Advisory Note

Urgent Field Safety Notice

Title / Subject:	Field Safety Notice: BWS-L Yoke 2019
Document ID:	FSN-001
Target Audience:	Customers of BWS-L (including integrated with other systems)
Date of Issue:	26 April 2019
Commercial name of the affected product:	Body-Weight Support Light (BWS-L)
FSCA ID:	FSCA-001
Type of action:	- Instruction given by manufacturer to inspect specific part of medical device. - Halt usage of the medical device for specific type of patients until inspection and potential correction has been completed.
Approval:	Approval by Motek Executive Management Board.

Arno Stienen, Director

1 Purpose

The safety of your patients and staff is very important to us, just as it is to you. For this reason we are contacting you today in order to continue to maintain the high safety status of your medical device. Today we need to ask you to support us in the implementation of this field safety notice, which concerns the use of the Body-Weight Support Light (BWS-L) that is part of your setup with either the GRAIL or the C-Mill.

Please pay special attention if you use the BWS-L with patients after recent craniotomy/craniectomy or comparable surgery. If so, stop using the BWS-L for treatment of these patients immediately, and follow the steps described below.

This notice has been shared with the appropriate regulatory agencies.

2 Description Medical Device and model designation

Body-Weight Support Light (BWS-L). The BWS-L can be used stand-alone, or can be provided together with another medical product, such as the C-Mill or the GRAIL.

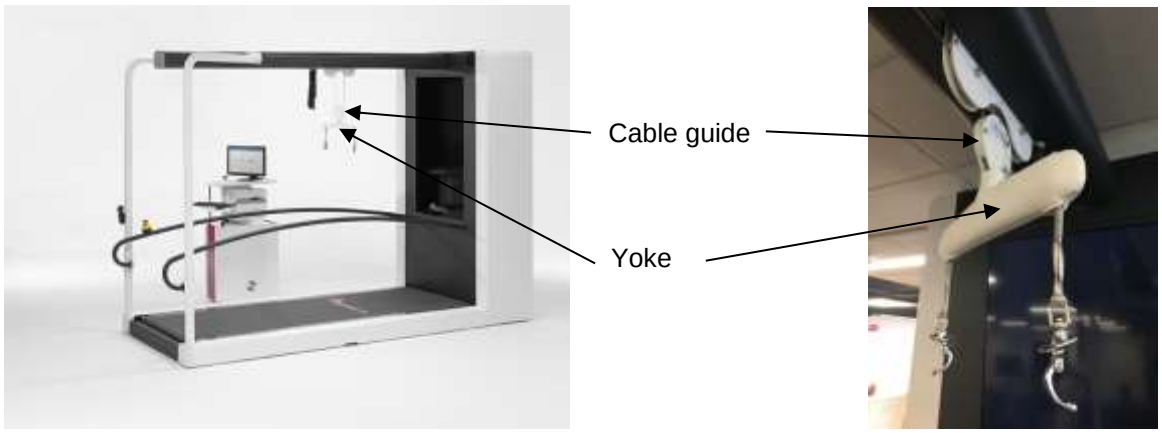
2.1 Serial Numbers or other identification of devices concerned

We identified that your setup is potentially affected from this issue. You can identify the affected system by the serial number. The Serial Number of the medical device can be found on the device label.

Body-Weight Support Light (BWS-L):	RB011-0060 to -0093.
C-Mill VR+:	SY012-0049, -0051, -0053 to -0073, -0079
GRAIL:	SY020-0012 and -0014, MMGRA-30140502

3 Reason for issuing Field Safety Notice

We have discovered a potential manufacturing deviation of the yoke of the BWS-L that can result in the yoke detaching from the cable guide.



3.1 Description of Potential Hazardous Situation

In our risk-analysis, we have determined that if the padded yoke detaches during treatment, the patient will be caught in the safety harness that is connected to the system via a separate safety belt. In such a situation, the padded yoke may make contact with the head of patient and can potentially cause significant discomfort.

Please pay special attention if you use the BWS-L with patients after recent craniotomy/craniectomy or comparable surgeries. If you are treating such patients, stop using the BWS-L for these patients immediately, as the hazardous situation of the detachment of the yoke might result in serious or even deadly harm.

4 Action to be taken

4.1 Dissemination of this Field Safety Notice

You will have to share this notice with all those within your organisation who need to be aware.

4.2 Confirmation

In your country, this field safety action is being coordinated with the respective national competent authority, and we are therefore required, without exception, to demonstrate the receipt of this information. We therefore ask you to confirm your receipt of this field safety notice. **Please send us at support@motekforcelink.com a filled out and signed copy of the Advisory Notice Confirmation (see last page of this notice) within 5 business days of receipt of this notice.**

4.3 Corrective and/or Preventive Action

- If you are treating patients after recent craniotomy/craniectomy or comparable surgeries, **stop using the BWS-L for these patients immediately**, as the hazardous situation of the detachment of the yoke might result in serious or even deadly harm.

  Follow the step below to enable us to check your BWS-L. We will inform you within two business days if additional steps are needed to before you can restart treatment for this specific category of patients.

- Visual inspection following our instructions can indicate whether your system is affected; if your system is affected, we will correct the error as soon as possible at our costs.

  We kindly ask you to assist us in this process by sending us a picture of the yoke of the BWS in your centre, taken similarly as Figure 1. It is important to take a picture perpendicular to the yoke. Note that you will need to move the cover a little out of the way to expose the two screws (see Figure 2). Make sure that the clearance between the yoke and the cable guide is visible. The quality of the picture is not essential, so feel free to use the camera in your smartphone.

Figure 1: Make sure that the clearance gap between the yoke and the cable guide is clearly visible.

Figure 2: Move the padded cover of the yoke out of the way to expose the screws.

  Please forward this picture to support@motekforcelink.com within 5 business days of receipt of this notice. Include the name of your center and/or the serial number of your device in the email. We will inspect the picture and advice you and your local representative within two business days if any future steps need to be taken.

Based on our risk-analysis, you can keep on using the systems for patients other than those after recent craniotomy/craniectomy surgery. If you think that your yoke and cable-guide combination does not look like the figures above, feel free to contact support@motekforcelink.com to acquire additional advice.

4.4 Contact reference person

In case of any questions with respect to this Field Safety Notice you are advised to contact Motek Medical BV (support@motekforcelink.com) or your local representative.

Advisory Notice Confirmation

Customer acknowledges that

☐ Information, notices and directives in this notice has been understood, and communicated and implemented in Customer's Organization.

Customer

Name institute:

Address:

City: **Postal code:**

Country:

Phone: **E-mail:**

Contact person: **Function:**

Signature : **Date:**

Device Name:

Device S/N: