

URGENT MEDICAL DEVICE CORRECTION

RE: STRYKER UNIVERSAL DRIVER

ATTENTION: RISK MANAGER, OR DIRECTOR, MATERIALS MANAGER

June 28, 2013

Dear Universal Driver Customer/Distributor,

The purpose of this letter is to advise you that Stryker Instruments is voluntarily recalling the following Universal Drivers:

| Stryker Product Number | Product Description | Stryker Serial Number | Date of Production |
|------------------------|-----------------------|--|-----------------------------------|
| 5400-099-000 | CORE Universal Driver | 0326801633, 0330802913, 0406200763, 0410401383, 0410600013, 0730101013, 0730101033, 0805000553, 0809829593, 013814003, 1126901343, | May 28, 2013 through May 31, 2013 |
| 6400-099-000 | RemB Universal Driver | 1314201603, 1314300713, 1314300733, 1314300743, 1314300753, 1314300783, 1314300813, 1314300853, 1314300883, | |

Product Description

The Stryker Total Performance System (TPS) is intended for use in the cutting, drilling, reaming, decorticating and smoothing of bone and other bone related tissues for a variety of applications such as ENT, dental orthopedic, maxillofacial, spinal, and plastic surgery. The instruments are also used in the placement of screws, wires, pins, and other fixation devices.

The Universal Driver is intended for use with the Consolidated Operating Room Equipment (CORE) System. When used with a variety of accessories, the driver is intended for surgical procedures involving drilling, reaming, driving wire or pins, and cutting bone and hard tissue. This drill may also be used with the Total Performance System (TPS).

The RemB Electric Universal Driver is intended for use with the Consolidated Operating Room Equipment (CORE) System. When used with a variety of accessories, the RemB Electric Universal Driver is intended for surgical procedures involving driving wire or pins into bone and hard tissue. This includes but is not limited to Dental, ENT (Ear, Nose, Throat), Neuro, and Endoscopic applications. The device can also be used with the Total Performance System (TPS).

For questions regarding this recall please contact Stryker Instruments:

Monday-Friday 8am-5pm (EST)
 Kara Spath / Jennifer Mars
 269-389-4518 / 269-389-3808
kara.spath@stryker.com / jennifer.mars@stryker.com

Product Issue:

During a Quality Inspection of the handpiece, it was discovered that the safety margin values that are detailed in the Engineering Design Document were entered incorrectly into the programming software between May 28, 2013 and May 31, 2013 when the specifications were transcribed from the previous TPS Handpiece Programmer to the newly implemented Micro Handpiece Programmer. Handpieces that have been programmed with the incorrect parameters could result in unintended activation.

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.

Actions to be taken by the Customer/User:

1. Immediately review this Recall Notification
2. Locate the units listed in this notification. A list of units shipped to your facility is included on the attached Business Reply Form.
3. Return the enclosed Business Reply Form to confirm receipt of this notification and identify how many affected units are currently in your inventory.
4. If you have further distributed this product, please forward this letter and the attached Business Reply Form (BRF) to all affected locations. Please indicate each location on the BRF.
5. Fax the completed Business Reply Form to Stryker Instruments Regulatory Department, 866-521-2762.
6. 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.
7. Send back all affected devices using the pre-paid shipper provided to you by Stryker.
8. If you require a loaner, please contact the Stryker Service Department to arrange for a loaner at 888-308-1983.

Report any serious adverse events or product quality problems to Stryker Instruments: 1-800-253-3210

Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to the FDA's MedWatch Adverse Event Reporting program either online, or by fax or phone.

Online: www.fda.gov/Safety/MedWatch/HowToReport/default.htm

Fax: (800) FDA-0178 Phone: (800) FDA-1088

We apologize for any inconvenience this action may cause your facility. Please forward a copy of this letter to any other personnel within your facility that you deem appropriate.

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BUSINESS REPLY FORM

PRODUCT: Stryker Universal Driver

| Part Number | Description | Serial Number |
|--------------|-----------------------|---------------|
| 5400-099-000 | CORE Universal Driver | |
| 6400-099-000 | RemB Universal Driver | |

1. Review and confirm the list of serial numbers listed above.
2. After receiving this 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.
3. If you require a loaner, please contact the Stryker Service Department to arrange for a loaner at 888-308-1983.

Please complete and sign this form. Your signature indicates that you have received and understand the attached notification. Fax or email the form to Kara Spath at Stryker Instruments Regulatory Department (see below).

Account #:

Print Customer Name _____ Customer Title _____

Contact Phone Number _____ Customer Signature _____ Date _____

Email Address _____ Fax Number _____

If you have further distributed any affected product, please indicate to whom below:

Name _____ Address _____ City _____ State _____ Zip _____

Contact Person _____ Part Number(s) and Quantities _____

Stryker Instruments, Kara Spath
Phone: 269-389-4518
Fax: 866-521-2762
Email: kara.spath@stryker.com

*Note: Please keep a copy of this completed, executed form for your records.