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).
☐ Periapical lesions on adjacent teeth ☐ Diseased mucous membrane ☐ Local infection ☐ Periodontal disease ☐ No

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
☐ Trauma/accident ☐ Peri-implantitis ☐ Poor bone quality/quantity ☐ Previous bone augmentation
☐ Sinus perforation ☐ Tongue pressure

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

Were exclusively original LASAK prosthetic components used, without being combined with components from any other manufacturer?
☐ Yes ☐ Unknown ☐ No, manufacturer and type of components used: _____

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

Implant area hygiene condition: ☐ Excellent ☐ Good ☐ Fair ☐ Poor

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

D) REQUIRED FOR ABUTMENTS AND LASAK CADCAM 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:

- **Original LASAK** surgical and prosthetic **components were used** exclusively and not in combination with any other manufacturer's products.
- Products must be returned within **60 days** from the event´s occurence.
- 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 s.r.o.
Českobrodská 1047/46
Hloubětín, 190 00 Prague 9
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 quarantee programs and that the information supplied is truthful and accurate.

Clinician's signature: _____ Date: _____