



## URGENT MEDICAL DEVICE RECALL NOTIFICATION

### PRODUCT: Stryker System G® handpieces

ATTN: Risk Manager, Operating Room Director, Materials Manager

#### DATE

The purpose of this notification is to advise you that Stryker Instruments is voluntarily recalling the Care Instructions (7300-001-700) packaged with the following System G handpieces:

Product Numbers	Dates of Distribution
7308-001-000 Sagittal Saw 7306-001-000 Reciprocating Saw 7305-001-000 Rotary Drill	Devices distributed between August 17, 2016 and May 4, 2017

#### Product Description:

The Stryker System G handpieces are surgical battery-powered instruments intended for use during a variety of orthopedic and trauma procedures, in conjunction with various accessories and/or attachments.

#### Reason for the Voluntary Recall:

Information has been updated in the Care Instructions to reflect that the recommended Ethylene Oxide (EO) Sterilization time should be 80 minutes, up from 60 minutes previously.

#### Risk to Health:

There is a potential risk of soft-tissue infection to the patient if a non-sterile System G Sagittal Saw is used. There is no risk associated with the System G Rotary Drill or System G Reciprocating Saw related to this recall.

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

1. Immediately review this Recall Notification.
2. Enclosed is a revised version of the System G handpiece Care Instructions. Please distribute the revised version to the appropriate person or department.
3. Remove and discard any previously distributed System G handpiece Care Instructions.
4. Please complete and sign the enclosed Business Reply Form (BRF), acknowledging your receipt and understanding of this Notification.
5. Return the completed BRF to <insert local contact information here>.

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

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**Stryker Instruments**

4100 E Milham Road, Kalamazoo, MI 49001 USA | P 269 323 7700 | F 866 521 2762