

## **CORE and RemB, and Total Performance System (TPS) Universal Drivers/ Stryker Recall (09/13)**

### **Reason/Information:**

This recall contains additional lot numbers from previous Stryker Recall. Stryker states that safety margin values were entered incorrectly into the programming software of the drivers, potentially leading to the unintended activation of the drivers.

### **Risk to Health:**

There is a potential for bone or soft tissue injury to the patient and/or injury to the user as a result of unintended forward or reverse activation. There is also the potential that the handpiece may not reach 100% speed at full trigger depression in both forward or reverse, the handpiece may exceed full speed in reverse or may have excessive dead trigger travel before motor rotation in reverse.

### **Disposition/Instructions:**

Check inventory. If you have the materiel, quarantine. Return the Business Reply Form on Message under Additional Documentation/Attachment) to confirm receipt of this information and identify how many affected units are currently in your inventory. Fax the completed Business Reply Form to Stryker Instruments Regulatory Department at 866-521-2762. Upon receipt of the Business Reply Form, Stryker will send you a pre-paid shipper to send your affected device(s) back to Stryker to be reprogrammed with the correct specifications. Questions or if you require a loaner, contact the Stryker Service Department at 888-308-1983, 269-389-4518/3803 or 269-385-2600.

**NOTE:** FDA Recall number continues Z-1741-2013 & Z-1742-2013

### **Item Information:**

NSN (FSC-NIIN): 6515-NS1  
Part Number: 5400-99 & 5400-099-000  
Nomenclature: CORE UNIVERSAL DRIVERS  
UI: EA  
Manufacturer: STRYKER

LOT / SN:  
0534203093 0627600783 0730101013 0730101033  
0805000553 0809829593 0935603083 1011903103  
1011903493 1013814003 1025400463 1025400643  
1126901343 1128022593

### **NOTES:**

NSN (FSC-NIIN): 6515-NS2  
Part Number: 6400-099-000  
Nomenclature: REMB ELECTRIC UNIVERSAL DRIVERS  
UI: EA  
Manufacturer: STRYKER

LOT / SN:

0910505713	1029801073	1225400823	1314300723
1314300763	1314300773	1314300793	1314300803
1314300823	1314300833	1314300843	1314300863
1314300873	1314300893	1314300903	1314804033
1314900053	1314906453	1314908193	

**NOTES:**

NSN (FSC-NIIN): 6515-NS3  
Part Number: 5100-99  
Nomenclature: TPS UNIVERSAL DRIVERS  
UI: EA  
Manufacturer: STRYKER

LOT / SN:  
0214200753

**NOTES:**

POC Contact Information:

USAMMC-E

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Phone (COMM): 011-49-6331-86-7118/7181  
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US ARMY

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US NAVY

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Phone (COMM): 301-619-3085  
Phone (DSN): 343-3085  
Fax: 301-619-2473

**Additional Message Recipients:**

Please ensure widest dissemination of information to all interested entities.

Command Channels  
Lab Staff

Medical Log Officers

Medical Staff

Supply Officers

Supported Activities/Centers

Clinical/Biomedical Engineering, Information Technology, Dentistry/Oral Surgery, Neurology,  
OR/Surgery, Orthopedics

**Additional Documentation/Attachments:**

[MMQC-13-1727\\_1.pdf](#)

US AIR FORCE

AF Activities Will Take Action As Prescribed In AFI 41-209, Medical Logistics Support, Chapters 3 And 9. For MAJCOMS & NGB--This Msg Has Been Transmitted To All Designated Subordinate Medical Activities.

US ARMY

See Army Regulation (Ar) 40-61, 28 January 2005, Chapter 4, And The Department Of The Army Supply Bulletin (Sb 8-75-11) For Applicable Policies And Procedures.