

2019-NOV-20 | 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

Dear Customer,

In April/May 2019 Maquet SAS has launched a field action concerning possible coating cracks that may appear on Volista Standop or Triop fork manufactured prior July 2017 (See fig. 1). This issue may result in a potential injury if particles fall during surgical operation in the surgical field, generating then possible infection to patient

You were informed at that time to inspect your equipment and then to contact your local Getinge representative if cracks were noted on the fork during inspection.

We want first to thank you for your collaboration in the resolution of this issue and we are fully conscious about inconvenience that event may have brought to your routine activities.

Today we want to inform you that the action on the field is continuing.

We have developed a temporary solution to be placed on devices in the market. This solution gives the advantage to be effective to avoid particle falling and minimize disruption of your operating room.

The solution consists on a validated adhesive strip that is resistant to mechanical stresses and to representative chemical agents used in the operating rooms. This solution has been used in some accounts with satisfactory results.

This is a temporary solution to allow you to safely continue to use your lights. However Maquet SAS is committed to replace each defective fork to ensure a fully remediated device for the rest of its shelf life.

Therefore, should you experienced the coating crack on the single or double fork of your Volista Standop/Triop surgical light, the following instructions which align with what we proposed in May 2019, are recommended:

- Contact your local Getinge representative,
- Getinge representative will then place the adhesive solution or provide you with (see fig.2),
- And as soon as practical, the Getinge representative will proceed with the replacement of the fork with a new generation of forks.

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In addition and to ensure that cracked forks that may develop over time, we recommend that attention be paid as well during scheduled maintenance, notably for the next following 2 years.

Please communicate this requirement to inspect the forks to your regular maintenance service provider to integrate this action into their program.

Should you use a Getinge maintenance service, please be sure that our team of technicians are already aware of, and will particularly inspect in depth your equipment.

We want to thank you again for your collaboration and, should you need any additional information, please contact your local Getinge representative or our International Technical Service.

Sincerely,

Bertrand LEAU  
International Technical Department  
Director

Pascal JAY  
Quality and Regulatory Affairs  
Director

**Fig. 1: Coating crack phenomenon**



**Fig. 2: Validated adhesive technical solution**



Localise the coating crack.



Wipe the fork surface with Isopropyl alcohol or equivalent



Wipe the adhesive upper surface with Isopropyl alcohol or equivalent



Peel the adhesive support



Place the adhesive strip covering the coating crack



Overlay the adhesive protection