

URGENT MEDICAL DEVICE RECALL PNEUMOSURE HIGH FLOW INSUFFLATOR

March 31, 2016



Attn: Distributor and/or hospital representative

FSCA identifier: RA 2016-020

Type of Action: Product correction

Description: PneumoSure High Flow Insufflator

Catalogue numbers: 620-040-600, 620-040-601, 620-040-602, 620-040-604, 620-040-610, 620-040-611, 620-040-613, 620-040-614

Serial Numbers: 1510CE0342 through 1601CE0581 (See Attachment A for detailed list)

Product owner: Stryker Endoscopy - 5900 Optical Court, San Jose, CA 95138, USA

Registration holder: Stryker Singapore Pte Ltd. 108 Pasir Panjang Road #03-04 Golden Agri Plaza Singapore 118535

SMDR listing: DE0008768

The purpose of this letter is to advise you that Stryker Endoscopy is voluntarily recalling the PneumoSure High Flow Insufflator

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 PneumoSure High Flow Insufflator. 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. (See Attachment A for location of Serial Number).
3. Segregate the affected units immediately
4. All customers with affected units must return unit(s) for re-work. Details on this return will be provided by your local Stryker representative
5. Inform Stryker of any past/present adverse events concerning the use of the subject devices.
6. **Response is required.**

Reporting of Adverse Events: Please report any adverse events associated with this product to your local Stryker representative or via the Stryker website: <http://www.stryker.com/productexperience/>. You may also report adverse events 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 appreciate your cooperation and we recognize the inconvenience this may cause your facility. Thank you for your support on this important matter. Please contact the undersigned should you have any questions or concerns.

Sincerely,



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&



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Attachment A

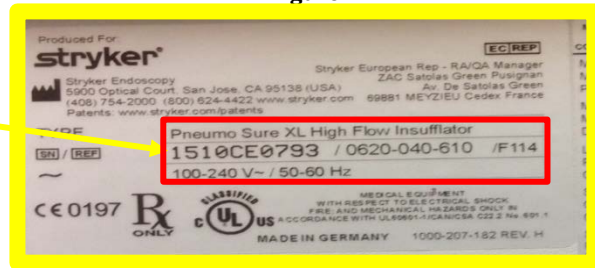
How to locate the serial number:

Please look on the back of the insufflator to locate the serial number. Please see Figure A and Figure B for an example.

Figure A



Figure B



Part Number: 620-040-600; Serial Numbers: Table Below

1510CE0851	1510CE0852	1510CE0853	1510CE0854	1510CE0855
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Part Number: 620-040-601; Serial Numbers: Table Below

1510CE0688	1510CE0691	1510CE0694	1510CE0697	1512CE0311	1512CE0314	1512CE0318	1512CE0367	1512CE0373
1510CE0689	1510CE0692	1510CE0695	1512CE0309	1512CE0312	1512CE0316	1512CE0365	1512CE0370	1512CE0374
1510CE0690	1510CE0693	1510CE0696	1512CE0310	1512CE0313	1512CE0317	1512CE0366	1512CE0372	

Part Number: 620-040-602; Serial Numbers: Table Below

1512CE0424

Part Number: 620-040-604; Serial Numbers: Table Below

1511CE0119	1511CE0241	1511CE0449	1512CE0595	1512CE0363	1512CE0488	1512CE0530	1512CE0550	1512CE0571	1512CE0584
1511CE0120	1511CE0242	1511CE0450	1512CE0325	1512CE0364	1512CE0489	1512CE0531	1512CE0551	1512CE0572	1512CE0585
1511CE0121	1511CE0243	1511CE0451	1512CE0326	1512CE0466	1512CE0490	1512CE0532	1512CE0552	1512CE0573	1512CE0586
1511CE0122	1511CE0244	1511CE0878	1512CE0327	1512CE0467	1512CE0491	1512CE0533	1512CE0561	1512CE0574	1512CE0587
1511CE0125	1511CE0245	1511CE0126	1512CE0328	1512CE0468	1512CE0492	1512CE0534	1512CE0562	1512CE0575	1512CE0588
1510CE0650	1511CE0246	1511CE0879	1512CE0355	1512CE0469	1512CE0493	1512CE0535	1512CE0563	1512CE0582	1512CE0589
1510CE0651	1511CE0442	1511CE0880	1512CE0356	1512CE0471	1512CE0494	1512CE0543	1512CE0564	1512CE0576	1512CE0591
1510CE0652	1511CE0443	1512CE0319	1512CE0357	1512CE0472	1512CE0470	1512CE0544	1512CE0565	1512CE0577	1512CE0590
1510CE0653	1511CE0444	1512CE0320	1512CE0358	1512CE0473	1512CE0495	1512CE0545	1512CE0566	1512CE0578	1512CE0592
1511CE0237	1511CE0445	1512CE0321	1512CE0359	1512CE0474	1512CE0526	1512CE0546	1512CE0567	1512CE0579	
1511CE0238	1511CE0446	1512CE0322	1512CE0360	1512CE0475	1512CE0527	1512CE0547	1512CE0568	1512CE0580	
1511CE0239	1511CE0447	1512CE0323	1512CE0361	1512CE0486	1512CE0528	1512CE0548	1512CE0569	1512CE0581	
1511CE0240	1511CE0448	1512CE0324	1512CE0362	1512CE0487	1512CE0529	1512CE0549	1512CE0570	1512CE0583	

Part Number: 620-040-610; Serial Numbers: Table Below

1511CE0842	1511CE0394	1511CE0627	1511CE0828	1512CE0010	1512CE0013	1512CE0016	1512CE0019
1511CE0091	1511CE0088	1511CE0827	1511CE0207	1512CE0011	1512CE0014	1512CE0017	1512CE0020
1511CE0720	1511CE0075	1511CE0087	1511CE0208	1512CE0012	1512CE0015	1512CE0018	

Part Number: 620-040-611; Serial Numbers: Table Below

1510CE0654	1510CE0655
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Part Number: 620-040-613; Serial Numbers: Table Below

1511CE0437	1511CE0439	1511CE0441	1511CE0882	1511CE0885	1512CE0426	1512CE0428	1512CE0430	1512CE0433
1511CE0438	1511CE0440	1511CE0881	1511CE0884	1512CE0425	1512CE0427	1512CE0429	1512CE0431	1601CE0150

Part Number: 620-040-614; Serial Numbers: Table Below

1601CE0150

Customer Response Form PneumoSure High Flow Insufflator

FSCA identifier: RA 2016-020
Type of Action: Product correction
Description: PneumoSure High Flow Insufflator
Catalogue numbers: 620-040-600, 620-040-601, 620-040-602, 620-040-604, 620-040-610, 620-040-611, 620-040-613, 620-040-614
Serial Numbers: 1510CE0342 through 1601CE0581 (See Attachment A for detailed list)

I acknowledge that have received and that I understand the Field Safety Notice regarding the attached FSCA for Pneumosure (RA2016-020) and confirm that:

We have located any of these devices in our inventory (circle the response that applies)		Yes No
We have located the following devices:		
Product Reference	Lot Number	Qty
We have further distributed subject devices to the following organisations:		
Facility Name		
Facility Address		

Form completed by:

Name _____

Facility _____

Address _____

Signature _____

Stamp _____

Please complete and email to sara.jato@stryker.com or give to your Stryker representative