4100 E. Milham Avenue
Kalamazoo, MI 49001
269-323-7700
www.stryker.com

stryker
Instruments

March 19, 2014

URGENT MEDICAL DEVICE RECALL NOTIFICATION

ATTENTION: RISK MANAGER, OR DIRECTOR, MATERIALS MANAGER

RE: STRYKER PENADAPT™

Dear Device Customer/Distributor,

The purpose of this letter is to advise you that Stryker Instruments is voluntarily recalling the PenAdapt™ for a potential sterility breach and the presence of foreign particulates/metal shavings in the packaging:

Stryker Part #	Stryker Lot #	Description	Dates of Distribution
0702-045-027	See attached list	PenAdapt™	4/11/11 through 12/11/13

Product Description:

The PenAdapt™ is for use with the Neptune 2 Ultra Rover System. PenAdapt™ is an aspiration sheath that fits over an electrosurgical pencil body and leaves the tip or blade exposed. This device is an accessory to an electrosurgical unit (ESU). The PenAdapt™ is used to remove smoke, particles, and body and casual fluids from the point of surgical activity during surgical procedures that use ESU for cutting and cauterizing.

For questions regarding this recall please contact Stryker Instruments:

Monday-Friday 8am-5pm (EST)
Angela Ragainis/Kelly Jo Whipple
269-389-4354 / 269-389-2921
angela.ragainis@stryker.com / kellyjo.whipple@stryker.com

4100 E. Milham Avenue
Kalamazoo, MI 49001
269-323-7700
www.stryker.com

stryker
Instruments

Reason for the Voluntary Recall:

During packaging verification testing, a failure occurred due to cuts in the packaging potentially causing a breach in the sterile barrier. Additional testing identified microscopic aluminum metal shavings and foreign particles estimated in size to be between 0.01inches x 0.015 inches to 0.03 inches x 0.04 inches that were introduced during the manufacturing process and were sterilized within the package of the product.

Risk to Health:

Although no complaints have been received, there is the potential for patient infection as a result of the patient being exposed to infectious material due to a breach in the sterile barrier of the packaging.

Although no complaints have been received, there is the potential for the patient to experience inflammation as a result of the patient being exposed to sterile foreign body material.

Due to the microscopic size of the aluminum shavings and foreign particles, no harms have been identified related to sharpness of the particles.

Request for Research:

As the particles and breaches are difficult to identify and may have been introduced to the surgical site, please research cases involving use of the recalled PenAdapt™ identified in this notification. Please indicate the number of patients experiencing inflammation and/or infection on the Business Reply Form and return a completed Complaint Form for each patient identified. Please report these occurrences to MedWatch if appropriate (see contact information below).

If your organization is unable to determine the relationship between the recalled PenAdapt™ and patient inflammation and/or infection, please indicate this on the attached Business Reply Form.

Actions to be taken by the Customer/User:

1. Immediately review this Recall Notification
2. If you have further distributed this product, please forward this letter and the attached Business Reply Form (BRF) to all affected locations. Please indicate each location on the BRF.
3. Immediately check all stock areas and/or operating room storage and quarantine any affected product found.
4. Please indicate on the BRF the quantity of affected PenAdapts™ you are returning.
5. Please indicate your response regarding the request for research results on the BRF.
6. Please complete and sign the Business Reply Form (even if you do not have any affected product).

   Note: *Your signature on the BRF indicates that you received and understand this Notification and have followed the instructions in this notification.*

For questions regarding this recall please contact Stryker Instruments:

Monday-Friday 8am-5pm (EST)
Angela Ragainis/Kelly Jo Whipple
269-389-4354 / 269-389-2921
angela.ragainis@stryker.com / kellyjo.whipple@stryker.com

4100 E. Milham Avenue
Kalamazoo, MI 49001
269-323-7700
www.stryker.com

7. Fax the Business Reply Form to Stryker Instruments Regulatory Department, 866-521-2762 (even if you do not have any affected product).

8. Immediately send back all affected product using the pre-paid shipper provided with this notification.

9. Upon receipt of the recalled product, a credit will be applied to your account.

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
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.

For questions regarding this recall please contact Stryker Instruments:

Monday-Friday 8am-5pm (EST)
Angela Ragainis/Kelly Jo Whipple
269-389-4354 / 269-389-2921
angela.ragainis@stryker.com / kellyjo.whipple@stryker.com

4100 E. Milham Avenue
Kalamazoo, MI 49001
269-323-7700
www.stryker.com

stryker
Instruments

Affected Lot Number List

0702-045-027 (PenAdapt™)	2011031286	2011080802	2011120114	2012030779	2012060453	2012100094	2013011467	2013060012
	2011031309	2011080828	2011121518	2012030780	2012060971	2012100289	2013011468	2013060013
	2011031559	2011080829	2011121882	2012031177	2012060972	2012100290	2013011490	2013060130
	2011031560	2011080830	2011122001	2012031178	2012061422	2012100436	2013011491	2013060131
	2011031561	2011081247	2011122002	2012040046	2012061425	2012100442	2013011528	2013060434
	2011040580	2011081463	2012010263	2012040082	2012061426	2012100713	2013011529	2013060435
	2011040581	2011081464	2012010312	2012040156	2012061657	2012100714	2013011816	2013060635
	2011041258	2011081747	2012010313	2012040157	2012061658	2012100965	2013011831	2013060636
	2011041259	2011082223	2012010315	2012040158	2012061921	2012100966	2013020169	2013061034
	2011050012	2011090801	2012010899	2012040629	2012061922	2012110016	2013020170	2013061044
	2011050013	2011090802	2012010900	2012040630	2012070311	2012110024	2013020227	2013070201
	2011050480	2011100270	2012010901	2012040631	2012070312	2012110025	2013020228	2013070202
	2011050481	2011100271	2012011040	2012041021	2012070578	2012110104	2013021309	2013070339
	2011050590	2011101072	2012011065	2012041022	2012070579	2012110106	2013021310	2013070340
	2011050694	2011101501	2012011903	2012041024	2012071012	2012110589	2013030153	2013071410
	2011050911	2011101502	2012011904	2012041629	2012071013	2012110590	2013030154	2013071411
	2011050912	2011101503	2012012239	2012041630	2012071177	2012110847	2013030394	2013071765
	2011051007	2011101504	2012012240	2012041631	2012071182	2012111078	2013030521	2013071766
	2011051008	2011102081	2012012241	2012050444	2012080701	2012111211	2013031635	2013080209
	2011051139	2011102082	2012020069	2012050445	2012080702	2012111212	2013031636	2013080210
	2011051141	2011110164	2012020070	2012051796	2012081475	2012111296	2013040020	2013080211
	2011051689	2011110165	2012020071	2012051797	2012081476	2012120095	2013040021	2013080714
	2011060019	2011110166	2012020215	2012051841	2012081976	2012120508	2013040565	2013080716
	2011060842	2011110173	2012020216	2012051842	2012081977	2012120509	2013041164	2013081294
	2011061311	2011110296	2012021049	2012051938	2012090018	2012120771	2013041284	2013081601
	2011061312	2011110297	2012021050	2012051939	2012090019	2013010005	2013041285	2013081602
	2011061313	2011110311	2012021142	2012060075	2012090376	2013010006	2013041414	2013090948
	2011061318	2011110537	2012021143	2012060076	2012090377	2013010507	2013050179	2013090949
	2011061605	2011110613	2012021400	2012060077	2012090463	2013010509	2013050180	2013090950
	2011062421	2011111032	2012021401	2012060229	2012090464	2013010572	2013050465	
	2011062422	2011111033	2012021480	2012060230	2012090715	2013010573	2013050628	
	2011062801	2011111670	2012021481	2012060231	2012090716	2013010726	2013050629	
	2011071891	2011111833	2012022062	2012060442	2012091009	2013010727	2013050947	
	2011071892	2011112455	2012030297	2012060445	2012091010	2013010816	2013050949	
	2011080405	2011112456	2012030647	2012060451	2012091235	2013010817	2013051828	
	2011080522	2011120113	2012030679	2012060452	2012100093	2013011033	2013051829	

For questions regarding this recall please contact Stryker Instruments:

Monday-Friday 8am-5pm (EST)
Angela Ragainis/Kelly Jo Whipple
269-389-4354 / 269-389-2921
angela.ragainis@stryker.com / kellyjo.whipple@stryker.com

4100 E. Milham Avenue
Kalamazoo, MI 49001
269-323-7700
www.stryker.com

stryker
Instruments

BUSINESS REPLY FORM

PRODUCT: STRYKER PENADAPT™

Below please find the quantity of PenAdapts™ that have been shipped to your location. All affected lot numbers can be found on the Customer Notification Letter.

Quantity Shipped (Boxes of 10)	Product Number	Quantity on Hand (Each)	Lot #(s) of quantity to be returned
	0702-045-027		

1. Please record above the quantity and lot number that you currently have on hand. (Please attach a separate sheet for multiple lot numbers).
2. Using the enclosed pre-paid shipper, please include a copy of this Business Reply Form and all of the recalled PenAdapts™ from your facility. Upon receipt of of the recalled Pen Adapts™, a credit will be applied to your account.

Please check one of the boxes below:

☐ There have been _____ (number) of cases in which the patient experienced inflammation and/or infection, after surgery involving a recalled PenAdapt™. Please indicate "0" if no cases were identified. Please attach a complaint form for each of the cases identified.

☐ Our organization is unable to determine the answer to the question regarding patient inflammation and/or infection in relation to the use of the recalled PenAdapt™.

Please complete and sign this form, even if you do not have affected product. Please fax or email the form to Angela Ragainis or Kelly Jo Whipple, Stryker Instruments Regulatory Department (see below).

Account #

Print Customer Name _____ Customer Title _____

Contact Phone Number _____ Customer Signature _____ Date _____

Email Address _____ Fax Number _____

If you have further distributed any affected product, please indicate to whom below:

Name Address City State Zip

Contact Person Part Number(s) and Quantities

Angela Ragainis / Kelly Jo Whipple
Phone: 269-389-4354 / 269-389-2921 Fax: 866-521-2762
Email: angela.ragainis@stryker.com / kellyjo.whipple@stryker.com

*Note: Please keep a copy of this completed, executed form for your records.

For questions regarding this recall please contact Stryker Instruments:

Monday-Friday 8am-5pm (EST)
Angela Ragainis/Kelly Jo Whipple
269-389-4354 / 269-389-2921
angela.ragainis@stryker.com / kellyjo.whipple@stryker.com