**DEVICE:**
Allied Healthcare Products manual resuscitator/self inflating resuscitation bag  

**PROBLEM:**
Manufacturing fault resulting in the fracture of the connector that attaches the mask to the bag during use, leaving the manual resuscitator inoperable.  

**ACTION BY:**
All those that use resuscitation equipment.  

**ACTION:**
Recall of model number L570-040, lot numbers 000431 and 000451  

**DISTRIBUTED to:**
Primary Care Trusts (England) – Chief Executives  

**CONTACTS:**
Details of supplier contacts, MHRA contacts for technical and clinical aspects.  

**FEEDBACK REQUIREMENTS:**
Please inform your distributor if you have an Allied Healthcare Products, LSP, adult disposable bag mask resuscitator, lot numbers 000431 and 000451.  

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* Further information supplied in the following pages.
DEVICE:
Allied Healthcare Products product code: L570-040
Lot numbers: 000431 and 000451

Blackwell Supplies have distributed the manual resuscitators both individually and within emergency oxygen kits. Blackwell Supplies product code is L07297.

PROBLEM:
The MHRA received several incident reports where the connector holding the mask in place broke and the mask disconnected from the manual resuscitator bag. This rendered the manual resuscitator inoperable.

This failure resulted from a change in the material used for the connector leading to difficulties in welding the mask adaptor to the connector. Once the manufacturer identified the problem a return was made to the original material. A recall was initiated on the potentially faulty devices affecting lot numbers 000431 and 000451.

There are two distributors in the UK, Draeger Medical Ltd and Blackwell Supplies Ltd. Draeger Medical have confirmed that all resuscitators they have distributed with these lot numbers have been recalled. However Blackwell Supplies, despite sending a recall notification to customers, cannot confirm that the relevant manual resuscitators have been recalled. The majority of these customers are dentists in primary care.

The only other European distributors are APOX VOF in the Netherlands and SMSP in France.

ACTION:
• Please check whether you have any Allied Healthcare Products LSP adult disposable bag mask resuscitators.
• Remove all resuscitators with lot numbers 000431 and 000451 from use.
• Ensure that an appropriate resuscitator is substituted immediately.
• Perform pre-use checks to confirm the correct operation.

DISTRIBUTION:
Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution by:

PRIMARY CARE TRUSTS to:
• Liaison officers (for onward distribution)
• General dental practitioners
• Dental practices

The full text of this notice is on our website: http://www.mhra.gov.uk
CONTACTS:
Enquiries to the supplier should be addressed to:

Mr R Fuller
Blackwell Supplies Ltd
Medcare House
Centurion Close
Gillingham Business Park
Gillingham
Kent, ME8 0SB
Tel: 01634 877620
Fax: 01634 877621
E-mail: rodfull@henryschein.co.uk

Enquiries to the MHRA should quote reference number 20021204.999-057 and be addressed to:

**Technical aspects**
Mr D McIvor or Dr C McNie
Medicines & Healthcare products Regulatory Agency
Hannibal House
Elephant and Castle
London SE1 6TQ
Tel: 020 7972 8193 / 8219
Fax: 020 7972 8113
E-mail: Douglas.McIvor@mhra.gsi.gov.uk
Catriona.McNie@mhra.gsi.gov.uk

**Clinical aspects**
Dr S Ludgate
Medicines & Healthcare products Regulatory Agency
Hannibal House
Elephant and Castle
London SE1 6TQ
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Fax: 020 7972 8111
E-mail: Susanne.Ludgate@mhra.gsi.gov.uk

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**HOW TO REPORT ADVERSE INCIDENTS**

Incidents relating to medical devices must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) as soon as possible.

Further information about reporting incidents, on-line incident reporting facilities and downloadable report forms are downloadable report forms are available from MHRA's website (http://www.mhra.gov.uk).

Alternatively, further information and printed incident report forms are available from:
MHRA Adverse Incident Centre
Medicines and Healthcare products Regulatory Agency
Hannibal House, Elephant and Castle, London SE1 6TQ
Telephone 020 7972 8080 or Fax 020 7972 8109
or e-mail: AIC@mhra.gsi.gov.uk
(An answerphone service operates outside normal office hours)

Medical Device Alerts are available in full text on the MHRA website: http://www.mhra.gov.uk

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