FO822-04

Notification Form

Please send to:
(Please select an address that applies to you)

DE **SDS Deutschland GmbH**
Warenannahme
Bücklestraße 5a
78467 Konstanz

CH **SDS Swiss Dental Solutions AG**
Warenannahme
Konstanzerstrasse 11
CH-8280 Kreuzlingen

USA **SDS Swiss Dental Solutions USA, Inc.**
Receiving department
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 notification 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 notification form,
we request an accurately completed notification report + x-rays + failed product.

Please complete a separate notification form for each failed product.
Please mail all supporting documentation, including this accurately completed notification form 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 notification form and any supporting documentation will be treated confidentially!

Thank you for your cooperation!

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SDS SWISS DENTAL SOLUTIONS

1. Practice stamp

Name of implantologist:_____

2. Patient-ID or initials: _____ Age: _____

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

Implant-type: _____ **Charge 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

4.9 Vitamin D3 value on the operation day _____ ng/ml

5. Special notifications 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:** _____ **Charge number:** _____

□ abutment fixed by screw **Type/ Charge number of screw**: _____

□ abutment cemented

□ abutment fixed by screw + cementation

6.3 Prosthetic restoration: □ crown □ crown-block □ bridge □ removable

7. Mark all the specific features of the patient (parafunctions and health factors):

□ Multimorbid Patient □ smoker □ alcohol □ diabetes □ bruxism □ limited oral hygiene

Other medical factors: _____

8. Detailed description of notification:

_____

_____

_____

_____

_____

9. In your professional opinion, for what reason did the implant not integrate/ did the product fail?

9.1 □ infection of implant bed

9.2 □ residual ostitis/ NICO (neuralgia inducing cavitational osteonecrosis)

9.3 □ insufficient bone quantity

9.4 □ insufficient bone quality

which bone quality was found? □ D1 □ D2 □ D3 □ D4

□ grease drops floating on blood during osteotomy?

□ vitamin D3 Level under 50 ng/ ml level: _____

9.5 □ biomechanical overload

9.5 □ fracture during insertion □ fracture after prosthetic restoration

9.6 □ other: _____

□ Yes, I wish a personal evaluation of this notification with my SDS area sales manager.

_____ _____

Place, Date Signature of the Reporter