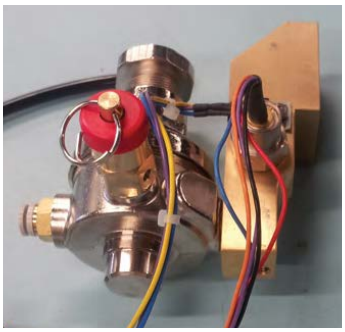
5900 Optical Court
San Jose, CA, 95138 USA
t: 408-754-2000

URGENT MEDICAL DEVICE RECALL
PNEUMOSURE HIGH FLOW INSUFFLATOR HIGH PRESSURE UNIT

March 28, 2016

Attn: Stryker Service Center
«Customer_Name»
«Ship_To_Address1» «Ship_To_Address2»
«Ship_To_City», «Ship_To_State» «Ship_To_Postal_Code»

Customer Number: «Customer_Number»



Description:	PneumoSure High Flow Insufflator High Pressure Unit (HPU)
Affected Component Part Numbers:	105-210-684
Affected Component Serial Numbers:	0005051337 through 000505052795

The purpose of this letter is to advise you that Stryker Endoscopy is voluntarily recalling the PneumoSure High Flow Insufflator and the High Pressure Unit which was found to have contributed to this event.

Reason for the Recall: When operating the device in high flow mode (40L/min, 15 mmHg) and connecting to a house gas inlet source, within seconds of insufflating the flow rate would drop to 0L/min and the red "Check Gas Supply" symbol would appear on the display, immediately suspending insufflation.

Risk to Health: The failure produced by the defective product is the red "Check Gas Supply" error on the display that occurs when the insufflator has a flow setting of 18L/min or greater. During a procedure, this would result in pressure decrease in the abdomen. Unclear image due to poor abdominal distention is the hazardous situation associated with low gas pressure during a procedure.

Actions to be taken: Recipients of this letter are confirmed to have received shipments of at least one High Pressure Unit. Please:

1. Inform individuals within your organization who need to be aware of this device removal.
2. Review inventory to determine if you have any affected product in stock. AND verify if any impacted components were utilized to repair an insufflator between November 2015-present
3. All customers with affected un-used units must return unit(s) to local Stryker Repair facility to be scrapped.
4. All customers with affected units used in repair are to provide a list of finished good serial numbers and customer information (Name, Account Address, Phone number) to endorecall@stryker.com.
5. **Response is required.**

We appreciate your cooperation and we recognize the inconvenience this may cause your facility. Thank you for your support on this important matter.

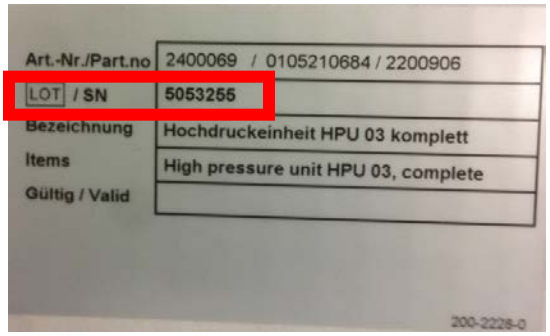
Sincerely,

[redacted]

Kimberly Lynch
Regulatory Compliance Manager
Stryker Endoscopy
endorecall@stryker.com

Health care professionals and consumers may report 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, by regular mail, fax or phone. Online: www.fda.gov/MedWatch/report.htm Mail: Use postage paid FDA form 3500 available at www.fda.gov/MedWatch/getforms.htm and mail to MedWatch, 5600 Fishers La ne, Rockville, MD 20852-9787 Phone: 1-800-FDA-1088 Fax: 1-800-FDA-0178

Attachment A



Part Number: 105-210-684

Lot Numbers: Table Below

5051522	5051773	5052165	5052795
5051570	5051774	5052178	
5051726	5051923	5052210	