

MEDICAL DEVICE ALERT

Issued: **18 September 2006 at 10:30**

Ref: **MDA/2006/053**

<input type="checkbox"/>	Immediate action
<input checked="" type="checkbox"/>	Action
<input type="checkbox"/>	Update
<input type="checkbox"/>	Information request

Device: Surgical dissecting tools – Medtronic: Midas Rex, Classic, GS and Legend.	► Page 2
Problem: Degradation of sterile packaging. Recall of devices distributed within the last three years.	► Page 2
Action by: Orthopaedic surgeons, neurological surgeons, ENT surgeons, theatre managers and all other staff responsible for the purchase and use of these devices.	
Action: Check all affected part numbers and return any stock having non-underlined lot numbers to the UK supplier, Medtronic Limited.	► Page 2
Distributed to: NHS trusts in England Healthcare Commission (CHAI) – Chief Executives* – Headquarters * via CE Bulletin	► Page 2
Contacts: Details of supplier contacts and MHRA contacts for technical and clinical aspects. Change of address or removal from address list for Healthcare Commission.	► Pages 2-3
Appendix: List of affected part numbers involved in this recall. Pictures of packaging illustrating underlined lot number.	► Pages 4-5 ► Page 6

Action deadlines for the Safety Alert Broadcast System (SABS)

Deadline (action underway): 22 September 2006

Deadline (action complete): 27 October 2006

This notice is also on our website: <http://www.mhra.gov.uk>

Device:

Midas Rex, Classic, GS and Legend dissecting tools for powered surgical systems – Medtronic (part numbers concerned are listed in the attached Appendix).

Problem:

These dissecting tools are designed to be used with the Midas Rex, Legend, Classic and Midas III reusable motors in surgery. The dissecting tools are single-use, are individually packed and have a use by date of 60 months (five years) from manufacture.

The manufacturer has noted an increase in the number of reports of 'brittle packages' which have the potential to compromise the sterile barrier. The manufacturer has instituted a recall of all devices distributed in the last three years. Customers should have received a letter asking for the return of all affected devices.

Devices having underlined lot numbers are not affected by this recall (see diagrams in Appendix).

Action:

Check stock against part numbers on the attached list. Return any devices found with a non-underlined lot number, as illustrated in the attached Appendix, to the UK supplier, Medtronic Limited.

Distribution:

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

Trusts to:

SABS liaison officers for onward distribution to all relevant staff including:

- ENT surgeons
- Health & safety managers
- Medical directors
- Modern matrons
- Neurological surgeons
- Nursing executive directors
- Orthopaedic surgeons
- Purchasing managers
- Risk managers
- Supplies managers
- Theatre managers

Healthcare Commission (CHAI) to:

Headquarters for onward distribution to:

- Hospitals in the independent sector
- Private hospitals

Contacts:

Enquiries to the UK supplier should be addressed to:

Hayley Williams
Medtronic Ltd
Suite One
Sherbourne House
Croxley Business Centre
Watford
WD18 8WW

Tel: 01923 205 148
Fax: 01923 205 190

David Dunham BSc PhD
Regulatory Affairs Manager
Medtronic Ltd
Suite One
Sherbourne House
Croxley Business Centre
Watford
WD18 8WW

Tel: 01923 212 213
Fax: 01923 241 004

E-mail: david.dunham@medtronic.com

Contacts (continued):

Enquiries to the MHRA should quote reference number **2006/008/002/291/003** and be addressed to:

Technical aspects:

Mrs Sara Vincent or Mr Richard Glover
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3169 / 3245

Fax: 020 7084 3209

E-mail: sara.vincent@mhra.gsi.gov.uk
richard.glover@mhra.gsi.gov.uk

Clinical aspects:

Dr Susanne Ludgate
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3123

Fax: 020 7084 3111

E-mail: susanne.ludgate@mhra.gsi.gov.uk

Change of address or removal from address list for Healthcare Commission:

Healthcare Commission
Finsbury Tower
103-105 Bunhill Row
London
EC1Y 8TG

Tel: 020 7448 0842

E-mail: contacts@healthcarecommission.org.uk

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 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
Market Towers, 1 Nine Elms Lane, London SW8 5NQ
Telephone 020 7084 3080 or Fax 020 7084 3109
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>

Further information about **SABS** can be found at www.info.doh.gov.uk/sar/cmopatie.nsf

Appendix to MDA/2006/053

Medtronic Midas Rex Classic, GS and Legend Dissecting Tool Recall August 2006.

List of Affected Part Numbers.

10AC50	14AC50	15MH22	7BA30D	8TD158	AM-147
10AC60	14AC60	16MH18	7BA30DC-MN	8TD178	AM-2
10BA10	14AC75	16MH22	7BA30D-MN	8TD208	AM-3
10BA10D	14AC90	16TA13	7BA30L-MN	9AC50	AM-31
10BA10D-MN	14BA20	16TA15	7BA30-MN	9AC60	AM-32
10BA10-MN	14BA20D	16TA17	7BA40	9AC75	AM-33
10BA20	14BA25	21AC60	7BA40D	9AC90	AM-330
10BA20D	14BA25D	21AC75	7BA40DC-MN	9BA30	AM-340
10BA20D-MN	14BA30	21AC90	7BA40D-MN	9BA30D	AM-340DXC
10BA20-MN	14BA30D	21BA60	7BA40F-MN	9BA40	AM-35
10BA30	14BA40	21BA75	7BA40-MN	9BA40D	AM-35D
10BA30D	14BA40D	21BA90	7BA50	9BA40DX	AM-370DXC
10BA30DC	14BA40DC	21MH30	7BA50D	9BA50	AM-51
10BA30D-MN	14BA40DX	21TA30	7BA50DC-MN	9BA50D	AM-52
10BA30-MN	14BA50	26AC60	7BA50D-MN	9BA50DX	AM-6
10BA40	14BA50D	26AC90	7BA50F-MN	9BA60	AM-8
10BA40D	14BA50DC	26BA50DX	7BA50-MN	9BA60D	AM-8D
10BA40DC	14BA50DX	26BA60	7BA60	9BA60DX	AM-9
10BA40D-MN	14BA60	26BA70DX	7BA60D	9BA75	B-1
10BA40DX	14BA60D	26BA75	7BA60DC-MN	9BA75D	B-3
10BA40-MN	14BA60DC	26BA90	7BA60D-MN	9BA90	B-3D
10BA50	14BA70DX	26CY75	7BA60F-MN	9CY50	B-5
10BA50D	14BA75	26CY90	7BA60-MN	9CY60	BC-1
10BA50DC	14BA80DX	26MH30	7BA70D-MN	9CY75	C-1
10BA50D-MN	14BA90	26TA30	7BA70-MN	9HM100	C2-411
10BA50DX	14CY50	7AC60-MN	7BA80D-MN	9HM126	DG2-10
10BA50-MN	14CY50B	7BA05-MN	7BA80-MN	9HM95	DG2-12
10BA60	14CY50L	7BA06D-MN	8AC60	9HS108	DG2-13
10BA60D	14CY60	7BA10	8MH17	9HS135	DG2-15
10BA60D-MN	14CY65DX	7BA10D	8MH17D	9MH30	F1/8TA15
10BA60DX	14CY75	7BA10D-MN	8MH22	9MH30D	F1/8TA15S
10BA60-MN	14HM95	7BA10L-MN	8MH22D	9MH30DC	F2/8TA23
10CY40	14MH30	7BA10-MN	8TA11	9OV55	F2/8TA23S
10CY50	14MH30D	7BA15	8TA17	9TA30	F3/9TA30
10CY60	14TA30	7BA15D	8TD104	A-10	G12-130
10CY65DX	14TA31	7BA15D-MN	8TD114	A-2	G12-130DC
10MH17	15AC60	7BA15-MN	8TD116	A-3	G12-350
10MH17D	15BA40	7BA20	8TD124	A-3D	G12-355D
10MH22	15BA40D	7BA20D	8TD126	AF-2	G12-370DXC
10MH22D	15BA40DX	7BA20DC-MN	8TD134	AF-3	G16-130
10MH30	15BA50	7BA20D-MN	8TD136	AF-5	G16-360
10MH30DC	15BA50D	7BA20L-MN	8TD154	AF-9	G2-130DC
10MH30D-MN	15BA60	7BA20-MN	8TD156	AM-1	G4-130
10MH30-MN	15BA60D	7BA25D		AM-10	G4-130D
10OV40	15CY50	7BA25D-MN		AM-11	G4-130DC
10OV40D	15MH17	7BA25-MN		AM-13	G4-320
10TA23	15MH17D	7BA30			

Appendix to MDA/2006/053

Medtronic Midas Rex Classic, GS and Legend Dissecting Tool Recall August 2006.

List of Affected Part Numbers.

G4-330	G8-340D	MC30	S6-122D	T14MH25
G4-330D	G8-350	O-1	S6-218	T14MH30D
G4-340	G8-350D	O-2	S6-305	T15MH25
G4-340D	G8-350DC	O-3	S6-305D	T15MH30D
G4-350	G8-360	O-8	S6-310	T9MH25
G4-350D	G8-360D	QL-1	S6-310D	TAC-120
G4-360	G8-365	R-1	S6-315	TAC-125
G4-365	G8-370	R-10	S6-315D	TAC-125D
G4-370	G8-370D	R-12	S6-320	TAC-130D
G4-380	G8-380	R-2	S6-320D	TDQ-130D
G4-380D	G8-450	R-3	S6-325	TLQ-125
G4-560	G8-460	R-31	S6-325D	TU-10
G4-570	G8-560	R-32	S6-330	WH-1
G4-590	G8-570	R-33	S6-330D	WH-2
G4-9250W	G8-760	R-8	S6-335DSS	WH-6
G4-932DC	G8-860	RX-8	S6-340	End
G6-130	G8-932	S-1	S6-340D	
G6-130D	IF-220	S12-117	S6-340DC	
G6-130DC	K-1	S12-117D	S6-350	
G6-223	K-3D	S12-330	S8-117	
G6-320	M-1	S12-330D	S8-117D	
G6-325	M-10	S12-340	S8-122D	
G6-325D	M-12	S12-340D	S8-305	
G6-330	M-17	S4-117	S8-310	
G6-330D	M-1717H	S4-122	S8-310D	
G6-330DC	M-17H	S4-122D	S8-315	
G6-340	M-18H	S4-212	S8-320	
G6-340D	M-2	S4-218	S8-320D	
G6-340DC	M-24	S4-218SP	S8-325	
G6-350	M-25	S4-305	S8-325D	
G6-350D	M-3	S4-310	S8-330	
G6-360	M-31	S4-310D	S8-330D	
G6-360D	M-31D	S4-315	S8-333	
G6-365	M-32	S4-315D	S8-335DC	
G6-370	M-32D	S4-320D	S8-340	
G6-370D	M-33	S4-325	S8-340D	
G6-380	M-330	S4-325D	S8-340DC	
G6-380D	M-33D	S4-330	S8-345DC	
G6-450	M-340	S4-340	S8-350	
G6-560	M-340DC	S4-340D	S8-350DC	
G6-570	M-35	S4-345DC	S8-360DC	
G6-6108H	M-350DC	S4-350	S8-440	
G6-6126	M-35D	S4DG1-08	S8-840	
G6-613	M-51	S4DG2-10	T12MH15	
G8-130	M-52	S4DG2-11	T12MH20	
G8-130D	M-8	S4DG2-12	T12MH20D	
G8-130DC	M-8D	S4DG2-14	T12MH25	
G8-325	M-8DC	S4DG2-15	T12MH25D	
G8-330	M-9	S6-117	T12MH30D	
G8-330D	MC16	S6-117D	T12MH35D	
G8-340	MC254	S6-122	T12MH45D	

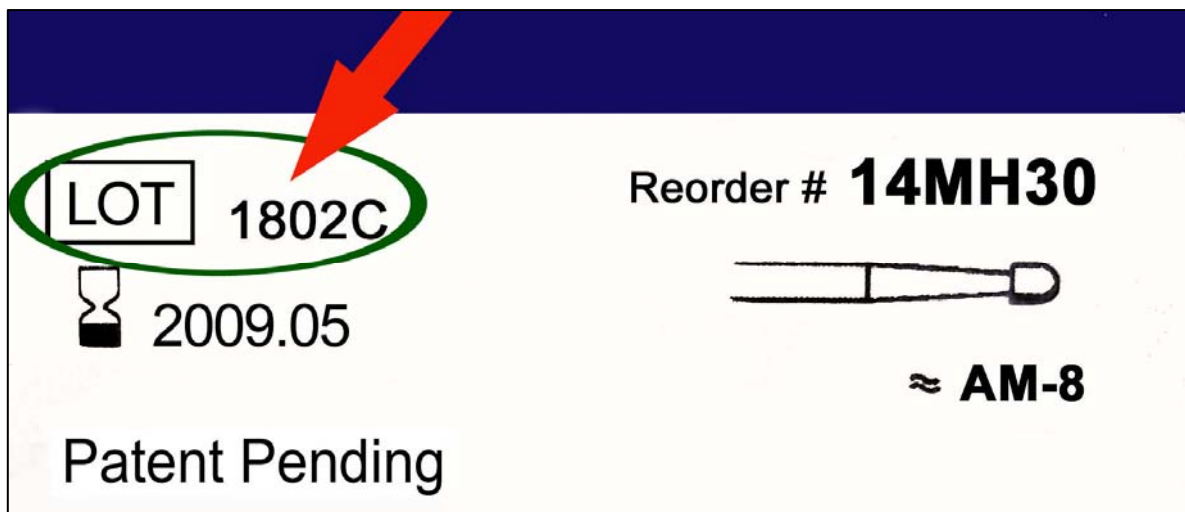
Pictures of packaging illustrating underlined lot number.

PLEASE NOTE:

THE AFFECTED PRODUCT IS IDENTIFIED BY EXAMINING THE PRODUCT LOT NUMBER ON THE INSERT LABEL AS SHOWN BELOW. **ONLY PRODUCTS WITHOUT UNDERLINED LOT NUMBERS NEED TO BE RETURNED.**

TRITON AND MEDNEXT DISPOSABLE TOOLS ARE NOT AFFECTED BY THIS RECALL.

LOT NUMBER NOT UNDERLINED – RETURN PRODUCT TO MEDTRONIC



LOT NUMBER UNDERLINED – DO NOT RETURN PRODUCT

