

Statement on media coverage regarding ImplantFiles

We have been developing, producing and marketing implants for artificial joint replacement since 1963. Being both a medical technology manufacturer and a Swiss family-owned company, we aspire to manufacture high-quality implants and instruments that meet the highest requirements. Our products, which are implanted on a daily basis all over the world, are designed to improve patients' quality of life. In the development and manufacture of our tried and tested products, top priority is uncompromisingly given to patient safety.

An FSCA is not automatically linked to patient injury

Despite strict quality controls and precisely defined manufacturing processes, undesired incidents may occur in the application of medical devices, which can result in FSCAs (Field Safety Corrective Actions). As a matter of principle, our reports are voluntary safety measures that are taken as corrective actions to protect the user and the patient.

The risk assessment underlying an FSCA is individual for each company and depends on the respective risk management. As a Swiss family business, we interpret our risk assessments very strictly and issue FSCAs at an early stage in order to be able to quickly contain any potential hazards. Since, in contrast to the media, we do not distinguish between «trifling cases» (e. g. labelling errors, packaging errors or new cleaning instructions) and potentially health-endangering incidents, increased FSCA rates are not to be seen as negative, but rather as proactive action for the safety of all parties involved.

Article in the Tagesanzeiger

In the newspaper *Tagesanzeiger* of 28 November 2018, we were described as being the Swiss manufacturer with the highest number of FSCAs. According to the Swiss Therapeutic Products Act, medical technology companies in Switzerland are obliged to report any safety-relevant corrective market measures to Swissmedic. As one of the few – and moreover largest – Swiss joint replacement manufacturers with product risk class III, we cannot be compared with manufacturers in lower product risk classes (e. g. insulin pumps, dental implants, etc.). Comparison between companies is not permissible and irrelevant as well, due to the individual risk assessments and the differing product risk classes.

Every day, in cooperation with our clinical partners, we strive to improve patients' quality of life. Transparent and open communication being our creed, we are at your service in the context of the critical dialogue with our industry as well.