

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/96

Issued: 19th November 2007

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section
<p>Medical Device/Equipment: Surgical tool bit/burr – Anspach cutting burrs with expiry dates from June 2008 to August 2011 (inclusive).</p>	▶ ①
<p>Problem: Possible breakdown of packaging leading to compromise of the sterile barrier</p>	▶ ②
<p>Action by: Theatre staff and supplies departments.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> • Check stock. • Quarantine affected devices (see appendix for list of relevant catalogue numbers). • Return to the supplier's representative. 	▶ 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 supplier 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:

Anspach cutting burrs: fluted ball, diamond ball, coarse diamond ball, extra coarse diamond ball, fluted router, spiral router, fluted oval, fluted pear, diamond pear, diamond flame, twist drills, diamond disc, coring and boring tools, diamond oval, fluted matchstick, diamond matchstick, fluted acorn, fluted drum, fluted bell, fluted barrel, coarse diamond matchstick (see appendix for catalogue numbers).

2. PROBLEM:

The manufacturer's continued post-market testing has found that the white film portion of the sterile packaging of these devices may become brittle before the end of the 60 month expiry date. This could compromise the sterile barrier and lead to contamination of the device prior to use. In addition, the packaging could become more difficult to open.

All devices produced with an expiry date from June 2008 to August 2011 (inclusive) are affected. They are being recalled by the manufacturer and will be replaced free of charge.

The expiry date is clearly indicated on the external packaging of the devices (a date next to an hourglass icon). The date is either in the format of 'mm/yy' or 'mm/yyyy' (e.g. 06/08 or 06/2008).

3. ACTION BY:

Theatre staff and supplies departments.

4. ACTION:

- Check stock.
- Quarantine affected devices (see appendix for list of relevant catalogue numbers).
- Return to the supplier's representative.

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:

- Health and safety managers
- Infection control departments
- Infection prevention and control directors
- Risk managers
- Supplies managers
- Theatre managers
- Independent Health and Social Care Providers – Private Hospitals and Clinics through RQIA

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Caroline Scott
Operations Director
Forth Medical Limited
Forth House
42 Kingfisher Court
Hambridge Road
Newbury
RG14 5SJ

Tel: 01635 550 100

Fax: 01635 550 050

E-mail: Caroline@Forthmedical.ltd.uk

Enquiries to NIAIC should quote reference number MDEA(NI)2007/96 and be addressed to:

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

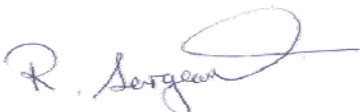
Tel: 028 9052 3868

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/2007/96



Catalog Number
A-CRN
A-CRN-S
ADG-10
ADG-11
ADG-13
ADG-155
ANS-AM-8
ANS-B-1
ANS-C-1
ANS-M-3
ANS-M-8
BLA-1
BLA-10
BLA-11
BLA-12
BLA-14
BLA-15
BLA-2
BLA-24
BLA-3
BLA-32
BLA-38
BLA-4
BLA-5
BLA-51
BLA-6
BLA-7
BLA-7-9
BLA-8
BLA-9
BLU-1
BLU-10
BLU-11
BLU-12
BLU-14
BLU-17-1
BLU-17-2
BLU-17-3
BLU-17-4
BLU-17-5
BLU-17-6
BLU-24
BLU-27
BLU-2S-25
BLU-2XL
BLU-3
BLU-32
BLU-38
BLU-39
BLU-4

Catalog Number
BLU-40-55
BLU-47
BLU-5
BLU-51
BLU-6
BLU-7
BLU-7-9
BLU-8
BLU-8-18
BLU-8-5
BLU-8D-32
BLU-8D-32C
BLU-8-M
BLU-9
BLU-9-10E
BLU-9-5
BLU-9-5E
BLU-9-68
BLU-97B
BLU-9-7E
BLU-9-8E
BLU-9-9E
BLU-9DCX
BLU-CS10
BLU-CS5
BLU-CS6
BLU-CS7
BLU-CS8
BLU-CS9
BLU-LS9-35
BLU-LS9-5
BLU-LS9-5E
CDA-1R
GOL-2
GOL-2S
GRE-1
GRE-1-M
GRE-1S
GREY-471-25
GREY-471-50
GREY-471-50M
GREY-471-70
GREY-472-00
GREY-MIA16-17-2
GREY-MIA16-17-2C
GREY-MIA16-17-3
GREY-MIA16-17-3C
GREY-MIA16-17-4C
GREY-MIA16-3
GREY-MIA16-4

Catalog Number
GREY-MIA16-8
GREY-MIA20-17-2
GREY-MIA20-17-2C
GREY-MIA20-17-3
GREY-MIA20-17-3C
GREY-MIA20-17-4
GREY-MIA20-17-4C
GREY-MIA20-17-75C
GREY-MIA20-3
GREY-MIA20-4
GREY-MIA20-7
GREY-MIA20-7-9
GREY-MIA20-8
IMRI-A-CRN
IMRI-S-1R
IMRI-S-4B
IMRI-SAFE
IMRI-SHD-6B
IMRI-SHD-6R
L-10DRC
L-1R
L-1SB
L-1SD
L-2SB
L-2SD
L-35DR
L-3SB
L-3SD
L-3SDC
L-4B
L-4D
L-4DC
L-4DRM
L-4DX
L-4OV
L-5AC
L-5B
L-5BA
L-5D
L-5DC
L-5DRC
L-5DRM
L-5DX
L-5OV
L-68DRMDX
L-6B
L-6D
L-6DC
L-6DRC
L-6DX

Catalog Number
L-7AC
L-7B
L-7DRC
L-8DRC
L-8N
L-8ND
L-8NS
L-8NSD
L-8NSDC
L-8NS-M
L-9B
L-9DRC
L-CRN
L-CRN-S
LHD-3SB
LHD-4B
LHD-5B
LHD-5DRM-L
LHD-64DRM
LHD-6AC
LHD-6B
LHD-7B
LHD-8NS
LHD-8NS-M
LHD-95DRM
LHD-LS9-76
M-05SD
M-15SD
M-15SDC
M-1B
M-1D
M-1DC
M-1R
M-1SB
M-1SD
M-1SDC
M-25SD
M-25SDC
M-2B
M-2D
M-2DC
M-2SB
M-2SD
M-2SDC
M-35SD
M-35SDC
M-3B
M-3D
M-3DC
M-3SB

Appendix to MDEA/2007/96



Catalog Number
M-3SD
M-3SDC
M-4B
M-4D
M-4DC
M-4DX
M-4FD
M-4OV
M-5AC
M-5B
M-5D
M-5DC
M-5OV
M-6B
M-6D
M-6DC
M-6DX
M-6P
M-7AC
M-7B
M-8N
M-8ND
M-8NS
M-8NSD
M-8NS-M
MA10-2SB
MA10-2SD
MA10-3SB
MA10-3SD
MA10-4D
MA10-8N
MA10-8N-18
MA10-8NS
MA10-8NSDC
MA15-15SD
MA15-2SB
MA15-2SD
MA15-3SB
MA15-3SD
MA15-4D
MA15-8N
MA15-8N-18
MA15-8NS
MA15-8NSDC
MDA-2SB
MDA-2SD
MDA-3SB
MDA-3SD
MDA-4D
MDA-8N-18

Catalog Number
MDA-8NSDC
MHD-15C
MHD-16CT
MHD-17DD
MHD-25DD
MHD-25R
MHD-3DRMC
MHD-6AC
MHD-6B
MHD-8NS
MHD-8NS-M
MHD-97B
MHD-98B
MIA16-3SB
MIA16-4B
MIA16-4D
MIA16-4DC
MIA16-6B
MIA16-6DC
MIA16-6DX
MIA16-8NS
MRA-8L
MRA-8M
MRA-8S
ORNG-1
ORNG-1275
ORNG-33
ORNG-35
ORNG-36
ORNG-37
ORNG-8-18
ORNG-8-23
P-CRN
PKS-3BA
PKS-5BA
QD11-17-1
QD11-17-2
QD11-17-3
QD11-17-4C
QD11-17-5C
QD11-17-6
QD11-1R
QD11-1SB
QD11-1SD
QD11-2SB
QD11-2SD
QD11-3SB
QD11-3SD
QD11-3SDC
QD11-40-5

Catalog Number
QD11-47DRM
QD11-4B
QD11-4D
QD11-4DC
QD11-4DRM
QD11-4DX
QD11-4OV
QD11-4OVD
QD11-4OVDC
QD11-5
QD11-5AC
QD11-5B
QD11-5B-12F
QD11-5BA-A
QD11-5D
QD11-5DC
QD11-5DRM
QD11-5DX
QD11-5OV
QD11-62DRM
QD11-6AC
QD11-6B
QD11-6BA
QD11-6BA-A
QD11-6D
QD11-6DC
QD11-6DX
QD11-6P
QD11-7B
QD11-8
QD11-8-18
QD11-8-23
QD11-8D-25
QD11-8N
QD11-8N-18
QD11-8ND
QD11-8NS
QD11-8NSDC
QD11-9-4
QD14-1
QD14-17-1
QD14-17-5C
QD14-17-6CX
QD14-1R
QD14-1SD
QD14-2SD
QD14-3SB
QD14-3SD
QD14-47DRM
QD14-4B

Catalog Number
QD14-4D
QD14-4DC
QD14-5
QD14-5B
QD14-5D
QD14-5DC
QD14-6
QD14-6B
QD14-6D
QD14-6DX
QD14-8N
QD14-8N-18
QD14-8ND
QD14-8NS
QD8-05B
QD8-05SD
QD8-1
QD8-15SB
QD8-15SD
QD8-17-1
QD8-17-2
QD8-17-3
QD8-17-4
QD8-17-4C
QD8-17-5
QD8-17-5C
QD8-1R
QD8-1SB
QD8-1SD
QD8-1SDC
QD8-25SB
QD8-25SD
QD8-25SDC
QD8-2SB
QD8-2SD
QD8-2SDC
QD8-35SD
QD8-35SDC
QD8-3SB
QD8-3SD
QD8-3SDC
QD8-4
QD8-4B
QD8-4D
QD8-4DC
QD8-4DRM
QD8-4DX
QD8-4OV
QD8-4OVD
QD8-5

Appendix to MDEA/2007/96



Catalog Number
QD8-5AC
QD8-5B
QD8-5BA
QD8-5D
QD8-5DC
QD8-5DX
QD8-5OV
QD8-6
QD8-62BE
QD8-62DRM
QD8-6AC
QD8-6B
QD8-6D
QD8-6DC
QD8-6DX
QD8-7B
QD8-8
QD8-8-23
QD8-8D-25
QD8-8N
QD8-8N-18
QD8-8ND
QD8-8NS
QD8-9-4
RED-1
RED-10
RED-11
RED-12
RED-17-55C
RED-17-75C
RED-2
RED-24
RED-3
RED-32
RED-38
RED-4
RED-5
RED-6
RED-7
RED-7-9
RED-8
RED-9
S-05D
S-06SD
S-08SD
S-1203TD
S-1254TD
S-12D
S-1504TD
S-1506TD

Catalog Number
S-1510TD
S-15B
S-15D
S-15DC
S-15SB
S-15SD
S-1B
S-1D
S-1DC
S-1R
S-1SB
S-1SD
S-1SDC
S-2004TD
S-2006TD
S-2433TD
S-25B
S-25D
S-25DC
S-25SB
S-25SD
S-25SDC
S-2B
S-2D
S-2DC
S-2SB
S-2SBT
S-2SD
S-2SDC
S-2SDCT
S-35B
S-35D
S-35DC
S-35SB
S-35SD
S-3B
S-3D
S-3DC
S-3SB
S-3SBF
S-3SBT
S-3SD
S-3SDC
S-3SDCT
S-4B
S-4D
S-4D-100
S-4DC
S-4D-L
S-4DX

Catalog Number
S-4OV
S-5AC
S-5B
S-5B-12F
S-5D
S-5D-100
S-5DC
S-5DC-40
S-5DX
S-68DRMDC
S-68DRMDX
S-6AC
S-6B
S-6D
S-6D-100
S-6DC
S-6DX
S-6IP
S-6P
S-6PD
S-6R
S-7B
S-7IP
S-8B
S-8DC
S-8N
S-8N-18
S-8ND
S-8NS
S-8NSD
S-8NS-M
S-9AC
S-9B
SHD-17DD
SHD-25DD
SHD-25R
SHD-3-10
SHD-325DS
SHD-4892DS
SHD-5B
SHD-6AC
SHD-6B
SHD-6DX
SHD-6R
SHD-75AC
SHD-8NS
SHD-9AC
SHD-DS-A
SIL-0
SIL-1

Catalog Number
SIL-10
SIL-11
SIL-1-3
SIL-14
SIL-14-17
SIL-15
SIL-1510
SIL-16
SIL-16-5
SIL-16XL2
SIL-17-1
SIL-17-1C
SIL-17-2
SIL-17-2C
SIL-17-3
SIL-17-3C
SIL-17-4
SIL-17-4C
SIL-17-4CX
SIL-17-5
SIL-17-5C
SIL-17-5CX
SIL-17-6
SIL-17-6C
SIL-17-6CX
SIL-18
SIL-19
SIL-1S
SIL-2
SIL-20
SIL-21
SIL-22
SIL-23
SIL-24
SIL-27
SIL-2S
SIL-2XL
SIL-3
SIL-3-10
SIL-32
SIL-38
SIL-39
SIL-3DS
SIL-4
SIL-464-4
SIL-466-6
SIL-47
SIL-5
SIL-58B
SIL-6

