

## **URGENT MEDICAL DEVICE UPGRADE NOTIFICATION**

### **RE: STRYKER SONOPET CONSOLE**

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

July 11, 2014

Dear Sonopet Customer,

The purpose of this letter is to advise you that Stryker Instruments is voluntarily performing a label upgrade to the following Sonopet Consoles:

<b>Stryker Product Number</b>	<b>Product Description</b>	<b>Stryker Serial Number</b>	<b>Dates of Distribution</b>
5450-850-000	Sonopet Console 110V	All products distributed through 6/20/2014	All products distributed through 6/20/2014
5450-851-000	Sonopet Console 100V		
5450-852-000	Sonopet Console 230V		
UST-2001	Sonopet Ultrasonic Console (Distributed by Mutoh Co, Ltd)		

#### **Product Description:**

The Stryker Sonopet Console, when used with the Handpiece, is intended for use in surgical procedures where fragmentation, emulsification, and aspiration of soft and hard tissue is desirable, including neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery, plastic and reconstructive surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, laparoscopic surgery, and thoracoscopic surgery.

#### **Reason for the Voluntary Recall:**

Stryker is sending you this URGENT MEDICAL DEVICE UPGRADE NOTIFICATION to update documentation to clarify how to set up a Sonopet system. This label upgrade includes an update to the Instructions for Use (IFU) and an on-device instructional label for proper irrigation set up.

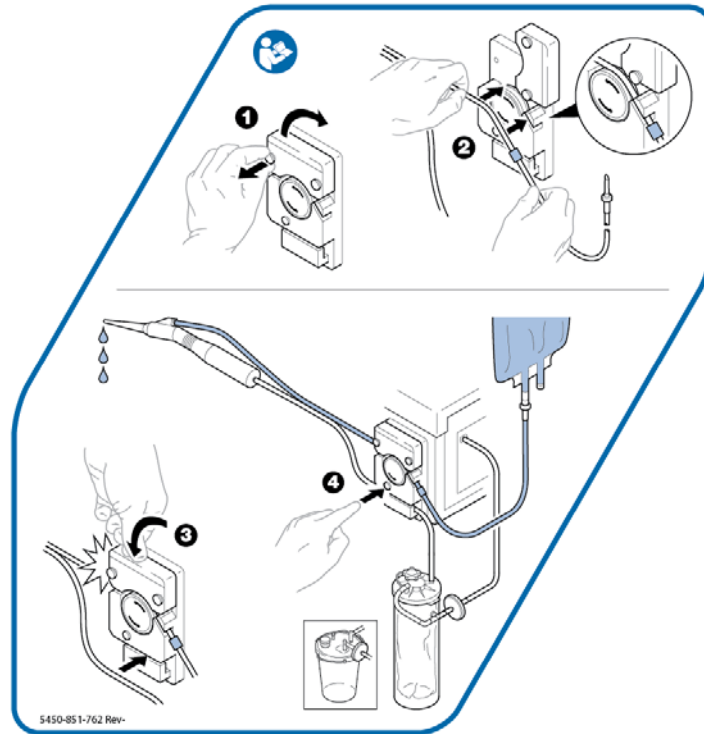
The updated IFU provided to you with this Customer Notification includes the following clarifications:

- DO NOT use a rigid non-collapsible irrigation container. Failure to comply may cause the flow of irrigation to be drastically reduced and result in overheating of the handpiece tip and/or tip cover. Only use a collapsible irrigation container.
- The irrigation tube must be properly routed through the irrigation pump with the pump cover fully closed and latched. Improper setup of the irrigation tubing may result in an inconsistent or lack of irrigation.
- Provide adequate irrigation to the tip to avoid excessive heat that could result in tissue damage due to unintended contact.

For questions regarding this recall please contact Stryker Instruments:

Monday-Friday 8am-5pm (EST)  
**Kelly Jo Davis**  
269-389-2921  
[kellyjo.whipple@stryker.com](mailto:kellyjo.whipple@stryker.com)

All existing Sonopet consoles will have an instructional irrigation setup label applied to the side of the console.



**Risk to Health:**

- Use of a rigid container or improper setup of the irrigation tubing may result in an inconsistent or lack of irrigation, which could result in excessive heat. Excessive heat from the Sonopet tip or handpiece due to insufficient irrigation may result in a risk of burning of critical soft tissue, burning of bone, and operator burn.

**Upgrade Information:**

- A Stryker representative will contact you and come to your location to place the instructional irrigation setup label onto your Sonopet console(s). The label upgrade will be scheduled with you in advance. Each unit will take approximately 10 minutes to upgrade.
- When the label upgrade is completed at your facility, you will be asked to sign an Upgrade Completion Form confirming that a Stryker representative has applied the instructional irrigation setup label to all Sonopet consoles.
- Your signature and return of the Business Reply Form (BRF), which is included with this Notification, and receipt of upgrade documentation, will close out this recall for your facility.

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

1. Immediately review this Upgrade Notification.
2. Verify that the serial numbers listed on the enclosed BRF are located at your facility.
3. Return the enclosed BRF to confirm receipt of this Notification, receipt of the updated IFU, and identify how many affected units are currently in your inventory.
4. Dispose of your existing IFU and replace with the updated IFU sent with this notification.
5. Stryker Instruments will dispatch a Stryker representative to your facility to perform the label upgrade to your console(s).
6. If you have further distributed this product, please forward this letter and the attached BRF to all affected locations. Please indicate each location and all Serial Numbers on the BRF.
7. If you have disposed of any of the affected units and they are no longer in use, please advise us of their obsolescence by providing us with the Serial Numbers.
8. Fax (866-521-2762) or email ([kellyjo.whipple@stryker.com](mailto:kellyjo.whipple@stryker.com)) the completed BRF to Stryker Instruments Regulatory Department, Attn: Kelly Jo Davis
9. When the label upgrade is completed at your facility by a Stryker representative, sign the Upgrade Completion Form and return to Stryker Instruments Regulatory Department.

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  
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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