

# Incident Report

Send to:  
SDS Deutschland GmbH  
Lohnerhofstraße 2  
78467 Konstanz

Swiss Dental Solutions is committed to achieving long-term, positive treatment success with our implant system.

Failures are always an unpleasant experience for everyone involved. This incident report will serve as mutual basis for discussion and will lead to improvement measures and higher quality.

It is designed solely to conduct research regarding the causes of failure and to fulfil the demands of pharmacovigilance and quality management.

It should assist SDS in identifying systematic product improvements and to refine training concepts and protocols.

In the spirit of this, we ask for an honest answer of the questions.

**IN ORDER FOR US TO PROCESS THIS INCIDENT REPORT, WE REQUEST AN ACCURATELY COMPLETED REPORT + X-RAYS + FAILED PRODUCT.**

Please complete a separate incident report for each failed product.

Please mail all supporting documentation, including this accurately completed incident report to our office along with the explanted, unsterilized implant (or other product) in a sealed autoclave pouch or other surgical container. The full X-ray documentation should also be included in this mailing in order to qualify for reimbursement.

**ALL INFORMATION INCLUDED WITHIN THIS INCIDENT REPORT AND ANY SUPPORTING DOCUMENTAION WILL BE TREATED CONFIDENTIALLY!**

Thank you for your cooperation!

**1. Practice stamp**

Name of implantologist: \_\_\_\_\_

**2. Patient-ID or initials:** \_\_\_\_\_ **Age:** \_\_\_\_\_

**3. Implant / drill / accessory (for incidents referring to abutments refer to point 6):**

**Implant-type:** \_\_\_\_\_ **Lot-number:** \_\_\_\_\_  
**Length:** \_\_\_\_\_ **Diameter:** \_\_\_\_\_

**4. Details of implantation:**

- 4.1 Position of implant: \_\_\_\_\_
- 4.2 Date of implantation: \_\_\_\_\_
- 4.3 Date of implant removal: \_\_\_\_\_
- 4.4 Type of implantation:  immediate implantation  delayed immediate implantation  
 late implantation
- 4.5 Insertion torque: \_\_\_\_\_ Ncm
- 4.6 Which bone quality was found?  D1  D2  D3  D4
- 4.7 Type of protection during osseointegration:  LTP  prostheses  protective splint  none
- 4.8 **X-RAY IMAGES: please send!**  pre-operative  post-operative

**5. Special incidents during implantation:**

- 5.1 Augmentation:  simultaneous  pre-operative
- 5.2 Sinus elevation:  
 internal sinus  Intralift™  
 external sinus  patients bone / PRF  bone graft material: \_\_\_\_\_

**6. Prosthetic restoration:**

- 6.1  temporary restoration  final prosthetic restoration
- 6.2 **Abutment-type:** \_\_\_\_\_ **Lot-number:** \_\_\_\_\_  
 abutment fixed by screw **Type / Lotnr. of screw:** \_\_\_\_\_  
 abutment cemented  abutment fixed by screw + cementation
- 6.3 Prosthetic restoration:  crown  crown-block  bridge  removable

