

LASAK guarantee fulfilment form

Reference number

LASAK internal use only

LASAK is always pleased to receive product feedback to help us to understand as much as possible about our products' performance and to meet regulatory reporting requirements. Please, **complete this form** and, where applicable, also send us **the explanted product** in a sterile condition with relevant **documentation as specified at the end of this form**, (not returned unless requested).

A) CUSTOMER INFORMATION

Customer details:

Facility name: _____

Clinician name: _____

Contact phone: _____

Contact e-mail: _____

Correspondence address:

Address 1: _____

Address 2: _____

City: _____

Country: _____ Post: _____

Shipping address:

Address 1: _____

Address 2: _____

City: _____

Country: _____ Post: _____

B) PRODUCT INFORMATION

Ref. No.: _____ Lot No.: _____

Placement date: _____ Event/Removal date: _____ Site: _____

Was the product modified? Yes No If yes, how? _____

Replace with same device(s)? Yes No If no, specify Ref. No(s): _____

C) REQUIRED FOR IMPLANTS

Insertion torque during the implant insertion: <20 Ncm 20–40 Ncm 41–60 Ncm >60 Ncm

Bone quality in site preparation (type): I II III IV

Was counterbore used? No Yes

Was treadformer used? No Yes

Was fork of guide wrench used? No Yes

Placement method: Manual (LASAK tools) Manual (other tools) Insertion wrench – mechanical

Was implant osseointegrated? N/A No Yes

Was there bone growth over the implant? N/A No Yes

Was there any surgical augmentation? No Sinus Ridge Other

Was a GTR membrane used? No Resorbable Non-resorbable Material used: _____

Were regenerative products used? No Yes, material used: _____

Were any of the following conditions present at the time of surgery? (Please, check all that apply).

Complication in site preparation Diseased mucous membrane Local infection Periodontal disease Subacute chronic osteitis

Which conditions, if any, were present in the event (please, check all that apply)?

Abscess Swelling Bleeding Dehiscence Fistula Hypersensitivity

Inflammation Mobility Paresthesia Pain Asymptomatic Other: _____

Which conditions, if any, were involved in the event (please, check all that apply)?

Adjacent to endodontic tooth Biomechanical overload Bone resorption Bruxism

Immediate extraction site Implant fracture Infection Nerve encroachment

Overheating of bone Peri-implantitis Poor bone quality/quantity Previous bone augmentation

Sinus perforation Tongue pressure Trauma/accident

Was a restoration installed? No Yes, date: _____ Type: Crown Bridge Extent of the bridge: _____

Was a recall interval followed? No Yes, interval period: _____

Implant area hygiene condition: Excellent Good Fair Poor

Reason for the event occurrence (clinician's opinion): _____

D) REQUIRED FOR ABUTMENTS AND LASAK CAD/CAM SOLUTIONS

CadCam order No.: _____ When did the event occur: On master cast On installation During use Other: _____

Restoration type: Crown Bridge RPD (upper) RPD (lower) Full (upper) Full (lower) Other: _____

Torque device used? Not known Non Yes, torque applied (Ncm): _____

Abutment installation date: _____ Abutment removal date: _____

Temporary restoration installation date: _____ Final restoration installation date: _____

Was a recall interval followed? No Yes, interval period: _____

Please, describe the event: _____

E) REQUIRED FOR INSTRUMENTS

Ensure instruments are **thoroughly cleaned** and **checked** before returning, often poor instrument performance is due to residual contamination.

Number of uses (cutting instruments): Initial use 2–5 6–10 10–20 More than 20

Cleaning method used: Manual Ultrasonic Thermodisinfection Other: _____

Disinfectant used: No Yes, type used: _____

Sterilization used: Autoclave Dry heat Chemiclave Other: _____

Reason for claim: Rust Other: _____

F) SUBMISSION INFORMATION

The conditions below must be met for replacement under the LASAK guarantee programs:

- Products must be returned within **60 days** from the event's occurrence.
- All returned items must be **sterilized** and **marked sterile**.
- Returned items must be shipped in **protective packaging** using a method that allows for shipment tracking.
- This completed LASAK guarantee fulfilment form must be delivered to LASAK together with the returned item.
- Details of treatment records, relevant X-ray (OPG, CT) before and after operation, after loading, before and after failure, including photographic documentation must be delivered to LASAK with this form (if applicable).
- All information must be translated into English.

Send shipment to: LASAK Ltd.
Českokobrodská 1047/46
190 01 Prague 9 – Hloubětín
Czech Republic

Questions: Phone: +420 224 315 663
E-mail: guarantee@lasak.cz

Upon receipt, LASAK will review the submitted information, assess the returned product and determine whether the defined conditions for replacement under the LASAK Guarantee have been met.

G) NOTES

H) SIGNATURE

I hereby state that I understand the terms and conditions of the LASAK guarantee programs and that the information supplied is truthful and accurate.

Clinician's signature: _____ Date: _____