# URGENT MEDICAL DEVICE MODIFICATION NOTIFICATION

## PRODUCT: Stryker System G® handpieces

ATTN: Risk Manager, Operating Room Responsible, Materials Manager

CC: Chairman Medical Board and relevant Head of Departments

5 Jun 2017

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

| Product Numbers | Dates of Distribution |
|---|---|
| 7308-001-000 Sagittal Saw<br>7306-001-000 Reciprocating Saw<br>7305-001-000 Rotary Drill | Devices distributed between<br>August 17, 2016 and<br>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 device modification:**
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, nor with steam sterilization related to this action.

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

1. Immediately review this 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 your local Stryker representative or email to ASEAN.PMS@stryker.com .

**Reporting of Adverse Events**
Please report any adverse events or product quality problems associated with this device to Stryker. Healthcare Professionals may also report any suspected adverse events associated with these devices to the Vigilance and Compliance Branch, Health Products Regulation Group, HSA at Tel: 6866 3538, Fax: 6478 9069, or report online at www.hsa.gov.sg/ae_online.

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.



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

Sincerely,

[redacted]

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stryker

# BUSINESS REPLY FORM

## PRODUCT: Stryker System G® handpieces

5 Jun 2017

1. Immediately review the enclosed Notification.
2. Distribute the revised version of the System G handpiece Care Instructions to the appropriate person or department.
3. Remove and discard any previously distributed System G handpiece Care Instructions.
4. If you have further distributed the System G handpieces, please forward the Notification and this Business Reply Form (BRF) to all affected locations. Please indicate each location below.
5. Return the completed, signed BRF to your local Stryker representative or email to ASEAN.PMS@stryker.com .

*Note: Your signature on the BRF indicates that you received and understand the Notification and have followed the instructions in the Notification.*

| | | |
|---|---|---|
| Facility name | Facility Stamp | |
| Print Customer Name | Customer Title | |
| Contact Phone Number | Customer Signature | Date |
| Email Address | Fax Number | |

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

| | |
|---|---|
| Contact Person | Facility Name |
| Address | Country |



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