

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/20

Issued: 20 February 2007

For:

| | |
|------------------|---|
| IMMEDIATE ACTION | |
| ACTION | ✓ |
| UPDATE | |
| INFORMATION | |



HEALTH ESTATES

creating healing environments

| | Section |
|--|---------|
| <p>Medical Device/Equipment: Grasping forceps – Conmed DetachaTip[®] endoscopic multiple use grasper and disposable hand held graspers and dissectors (ratcheted and non-ratcheted).</p> | ▶ ① |
| <p>Problem: The tips of devices manufactured between 25 August 2003 and 24 March 2005 may be susceptible to breaking. In all reported incidents, the failure point has been the junction of the jaw and the tube. The manufacturer has undertaken a recall of all devices, both single-use and reusable, manufactured during this period.</p> | ▶ ② |
| <p>Action by: Surgeons, theatre staff and those responsible for the purchase and storage of these devices.</p> | ▶ ③ |
| <ul style="list-style-type: none"> • Check both single-use and reusable stock for devices with lot codes between 0308251 and 0503241. • Any identified instruments should be removed from stock, quarantined and returned to the manufacturer. | ▶ ④ |
| <p>Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p> | ▶ ⑤ |
| <p>Contacts Details of manufacturer contacts and NIAIC contacts for technical aspects</p> | ▶ ⑥ |
| <p>Feedback Requirements to NIAIC None required</p> | ▶ ⑦ |

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

All these devices are used during endoscopic surgery.

The lot code for these devices can be found either on the packaging or (in the case of the reusable instruments) on the grey hub of the device.

For ease of reference the lot code represents the date of manufacture. On the packaging this is the first six digits (yyymmdd) and on the device this is the five digit code (ymmdd).

2. PROBLEM:

Due to the widespread use of these devices and the mixture of single-use and reusable devices, we are issuing this Medical Device Alert to aid the manufacturer with this recall.

3. ACTION BY:

Surgeons, theatre staff and those responsible for the purchase and storage of these devices.

4. ACTION:

- Check both single-use and reusable stock for devices with lot codes between 0308251 and 0503241.
- Any identified instruments should be removed from stock, quarantined and returned to the manufacturer.

5. ONWARD DISTRIBUTION TO:

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

- Clinical governance leads
- Colposcopy departments
- Day surgery units
- Endoscopy departments
- Gastroenterologists
- Gastro-intestinal surgeons
- General surgeons
- Gynaecologists
- Health and safety managers
- Independent Health and Social Care Providers – Private Hospitals & Clinics through RQIA
- Medical directors
- Nurse endoscopists
- Nurse executive directors
- Obstetricians
- Outpatient theatre managers
- Purchasing managers
- Respiratory physicians
- Risk managers
- Sterile services departments
- Supplies managers
- Theatre managers
- Urological surgeons
- Urological surgery, directors of
- Urology departments

6. CONTACTS:

Enquires to manufacturer should be addressed to:

Nancy Crisino
ConMed Corporation
525 French Road
Utica
New York 13502-5945
USA

Tel: 00 1 315 624 3078

Fax: 00 1 315 624 3089

E-mail: Nancy_Crisino@mail.conmed.com

Enquires to NIAIC should quote reference number MDEA(NI)2007/20 and be addressed to:

Northern Ireland Adverse Incident Centre
(NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

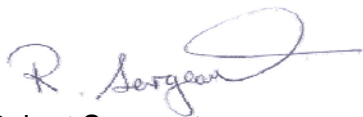
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

None Required



Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2006/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety

Appendix to MDEA/2007/20



URGENT: DEVICE RECALL

October 12, 2006

RE: DetachaTip Multi-Use Laparoscopic Instruments and Disposable Hand Held Graspers and Dissectors (Ratcheted and Non-ratcheted)

ConMed Corporation is sending this communication to provide you with important information concerning the DetachaTip Multi-Use Laparoscopic instruments and the line of Disposable Graspers and Dissectors. ConMed Corporation previously recalled the 33cm length versions of the DetachaTip device, product codes 1-1008 and 1-1028, which are in the process of being closed with FDA. ConMed Corporation failed to include other product codes of DetachaTip and the disposable products in the original recall. All suspect product codes are listed in Attachment I.

Devices that were manufactured by ConMed Corporation between August 25, 2003 and March 24, 2005 have grasper jaws that are susceptible to breakage. The company has been made aware of instances where the grasper jaws broke during laparoscopic procedures, for product codes 1-1005, 1-1009, and 60-6045-005. When the grasper jaws have broken they have done so at the junction of the jaw and the tube. In no instances has it been reported to the Company that small pieces have broken off of the grasper jaws. Consequently, we are requesting that these devices be removed from both your inventory and from any facility to which you have supplied this product.

Return devices in the Attachments immediately to Attn. Nancy Crisino, ConMed Corporation, 525 French Road, Utica, NY 13502 USA, using FedEx Account # 013500444. Also include the following information ConMed FDA Reg.# 1317214, MDL# B090316 510K# K924283 (for DetachaTip) and MDL # A440212 510K# K943327 (for disposables). Please process a commercial invoice for the return to the United States referencing your purchase price as a value for Custom's purposes and note on the commercial invoice the return is for evaluation purposes. *Please indicate with your returned devices, if you are requesting credit or replacement of the devices.* Please properly clean the multi-use product before returning and do not return used disposable devices. As a distributor we are asking that you contact all of those facilities that you may have supplied these products to. It is imperative that all end users of these devices receive this notice. If you have questions, please contact Nancy Crisino at +315-624-3078, or fax to +315-624-3089 or email nancy_crisino@mail.conmed.com.

We apologize for any inconvenience this will cause you or your staff. The US Food and Drug Administration and the appropriate Competent Authorities have been notified of this action.

Sincerely,

A handwritten signature in black ink that reads 'Dirk E. Stevens'.

Dirk E. Stevens, Ph.D.
Vice President, Quality and Regulatory

ConMed Corporation, 525 French Road, Utica, NY 13502 USA

BUSINESS REPLY FORM



DetachaTip

| Product Description | Detacha Tip Code | Disposable Grasper | Disposable Dissector | Label Lot Codes | Quantity On Hand |
|--|------------------|--------------------|----------------------|-------------------------|------------------|
| Allis, 5mm x 33cm length | 1-1019 | 60-6045-006 | 60-6040-006 | 0308251 through 0503241 | |
| Allis, 5mm x 43cm length | 1-4319 | 60-6045-436 | 60-6040-436 | | |
| Babcock, 5mm x 33 cm length | 1-1005 | 60-6047-001 | NA | | |
| Babcock, 5mm x 43 cm length | 1-4305 | 60-6047-431 | NA | | |
| Curved "Maryland" , 5mm x 33cm length | 1-1009 | 60-6045-002 | 60-6040-002 | | |
| Curved "Maryland" , 5mm x 43cm length | 1-4308 | 60-6045-432 | 60-6040-432 | | |
| Endoweave 5mm x 33cm length | NA | 60-6045-005 | 60-6040-005 | | |
| Endoweave 5mm x 43cm length | 1-4328 | 60-6045-435 | 60-6040-435 | | |
| Fenestrated (Duckbill) 5mm x 33cm length | NA | 60-6045-003 | 60-6040-003 | | |
| Fenestrated (Duckbill) 5mm x 43cm length | 1-4307 | 60-6045-433 | 60-6040-433 | | |
| Meeker (Right Angle), 5mm x 33cm length | 1-1017 | 60-6045-004 | 60-6040-004 | | |
| Meeker (Right Angle), 5mm x 43cm length | 1-4317 | 60-6045-434 | 60-6040-434 | | |

Please fax this completed form to Nancy Crisino at 315-624-3089, and place a copy of the completed form with your product return.

Event 1670
 ID 15841626
 Any Business Name



Appendix to MDEA/2007/20



ATTACHMENT I PRODUCT CODE LISTING

| Product Description | DetachaTip Code | Disposable Grasper | Disposable Dissector |
|--|------------------------|---------------------------|-----------------------------|
| Allis, 5mm x 33cm length | 1-1019 | 60-6045-006 | 60-6040-006 |
| Allis, 5mm x 43cm length | 1-4319 | 60-6045-436 | 60-6040-436 |
| Babcock, 5mm x 33 cm length | 1-1005 | 60-6047-001 | NA |
| Babcock, 5mm x 43 cm length | 1-4305 | 60-6047-431 | NA |
| Curved "Maryland", 5mm x 33cm length | 1-1009 | 60-6045-002 | 60-6040-002 |
| Curved "Maryland", 5mm x 43cm length | 1-4308 | 60-6045-432 | 60-6040-432 |
| Endoweave 5mm x 33cm length | NA | 60-6045-005 | 60-6040-005 |
| Endoweave 5mm x 43cm length | 1-4328 | 60-6045-435 | 60-6040-435 |
| Fenestrated (Duckbill) 5mm x 33cm length | NA | 60-6045-003 | 60-6040-003 |
| Fenestrated (Duckbill) 5mm x 43cm length | 1-4307 | 60-6045-433 | 60-6040-433 |
| Meeker (Right Angle), 5mm x 33cm length | 1-1017 | 60-6045-004 | 60-6040-004 |
| Meeker (Right Angle), 5mm x 43cm length | 1-4317 | 60-6045-434 | 60-6040-434 |

NA = Not Applicable

Appendix to MDEA/2007/20



ATTACHMENT II
PRODUCT IDENTIFICATION



Allis



5mm Babcock



Maryland



Endoweave™



Fenestrated (Duckbill)



Meeker

Appendix to MDEA/2007/20

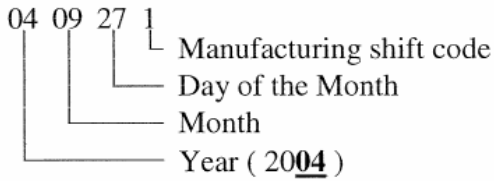


ATTACHMENT III LOT CODE IDENTIFICATION

Identification of Affected Devices:

Lot codes on unopened boxes and packaging contain a lot code in the following form:

0409271



Box Label

DetachaTip® Shaft

Multiple Use Grasper, Endoweave™
 Griber til flere formål, Endoweave™
 Pince à usage multiple, pour autosuture
 Mehrzweck-Greifzange, Endoweave™
 Pinze multuso, Endoweave™
 Pinzas de tracción reutilizables, Endoweave™
 Pinça de uso múltiplo, Endoweave™
 Αρπάγη πολλαπλής χρήσης, ενδο-ύφρινση
 多功能抓握器, Endoweave™
 Gripper voor meermalig gebruik, Endoweave™
 Flerfunktions gripverktøj, Endoweave™
 多目的グラスパー, エンドワイヤー

REF 1-1028

5mm X 33cm

English
Dansk
Français
Deutsch
Italiano
Español
Português
Ελληνικά
中文
Nederlands
Svenska
日本語

(01)20653405036835(17)090900(30)1(10)0409071

LOT 0409071

 2009-09

P/N 10560 REV A 11/01

Packaging Label

REF 1-1028

Multiple Use Grasper, Endoweave™
 Griber til flere formål, Endoweave™
 Pince à usage multiple, pour autosuture
 Mehrzweck-Greifzange, Endoweave™
 Pinze multuso, Endoweave™
 Pinzas de tracción reutilizables, Endoweave™
 Pinça de uso múltiplo, Endoweave™
 Αρπάγη πολλαπλής χρήσης, ενδο-ύφρινση
 多功能抓握器, Endoweave™
 Gripper voor meermalig gebruik, Endoweave™
 Flerfunktions gripverktøj, Endoweave™
 多目的グラスパー, エンドワイヤー

5mm X 33cm

English
Dansk
Français
Deutsch
Italiano
Español
Português
Ελληνικά
中文
Nederlands
Svenska
日本語

(01)00653405036831(17)090900(30)1(10)0409071

LOT 0409071

 2009-09

P/N 10576 REV A 11/01

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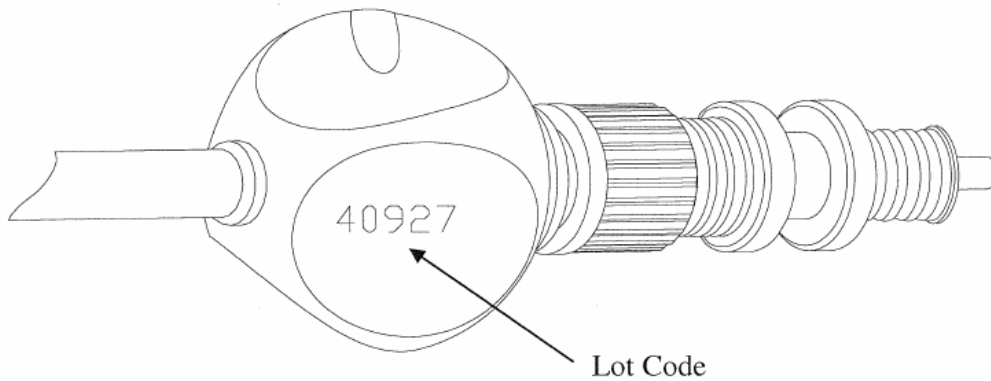
ATTACHMENT III LOT CODE IDENTIFICATION

Lot codes are located on the device in the following location and form:

40927

4 09 27
└─┬─┬─┘ Day of the Month
└─┬─┘ Month
└──┘ Year (2004)

Lot Code is embossed on the grey hub (DetachaTip Only) (See drawing below).



Devices affected were manufactured on the following dates and contain the following lot codes:

| | |
|---|---------------------------|
| Manufactured from: August 25, 2003 | to: March 24, 2005 |
| Label Lot Codes from: 0308251 | through: 0503241 |
| Device Lot Codes from: 30825 | through: 50324 |