

Incident Report

Send to:

**SDS Swiss Dental Solutions Inc.
34 Main Street Ext., Suite 202
Plymouth, MA 02360 USA**

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.

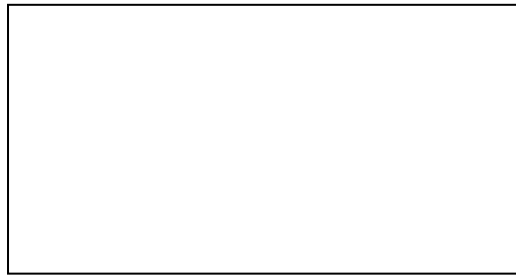
Please complete a separate incident report for each failed product.

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. The full X-ray documentation should also be included in this mailing 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

