

# Terms and conditions of use of LASAK guided surgery

**These terms and conditions of use apply to LASAK guided surgery and its related products including the surgical instruments, surgical guides and planning services (further collectively referred to as the „Product“).**

Your use of the Product is subject to these terms of use, which is a legal agreement between you and LASAK s.r.o., Id.No. (IČO): 442 65 789, with its registered office at Praha 9 - Hloubětín, Českobrodská 1047/46, PSČ 19001, Czech Republic (the „**LASAK**“) governing the use of the Product. Please read the terms of use carefully before you start to use the Product. By signing of the document „Record of training in the handling and use of medical devices“, or by using the Product, you agree to be bound by these terms and conditions, and any other terms and conditions that are incorporated herein by reference (the „**Terms**“). If you do not agree with these Terms, do not check the terms and conditions checkbox and do not use the Product. In the event of any conflict between the English and other language versions of these terms of service, the Czech version shall prevail.

## 1. DESCRIPTION OF PRODUCT

The Product provides you, as an Authorized User, with the surgical instruments including instruction for use, planning services or surgical guides to be used for guided implant placement. Unless explicitly stated otherwise, any new features that augment or enhance the current Products, including the release of new tools and resources, shall be subject to these Terms. LASAK will provide the Product in accordance with these Terms. LASAK may at its sole discretion modify the features of the Product from time to time without prior notice.

## 2. PROFESSIONAL USE ONLY

By using the Product you confirm that you are a professional surgeon or dentist who has medical qualifications required by applicable laws and regulations (the “**Authorized User**”) and that you take full legal and medical responsibility for your use of the Product.

As an Authorized User you expressly warrant and represent that you are using the Product for authorized purposes only, with professional care, and in compliance with all applicable laws, including but not limited to applicable data privacy regulations, and subject to all terms and conditions contained in these Terms.

## 3. INTELLECTUAL PROPERTY RIGHTS

The trademarks, logos, product and service marks, designs and slogans (collectively the “**Trademarks**”) displayed in or on the Product or in the Manuals are registered or unregistered Trademarks of LASAK or Trademarks of third parties. In order to improve readability, LASAK does not use <sup>™</sup> or <sup>®</sup> in the running text or on pictures and other images in or on the Product or in the Manuals, either for its own

Trademarks or for the Trademarks of third parties. By doing so, however, LASAK does not waive any rights to its Trademarks.

#### **4. PROHIBITED USES**

You may use the Product only for lawful purposes and in accordance with these Terms. It is your responsibility to determine with professional care if the Product fits to the individual patient situation. The Product is part of an overall concept and must be used only in conjunction with the corresponding original components and instruments distributed by LASAK, or its affiliates and suppliers. You may use the Product only in accordance with the manuals and instructions for use provided to you by LASAK (the „**Manuals**“). Please note that besides the information provided in Manuals, knowledge of dental implantology including the previous practical experience with and knowledge of using the BioniQ implant system is necessary to use the Product. Also please note that upon publication of a new version of Manuals, all previous versions are superseded.

#### **5. PATIENT DATA**

In order to deliver the service related to the Product, LASAK may need you to submit patient-specific scans and/or other specific details. However, LASAK requests that you refrain from and you agree not to submit any identifiable patient information such as information or materials relating to an individual’s medical condition or care from which any individual can be identified, including but not limited to a patient’s personal identification number. You agree to take all necessary precautions not to share such personal data with LASAK. We do however allow you to enter a patient-specific reference in a pseudonymized manner such as the patient number to facilitate your needs of being able to identify the patient. You agree to comply with all applicable privacy regulations and you hereby warrant to LASAK and agree that prior to any personal data, as defined in the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679), such as patient scans is being shared with LASAK to have obtained a valid consent from the patient in accordance with the GDPR that allows LASAK or any of its affiliated companies or service providers to process this data as necessary to fulfill its obligations related to the Product. The consent shall furthermore include all relevant information that is required according to Article 13 of the GDPR.

#### **6. DISCLAIMER OF WARRANTIES**

Your use of the Product is at your risk. LASAK neither warrants nor represents that your use of the Product or its related services will not infringe rights of third parties not owned by or affiliated with LASAK. Without limiting the foregoing, the Product and its related services are provided to you “as is” without warranty of any kind, either expressed or implied, including, but not limited to, the implied warranties of merchantability, suitability for a particular purpose, or non-infringement. Please note that some jurisdictions may not allow the exclusion of implied warranties, so some of the above exclusions may not apply to you.

## 7. LIMITATION OF LIABILITY

You assume all risk and liability resulting from the use of the Product or its related services used separately or in combinations with other products. To the maximum extent permitted by applicable law, in no event will LASAK or its affiliates, suppliers or resellers be liable for any special, incidental, indirect, exemplary or consequential damages whatsoever (including, without limitation, damages to health, damages for loss of business profits, business interruption, loss of business information, or any other pecuniary loss or damages) arising out of the use of or inability to use the Product, or the provision of or failure to provide technical or other support services, whether arising in tort (including negligence), contract or any otherwise, even if LASAK, its affiliates, suppliers or resellers have been advised of the possibility of such damages. To the maximum extent permitted by applicable law, in any case, LASAK, its affiliates', suppliers' and resellers' maximum cumulative liability and your exclusive remedy for any claims arising out of or related to these Terms or the use of the Product or its related services, shall be limited to the amount actually paid by you for the respective individual Product or its related services (if any).

## 8. INDEMNIFICATION

In addition to any other remedy available to LASAK, you, as an Authorized User, shall defend, indemnify and hold harmless LASAK, its affiliates or licensors, and their respective officers, directors, partners, shareholders, employees and agents from and against any all damages, losses, deficiencies or liabilities resulting from, arising out of, or in connection with any breach of any term or condition of these Terms by yourself, your agents or employees, wrongful or erroneous use of the Product or its related services, and/or the enforcement of LASAK rights under these Terms.

## 9. NO MEDICAL ADVICE

By delivering the Product and/or its related services, LASAK does not provide medical advice. A treatment plan or any other file created and delivered by LASAK or its suppliers, based on your input, is the result of image processing operations such as reformatting and cropping of original CT images and shall only be considered as part of the technical assistance and support to you and shall not in any way be considered as medical advice from LASAK in any form. You shall always refer to the original CT images for a full radiological assessment, such as evaluating presence of tumors or infections outside the implant placement region, and you shall carefully review and control the treatment plan or any other file or related product before using it. Before using the Product, you must be satisfied with the medical and clinical aspects of the planning, you must ensure with all available professional care that the marking of the mandibular canal and critical zones have been carried out correctly, that during the implant position planning, there is no collision of the implant and its elements with the mandibular canal, other implants, teeth and other anatomical structures, that the most appropriate implant and related elements were selected, the safety zone was taken into account towards the existing teeth, dental restorations, main anatomical structures and the proposed final restoration solution. You should know and **understand the peculiarities of use of surgical and related instruments intended for use during operation.** You should be familiar with the **technical limitations that govern the**

**manufacture of the surgical guide and you confirm that you will check the quality, functions of the surgical guide before performing the operation. By using the Product, you confirm that the surgical guide is designed correctly, ensures a stable and firm fit throughout the operation, fulfills the intended functions and that you familiarized yourself with the surgical protocol before the operation and check the compliance of the information in the protocol to the planned operation and the tools intended for use.**

By using the treatment plan or any other file or related product, you automatically release LASAK from any and all liability in any way related to the use thereof. You hereby declare having adequate medical qualifications required by applicable laws and regulations, that you shall follow all applicable laws and take full legal and medical responsibility for the use of the treatment plan or any other file or related product.

## 10. CHANGES TO TERMS

LASAK may at any time in its sole discretion revise or update these Terms and/or Manual by updating the respective document available on the website of LASAK. All changes are effective immediately when they are posted and apply to any use of the Product thereafter. Your continued use of the Product following the posting of revised Terms and/or Manual means that you accept and agree to the changes. You are expected to check this page from time to time so you are aware of any changes, as they are binding on you.

## 11. CHANGES TO THE PRODUCT

LASAK reserves the right to change the Product and any of its related services in its sole discretion and without notice. LASAK will not be liable if for any reason all or any part of the Product is unavailable at any time or for any period. From time to time, LASAK may, in its sole discretion, restrict access to some parts of the services related to the Product.

## 12. EXTERNAL LINKS

Any links contained in the Manual and/or on the Product to other sites or resources provided by third parties are provided for your convenience only. LASAK has no control over the contents of those sites or resources, and accepts no responsibility for them or for any loss or damage that may arise from your use of them. If you decide to access any of the third-party websites linked to the Product, you do so entirely at your own risk and subject to the terms and conditions of use for such websites.

## 13. MISCELLANEOUS

All LASAK products and services related to the Product are intended for purchase by a licensed physician only. Some products or services may not be available or regulatory cleared, released or licensed for sale in all markets. For current availability and assortment please contact LASAK or its local representative. Product images may not necessarily be to scale.

#### 14. CHOICE OF LAW AND FORUM

All matters relating to the Product and these Terms and any dispute or claim arising therefrom or related thereto (in each case, including non-contractual disputes or claims), shall be governed by and construed in accordance with the laws of the Czech Republic. **All disputes arising from the use of the Product and/or in connection with it shall be finally decided with the Arbitration Court attached to the Czech Chamber of Commerce and the Agricultural Chamber of the Czech Republic by three arbitrators in accordance with the Rules of that Arbitration Court.**

#### 15. WAIVER AND SEVERABILITY

No waiver by LASAK of any term or condition set forth in these Terms shall be deemed a further or continuing waiver of such term or condition or a waiver of any other term or condition, and any failure of LASAK to assert a right or provision under these Terms shall not constitute a waiver of such right or provision. If any provision of these Terms is held by a court or other tribunal of competent jurisdiction to be invalid, illegal or unenforceable for any reason, such provision shall be eliminated or limited to the minimum extent such that the remaining provisions of these Terms will continue in full force and effect.