

Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/32

Issued: 2 July 2004

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION REQUEST	✓



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
Medical Device/Equipment: Tyco Auto Suture TA* single use linear staplers	▶ ①
Problem: Risk of misfire resulting in failure to form staple lines.	▶ ②
Action by: Surgeons Operating theatre managers Supplies managers	▶ ③
Action: <ul style="list-style-type: none"> Identify and quarantine all staplers with the affected lot numbers Return affected staplers to the manufacturer (see Tyco's letter of 10/5/2004 at appendix 1) Report any incidents of misfire to the NIAIC and the manufacturer 	▶ ④
Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers	▶ ⑤
Contacts Details of manufacturer contacts, NIAIC contacts for technical aspects.	▶ ⑥
Feedback Requirements to NIAIC Report any cases of failure of surgical staplers to NIAIC and the manufacturer	▶ ⑦

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

1. DEVICE/EQUIPMENT:

TA* single use linear staplers, model numbers TA30V3S, TA3035S, TA3048S, TA4535S, TA4548S, TA6035S, TA6048S, TA9035S, TA9048S. A full list of the affected batch numbers can be found in appendix 2.

2. PROBLEM:

Tyco Healthcare UK Ltd has initiated a recall of all Auto Suture TA* single use staplers distributed between June 2002 and March 2004.

During routine quality assurance checks Tyco identified that some instruments had a spring mis-assembled in the instrument handle. Tyco has received three reports of misfire from users in the USA but no incidents in the UK have been reported to date.

These staplers have the potential to clamp and fire without the staples being formed into the tissue. This could have potentially serious consequences for the patient.

188 hospitals in the UK have received devices from the 497 affected batches.

3. ACTION BY:

Surgeons

Operating theatre managers

Supplies managers

4. ACTION:

- Identify and quarantine all staplers with the affected lot numbers
- Return affected staplers to the manufacturer (see Tyco's letter of 10/5/2004 at appendix 1)
- Report any incidents of misfire to the NIAIC and 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:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Medical Directors
- Nursing Directors
- Medical & Nursing Staff
- Supplies Staff (RSS)
- Surgeons
- Theatre Managers
- Independent Health and Social Care Providers – Private Clinics through HSS Board R&I Units

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Jeanette James

Tyco Healthcare UK Ltd

154 Fareham Road

Gosport

Hampshire PO13 0AS

Tel: 01329 224468

Fax: 01329 224390

E-mail: jeanette.james@emea.tycohealthcare.com

Enquires to NIAIC should quote reference number MDEA(NI)2004/32 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:

Report any cases of failure of surgical staplers to NIAIC and the manufacturer



Brian Godfrey
NIAIC 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)2004/01. 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 1 – Recall letter

Ref: JSJ/TA/SF

10th May 2004

Dear Customer,

Subject: Voluntary Product Recall - TA* Staplers

Order Codes: TA30V3S, TA3035S, TA3048S, TA4535S, TA4548S, TA6035S, TA6048S, TA9035S, TA9048S

Through routine quality assurance procedures, U. S. Surgical / Tyco Healthcare has determined that certain lots of TA* Single Use Staplers have a potential condition which could cause the device to clamp and fire without the staples being formed into tissue. If this condition occurs, there is the potential for patient injury.

Therefore, we have initiated a voluntary product recall for specific lots. This recall is limited to only the TA* Stapler lots on the attached list. **The single use loading units (SULU's) are not subject to this recall.**

Please follow the steps outlined below to expedite this process:

1. Review your inventory and segregate any product with the affected lot numbers only. Complete the attached product recall form including the lot numbers and unit quantities.
2. Contact the UK Customer Service Department on 01329 224411 for a return authorization number. This will facilitate an immediate return for credit as well as allow you to place purchase order for replacement product.
3. Fax a copy of the Product Recall Notification Document to Jeanette James on 01329 224390.
4. If you do not have any product with the affected lot numbers, please complete the product recall form anyway and return via fax on 01329 224390.

Your local UK Surgical Product Specialist will contact you shortly.

We sincerely apologize for any inconvenience this may have caused. If you have any queries relating to this recall please do not hesitate to contact either your Product Specialist or myself.

Yours sincerely



Jeanette James
Commercial Manager, Surgical

*Trademark
Attachment

Appendix 2 - Lot numbers affected by recall

TA6035S

LOT#	
P2G906	P3J460
P2G907	P3J48
P2G908	P3J49
P2J239	P3J50
P2J239A	P3J719
P2J451	P3K22
P2J559	P3K23
P2K1053	P3K24
P2K1054	P3K25
P2K1055	P3K358
P2K334	P3K359
P2K617	P3L1000
P2L129	P3L1001
P2L130	P3L1002
P2L131	P3L1003
P2L651	P3L1144
P2L652	P3L1145
P2L653	P3L1146
P2L654	P3L1148
P2M194	P3L225
P2M195	P3L226
P3A119	P3L227
P3A120	P3L228
P3A121	P3L452
P3A415	P3L453
P3A416	P3L454
P3A417	P3L455
P3A646	P3L456
P3A910	P3L633
P3B33	P3L634
P3B34	P3L635
P3C627	P3L636
P3C738	P3L637
P3D249	P3L999
P3D251	P3M551
P3D252	P4A130
P3D571	P4A133
P3D572	P4A135
P3D582	P4A560
P3D583	P4A641
P3F464	P4A888
P3F465	P4B243
P3F466	P4B267
P3F467	U2F03
P3F685	U2F07
P3G195	U2F12
P3G196	U2F27
P3G197	
P3G766	
P3G871	
P3H248	
P3H250	

TA6048S

LOT#	
P2H15	U2F28
P2J240	U2F30
P2J240A	
P2J265	
P2J784	
P2J786	
P2K827	
P2L124	
P2L655	
P2L656	
P2M96	
P3A418	
P3A648	
P3A940	
P3A98	
P3C01	
P3C423	
P3C626	
P3D21	
P3D280	
P3D584	
P3D951	
P3F468	
P3G914	
P3H249	
P3H444R	
P3H566	
P3J238	
P3J462	
P3J463	
P3L1149	
P3L1150	
P3L229	
P3L230	
P3L240	
P3L241	
P3L458	
P3L459	
P3L460	
P3L638	
P3L730	
P3L994	
P3L995	
P3L996	
P4A138	
P4A889	
P4B270	
P4B591	
P4B714	
P4B716	
U2E13R	
U2F08	

TA9035S

LOT#
P2H679
P2J642
P2K1113
P2K534
P2K66
P2L609
P2L610
P2L611
P2L649
P2M692
P3A650
P3C425
P3C800
P3E304
P3F686
P3G15
P3G414
P3J249
P3J250
P3J256
P3L1013
P3L1141
P3L242
P3L44
P3L462
P3L639
P4A547
P4A642
P4A890
P4B727
U2G21

TA9048S

LOT#
P2H677
P2H678
P2J787
P2J788
P2L645
P2L646
P2L650
P2M226
P2M693
P3A652
P3B308
P3B613
P3C426
P3C432
P3C819
P3D953
P3E649
P3F116
P3F841
P3G16
P3G17
P3H281
P3H282
P3H447
P3H448
P3K27
P3K362
P3L1014
P3L1015
P3L1142
P3L231
P3L232
P3L45
P3L464
P3L465
P3L466
P3L731
P4A546
P4A643
P4A891
U2G15

Appendix 2 - Lot numbers affected by recall

TA3035S

TA3048S

TA30V3S

TA4535S

TA4548S

LOT#
P2J505
P2J971
P2K1031
P2K813
P2L332
P2L603
P2L604
P2M227
P2M228
P2M235
P2M82
P3A1151
P3A323
P3A443
P3A908
P3B336
P3B607
P3C710
P3C802
P3D563
P3D944
P3E233
P3E294
P3G08
P3G09
P3G417
P3G621
P3G769
P3H288
P3H638
P3J41
P3J456
P3K05
P3K06
P3K07
P3K08
P3L1007
P3L1008
P3L11
P3L1129
P3L1130
P3L12
P3L243
P3L42
P3L425
P3L440
P3L441
P3M368
P3M369
P4A634
P4A881
U2H02
U2H08

LOT#
P2J506
P2J508
P2K1032
P2K186
P2K614
P2L333
P2M236
P2M549
P2M550
P2M703
P3A1149
P3A1150
P3A453
P3B340
P3C803
P3D86
P3E234
P3E296
P3G10
P3H287
P3H639
P3J245
P3J458
P3K10
P3K11
P3L1009
P3L1010
P3L1131
P3L1132
P3L233
P3L234
P3L43
P3L443
P3L445
P3L446
P3L727
P3L87
P3M366
P3M367
P3M550
P4B161
U2H01
U2H09

LOT#
P2J507
P2J972
P2K1034
P2K616
P2L334
P2L335
P2L607
P2M694
P2M695
P3A83
P3B307
P3D245
P3D564
P3E236
P3E309
P3F683
P3G300
P3G855
P3H21
P3J263
P3J408
P3J42
P3K13
P3L1011
P3L1012
P3L1133
P3L1134
P3L13
P3L237
P3L447
P3L628
P3L728
P3M558
P3M668
P4A636
P4B176
U2H11
U2H17
U2J01
U2J02

LOT#
P2J450
P2J795
P2J796
P2J797
P2J798
P2L657
P2M193
P2M241
P2M542
P2M98
P3A412
P3A91
P3A92
P3A93
P3B345
P3B608
P3B609
P3B610
P3C238
P3D246
P3D568
P3D947
P3E237
P3E300
P3E523
P3F113
P3F684
P3G960
P3J237
P3J43
P3J44
P3J459
P3J711
P3K15
P3L1135
P3L1136
P3L1152
P3L235
P3L236
P3L448
P3L449
P3L629
P3L997
P3L998
P3M672
P3M673
P4A554
P4A637
P4A883
P4B585
U2E11
U2F13
U2F17
U2G02
U2G03

U2G11
U2G13

LOT#
P2H776
P2J263
P2J607
P2J792
P2J793
P2L647
P2L648
P2M243
P2M244
P2M552
P3A118
P3A413
P3A909
P3B341
P3B342
P3B343
P3B344
P3B611
P3B848
P3C239
P3C241
P3C437
P3C439
P3C588
P3E18
P3E238
P3E301
P3E524
P3E525
P3E647
P3F115
P3F225
P3F352
P3F446
P3H252
P3H280
P3H404
P3H431
P3H432
P3H640
P3H641
P3J45
P3J46
P3J47
P3J712
P3J713
P3K20
P3L1004
P3L1005
P3L1006
P3L1138
P3L1139
P3L238
P3L239
P3L450

P3L630
P3L631
P3L729
P3M464
P4A126
P4A128
P4A336
P4A337
P4A338
P4A544
P4A549
P4A884
P4A885
P4B242
P4B587
P4B710
U2E10
U2E12
U2F02
U2F16
U2F20
U2G04
U2G06
U2G09