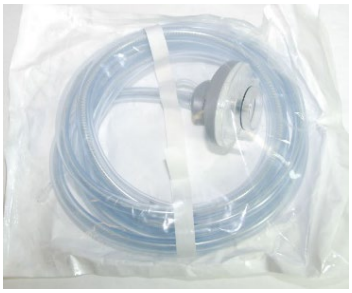
5900 Optical Court, San Jose, CA 95138 USA | t: 408-754-2000

URGENT MEDICAL DEVICE RECALL NOTIFICATION

PNEUMOSURE HEATED TUBESET WITH RTP, HIGH FLOW II TUBESET, and HIGH FLOW TUBESET WITH RTP



March 7, 2019

Attn: Product Recall Coordinator
Dear Customer,
Cc: Chairman Medical Board and relevant Head of Department

RESPONSE REQUIRED BY MAY 31, 2019

Device Description: Pneumosure Heated Tubeset with RTP, High Flow Tubeset with RTP, and High Flow II Tubeset
Affected Part Number: 0620-040-690, 0620-040-680, 0620-040-660
Affected Lot Numbers: See Attachment A

The purpose of this notification is to advise you that Stryker Endoscopy is conducting a voluntary recall of the Pneumosure Heated Tubeset with RTP, High Flow II Tubeset, and High Flow Tubeset with RTP. All units that have a lot listed on Attachment A must be returned to the Stryker Endoscopy.

Reason for the Voluntary Recall:
Stryker has received complaints regarding tube sets potentially detaching from the cassette.

Risk to Health:
A detached tube set can lead to leaking gas or a hissing sound. In addition to the normal risk that any procedure carries, there is an additional potential for this to result in lack of insufflation making it difficult to visualize surgical locations. **To date, there has been one report of an adverse event.**

Actions to be taken by the Customer/User:

1. Inform individuals within your organization who need to be aware of this device recall.
2. Check all stock areas and/or operating room storage to determine if any devices from the affected product list are at your facility. **Response is required by May 31, 2019.**
3. Quarantine and discontinue use of the recalled devices.
4. 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).
5. If no product is found, complete acknowledgement form, Attachment B on page 4 of this recall letter. Complete and return acknowledgement form to endorecall@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 endorecall@stryker.com.

Sincerely,

[redacted]

Valerie Estrada
Assoc. Regulatory Compliance Manager
Stryker Endoscopy

The US Food and Drug Administration has been notified of this action. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Attachment A – Affected Lot Numbers

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Part Number: 0620-040-690

Product Long Description: Pneumosure Heated Tubeset with RTP

Lot Numbers: Table Below

56004333	56004602	56005077	56005175	56005382	56005580	56005995	56006305
56004335	56004626	56005081	56005177	56005384	56005582	56006006	56006307
56004337	56004630	56005083	56005186	56005397	56005619	56006008	56006317
56004342	56004643	56005085	56005190	56005409	56005644	56006014	56006342
56004352	56004645	56005087	56005192	56005415	56005665	56006146	56006344
56004375	56004649	56005089	56005194	56005417	56005680	56006148	56006376
56004393	56004651	56005091	56005218	56005419	56005682	56006150	56006407
56004419	56004710	56005093	56005223	56005431	56005726	56006163	56006424
56004421	56004723	56005110	56005230	56005433	56005738	56006185	56006426
56004423	56004725	56005112	56005236	56005435	56005759	56006187	56006442
56004435	56004741	56005114	56005247	56005448	56005799	56006189	56006450
56004445	56004752	56005116	56005253	56005463	56005808	56006210	56006463
56004447	56004754	56005117	56005269	56005465	56005829	56006218	56006523
56004465	56004757	56005124	56005275	56005500	56005854	56006220	56006525
56004481	56004782	56005126	56005292	56005502	56005856	56006242	56006574
56004485	56004786	56005141	56005292	56005511	56005887	56006255	56006576
56004512	56004793	56005143	56005299	56005517	56005890	56006259	56006578
56004520	56004836	56005145	56005310	56005519	56005909	56006261	56006601
56004534	56004838	56005147	56005349	56005521	56005911	56006263	56006609
56004541	56004840	56005149	56005355	56005525	56005919	56006282	56006620
56004575	56004850	56005164	56005362	56005550	56005929	56006284	56006622
56004577	56004863	56005168	56005364	56005552	56005937	56006286	56006631
56004586	56004884	56005171	56005366	56005576	56005952	56006301	56006641
56004597	56005075	56005173	56005368	56005578	56005970	56006303	56006643

Part Number: 0620-040-680

Product Long Description: Pneumosure High Flow Tubeset with RTP

Lot Numbers: Table Below

18G0273	56004478	56004708	56005380	56005633	56005989	56006340	56006606
18H0323	56004526	56004784	56005411	56005635	56005997	56006434	
18H0354	56004592	56004832	56005450	56005744	56005999	56006521	
56004327	56004665	56005325	56005459	56005790	56006142	56006527	
56004391	56004667	56005376	56005538	56005899	56006154	56006556	
56004434	56004706	56005378	56005540	56005901	56006270	56006560	

Attachment A – Affected Lot Numbers (con't)

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Part Number: 0620-040-660

Product Long Description: Pneumosure High Flow II Tubeset

Lot Numbers: Table Below

18G0269	56004614	56004846	56005198	56005504	56005732	56005965	56006413
18H0353	56004616	56004852	56005200	56005506	56005734	56005972	56006415
18K0379	56004624	56004881	56005206	56005508	56005749	56005974	56006430
56004320	56004628	56004909	56005212	56005532	56005751	56005987	56006432
56004325	56004632	56004913	56005229	56005534	56005753	56006156	56006454
56004329	56004681	56004919	56005232	56005544	56005763	56006191	56006471
56004356	56004686	56004925	56005246	56005555	56005765	56006201	56006473
56004366	56004696	56004927	56005251	56005557	56005769	56006212	56006475
56004373	56004704	56004929	56005267	56005588	56005772	56006216	56006491
56004384	56004719	56004938	56005295	56005590	56005779	56006222	56006493
56004387	56004721	56004950	56005297	56005599	56005812	56006224	56006495
56004426	56004735	56004955	56005301	56005613	56005827	56006235	56006497
56004432	56004737	56004957	56005323	56005615	56005833	56006249	56006501
56004441	56004739	56004959	56005331	56005628	56005835	56006251	56006503
56004443	56004748	56004970	56005339	56005631	56005837	56006268	56006506
56004451	56004750	56004974	56005341	56005637	56005839	56006309	56006508
56004459	56004760	56004976	56005343	56005640	56005850	56006311	56006510
56004461	56004771	56004995	56005351	56005642	56005852	56006313	56006512
56004487	56004791	56005003	56005353	56005671	56005858	56006321	56006542
56004494	56004795	56005016	56005357	56005673	56005862	56006323	56006549
56004502	56004809	56005018	56005360	56005686	56005874	56006325	56006554
56004508	56004811	56005020	56005370	56005688	56005876	56006332	56006613
56004515	56004816	56005097	56005372	56005694	56005895	56006334	56006633
56004518	56004818	56005099	56005374	56005697	56005897	56006346	56006637
56004528	56004820	56005104	56005426	56005710	56005913	56006348	
56004551	56004822	56005108	56005428	56005714	56005915	56006368	
56004565	56004826	56005128	56005440	56005717	56005933	56006372	
56004573	56004830	56005130	56005480	56005719	56005935	56006374	
56004584	56004842	56005132	56005484	56005728	56005950	56006378	
56004600	56004844	56005139	56005486	56005730	56005954	56006411	

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Attachment B

URGENT MEDICAL DEVICE RECALL
NOTIFICATION ACKNOWLEDGMENT FORM

RESPONSE REQUIRED by May 31, 2019

Device Description: Pneumosure Heated Tubeset with RTP, High Flow Tubeset with RTP, and High Flow II Tubeset
Affected Part Number: 0620-040-690, 0620-040-680, 0620-040-660
Affected Lot Numbers: See Attachment A

<Ship To Customer Name>
<Ship To Address 1>, <Ship To Address 2>
<Ship to City>, <Ship to State>, <Ship to Zip>

Account Number: <Account Number>

By completing this form, I acknowledge that this facility has physically checked our inventory and we do not have the affected product(s) listed on attachment A.

Name	
Title	
Email Address	

_____ _____

Signature Date

By signing this, you are acknowledging you have read and understand the notification from Stryker Endoscopy dated March 7, 2019 stating that they initiated a voluntary Product Recall for the above referenced product.

Return the completed Business Reply Form to Stryker Endoscopy via email (endorecall@stryker.com**).**