2013/2014 and passed a number of relevant tests to support a new expiry date.
- When potential issues were identified in May 2020, a sample size of 7 lots was put through additional testing by the manufacturer in June 2020.
  6 lots did not pass a material inspection of the foam strip.
- However, these masks meet the breathability, filtration and splash resistance requirements of BS EN 14683.

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

CAS and NICAS liaison officers for onward distribution to all relevant staff including:

- All departments
- All staff
- All wards

Public Health England

Directors for onward distribution to:

- Collaborating centres
- Consultants in communicable disease control
- Divisional directors
- Heads of department
- Heads of health, safety and quality
- Health protection nurses
- Laboratory managers
- PHE laboratories
- Regional business managers
- Regional directors
- Regional epidemiologists
- Regional leads
- Regional microbiologists
- Risk manager
- Safety officers

General Practice
For onward distribution to all relevant staff including GPs, Practice Managers and Practice Nurses.

NHS England and NHS Improvement Regional Offices
For onward distribution to:

- Community pharmacy
- Dentists
- Optometrists

Social services
Liaison officers for onward distribution to all relevant staff including:

- Back care/manual handling advisors
- Care at home staff
- Care management team managers
- Children's disability services
- Community care staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- Disability equipment stores
- Education departments for equipment held in schools
- Environmental health officers
- Equipment stores
- Equipment supplies managers
- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes
- Loan store managers
- Loaned equipment store managers
- Occupational health departments
- Occupational therapists
- Schools with hoists
- Transport managers
- Wheelchair and seating service managers

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Domiciliary care providers
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Establishments registered with OFSTED

- Children's services
- Educational establishments with beds for children
- Residential special schools

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number MDA/2020/021 or 2020/005/014/401/005.

Technical aspects

Email: DSS-TM@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the Yellow Card reporting page

Northern Ireland

Northern Ireland Adverse Incident Centre (NIAIC), CMO Group, Department of Health (Northern Ireland)

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk

To report an adverse incident involving a medical device in Northern Ireland use the forms on the website.

Alerts in Northern Ireland are distributed via the NICAS system.

Scotland

Incident Reporting and Investigation Centre (IRIC), Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.iric@nhs.net

To report an adverse incident involving a medical device in Scotland, email IRIC to request a webform account.

For more information, or if you can't access the webform, visit the website: how to report an adverse incident

Wales

Population Healthcare Division, Welsh Government

Tel: 03000 255278 or 03000 255510

Email: Haz-Aic@gov.wales

To report an adverse incident involving a medical device in Wales, use the Yellow Card reporting page and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).