
Field Safety Notice no. 2a - Irish Market

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

Subject: Cracked coating fork on VOLISTA light

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

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 forks manufactured prior to 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 patients.

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.

In November 2019, you were informed, as all of our customers worldwide, that the action on the field was continuing, and you did receive our Field Safety Notice no. 2 informing:

- on one hand, that we developed a temporary solution called validated adhesive strips to be placed on devices in the market that have coating cracks, and which gives the advantage to be effective to avoid particle falling and minimize disruption of your operating room,
- on the other hand, that Maquet SAS, after placing the adhesive strip will replace each defective fork to ensure a fully remediated device for the rest of its shelf life,
- And in addition we recommended to pay attention to possible coating crack during scheduled maintenance for the following 2 years.

Today we want to inform you that, specific to the Irish market and our Irish customers, Maquet SAS will proceed to the replacement of the fork on all the devices installed that are in the scope of the field action.

The goal of this specific action in Ireland is to free the customers from the additional 2-years surveillance.

You have been already contacted by your local Getinge representative. Please be sure that he will proceed to the replacement of your Volista light fork before the end of March 2020.

We want again to thank you for your collaboration in the resolution of this issue 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

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Quality and Regulatory Affairs
Director

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