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Urgent Field Safety Notice

VS3 Iridium- MMS-IR and Beam-Combiner

Notification

Product	GTIN #	Part # / CFN #	Serial Numbers
VS3 IR SYSTEM 174-0012 FLRSENCE MMS	18130400103489	174-0012	See Attachment 1: Affected Serial Numbers
VS3-IR 175-0012 785NM MMS	10813040013711	175-0012	
VS3 IR LIGHT 161-0001 BEAM COMBINER	18130400103625	161-0001	

October 2022

Medtronic Reference: FA1280

EU Manufacturer Single Registration Number (SRN): IL-MF-000019980

Dear Healthcare Professional,

The purpose of this letter is to advise you that Medtronic is initiating a voluntary Urgent Field Safety Notice for the EleVision IR (VS3 Iridium) MMS-IR and Beam-Combiner serial numbers listed above.

Reason for this Field Action
This Urgent Field Safety Notice is being issued following five (5) complaint reports to Medtronic reporting a broken optical fiber cable. Four (4) of the complaints were specific to the Beam-Combiner optical fiber cable and reported loss of function; one (1) was specific to the MMS optical fiber cable and reported thermal damage and loss of function. Medtronic's evaluation of the optical fiber cable breakage identified that cable damage can occur through handling or bending and can lead to loss of functionality and heating/melting of the outer cable surface. Medtronic has redesigned the cable to reduce the likelihood of breakage.

Risk to health
The potential harm to the patient from a broken optical fiber cable is delay of treatment and tissue injury (from moving from laparoscopic to an open procedure). The potential harm to the user is eye injury and thermal burn. Five (5) complaints have been received to date for the issues. In one (1) of the five (5) complaints, tissue injury occurred when loss of functionality due to the broken optical fiber cable resulted in conversion from a laparoscopic approach to an open

approach. Another one (1) of the five (5) complaints was related to melting of the outer cable and melting of the instrument drape. No patient or user injury was reported in that or the other three (3) complaints.

This Urgent Field Safety Notice notification has no impact on patients who have previously undergone a procedure using the VS3 Iridium- MMS-IR or Beam Combiner. These patients should continue to be monitored per your practice's normal follow-up procedures.

Actions to mitigate risk:

1. Prior to use, visually check the Beam-Combiner and MMS optical fiber cable for signs of being pinched, kinked or damaged. Avoid folding the cables and handle with care to prevent damage.
2. After the white balance has been performed as per IFU guidance, test the EleVision IR system at the beginning of the surgical procedure as follows:
    a) Turn on the laser.
    b) For the laparoscopic configuration of the EleVision IR system, point the distal end of the endoscope towards a bright surface, keeping the scope approximately 3 cm from the target. This prevents the white light from scattering. For the open configuration of the EleVision IR system, position the distal face of the MMS approximately 30 cm from any object. If you see a message on the screen indicating that the device is too close to tissue, move the device further away from the object until this message disappears.
    c) After two (2) seconds, the monitor screen should show a message indicating that the laser is on, a blinking red dot, and a running clock. If all these indications are seen properly on the monitor screen, turn off the laser after five (5) seconds.

If the screen does not show an indication that the laser is on, a blinking red dot, and a running clock, the laser is not functioning properly and the EleVision IR system should not be used in the surgical procedure.

If any pinching, kinking, or damage of the optical fiber cable is noted, or if the system does not work properly during the above-described laser test, do not use the system. Please report a complaint and arrange for servicing of the Beam Combiner and / or MMS device by contacting your Medtronic Representative.

If your system is operating properly, please continue to use the EleVision IR system for your procedures. Medtronic will contact you to schedule servicing of your Beam Combiner and/or MMS device, as the product becomes available. Medtronic is prioritizing servicing for the customers reporting EleVision IR system problems.

Additional actions:

- Immediately notify all personnel in all care environments in which the EleVision IR (**VS3 Iridium) - MMS and/or Beam Combiner** are used about this Field Action.
- Please post this notification in a prominent location and maintain awareness of this matter until the issue is resolved with a redesigned cable replacement.
- If your facility has distributed the **VS3 Iridium MMS and/or Beam Combiner** to other persons or facilities, please promptly forward a copy of this letter to those recipients.

Additional information:
Medtronic has notified the Competent Authority of your country of this action.
We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic representative.

Sincerely,

Medtronic (Schweiz) AG

Enclosure: Attachment 1 (Affected Serial Numbers)

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Attachment 1: Affected Serial Numbers

Note: Serial number can be found on the housing of the MMS-IR and the housing of the Beam-Combiner.

Product	GTIN #	Part # / CFN #	Serial Numbers
VS3 IR SYSTEM 174-0012 FLRSENCE MMS	18130400103489	174-0012	3784634, 3784711, 3784722, 3784656, 3784809
VS3-IR 175-0012 785NM MMS	10813040013711	175-0012	3784803
VS3 IR LIGHT 161-0001 BEAM COMBINER	18130400103625	161-0001	3611026, 3611095, 3611169, 3611219