

Risk Assessment / Corrective Action Plan

Date of Report September 2025
Subject: Paint flaking in Leksell Vantage Stereotactic System.
Product: Leksell Vantage Arc System
Manufacturer: Elekta Solutions AB
Elekta Reference #: FCA-ESAB-0007

Details of the defect or deficiency

For the specified serial numbers, there is an increased risk that paint flakes from the engravings may separate from the Leksell Vantage Arc System components. Separation of paint flakes is likely to occur during cleaning and sterilization. If paint flakes are not washed away during the cleaning and sterilization process, these could remain on the Leksell Vantage Arc System when used in surgery. This poses a risk of paint flakes entering the surgical area. This situation has not been observed in clinical practice, but the risk should be fully considered and mitigated. The paint does not include any metallic components and is not magnetic.

Potential Failure mode (Clinical Impact)

In a worst-case scenario, an undetected sterile fragment of non-metallic paint may inadvertently enter the wound. Potential risks associated with this occurrence include infection, inflammation, delayed healing, and possible migration into surrounding tissues which may result in further complications depending on the affected area.

The probability of this hazard occurring is considered very low as it has not been reported to have been observed in clinical practice

Failure rate

Failure rate=0%.

Failure rate = Number of cases of actual patient injury or harm caused by paint flaking reported to the manufacturer / Number of affected devices on the market.

How the defect was identified

Elekta became aware of this issue in 2019 from a complaint in the field (where paint was missing from the engravings on the arc).

Any reported patient injuries

No mistreatment has been reported.

Severity and probability of occurrence

Severity has been assessed as Critical. *Probability* has been assessed as Incredible.

Potential root causes

The root cause of the occurrence has been identified to be incorrect cleaning prior to adding the paint into the engravings during the production stage.

Stock affected

Sites affected will be customers with Arc and Support Arc with serial numbers: SH00001 - SH00338

Proposed Actions by Manufacturer

Corrective Action #1: Release of Important Field Safety Notice

Elekta will send an Important Field Safety Notice 100-01-301-011 to all affected customers from 30-SEP-25. The notice informs users of the specific product and version numbers affected by the issue, and any work around that can be used to avoid the issue.

- Sites affected will be customers with Arc and Support Arc with serial numbers: SH00001 - SH00338

A copy of the Important Field Safety Notice is to be kept with the most current labelling and all personnel working with the product should be made aware of the content of the letter.

The customers are instructed to complete and return the Important Field Safety Notice Acknowledgement form to their local Elekta representative as soon as possible but no later than 30 days from receipt.

Matilda Forsberg

Matilda Forsberg

Director Regulatory Affairs BL

Neuro Solutions

Elekta Solutions AB

22 SEP 25

Date