EU MDR Complaint Form

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PCF-01-A8 Complaint Form.pdf

Complaints are written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety, or performance of a medical device that has been released from the organization's control or related to a service that affects the performance of such medical devices.

When you receive a complaint, check our status page to see if it has already been reported: https://trice.statuscast.com/#!/ This page is updated for issues affecting a large subset of users.

A complaint must be reported within **48 hours** of receiving it. To report a complaint to Trice Imaging, complete Section 1 of the Distributor Complaint Form available to download at the top of this page. Please include:

- Affected customer(s) name/clinic information
- Date of contact (remember all complaints must be reported within 48 hours of the date of contact)
- Detail of the issue- provide as much detail as possible

Submit this form to your Trice Sales Manager, we will reach out to you with any questions.

Your Trice Sales Manager will update you after the complaint has been investigated, with an estimated timeline for releasing a fix. Once the resolution is released, the Sales Manager will complete Section 2 of the Complaint Form and return it for your records.

The MDR requires EU distributors to maintain a registrar of complaints so file and retain your complaint form in accordance with the MDR.