W.O.M. WORLD OF MEDICINE GmbH | Salzufer 8 | 10587 Berlin

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

URGENT MEDICAL DEVICE RECALL NOTIFICATION

PNEUMOCLEAR HEATED HIGH-FLOW TUBE SET

October 26, 2018

Dear Customer
Cc: Chairman Medical Board and relevant Head of Department

RESPONSE REQUIRED BY JANUARY 31st, 2019

Device Description: PneumoClear Heated High-Flow Tube Set
Affected Part Number: 0620-050-200
Affected Lot Numbers: See Attachment A
Stryker Ref Number: 1885622

The purpose of this notification is to advise you that Stryker Endoscopy, under direction of World of Medicine (W.O.M.) is conducting a voluntary recall of the PneumoClear Heated High-Flow Tube Set. Attachment A lists affected units that must be returned to the manufacturer, WOM.

Reason for the Voluntary Recall:
This recall is being conducted after a complaint was received regarding a puncture of the sterile pouch packaging due to a kinked tube set which orientated the prongs of the connection toward the pouch packaging.

Risk to Health:
A kinked tube set can lead to a sterile barrier breach in the packaging. In addition to the normal risk of infection that any procedure carries, there is an additional potential risk that if the product is used in a procedure, an infection may occur that may require medical treatment. To date, there have been no reports of any adverse events or serious injuries

Actions to be taken by the Customer/User:

1. Inform individuals within your organization who need to be aware of this device removal.
2. Check all stock areas and/or operating room storage to determine if any devices with lot numbers from the Attachment A are at your facility.
3. If affected product is found, segregate the product and call Stryker customer service at 1-800-624-4422 (Option 3) or email endocustomersupport@stryker.com to arrange for product return and issuance of credit or replacement (upon availability).
    a. Quarantine and discontinue use of the identified non-conforming recalled devices.
    b. When returning units please enclose Business Reply Form on Attachment B.
4. If affected product is NOT found:
    a. Please complete Business Reply Form on Attachment B and return to WOMRecall@Stryker.com.

Please forward a copy of this letter to any other personnel within your facility that you deem appropriate.

We appreciate your cooperation and we recognize the inconvenience this may cause your facility. Thank you for your support on this important matter. Please send any questions to WOMrecall@stryker.com.

Sincerely,

[redacted]

Kimberly Lynch, *Regulatory Compliance Manager, Stryker Endoscopy*

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Attachment A – Affected Lot Numbers

4011926	4012198	4012213	4012340	4012546	4012599	4012819
4011927	4012199	4012214	4012341	4012547	4012600	4012827
4011928	4012200	4012215	4012440	4012569	4012601	4012847
4012078	4012201	4012216	4012441	4012570	4012602	4012860
4012079	4012202	4012217	4012442	4012571	4012604	4012861
4012080	4012203	4012218	4012443	4012572	4012605	4012875
4012081	4012204	4012219	4012444	4012574	4012606	4012886
4012082	4012205	4012220	4012445	4012575	4012667	4012889
4012083	4012206	4012333	4012446	4012576	4012677	4012890
4012084	4012207	4012334	4012447	4012577	4012738	4012892
4012193	4012208	4012335	4012448	4012578	4012739	4012894
4012194	4012209	4012336	4012449	4012595	4012742	4012895
4012195	4012210	4012337	4012450	4012596	4012743	4012863
4012196	4012211	4012338	4012451	4012597	4012744	4013202
4012197	4012212	4012339	4012452	4012598	4012752	

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Attachment B

URGENT MEDICAL DEVICE RECALL
NOTIFICATION ACKNOWLEDGMENT FORM

RESPONSE REQUIRED

Customer Name:

Address:

Device Description: PneumoClear Heated High-Flow Tube Set
Affected Part Number: 0620-050-200
Affected Lot Numbers: See Attachment A
Stryker Ref Number: 1885622

Do you have non-conforming units?

☐ No, we have physically checked our inventory and we do not have the affected product(s).

- Return this form to WOMrecall@stryker.com.

☐ Yes, we have the items referenced in the enclosed letter. We will be returning _____ affected unit(s).

- Return this form to WOMrecall@stryker.com and insert a copy of this form with your return shipment.

Name	
Title	
Email Address	

_____ _____

Signature Date

By signing this, you are acknowledging you have read and understand the notification from Stryker Endoscopy dated October 26, 2018 stating that they initiated a voluntary Product Recall for the above referenced product.

Return the completed Business Reply Form to Stryker Endoscopy via email (WOMrecall@stryker.com). Must also include this completed form in box with all returns.