

Failure analysis of implants

Failure analysis covers the elucidation of the causes of failure, and the prevention of future damage. The knowledge gained can be used for overall risk assessment as part of a technical documentation. Thus the failure analysis – besides elucidating the cause and identifying risks and hazards – provides useful information for designers, product developers, and users (surgeons). In the area of Post Market Surveillance, damage analyses provide continuous feedback about the implants on the market and can help to document implants to a high quality and develop a high product standard.

With over 25 years of experience in the field of implant failure analysis and the ability to act as a neutral party in litigations, the RMS Foundation is an important partner for manufacturers, users and patients.

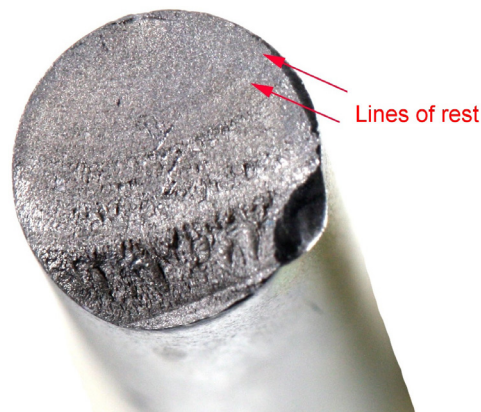


Figure 1: Macro image of a fracture surface on a titanium rod (spinal implant). The curved lines of rest are evidence of a fatigue failure.

In the first step of failure analysis the broken implant is checked for sufficient labeling/identification. The data on the implant is compared with the data from the production order and the corresponding raw material inspection certificates. This provides an indirect verification of traceability and complete documentation of the production order. Depending on the completeness of the documents and after consulting with the manufacturer, it is decided if an entire

material investigation is to take place or whether an investigation of the fracture surface by scanning electron microscopy (SEM) is sufficient. For a complete material investigation, firstly the broken implant and all other supplied implants are documented macroscopically by photography or light microscopy. Some initial conclusions on how the failure occurred can already be made at this point. Next, the dimensions of the implants are measured and compared with the data from the technical drawing of the manufacturer. Finally, a fracture surface analysis is performed using SEM.

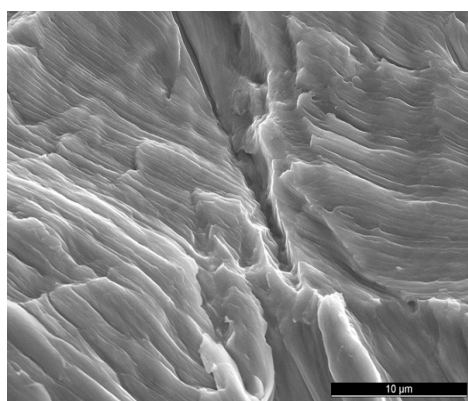


Figure 2: The scanning electron micrograph shows fine fatigue striations. These are a conformation for a fatigue fracture.

Depending on the condition of the fracture surface, a statement about the type of fracture, the initiation and propagation can be made. Finally, all the results are summarized in a technical report. Surgical techniques, hospital reports and X-rays are important additional sources of information to provide a complete picture for the understanding and clarification of the causes of damage. A cause analysis including a statement on the location/positioning of the implant under the aspects of fracture mechanics, can be made due to our many years of experience in this field.

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Our offers for failure analysis:

- Fracture analysis: type of fracture, fracture initiation, fracture propagation
- Elucidation of the fracture cause
- Verification of traceability
- Verification of material properties
- Verification of implant dimensions
- Important feedback for designers; design, material selection, risk analysis, Post Market Surveillance

Feel free to contact us regarding your specific requirements. We are happy to answer your questions.

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More information as well as our service catalogue can be found on our website.

The RMS Foundation has been certified according to ISO 9001 and is an ISO/IEC 17025 accredited laboratory type C.

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