

SafeAir Smoke Evacuation Pencil

Attn: Risk Manager, Materials Manager, OR Director

September 2, 2025

This notification is to inform you that Stryker Instruments has expanded the scope of the attached recall, which was previously initiated in October 2024. Please be advised that an additional 47 lots have been added to the scope of this recall. These newly affected lots are listed below under "Additional Lots". We appreciate your previous response and request your attention to the actions outlined below.

Catalog Number	Product Description	GTIN	Lot Number
0703-047-000	Rocker-Switch Smoke Evacuation Pencil, Coated	07613327117202	See table, "Additional Lots"
0703-047-002	Smoke Evacuation Pencil Coated Rocker-Switch, Non-Sterile	07613327379471	

Additional Lots

A total of 47 lot numbers across two catalog numbers are listed below. Distribution dates in scope range from 03/29/2023 – 05/17/2024.

Smoke Evacuation Pencil Coated Rocker-Switch, Non-Sterile (0703-047-002)						
64917537	65342956	66487443	67787272	67840867	68672644	
64917538	66487442	67787271	67840866	67840868	68672645	
Rocker-Switch Smoke Evacuation Pencil, Coated (0703-047-000)						
64262566	66387346	66599251	66758654	67377504	67652611	67794514
64973268	66387347	66705549	66758655	67377505	67652612	68735135
65178952	66387348	66705550	67017675	67377506	67652613	68735136
65178953	66387349	66758652	67017676	67481713	67794512	68735137
66387345	66599250	66758653	67207470	67652610	67794513	68735138

Actions Needed

1. Immediately review your inventory to locate and quarantine any affected products at your facility.
2. Return **a new copy** of the enclosed Business Reply Form (BRF), even if the affected product is no longer in inventory, to the email Instruments.Recalls@stryker.com.
3. Upon receipt of the completed BRF, Stryker will provide a shipping label to return recalled product on-hand.
4. A replacement will be provided upon receipt of the recalled product.
5. Maintain awareness of this communication internally and inform Stryker if any of the subject devices have been distributed to other organizations. If so, provide contact details so Stryker can inform the recipients accordingly.

On behalf of Stryker, we thank you sincerely for your help and support in completing this action and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards and your expectations, remain on the market. If you have any questions about this matter, contact Stryker Instruments recall team directly by calling (269) 290-0524 or email at Instruments.Recalls@stryker.com.

Sincerely,
Brooke Thompson - Recall Coordinator

For reporting any serious adverse events or product quality problems contact Stryker at 1-800-253-3210, ext. 5555 8:00 A.M. to 7:00 P.M. (Eastern Time), Monday – Friday or by email at inst.stryker.cs@stryker.com. In addition to contacting Stryker, healthcare professionals and consumers may report any potential quality problems or adverse reactions, or events associated with the use of this product may be reported 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.

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Business Reply Form

SafeAir Smoke Evacuation Pencil - Expansion

September 2, 2025

Please select from the options below and complete this form. Email the completed form to Instruments.Recalls@stryker.com.

RESPONSE IS REQUIRED.

- ☐ No remaining affected products on-hand.
- ☐ I, the customer, choose to return the following product(s) for replacement:

Catalog number	Product	Lot number(s)	Quantity on hand (EA)*
0703-047-000	Rocker-Switch Smoke Evacuation Pencil, Coated		
0703-047-002	Smoke Evacuation Pencil Coated Rocker-Switch, Non-Sterile		

*If all devices have been used and none remain for return, please indicate 0 (zero) for quantity on hand.

Form completed by:

Facility Name			
Facility Address			
Printed Name		Title	
Email		Phone	
Signature		Date	

Note: Your signature indicates that you have received and understand the enclosed notification and that you have performed all actions requested.

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

Facility Name		Contact Person	
Full Address			

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SafeAir Smoke Evacuation Pencil

Attn: Risk Manager, Materials Manager, OR Director
October 4, 2024

This notification is to inform you that Stryker Instruments is voluntarily recalling specific products of the SafeAir Smoke Evacuation Pencil.

Catalog Number	Product Description	GTIN	Lot Number
0703-047-000	Rocker-Switch Smoke Evacuation Pencil, Coated	07613327117202	Refer to Appendix A
0703-047-002	Smoke Evacuation Pencil Coated Rocker-Switch, Non-Sterile	07613327379471	
0703-047-001	Rocker-Switch Smoke Evacuation Pencil, Un-coated	07613327117219	64117291
0703-046-000	Smoke Evacuation Pencil Coated Push-Button	07613327117202	Refer to Appendix B
0703-046-001	Smoke Evacuation Pencil Uncoated Push-Button	07613327117196	Refer to Appendix B
0703-046-002	Smoke Evacuation Pencil Coated Push-Button, Non-sterile	07613327379488	Refer to Appendix B

Product Description

The Neptune SafeAir pencils are designed for general electrosurgical applications, including cutting and coagulation, and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.

Product Issue

There is a potential for the product to activate without manual input when plugged into a power source or remain active after buttons are released. 134 complaints were identified against rocker-switch, and 19 complaints against push-button.

Potential Risks

Unintentional activation of the device may result in localized burns to the patient or physician from electrical currents carried through conductive objects or fluids. Medical/surgical intervention may be needed to correct these injuries.

Actions Needed

1. Immediately review your inventory to locate and quarantine any affected products at your facility.
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On behalf of Stryker, we thank you sincerely for your help and support in completing this action and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards and your expectations, remain on the market. If you have any questions about this matter, contact Stryker Instruments recall team directly by calling (269) 290-0524 or email at Instruments.Recalls@stryker.com.

Sincerely,
Brooke Thompson - Recall Coordinator

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Appendix A – Rocker-Switch

A total of 189 lot numbers across two catalog numbers are listed below. Distribution dates in scope range from 01/26/2022 – 09/19/2024.

Rocker-Switch Smoke Evacuation Pencil, Coated (0703-047-000)						
53863666	54409859	56319954	56945653	57699375	59053479	65178945
53863667	54409860	56319955	56945654	57699376	59053480	65178946
53863668	54409862	56319956	57699353	57699377	59053481	65178947
53863669	54409919	56319957	57699354	57699378	59053482	65178949
53863670	54409920	56319958	57699355	57699379	59053483	65347997
53863671	54409921	56319959	57699359	57699380	61288937	65784636
54403959	54409922	56319960	57699360	57699381	61288943	65784637
54403960	54409923	56319961	57699361	57699382	62825781	65784638
54403961	54409924	56892676	57699362	57805609	64117282	65784639
54403962	54409925	56892677	57699363	57805610	64477143	65876797
54403963	54409926	56892689	57699364	57805611	64477144	65961918
54403964	54409927	56932527	57699365	58320366	64477145	66133414
54403965	54533880	56932528	57699366	58514707	64855504	66275138
54409851	54533881	56932533	57699367	58766534	64855505	V53051139
54409852	54533882	56932534	57699368	58766535	64855515	V53051140
54409853	54533883	56945645	57699369	58766536	64855516	V53267506
54409854	54533884	56945646	57699370	58766539	64973261	V53526100
54409855	54654973	56945647	57699371	58766540	64973262	V53708277
54409856	54665296	56945648	57699372	58791419	64973263	V53708278
54409857	56319952	56945651	57699373	59053477	64973266	V53934891
54409858	56319953	56945652	57699374	59053478	64973267	V53934892
						V53934893

Smoke Evacuation Pencil Coated Rocker-Switch, Non-Sterile (0703-047-002)							
53700305	53864207	53864241	53864247	60308905	62012084	64112630	65342955
53700306	53864212	53864243	53864248	60308906	62291715	64112631	65869470
53700307	53864213	53864244	53864249	60308907	62291717	64142443	65869471
53700308	53864214	53864245	53864257	61283868	62821201	64968515	65954806
53864205	53864219	53864246	60308904	61283869	64112629	64968516	66005707
53864206							

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Appendix B – Push Button

A total of 271 lot numbers across three catalog numbers are listed below.

Smoke Evacuation Pencil - Coated Push Button (0703-046-000)							
54409778	59692168	62016967	63292654	64324200	64855491	65961907	67325428
57699286	60313543	62016978	63292655	64324201	64855498	65961908	67377503
57738329	60313544	62296666	63632847	64324207	64855499	65961909	67481708
57738330	60313545	62296667	63632848	64324208	64855500	66012917	67481709
57738331	60313546	62296668	63632851	64354844	64855501	66012918	67481710
57738332	60313547	62382103	63632852	64354845	64973248	66133412	67481711
57738333	60313549	62382104	63842616	64354846	64973249	66387344	67481712
57738334	60834119	62382105	63842618	64354847	64973253	66494921	67652608
58014507	60834120	62678399	63842619	64354850	64973254	66494922	67652609
58014508	60834121	62678400	63842620	64354851	64973255	66494923	67722909
58014509	60834122	62678401	63871520	64477131	64973256	66494924	67794511
58014519	60834123	62678402	63871521	64477132	64973257	66494925	V56951192
58514679	60834124	62678403	63871522	64477135	64973258	66599248	V56951193
58514680	60834125	62678404	63871523	64477136	64973259	66599249	V56951194
59053422	61288888	63090872	63871524	64573557	64973260	66705547	V56951195
59053423	61288889	63090873	64117262	64573561	65178940	66705548	V56951196
59417841	61288890	63090874	64117263	64573562	65178942	66758641	V56951197
59417842	61288891	63090875	64117264	64573563	65178943	66758642	V58582358
59417843	61288892	63090876	64117265	64573564	65178944	66758643	V58582359
59417844	61288893	63090877	64117266	64604782	65784634	66758644	V58582360
59417845	61288895	63248661	64147006	64604783	65876788	66758645	V58582361
59692163	62016962	63292646	64247932	64604784	65876789	66947800	V58582362
59692164	62016963	63292647	64262541	64855487	65876790	66947801	V58582363
59692165	62016964	63292648	64262542	64855488	65876791	67017673	
59692166	62016965	63292649	64262543	64855489	65876792	67017674	
59692167	62016966	63292650	64262549	64855490	65961906	67325427	

Smoke Evacuation Pencil Coated Push Button (0703-046-001)				
53867671	54409847	59053476	64855502	66494932

Smoke Evacuation Pencil Coated Push-Button Non-Sterile (0703-046-002)							
53864143	57458172	58761873	63837701	64258041	65777003	66126554	66751061
54406823	57458173	58761874	63837702	64258042	65777004	66487383	67200500
54406824	57458174	60308898	63866394	64258044	65954742	66487384	67200501
54406825	57458175	60308899	63866395	64850548	65954743	66487385	67200502
54406826	57694644	62291709	64052771	64850549	65954744	66487386	67715714
54406827	57733684	62377382	64112622	64968511	65954745	66751059	67787217
54406828	58009712	62537206	64112623	64968512	66126553	66751060	68200024

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