

Guarantee Questionnaire

1. CUSTOMER INFORMATION

| | | | |
|-----------------|----------------------|------------------|----------------------|
| Customer's Name | <input type="text"/> | Customer Account | <input type="text"/> |
| Address | <input type="text"/> | Telephone | <input type="text"/> |
| | <input type="text"/> | Country | <input type="text"/> |
| | <input type="text"/> | Reported by | <input type="text"/> |

2. PRODUCT INFORMATION (Please list all involved MEDENTiKA® Products)

| Article Number | LOT Number | Placement Date (D/M/Y) | Removal/Event Date (D/M/Y) | Regio |
|----------------------|----------------------|------------------------|----------------------------|----------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

3. GENERAL PATIENT INFORMATION

Patient ID No* Age ☐ Female ☐ Male

*For data privacy reasons DO NOT insert patient's name

Medical Record:

| | | |
|--|---|---|
| <input type="checkbox"/> Diabetes Mellitus | <input type="checkbox"/> Psychological disorder | <input type="checkbox"/> Uncontrolled endocrine illness |
| <input type="checkbox"/> Radiation Tx-head/neck area | <input type="checkbox"/> Xerostomia | <input type="checkbox"/> Compromised immuno resistance |
| <input type="checkbox"/> Illness requiring steroids | <input type="checkbox"/> Lymphatic disorder | <input type="checkbox"/> Blood coagulation disorder |
| <input type="checkbox"/> Chemotherapy around time of implant placement | | <input type="checkbox"/> Drug or alcohol abuse |

Allergies:

Other local or systemic diseases which may be significant:

Does the patient smoke? ☐ Yes ☐ No ☐ No significant findings

4. SURGICAL INFORMATION (Only required with implant complaints)

☐ Manual placement ☐ Handpiece adapter

If implant was placed and removed the same day, was another implant successfully placed in the site during surgery?

☐ Yes ☐ No

Any problems with:

| | |
|---|---|
| <input type="checkbox"/> Implant insertion into bone | <input type="checkbox"/> Removal of device from implant |
| <input type="checkbox"/> Removal of implant from vial | Other: <input type="text"/> |

At the time of surgery, were any of the following present:

| | |
|--|--|
| <input type="checkbox"/> Periodontal disease | <input type="checkbox"/> Diseased mucous membrane |
| <input type="checkbox"/> Local infection/subacute chronic osteitis | <input type="checkbox"/> Complication in site preparation |
| Bone quality <input type="checkbox"/> D I | <input type="checkbox"/> D II <input type="checkbox"/> D III <input type="checkbox"/> D IV |
| Was the site tapped? <input type="checkbox"/> Yes | <input type="checkbox"/> No <input type="checkbox"/> N/A |
| Holding Key used <input type="checkbox"/> Yes | <input type="checkbox"/> No <input type="checkbox"/> N/A |
| Was primary stability achieved? <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Did implant achieve osseointegration? <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Was the implant surface completely covered with bone? <input type="checkbox"/> Yes | <input type="checkbox"/> No |

Was augmentation performed at the time of surgery?

☐ No ☐ Sinus ☐ Ridge

Material used:

Was GTR membrane used?

☐ No ☐ Yes ☐ Resorbable

☐ Non-resorbable

Material used:

Guarantee Questionnaire

5. EVENT INFORMATION (Only required with implant complaints)

Hygiene around implant ☐ Excellent ☐ Good ☐ Fair ☐ Poor

Were any of the following involved in the event?

| | | |
|---|--|---|
| <input type="checkbox"/> Trauma/Accident | <input type="checkbox"/> Implant fracture | <input type="checkbox"/> Inadequate bone quality/quantity |
| <input type="checkbox"/> Biomechanical overload | <input type="checkbox"/> Overheating of bone | <input type="checkbox"/> Previous bone augmentation |
| <input type="checkbox"/> Immediate extraction site | <input type="checkbox"/> Peri-implantitis | <input type="checkbox"/> Nerve encroachment |
| <input type="checkbox"/> Adjacent to endodontic tooth | <input type="checkbox"/> Infection | <input type="checkbox"/> Sinus perforation |
| <input type="checkbox"/> Tongue (pressure) | <input type="checkbox"/> Bruxism | <input type="checkbox"/> Bone resorption |

Other: _____

At the time of implant failure, there was (check all that apply):

| | | | |
|---|--|---------------------------------------|---------------------------------------|
| <input type="checkbox"/> Pain | <input type="checkbox"/> Bleeding | <input type="checkbox"/> Swelling | <input type="checkbox"/> Numbness |
| <input type="checkbox"/> Mobility | <input type="checkbox"/> Fistula | <input type="checkbox"/> Asymptomatic | <input type="checkbox"/> Inflammation |
| <input type="checkbox"/> Hypersensitivity | <input type="checkbox"/> Increased sensitivity | <input type="checkbox"/> Abscess | Other: _____ |

Was the prosthesis fitted? ☐ No ☐ Yes If yes, please complete section 6.

If the implant is not being removed, is there evidence of the following (check all that apply)?

Extent (mm): Bone Loss _____ Dehiscence _____ Peri-implantitis _____ Fenestration _____ Other _____

Please comment on why you think the implant failed/was removed:

6. PROSTHESIS INFORMATION (Only required for prosthetic complaints)

CADCAM Project no.: _____ ☐ Model ☐ Insertion ☐ In use

Type of restoration? ☐ Crown ☐ Bridge ☐ RPD (upper) ☐ RPD (lower)

☐ Full (upper) ☐ Full (lower) Other: _____

Date abutment was installed Date of abutment removal (D/M/Y)

Torque Control Device used? ☐ Yes ☐ No ☐ Unknown

Torque applied Ncm

Date of temporary restoration installation Date of final restoration installation

Was the recall appointment schedule followed ☐ Yes ☐ No

☐ Abutment fracture ☐ Screwfracture ☐ Surface abrasion

Other: _____

7. INSTRUMENTS (Only required for instrument complaints)

Approximate number of uses: ☐ initial use ☐ 2-5 ☐ 6-10 ☐ 10-15 ☐ more than 15

(Cutting instruments only)

Type of cleaning method used ☐ Manual ☐ Ultrasonic ☐ Thermidisinfection Other: _____

Type of sterilization method used ☐ Autoclave ☐ Dry heat

Short description of incident:

Please return questionnaire, autoclaved product and include X-rays (as appropriate). Use a padded pouch to return items – failure to do so could result in items lost during shipment and void guarantee program. Autoclave all products and label them as sterile.

Please note that your data will be transferred to Institut Straumann AG, Basel, Switzerland but may also be transferred for further investigations to the countries where the respective manufacturer of the product is domiciled. This may include countries outside the European Union for which there is no European Commission decision that they ensure an adequate level of protection for personal data.

Doctor's Signature: _____ Date: _____

For internal use only

| | | | | | |
|------------------------------|------------------------------|------------------------------|------------------------------|--|---------------------------------|
| <input type="checkbox"/> CSN | <input type="checkbox"/> PSO | <input type="checkbox"/> ASR | <input type="checkbox"/> RPC | <input type="checkbox"/> Info incomplete | <input type="checkbox"/> Std/No |
|------------------------------|------------------------------|------------------------------|------------------------------|--|---------------------------------|