# Urgent
# FIELD CORRECTIVE NOTICE

March 19, 2012

- Account #-
-Customer Address-

**Voluntary Recall # 2012-0014 COMBO REAMER DRILL**

Dear Stryker Customer,

Stryker® Osteosynthesis is initiating a Voluntary Recall of the Combo Reamer Drill which was manufactured from Nov. 26th 2010 until Nov. 17th 2011 and is included in the following article numbers and comprehends the lots as listed below:

**Table 1: Distribution list**

| Article number | Article name | Lot# | Number of devices |
|---|---|---|---|
| 704006 | Combination Reamer Assembly Omega SHORT | X11939 | |
| 704006 | Combination Reamer Assembly Omega SHORT | X25533 | |
| Summation | | | |

| Article number | Article name | Lot# | Number of devices |
|---|---|---|---|
| 704005-10 | Combo Reamer Drill | X20174 | |
| 704005-10 | Combo Reamer Drill | X22771 | |
| 704005-10 | Combo Reamer Drill | X29905 | |
| **Summation** | | | |

| Article number | Lot# | Distributed in: | Kit Ref# | Kit Lot# | Number of devices |
|---|---|---|---|---|---|
| 704005 | W34411 | Instrument Set Omega 3 | 990263 | W35033 | |
| 704005 | W37630 | Instrument Set Omega 3 | 990263 | X03620 | |
| 704005 | X05215 | Instrument Set Omega 3 | 990263 | X06186 | |
| 704005 | X05749 | Instrument Set Omega 3 | 990263 | X10987 | |
| 704005 | X05751 | Instrument Set Omega 3 | 990263 | X06186 | |
| 704005 | X07692 | Instrument Set Omega 3 | 990263 | X10987 | |
| 704005 | X07695 | Instrument Set Omega 3 | 990263 | X10987 | |
| 704005 | X07696 | Instrument Set Omega 3 | 990263 | X10987 | |
| 704005 | X07697 | Instrument Set Omega 3 | 990263 | X10987 | |
| 704005 | X09625 | Instrument Set Omega 3 | 990263 | X10987 | |
| **Summation** | | | | | |

| Article number | Article name | Lot# | Number of devices |
|---|---|---|---|
| 704005 | Combination Reamer Assembly Omega STANDARD | W34410 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | W37630 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | W38887 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X00014 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X00032 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X00500 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X05215 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X05749 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X05752 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X07693 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X07694 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X09624 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X09625 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X11934 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X11935 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X14821 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X14826 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X14827 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X18594 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X20168 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X23220 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X23318 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X24344 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X27821 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X30015 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X30646 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X31275 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X31276 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X32729 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | X32730 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | Z00136 | |
| 704005 | Combination Reamer Assembly Omega STANDARD | Z00137 | |
| **Summation** | | | |

**Issue**

Stryker Osteosynthesis has become aware of the fact that the cutting performance of the Combo Reamer Drill might be not as expected which could increase the time for drilling during the surgery or even make it necessary to exchange the instrument or to change to another OP technique.

The Combination Reamer Drill is part of the Combination Reamer Assembly, as well as a single instrument, both being part of the Omega 3 instrument set.

**Potential Hazards**
Potential hazards associated with the use of the instrument are:

- Exchange of instrumentation might become necessary
- Change of surgery method (opening procedure or other OP technique) might become necessary
- High friction of the blunt drill tip might lead to heat generation during drilling
- Surgery time might be extended by change of instrument or surgery method
- The drill might break or might not be able to penetrate the bone, but additional equipment might not be available

**Risk Mitigation**
A functional check of instruments should be executed before using instruments in a surgery.
The Osteosynthesis Reprocessing Guide "Instructions for Cleaning, Sterilization, Inspection and Maintenance" (ref L24002000) includes an instruction for the functional check of reamers in appendix 3. This check also points out to check for blunt and dull cutting flutes.
It is not likely, though, that the non-conformance of the Drill can be detected by standard visual inspection of the hospital staff without the knowledge of the non-conformance and its visual appearance.

A factor that obscures hazard awareness can be softer bone density, e.g. elderly patients, osteoporotic bone. Factors that heighten hazard awareness are verification of the device prior to each clinical use (compare IFU) and no penetration through cortex while drilling to be noticed by Health Care Professionals during surgery.

**Actions Needed**
Our records indicate that you have received the above referenced product(s) and we are requesting that you assist us in this Field Corrective Action by:

- Passing this Field Safety Notice to all those who need to be aware of it within your organization.
- 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.
- Immediately check all stock areas or operating room storage and quarantine any affected product(s) found.
- Mark product as “PFA #2012-014 RECALLED PRODUCT”.
- Please indicate on the BRF the quantity of affected Combo Reamer Drills you are returning and fill in the form completely.
- Sign the BRF (**even if you do not have any affected product**).
  ***Note:*** *Your signature on the BRF indicates that you have received and understand this notification and are returning all affected product(s) from your facility.*
  Return the Business Reply Form as fax within 5 business days to Stryker Osteosynthesis, Regulatory Department, to acknowledge your receipt and understanding of this information. (need fax number*)
- Upon receipt of the BRF, Stryker will contact you to coordinate the return of all affected product that you have on hand.
- Send back all affected product using the pre-paid shipper provided to you by Stryker.

We sincerely regret any inconvenience caused to you by this action, however we know that you share our desire to ensure the highest quality standards in our products and reduce risks to patients. We would like to thank you for your co-operation in this matter. Should you require any further information or have any queries on the matter please do not hesitate to contact the undersigned.

Yours faithfully,

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Name
Position
(address)
phone: xxxx-xxxx
fax: xxxx-xxxxxx
email: XXX.XXX@stryker.com

**Enclosures:**
Distribution List
Customer Response on Receipt
Customer Response on Return

## CUSTOMER RESPONSE ON RECEIPT

We have received your letter dated March 19th, 2012 Ref. Voluntary Recall # 2012-0014, concerning the Combo Reamer Drill and Assembly ref. 704005, 704005-10 and 704006 with lots listed in the above given letter and will return all affected products available at our location to:

Stryker Trauma SA
Andreas Seiss
Ref. PFA #2012-014
2545 Selzach
Switzerland

Please return this page after completion to forename Name by email, fax or letter to:

Name
Position
(address)
phone: xxxx-xxxx
fax: xxxx-xxxxxx
email: XXX.XXX@stryker.com

Hospital / Customer Name: _____

Date / Printed Name / Signature: _____

## CUSTOMER RESP0NSE FORM

***Please complete this form even if you do not have any product to return. This will preclude the need for future notices.***

| | | | | |
|---|---|---|---|---|
| **Stryker RA Reference Number** | 2012-014 | | | |
| **Product Description** | ***COMBO REAMER DRILL and COMBO REAMER ASSEMBLY*** | | | |
| **Product Code/Cat No** | From: | 704005-10;<br>704005;<br>704006;<br>990263 | To: | n/a |
| **Lot/Serial Numbers** | See attachement. PFA 2012-014 Trace affected lots | | | |

***Please check your inventory for affected product and return completed form to our Quality Department as soon as possible. Please note only the product codes/catalogue numbers specified are affected by this action.***

## Product Disposition (Completed by Customer)

| Product Code/Cat No. | Lot/ Serial No | Qty to be returned | Qty /Used Implanted | Qty Disposed /or destroyed | Qty not located | Upgraded |
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## Customer Details

***Response requirements (please complete/delete appropriate section)***

**I have checked inventory and can confirm that we do not have any affected product at this location.**

**I have checked inventory and completed the product disposition table. Please arrange for collection of product.**

**I have completed the upgrade/maintenance of all the product listed above in accordance with the Product Field Action.**

**Please have Stryker service contact our maintenance department to arrange upgrade of the above listed product.**

**Please sign and return this form to acknowledge receipt of product notice.**

| | | | |
|---|---|---|---|
| **Name of Hospital/ Organisation** | | **Address** | |
| **Contact Name** | | | |
| **Contact Title** | | | |
| **Contact Signature** | | | |
| **Contact Phone No.** | | **Date** | |

## Completion Instructions

1. Complete and fax back this form to Stryker, Andreas Seiss, Fax: +41 32 641 66 60
2. A Stryker Representative will call you to arrange collection of product/upgrade if necessary.
3. Please ensure that the outer package is labelled with Stryker RA Reference number PFA 2012-014
4. Ensure that forms are secured in a document wallet on the outer of the package.
5. Please ensure that where appropriate a decontamination certificate is returned with product.