

Medical Device Alert

Ref: MDA/2011/082 Issued: 21 July 2011 at 14:30

Device

HandyVac™ low vacuum surgical wound drainage systems and accessories.

Manufactured by Unomedical a/s – a ConvaTec company.

Specific product ID codes (reference numbers) and lot numbers are affected – see appendix.



Problem	Action	
<p>The connector between the drainage tube and bellows may leak, resulting in the loss of active drainage and an increased risk of infection and/or haematoma formation requiring medical intervention.</p> <p>The manufacturer has recalled affected devices.</p>	<p>If you are affected by this recall:</p> <p>Do not use affected devices.</p> <p>Return affected devices as described in the Field Safety Notice (FSN) issued by Unomedical on 31 May 2011.</p>	
Action by	<p>Complete and return the Recall Questionnaire</p> <p>Note: The deadlines given in the FSN for return have been extended.</p>	
<p>All healthcare workers who use these devices.</p> <p>Personnel involved in the purchase, supply and distribution of these devices.</p>	<th data-bbox="798 1718 1477 1785">Contact</th>	Contact
CAS deadlines	<p>Manufacturer Sara Collins Unomedical Ltd – a ConvaTec company Tel: 01527 583 622 Fax: 01527 591 198 Email: sara.collins@convatec.com</p>	
<p>Action underway: 28 July 2011</p> <p>Action complete: 04 August 2011</p>		

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- All theatres
- Medical directors
- Nurse executive directors
- Supply managers

Independent distribution

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

This alert should be read by:

- Hospitals in the independent sector
- Independent treatment centres

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 Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Contacts

Manufacturer

Sara Collins
Customer Service Supervisor
Unomedical Ltd. a ConvaTec Company
First Floor, Unit 3 West Wing
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Redditch
Worcestershire
B98 9DW

Tel: 01527 583 622 Fax: 01527 591 198
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Contact address after September 2011

Jo Snead
UK Customer and Services Distribution Manager
ConvaTec Ltd.
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Deeside
Flintshire
CH5 2NU

Tel: 01244 584 285 Fax: 01244 284 892
Email: Jo.snead@convatec.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/082** or **2011/005/004/291/010**

Technical aspects

Ainsley Wickens or Ann Seeruttun
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Floor 4
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Clinical aspects

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How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>

Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate
Dundonald BT4 3SQ

Tel: 02890 523 704

Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>

Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: nss.irc@nhs.net

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes
Senior Medical Officer
Medical Device Alerts
Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk

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Addressees may take copies for distribution within their own organisations

Appendix



Product ID#	Product Description	Lot #
40031181	Drain spiral CH14/green x-ray	626121
		629479
		633015
40031182	Drain spiral CH14/green x-ray	628970
		632764
		510926
		506562
		508101
		509533
		513069
		514073
40031183	Drain spiral CH14/green x-ray	630811
40031185	Drain spiral CH14/green x-ray	630721
40105181	HandyVac 700ml/1 drain CH14	625653
		626126
		626331
		627819
		628903
		629045
		629684
		630150
		630448
		631117
		632781
		632884
		633076
		633484
		633668
		634459
		625840
		627919
		629483
		630702
631220		
631479		
634968		
40105182	HandyVac 700ml/1 drain CH14	631152
		632766
		633527
		634045
		634734
		625918
		628850
		630937
633485		
40105183	HandyVac 700ml/1 drain CH14	634292
40105183	HandyVac 700ml/1 drain CH14	629381



Product ID#	Product Description	Lot #
40125181	HandyVac/1dr.CH14/steel needle	625655
		626128
		627628
		627822
		628905
		629484
		630449
		630869
		631118
		633016
		633549
		634377
		635107
		631185
632768		
40125182	HandyVac/1dr.CH14/steel needle	633529
		634047
		631185
40125183	HandyVac/1dr.CH14/steel needle	632768
		633529
		626491
		628121
40137181	Female connector CH 14	628705
		629382
40196182	Drain CH14 soft/steel troac.	629486
		633077
		625924
		628911
		634736
		634381
		509561
		509528
		509530
		511501
40201182	HandyVacATS/2dr.CH14/injec	627874



Product ID#	Product Description	Lot #
40203182	HandyVacATS/2dr/st.need./injec	629390
		625501
		626131
		626669
		628689
		629588
		630323
		630968
		631124
		631355
		633268
		633939
		634680
		635167
629990		
40203183	HandyVacATS/2dr/st.need./injec	632770
		625583
40219181	HandyVacATS/1dr/st.need./injec	625842
		629383
		630153
40219182	HandyVacATS/1dr/st.need./injec	632784
		627875
40223182	HandyVac/1dr.CH14/steel needle	635003
		634050
40223183	HandyVac CH14, 1 drain,metal	625587
		629360
		630157
		633789
		634468
40226181	Passive drainage set/1drn CH14	631125
		632785
40235182	HandyVac/1dr.CH14/steel needle	625941
		625973
		627350
		627351
		627879
		629688
		631387
		632719
		629634
		631188
		633532
		634739
		635308
636017		