

## **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!

|       |                              |  |                | <b>−</b> 2D     | S sc   | LUTIONS          |  |
|-------|------------------------------|--|----------------|-----------------|--|------------------|--|
| 1. Pr | actice stamp                 |  |                |                 |  |                  |  |
|       |                              |  |                |                 |  |                  |  |
|       |                              |  |                |                 |  |                  |  |
|       |                              |  |                |                 |  |                  |  |
|       |                              |  |                |                 | □ D2 □ D3 □ D4 □ prostheses □ protective splint □ none tive □ post-operative □ pre-operative □ Intralift™ □ bone graft material: |                  |  |
| Name  | e of implantologist:         |  |                |                 |  |                  |  |
|       |                              |  |                |                 |  |                  |  |
| 2. Pa | tient-ID or initials:        |  |                | Ag              | je:  |                  |  |
|       | . 1 4 / 1 20 / /6 .          |  |                |                 |  | 2)               |  |
|       |                              |  |                |                 |  |                  |  |
|       | ant-type:                    |  |                |                 |  |                  |  |
| Leng  | th:                          |  | Diame          | ter:            |  |                  |  |
| 4. De | tails of implantation:       |  |                |                 |  |                  |  |
| 4.1   | Position of implant:         |  |                |                 |  |                  |  |
| 4.2   | Date of implantation:        |  |                |                 |  |                  |  |
| 4.3   | Date of implant removal:     |  |                |                 |  |                  |  |
| 4.4   | Type of implantation:        | □ immed  | iate implantat | tion   delayed  | d immediate  | e implantation   |  |
|       |                              | □ late im  | plantation     |                 |  |                  |  |
| 4.5   | Insertion torque:            |  |                | Ncm             |  |                  |  |
| 4.6   | Which bone quality was fo    | und?   | □ D1           | □ <b>D2</b>     | □ D3   | □ <b>D</b> 4     |  |
| 4.7   | Type of protection during os | seointegrati   | on: 🗆 LTP      | □ prostheses    | □ protectiv  | re splint 🗆 none |  |
| 4.8   | X-RAY IMAGES: please s       | send!  | □ pre-ope      | rative          | □ post-op  | erative          |  |
|       |                              |  |                |                 |  |                  |  |
| 5. Sp | ecial incidents during imp   | lantation:   |                |                 |  |                  |  |
| 5.1   | Augmentation:                | □ simultaneous   |                | □ pre-operative |  |                  |  |
| 5.2   | Sinus elevation:             |  |                |                 |  |                  |  |
|       | □ internal sinus             |  |                | □ Intralift™    |  |                  |  |
|       | □ external sinus             | □ patients   | bone/ PRF      | □ bone graft ı  | material:  |                  |  |
|       |                              |  |                |                 |  |                  |  |
| 6. Pr | osthetic restoration:        |  |                |                 |  |                  |  |
| 6.1   | □ temporary restoration      | □ fir  | nal prosthetic | restoration     |  |                  |  |
| 6.2   | Abutment-type:               | Lo   | ot-number:     |                 |  |                  |  |
|       | □ abutment fixed by screw    |  |                |                 |  |                  |  |
|       | □ abutment cemented          | □ ab   | outment fixed  | by screw + cer  | nentation  |                  |  |
| 6.3   | Prosthetic restoration:      | Prosthetic restoration:   □ crown □ crown-block □ bridge □ removable |                |                 |  |                  |  |

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| □ smo   | ker  | □ alcohol       | □ diabetes     | □ brux       | ism       | □ limited ora | al hygiene     |                 |  |
|---------|--|-----------------|----------------|--------------|-----------|---------------|----------------|-----------------|--|
| Other   | medica   | al factors:     |                |              |           |               |                |                 |  |
|         |  |                 |                |              |           |               |                |                 |  |
| 8. Det  | ailed o  | description of  | f incident     |              |           |               |                |                 |  |
| 0. 20.  | .u.iou (   |                 | moraone        |              |           |               |                |                 |  |
|         |  |                 |                |              |           |               |                |                 |  |
|         |  |                 |                |              |           |               |                |                 |  |
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|         |  |                 |                |              |           |               |                |                 |  |
|         |  |                 |                |              |           |               |                |                 |  |
| 9. ln y | our pro  | ofessional opi  | nion, for what | t reason d   | id the in | nplant not in | tegrate/ did t | he product fail |  |
| 9.1     | □ infe   | ction of impla  | nt bed         |              |           | -             |                | •               |  |
| 9.2     | □ residual ostitis/ NICO (neuralgia inducing cavitational osteonecrosis) |                 |                |              |           |               |                |                 |  |
| 9.3     | □ ins  | ufficient bone  | quantity       |              |           |               |                |                 |  |
| 9.4     | □ inst   | ufficient bone  | quality        |              |           |               |                |                 |  |
|         | which  | bone quality    | was found?     | □ <b>D</b> 1 | □ D2      | □ <b>D3</b>   | □ <b>D</b> 4   |                 |  |
|         | □ grease drops floating on blood during osteotomy?                       |                 |                |              |           |               |                |                 |  |
|         | □ vitamin D3 Level under 50 ng/ ml level: _                              |                 |                |              |           |               |                |                 |  |
| 9.5     | □ bioı   | mechanical ov   | erload:        |              |           |               |                |                 |  |
| 9.5     | □ frac   | cture during in | sertion        | □ fractu     | re after  | prosthetic re | storation      |                 |  |
| 9.6     | □ oth  | er:             |                |              |           |               |                |                 |  |
|         |  |                 |                |              |           |               |                |                 |  |
|         |  |                 |                |              |           |               |                |                 |  |
|         |  |                 |                |              |           |               |                |                 |  |
|         |  |                 |                |              |           |               |                |                 |  |
|         |  |                 |                |              |           |               |                |                 |  |
|         | Yes,   | I wish a perso  | nal evaluation | of this inc  | cident wi | th my SDS a   | area sales ma  | anager.         |  |
|         |  |                 |                |              |           |               |                |                 |  |
|         |  |                 |                |              |           |               |                |                 |  |
|         |  |                 |                |              |           |               |                |                 |  |
| Dlace   | <br>Place, Date  |                 |                |              |           |               | nature Incide  | nt Poportor     |  |
|         |  |                 |                |              |           |               |                |                 |  |