

Field Safety Notice

2019-APR-17 | REF-MSA-2019-001-IU|

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: Cracked coating fork on VOLISTA light

Products affected: All Getinge VOLISTA light head of model STANDOP and TRIOP manufactured until July 2017

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

Dear Customer,

The purpose of this letter is to inform you about a potential issue found in the VOLISTA StandOP and TRIOP light head. Our records indicate that your facility has received one or more of these devices.

Intended use

Under normal circumstances, VOLISTA StandOP and TRIOP surgical lights is designed to illuminate the body of a patient during surgical procedures, diagnostics or treatment.

The following has been discovered

Under certain conditions, we have identified an issue that might prevent the device from performing as intended. Maquet SAS, the manufacturer, received some complaints regarding light head fork (yokes). It was established that the coating of those forks might show cracks. Therefore, there is a risk that particles may fall and generate infection. Maquet SAS didn't received any adverse event (i.e. infection) regarding this issue.

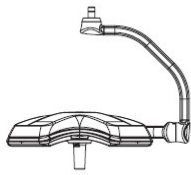
Potential hazards

This issue may result in a potential injury if particles fall during surgical operation in the surgical field generating then possible infection to patient

Preventive Action

- Before using the device, please inspect the fork and check if cracks on the coating are visible, as shown in the picture here below

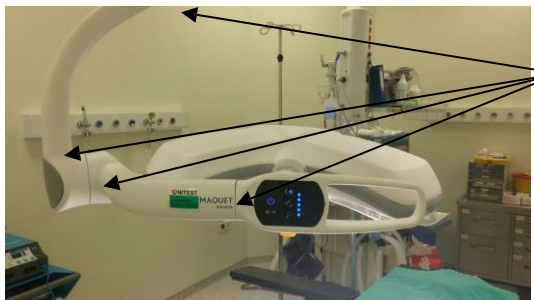
Daily checks (performed by the user)
Corrective actions are set out in Troubleshooting section 15



- Check the lighthead for chipped paint, impact marks and any other damage.
WARNING! Any damaged paintwork must be touched up immediately.
- Consult Maquet if necessary for further information regarding repairs.

NU_STANDOP_VOLISTA_01761EN09 : Chapter 11 Maintenance page 66

- The coating cracks can be observed on both side of each fork, as you can see on the pictures below:



4 possibles locations of cracks

- The coating cracks can be different size, as explained below:



Pictures of the coating crack with different size

If you detect a coating crack on the fork, please STOP USING the device and contact your Getinge representative.

Please complete & return the attached acknowledgement of receipt form and maintain awareness on this notice and related actions

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

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

Sincerely,

Bertrand Leau u2331522
17 April 2019 3:40 PM

