

Medical Device Alert

Ref: MDA/2011/074 Issued: 05 July 2011 at 14:30

Device

Cortoss™ Delivery Gun - used to deliver Cortoss™ Bone Augmentation Material.

Manufactured by Orthovita Inc.
Distributed in the UK by Orthovita UK Ltd.

Part number 2110-0008.

Problem

The manufacturer issued a Field Safety Notice (FSN) for this device on 15 April 2011, but has not had sufficient confirmation from users that they have received and acted on this information.

A copy of the FSN is in the appendix of this alert, and it is also available on the MHRA website.

This alert has been issued in support of the manufacturer's actions.

Action by

Orthopaedic surgeons, supplies managers and theatre managers.

Action

- Ensure that relevant members of staff are aware of the problem.
- Carry out the actions described in the manufacturer's FSN, including sending any confirmation requests.

CAS deadlines

Action underway: 19 July 2011

Action complete: 02 August 2011

Contact

Manufacturer

Kaysha Christie
Orthovita UK Ltd

Tel: 0808 101 27 75

Fax: 0808 101 27 76

Email: euorders@orthovita.com

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- 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:

- Orthopaedic surgeons
- Orthopaedic theatre staff
- Supplies managers
- Theatre managers

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

Kaysha Christie
Orthovita UK Ltd
72 London Road
St. Albans
Hertfordshire
AL1 1NS

Tel: 0808 101 27 75

Fax: 0808 101 27 76

Email: euorders@orthovita.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/074** or **2011/004/027/081/002**

Technical aspects

Miss Juliet Aharoni or Dr Crina Cacou
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7177 / 7338

Fax: 020 8754 3965

Email: juliet.aharoni@mhra.gsi.gov.uk
crina.cacou@mhra.gsi.gov.uk

Clinical aspects

Dr Nicola Lennard
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ
Tel: 020 3080 7126
Fax: 020 8754 3965
Email: nicola.lennard@mhra.gsi.gov.uk

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



ORTHOVITA® UK Limited

15 April 2011

**RE: Urgent Field Safety Notice
Potential Problem with Packaging of Cortoss Delivery Gun**

Dear Customer:

This letter is to inform you that Orthovita has identified a deficiency with the packaging configuration of the Cortoss Delivery Gun (Part Number 2110-0008).

When does this issue occur and what are the potential risks?

Orthovita has discovered through internal testing that the Cortoss Delivery Gun may abrade its packaging material under certain transportation and handling conditions. This abrasion may cause small holes or tears in the packaging material, which may not be immediately visible to the user. Although the Cortoss Delivery Gun is provided in double pouches and there have been no reported complaints on this issue, the product's sterility within its current packaging cannot be guaranteed. The Company requests that you return the product to them so that an appropriate replacement can be provided.

It should be noted that this issue only applies to the below lots of the Cortoss Delivery Gun. This issue does not affect the Cortoss Cartridge and Mix Tip.

**Lot numbers of Cortoss Delivery Guns
(Part Number 2110-0008) affected by this issue:**

A804034	A905039
A812057	A906004
A902032	A910016
A902063	A910021
A903003	A912029
A904005	A912039
A905009	A1001020

Lot numbers of Cortoss Delivery Guns NOT affected by this issue:

A1001020R	A1004022
A1001028	A1101024

What steps can the user take to avoid the potential risk of this issue?

In order to avoid the potential risk associated with this issue, Orthovita requests that you immediately identify and discontinue using any affected lots of Cortoss Delivery Gun within your facility. Affected units of this product in your possession should be quarantined. Please complete and fax or email the enclosed Acknowledgement Form as soon as possible. An Orthovita Customer Service employee will contact your facility shortly to arrange for the return or destruction of any affected product. Upon receipt of the affected material or certification of destruction, Orthovita will provide you with replacement product at no charge. Alternately, you can contact Orthovita's Returned Goods Administrator to initiate the return process immediately. The contact information for Orthovita's Returned Goods Administrator is provided below:

- If you are located in the EU, contact Els Haine at +32 16 39 28 90 or at euorders@orthovita.com
- If you are located in the UK, contact Kaysha Christie at +44 (0) 808 101 27 75 or at euorders@orthovita.com

72 London Road
St. Albans
Hertfordshire AL1 1NS
United Kingdom

Telephone +44 (0)808 101 27 75
Telefax +44 (0)808 101 27 76
E-mail euorders@orthovita.com
Website www.orthovita.com

Bankers KBC, 5th Floor, 111 Old Broad Street, EC2N 1BR London
Account number 03090191 / KBC sort code 165487
Bic or Swift KREDGB2X / IBAN GB52KRED16548703090191
Registered in England and Wales 6616463 / VAT GB 934 9589 67



How will the issue be resolved?

Orthovita has identified and qualified an improved packaging configuration that will prevent this potential issue in the future. The replacement product will be provided to you in this improved packaging.

We appreciate your understanding and cooperation with this safety notice and ask you to immediately instruct your personnel accordingly. Your personnel should maintain awareness of this issue until all affected product has been removed from your facility.

If you have purchased this device and it is no longer in your possession, we kindly ask that you inform us about the new owner so that we may take appropriate measures to notify them of this issue. Should you have any questions regarding the content of this letter, please contact Orthovita's Returned Goods Administrators using the contact information provided above.

Sincerely,

A handwritten signature in black ink, appearing to read "William Allan".

William Allan
Vice President of OUS Operations

A handwritten signature in purple ink, appearing to read "Jacqueline A. Ferro".

Jacqueline Ferro
Director of Quality

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