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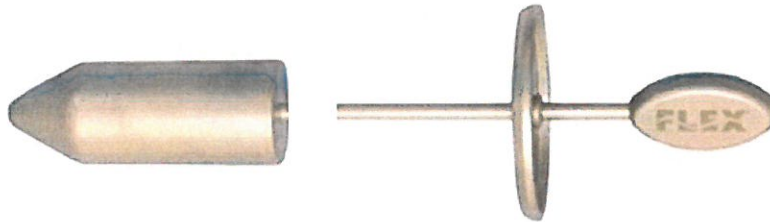
February 13, 2019

customerservice@medrobotics.com

URGENT: FIELD SAFETY NOTICE

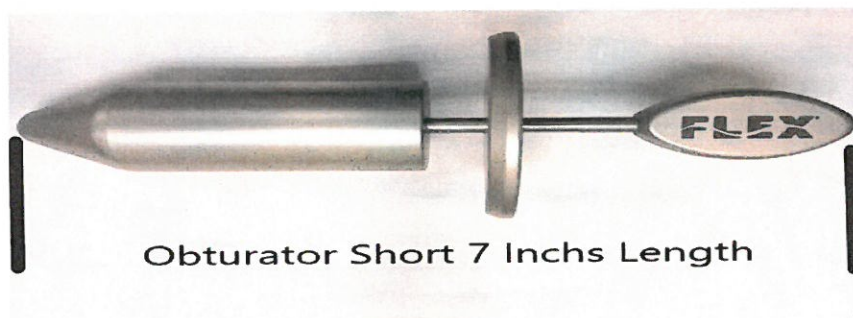
DEVICE: OBTURATOR (an accessory to the Flex® Rectoscope)

REASON: Potential for the handle of the Obturator to detach with the cone remaining in the patient's rectum



Obturator with failed weld (cone separated from shaft)

RECALLED DEVICE: OBTURATORS



Obturator, short cone (7" total length)

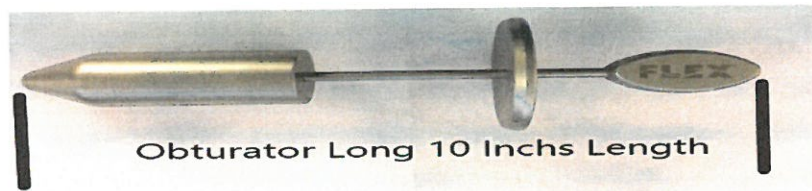
Part number: 26114

Lot numbers: 19419-01, 19669-06, 19684-06



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Obturator, long cone (10" total length)

Part number: 25162

Lot numbers: 18832-17, 19042-07, 19042-01, 18832-17, 19199-01, 19669-05, 19684-05, 19042-07

Medrobotics Corporation is conducting a field safety corrective action and recalling all short cone and long cone Obturators. These Obturators are accessories to the Flex® Rectoscope and have been sold as part of a Flex® Rectoscope Kit (pn 23426) or as a separate item. We are contacting you as one or more of these Obturators may have been supplied to your organization. The appropriate regulatory authorities have been made aware of this field safety corrective action.

REASON FOR THE RECALL

The long or short Flex® Rectoscope is designed to be used with the corresponding long or short cone Obturator fully inserted in the Rectoscope body. When the Obturator is correctly inserted, the leading tapered surface of the Obturator protrudes from the Flex® Rectoscope. This taper is intended to assist in dilating the anus and rectum so that the Flex® Rectoscope tube/body may be introduced into the patient.

The handle of either Obturator consists of a rod which, in production, is inserted into a hole in the cone and then welded circumferentially to join the cone to the rod. Medrobotics has recently become aware that this weld may break resulting in the rod separating from the cone.

This potential failure applies to both the long and the short cone Obturators. There is no means to identify when an Obturator may be affected, as a potential weld failure cannot be detected by visual examination, physical twisting or stress, or lot number. Therefore, the handle of **ANY** Obturator may be at risk of separating from the cone at any time.

HEALTH RISK

If the Obturator is inserted into the patient's colo-rectal anatomy and the handle separates from the cone, there will be nothing attached to the cone which can be grasped to facilitate its withdrawal from the patient's anatomy. Physician intervention then may be required to remove the cone from the patient's rectum.

THEREFORE, YOU SHOULD IMMEDIATELY CEASE USE OF ANY OBTURATOR.



ACTIONS TO TAKE

Immediately check your inventory of and quarantine all Obturators that you have on hand to prevent their further use. Note: An Obturator may be located in the same sterilization tray as the Flex® Rectoscope.

Lot Numbers:

Please immediately complete the attached Acknowledgement form -- even if you have no Obturators -- and return the form to Medrobotics by fax: +1-508-823-1703 or by email customerservice@medrobotics.com.

Ensure relevant staff members -- including clinicians, OR staff, engineers, and product returns staff -- are informed of this recall.

If you have supplied any Obturators to any other organization, please advise that organization of this recall and notify Medrobotics of that organization's name, address, and contact person so that we may contact them immediately.

RETURN AND REPLACEMENT

Your local Medrobotics Account Representative will be in contact with you in the next few days to schedule a time to collect any Obturators at your facility. Our Representative will provide a shipping box and will have the relevant serial numbers to identify each Obturator your hospital has in its possession to ensure all Obturators are removed and returned to Medrobotics.

Medrobotics is in the process of reworking our existing Obturator inventory to reinforce the weld connecting the rod of the handle to the cone. Your local Medrobotics Account Representative will contact you directly to schedule a time for delivery of replacement Obturators.

Please contact Medrobotics Customer Service at 1+508-692-6104 or at customerservice@medrobotics.com if you have any questions or need additional information.

Sincerely,

John D. Bonasera
Vice President of Quality, Regulatory & Clinical Affairs



RECALL ACKNOWLEDGEMENT & STOCK STATUS FORM

MANUFACTURER: Medrobotics Corporation

PRODUCTS AFFECTED

**Obturator, short cone (7" total length) Part number 26114
 Lot numbers: 19419-01, 19669-06, 19684-06**

**Obturator, long cone (10" total length) Part number 25162
 Lot numbers: 18832-17, 19042-07, 19042-01, 18832-17, 19199-01,
 19669-05, 19684-05, 19042-07**

Instructions:

1. Please immediately review the attached **URGENT: VOLUNTARY MEDICAL DEVICE RECALL NOTIFICATION LETTER**
2. Check for Obturators that may be in inventory. Note: An Obturator may be located in the same sterilization tray as the Flex® Rectoscope.
3. List quantity of each model of obturator that you will return to Medrobotics Corp. on the form below
4. If you have no obturators in inventory check the line below indicating NO PRODUCT IN INVENTORY TO RETURN

_____ We have no product in inventory to return.

_____ We have the following obturators at our facility and have discontinued using it. We have quarantined these obturators and will return the following quantities to Medrobotics.

OBTURATORS TO BE RETURNED	QUANTITY
Obturator, Long Cone pn 25162	
Obturator, Short Cone pn 26114	

5. Please immediately complete the attached Acknowledgement form -- even if you have no Obturators -- and return the form to Medrobotics by fax: +1-508-823-1703 or by email customerservice@medrobotics.com.



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6. A Medrobotics representative will provide you with a shipping box with a pre-filled mailing label in which to return the obturators. A Return Authorization Number will be included in the box. Place a copy of this completed form in the box.
6. Medrobotics will provide replacement obturators as soon as possible.
7. Please contact Medrobotics Customer Service at 1+508-692-6104 or at customerservice@medrobotics.com if you have any questions or need additional information.

Print name and Title

Date

Signature

Telephone Number

Email Address

Name of Institution

Street Address

City and mailing (zip) code

Country

Please return the completed form to:

Fax +1-508-823-1703

Email customerservice@medrobotics.com