Field Safety Notice

2018-06-1 | MSA-2018-001-IU |

CC: Chairman of Medical Board and Head of Department

Please forward this information to all relevant users, [biomedical staff for capital equipment, materials management and/or purchasing for consumables] and risk management department concerned in your facility

Subject: Volista bracket detachment

Products affected: All Getinge Volista cupolas of model Access, StandOP, Triop and Quicklock made until December 2016

Product	Article No.	S/N or Batch No.
The complete list of affected devices (with product names, articles numbers, serial numbers…) for your market are listed in a separate document (Consignee list)		

Dear Customer,

The purpose of this letter is to inform about a potential issue found in the Getinge Volista cupolas.
Our records indicate that your facility has received one or more of these devices.

Normal use and Indications

Under normal circumstances, Volista surgical lights are intended to be used to provide visible illumination of the surgical area or the patient during surgical operations, diagnostics and treatment.

The following has been discovered

Under certain conditions, we have identified that an issue might prevent the device from performing as intended. It was established that, with some of the manufactured units, a screw has been forgotten on the racket of the cupola on some devices in production or that the screws have loosened over the course of life. As a consequence the light head shaft could break and the cupola could detach itself when manipulated and be held only by its cables. It appears such event is more likely to happen mainly during maintenance, cleaning and surgery preparation.

Potential hazards

This issue may stop the intended functioning of the device resulting in potential injury if the cupola falls on a patient or the medical staff. The injury could go from a simple pain to a serious injury, depending on the circumstances when and where such a drop would occur.

Precautions

The device can continue to be used in accordance to the instructions for use, with extra attention to the following:

- Make sure to check if the cupola has mechanical play. A mechanical play is a phenomenon happening when there is space between two parts assembled imperfectly. You can detect it by trying to move the cupola in a way that is not planned for the device. In our case here is how to proceed to detect a play on the Volista cupola :
  Hold the cupola with both hands (as shown in the picture below), and check for play by trying to move the cupola up and down (as shown by the arrow). If there is play in the cupola, you will feel it in the zone circled in red below.

  If you detect play in the cupola, please cease to use the device and inform your local Getinge representatives immediately.
- However, if there is no play in the cupola, it is safe to continue to use.

Corrective action

A solution that will correct this issue has been developed.
Getinge will initiate a field action of all affected device units. You will be contacted by your Getinge sales or service representative to plan for the update of your device.

Please complete & return the attached acknowledgement form and maintain awareness on this notice and related actions until your cupolas have been serviced to ensure effectiveness of the corrective action.

We apologize for any inconvenience this may cause and we will do our outmost to carry through this action as swiftly as possible.

Should you have questions or require additional information, please contact your local Getinge representative.

Sincerely,

Françoise GAUDUCHON
Quality Manager, Surgical Workflows
Maquet SAS
Parc de Limère, Avenue de la Pomme de Pin
CS 10008 Ardon, 45074 Orléans Cedex 2
FRANCE