# URGENT MEDICAL DEVICE RECALL NOTIFICATION

## PRODUCT: Stryker® Navigation Thoracic Pedicle Feeler

### ATTENTION: OR DIRECTOR, RISK MANAGER, MATERIALS MANAGER

October 16, 2017

The purpose of this notification is to advise you that Stryker Instruments and Stryker Leibinger GmbH & Co. KG are voluntarily recalling the following Thoracic Pedicle Feelers that are used in conjunction with the Stryker® Navigation System.

| Stryker Product Number | Product Description | Serial Numbers | Dates of Distribution |
|---|---|---|---|
| 6002-350-000 | Thoracic Pedicle Feeler | 10897, 10898, 10899, 10900, 10901, 10902, 10903, 10904, 10905, 10906, 10907, 10908, 10909, 10910, 10911, 10912, 10913, 10914, 10917, 10919, 10920, 10921, 10922, 10923, 10925, 10926, 10927, 10928 | June 19, 2017 – Aug 30, 2017 |

**Reason for the Voluntary Recall:**
A laser marking machine is used to create the distance markings on the tip of the Thoracic Pedicle Feeler. The settings on the machine were higher than intended. This change led to increased energy directed onto the tip of the Thoracic Pedicle Feeler which caused material degradation where the laser marks exist.

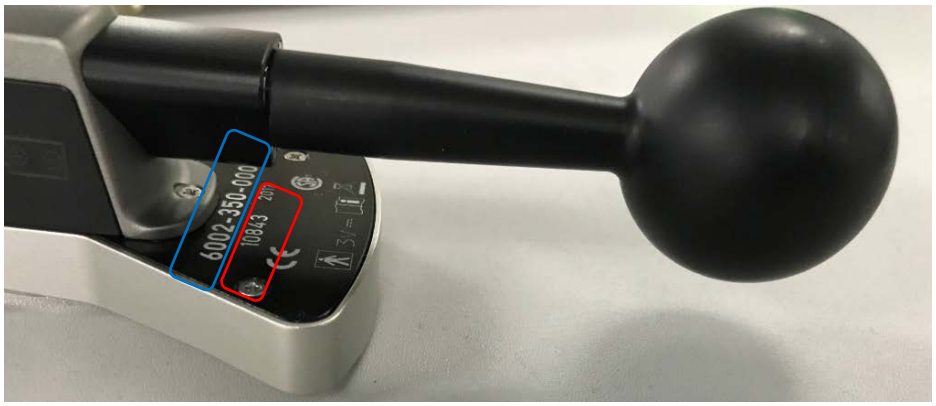
**Risk to Health:**
There is the potential for the tip of the Thoracic Pedicle Feeler to break during use. If the tip breaks within the patient, migration of the broken tip could result in soft tissue or peripheral nerve injury requiring surgical intervention.

**Product Description:**
The Thoracic Pedicle Feeler is a reusable accessory to the Stryker Navigation System. It is intended to be advanced into the pedicle and its position, as it relates to the patient anatomy, is displayed on the monitor.

**Location of Product Number (blue) and Serial Number (red) on the packaging label:**


Stryker Instruments
4100 E Milham Road, Kalamazoo, MI 49001 USA | P 269 389 4518| F 866 521 2762

**Location of Product Number (blue) and Serial Number (red) on the Product:**




**Actions to be taken by the Customer/User:**

1. Immediately review this Recall Notification.

2. Immediately check all stock areas and/or operating room storage for affected equipment. Quarantine and discontinue use of any affected Thoracic Pedicle Feelers.

3. Complete the enclosed Business Reply Form (BRF) to confirm receipt of this Notification and identify how many affected items are currently in your inventory. Please complete and return the BRF even if you don't have any affected product on hand. Fax the completed BRF to Stryker Instruments at 866-521-2762, or email a copy to kara.spath@stryker.com.
   *Note: Your signature on the BRF indicates that you received and understand this Notification and have followed the instructions in the Notification.*

4. If you have further distributed this product, please forward this Notification and the attached BRF to all affected locations. Please indicate each location on the BRF.

5. If the BRF for your facility indicates that recalled product is currently on hand, we will contact you to arrange for the return of the product for repair/replacement.

**If discontinuing use of the specific Thoracic Pedicle Feeler(s) listed will cause disruption at your facility, please contact Kara Spath, at mobile number 269-365-7849.**

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.



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 by fax or phone, or online. Fax: (800) FDA-0178 Phone: (800) FDA-1088
Online: www.fda.gov/Safety/MedWatch/HowToReport/default.htm

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