

**Urgent:  
Medical Device Recall**

**Safelight Fiber Optic Cable**



**Attn: Branch Manager / Agency Principal and Quality / Inventory Contacts**

**Recall Number: RA2023-3234487**

**March , 2023**

**Product affected**

<b>Catalog number</b>	<b>GTIN</b>	<b>Product description</b>	<b>Lot number</b>	<b>Distribution Dates</b>
0233050100	07613327051650	SAFELIGHT FIBER OPTIC CABLE CLEAR, 5MM X 10FT 3.05M	See "Attachment A"	01/15/2021 - 12/07/2022
0233050200	07613327051643	SAFELIGHT FIBER OPTIC CABLE GREY, 5MM X 10FT 3.05M	See "Attachment A"	01/15/2021 - 12/07/2022

The purpose of this notification is to advise you that Stryker Endoscopy is conducting a voluntary recall of Safelight Fiber Optic Cable Clear, 5MM X 10FT 305M (0233050100) and Safelight Fiber Optic Cable Gray, 5MM X 10F 3.05M. Please note that multiple lot numbers are affected by this issue.

**Product description**

The cable features Electronic Scope-Sensing Technology (ESST), which detects when the cable is disconnected from the scope adapter, and it automatically powers off a compatible Stryker light source to prevent burns and fires. It is available in two models: 0233050100 (clear cable) and 0233050200 (gray cable). The cables are compatible with all Stryker light sources and requires a SafeLight scope adapter to connect to different brands of endoscopes.

The SafeLight™ Fiber Optic Cable is intended to transmit light from a light source to an endoscope during endoscopic procedures.

**Product issue**

During the investigation of a customer complaint it was determined that multiple lots of cables were not assembled with enough epoxy on the proximal end, creating light output issues.

**Potential risks**

There is potential for user dissatisfaction and patient harm, as this could cause a clinical delay while replacing the light cable or result in a procedure being converted to open.

To date there have been 16 reported adverse events.

## Actions needed

1. Inform individuals within your organization who need to be aware of this action.
2. Check your internal inventory to locate the product listed in the product affected grid.
3. If affected product is found, segregate the product and call your Stryker representative to arrange for product return and issuance of credit or replacement (upon availability).
  - a. Remove the affected products, quarantine, and discontinue use of the identified product.
  - b. Please complete Business Reply Form
4. If affected product is NOT found:
  - a. Please complete Business Reply Form
5. Maintain awareness of this communication internally until all required actions have been completed within your facility. **Response is required.**

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name:	Position:	email:
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In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

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 high quality standards and meeting your expectations.

Sincerely,

## Business Reply Form

### Safelight Fiber Optic Cable

Recall Number: RA2023-3234487

March, 2023

Please complete and sign this form. Email the completed form to [xxxx@stryker.com](mailto:xxxx@stryker.com) by DD-MMM-2023.

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

Set Lot #(s) inspected:

Catalog number	Product	Lot numbers	Quantity on hand*
0233050100	SAFELIGHT FIBER OPTIC CABLE CLEAR, 5MM X 10FT 3.05M		
0233050200	SAFELIGHT FIBER OPTIC CABLE GREY, 5MM X 10FT 3.05M		

\*If no affected devices are available for return please enter 0 (zero).

#### Form completed by:

Printed Name		Title	
Signature		Phone	
Date		Email	

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

Product(s) Distributed		Quantity Distributed	
Facility Name		Contact Person	
Full Address			

I have read and understand the instructions provided and acknowledge receipt of the subjected FSN.

I also agree to further distribute and communicate this important information from this letter to those whom I have distributed any of subjected devices noted in this letter.

Name (print) \_\_\_\_\_ Signature \_\_\_\_\_ Date :

## Affected Products

### Attachment A Safelight Fiber Optic Cable

#### Part number 0233050100 (SAFELIGHT FIBER OPTIC CABLE CLEAR, 5MM X 10FT 3.05M)

The following lot numbers are affected:

159190	159191	159192	159194	159195	159196	159197	159198	159199	159200
159201	159202	159203	159204	159205	159206	159207	159208	159209	159210
159211	159212	159213	159214	159215	159216	159217	159218	164764	164765
164766	164767	164768	164769	164770	164771	164772	164773	164774	164775
164776	164777	164778	164779	164780	164781	164782	164783	164784	164785
164786	164787	164788	164789	164790	164791	164792	164793	164794	164795
164796	164797	164798	164799	164800	164801	164802	164803	164804	164805
164806	164807	164808	164809	164810	164811	164812	164813	164814	164815
164816	164817	164818	164819	164820	164821	164822	168940	168941	168942
168943	168944	168945	168946	168947	168948	168949	168950	168951	168952
168953	168954	168955	168956	168957	168958	168959	168960	168961	168962
168963	168964	168965	168966	168967	168968	168969	168970	168971	168972
168973	168974	168975	168976	168977	168978	168979	168980	168981	168987

#### Part number 0233050200 SAFELIGHT FIBER OPTIC CABLE GREY, 5MM X 10FT 3.05M

The following lot numbers are affected:

158865	158868	158869	158872	158874	158875	158878	158884	165446	165448
165451	165457	165458	165459	165461	165462	165464	168909	168910	168911
168912	168913	168914	168915	168916	168917	168918	168919	168920	168921
168923	168924	168925	168926	168927	168928	165463			