GUIDEMIA ONLINE STORE TERMS AND AGREEMENTS

GUIDEMIA TECHNOLOGIES, LLC

Thank you for choosing GuideMia.

This document includes three components:

Part 1 – Terms of Service, applied to surgical guide manufacturing and treatment planning services
Part 2 – GuideMia End User License Agreement, applied to all GuideMia software licensing
Part 3 – GuideMia instruction of use, applied to all GuideMia software licensing

GUIDEMIA TERMS OF SERVICE

GuideMia offers its customers the latest 3D printing technology to print surgical guides and related 3D models. To use the online services GuideMia offers, including but not limited to training, surgical guide and model printing, implant treatment planning and surgical guide service, you agree to the following terms of services:

1. Contracting Parties. The parties in this License Agreement are GuideMia Technologies, LLC (“Company”) and the user of the services (“User”).

2. Company makes surgical guides with equipment and materials from vendors. To Company’s best knowledge, the vendors recommend the equipment and materials are adequate for surgical guide manufacturing.

3. It is the User’s responsibility to examine and make sure if a manufactured surgical guide from GuideMia will actually fit onto patients’ anatomy properly and will produce expected surgery outcome.

4. Users should notify GuideMia immediately if any problems are found with GuideMia’s products.
5. Limitation of Liability. To the full extent permitted by applicable law, The User recognizes and accepts that: a)) the Company does not warrant that the services and products meet the specific needs of the User; and b) The User expressly disclaims any responsibility for any damage, loss of profits, loss of business, loss of data, damage to computer or peripheral equipment, or any other direct, indirect, incidental, CONSEQUENTIAL, special or punitive damages, and all losses of any kind, arising directly or indirectly from the use of the products and services of the Company, caused to the User, patient or any third party.

USER HEREBY ACKNOWLEDGES THAT HE/SHE HAS READ THIS AGREEMENT, UNDERSTANDS IT, HAS THE AUTHORITY TO ENTER INTO THIS AGREEMENT AND HEREBY DOES AGREE TO THE TERMS AND CONDITIONS OF THIS AGREEMENT.

GUIDEMIA END USER LICENSE AGREEMENT

This License Agreement is provided for your reference. To complete the installation and to use the GuideMia software package, you will need to agree to the following terms and conditions:

1. Contracting Parties. The parties in this License Agreement are GuideMia Technologies, LLC (“Licensor”) and the user of the software (“Licensee”).

2. License Grant. The Licensor grants the Licensee a single, non-exclusive and non-transferable license to use the Software, provided Licensee complies with all terms and conditions of this Agreement.

3. Accession to the Agreement. Installing, copying or otherwise using the software signifies that you are expressly agreeing and are bound to the terms and conditions of this Agreement. If you do not agree to the terms and conditions, you may not install, license or use the software, and the software in your possession must be immediately deleted and destroyed.

4. Media Elements. The Licensee agrees that the software may include photographs, clip-art files, templates, forms, animations, sounds, music, advertisements, product promotion and video clips identified for use in the software (collectively called “Media Elements”).

5. Proprietary Rights. The Licensee expressly acknowledges that, as between Licensor and Licensee, the software and the logos, trademarks, emblems, symbols, distinguishing marks, manual(s), technical documentation, Media Elements and other associated material related to the software belong to and are owned by the Licensor and that Licensee has no proprietary interest therein.

6. Transfer. It is expressly forbidden for the Licensee to transfer, license, sublicense, rent, lease or lend the software to any third party or export it outside of the country in which it is licensed to Licensee. Licensee may not assign this Agreement.

7. Consent for Use of Data. The Licensee agrees that the Licensor and its affiliates may collect and use all information gathered and provided by the Licensee during the use of the software. The Licensor may use such information for business purposes, to improve products, provide customized services, distribute marketing material or to sell other products or software. In doing so, the Licensor will not identify the Licensee.
8. Links to Third-Party Sites. The Licensor is not liable for: (a) the content of any third party sites or services, (b) links contained in third-party sites or services, or (c) for any changes or updates to sites or services of third parties. As applicable, the Licensor shall include links, access to sites and services of third parties only for your convenience and inclusion of any link or access does not imply the endorsement of Licensor of such sites or services.

9. Software/Services. This Agreement applies to updates, supplements, or components of services for the software (collectively called “additional services”) that the Licensor may provide or make available to the Licensee after the date of obtaining the original copy of the software, unless such services are accompanied by separate terms and conditions.

10. The license provided to the Licensee is for a limited time period only. The time period is contained in the activation code for the Licensee’s license. Once the license expires, the Licensee will have to submit a request for a new license. The Licensor can refuse a license request from any Licensee according to the Licensor’s sole discretion.

11. System Requirements. The hardware on which the software is installed conforms to the following minimum system requirements:

- Operating system: Windows 7, or 8. 64bit is recommended.
- Processor: Intel i5 and above.
- RAM memory: 4GB (recommended 6GB)
- Video Card: 1GB dedicated video memory.
- Monitor: 15 inch / resolution 1024 x 768
- Hard Disk: 500Mb of free space

The Licensor does not guarantee to the Licensee any form of training, support or instruction upon the use of the software.

12. Supervision. The software may be used only by or under the supervision of a licensed practitioner or to fabricate scan appliances or stents for a licensed practitioner.


14. Updates. Periodic updates for the software may become available and it is the Licensee’s responsibility to inform Licensor of email address changes. Licensees are urged to check Licensor’s website (www.guidemia.com) for software upgrade announcements.

15. LIMITATION OF LIABILITY. TO THE FULL EXTENT PERMITTED BY APPLICABLE LAW, THE LICENSEE RECOGNIZES AND ACCEPTS THAT: A) THE SOFTWARE IS FURNISHED “AS IS” AND LICENSOR DOES NOT WARRANT THAT THE SOFTWARE IS FREE OF BUGS, FLAWS AND DEFECTS; B) THE LICENSOR DOES NOT WARRANT THAT THE SOFTWARE MEETS THE SPECIFIC NEEDS OF THE LICENSEE; AND C) THE LICENSOR EXPRESSLY DISCLAIMS ANY RESPONSIBILITY FOR ANY DAMAGE, LOSS OF PROFITS, LOSS OF BUSINESS, LOSS OF DATA, DAMAGE TO COMPUTER OR PERIPHERAL EQUIPMENT, OR ANY OTHER DIRECT, INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL OR PUNITIVE DAMAGES, AND ALL LOSSES OF ANY KIND, ARISING DIRECTLY OR INDIRECTLY FROM THE USE OF THE SOFTWARE, CAUSED TO THE LICENSEE, PATIENT
16. **Exculpation.** The licensor makes no representations or warranties, express or implied, to the licensee, a patient or any third party, including, without limitation, warranties of merchantability and fitness for a particular use.

17. **Back-up.** The licensor strongly recommends that the licensee make a back-up of files regularly. The licensor is not in any way responsible for the loss of files, data or other information which may be associated with the software.

18. **Licensor’s Responsibility.** The licensor does not take any responsibility for products or services produced by the licensee, other labs, scan sites or other companies in the dental industry, whether they are using the software or not. The licensor is in no way responsible, financial or otherwise, for any complications, injury, discomforts which may result from implant surgery, drugs, anesthetics or otherwise. The use of any software, treatment plan, surgical template or any other related equipment and the effects it has on a patient is solely the responsibility of the clinician.

19. **Severability.** If any provision of this agreement is held unenforceable, the remaining provisions will remain in effect with the unenforceable provision omitted.

20. **Miscellaneous.** a) The intent of licensor is that the terms and conditions of this agreement comply with all applicable laws and regulations; b) the licensee is aware that there are technological measures in the software created to prevent the use of non-licensed software; c) the licensee may have to reactivate the software if the computer hardware is modified; d) the licensee may not use any service available on the Internet or otherwise that could damage, disable, overburden, or impair the functionality of the software; and e) licensee may not modify the software.

21. **Licensee’s Use.** The licensee may not copy, reverse engineer, decompile or disassemble the software or cause business or financial damage to the licensor.

22. **Integration.** This agreement constitutes the entire agreement between licensee and licensor. It will override all communications, proposals, representations and warranties, written or oral and prevails over any conflicting or additional terms.

23. **Termination.** This agreement may be terminated by the licensor at any time, without prejudice to its right to claim damages, if the licensee violates any of the provisions of this agreement.

24. **Governing Law.** This agreement shall be governed by and construed under the internal laws of the State of Illinois, U.S.A., without reference to the principles of conflicts of laws. All disputes hereunder shall be resolved exclusively in the appropriate state or federal court in the city of Los Angeles, State of California. Licensee consent to exclusive jurisdiction in such venue.

Licensee hereby acknowledges that he/she has read this agreement, understands it, has the authority to enter into this agreement and hereby does agree to the terms and conditions of this agreement.
INDICATIONS

The GuideMia system is intended as software interface to transfer DICOM images generated by CT scanners into 3D models, an image segmentation system to create dental anatomies from scan images, and a pre-operative software for simulating/evaluating dental implant placement and surgical treatment options.

CONTRAINDICATIONS

Implants should not be placed anytime when there are general contraindications associated with elective oral surgery. Absolute and relative contraindications include, but are not limited to: cardiac and vascular disease, bleeding disorders, psychological disorders, uncontrolled diabetes mellitus, mineral, bone, or connective tissue disorders, renal disease, hepatic disease, auto-immune disorders, decreased immune function due to disease or medications, infectious disorders, and adverse conditions caused by medications. Further relative contraindications include poor oral hygiene, bruxism, malnutrition, alcoholism, tobacco usage, and history of radiation therapy.

In addition, the patient needs an adequate volume of residual bone for the placement of implants of sufficient size and number to support the anticipated functional loads to which the patient will subject these implants. Narrow implants and angled abutments are not intended for use in the posterior region of the mouth.

WARNING

The software can only be used when patients have been scanned according to specific protocols and procedures, and study models have been made and scanned if necessary.

The treatment planning is based on patient's CT (or cone beam CT) scan and scan appliance (such as radiographic guide). Often time the scanning of a patient wearing a radiographic guide is necessary. Fail to properly place the radiographic guide before CT scan can cause serious errors and pose lots of risks to the surgery.

Implant treatment planning should be performed only by practitioners or lab technicians who are trained to do so. Adequate studies should be performed to examine the anatomic structures and to assess the biomechanical, functional, and esthetic requirements of each case. Radiographs or other diagnostic reviews should be performed to determine position and topography of the maxillary sinus, nasal cavities,
inferior alveolar nerve, mental foramen, natural tooth positions and other anatomical features that may affect implant placement or prognosis. Consultation between the surgeon, restorative dentist, and dental laboratory is essential for success. All implants must be placed to have sufficient clearance between implants, teeth, and patients nerve structures. Risks of improper implant placement and restoration include, but are not limited to: infection, implant failure, loss of bone and soft tissue, unfavorable aesthetic result, anesthesia, dysesthesia and paresthesia in the oral and facial areas, sinus infection, dislodgement of implants and instruments in the surrounding structures, damage to adjacent teeth, non-restorable implants, fracture of implants or restorative components, and loosening of implants or restorative components.

Each implant system has unique measuring characteristics to allow full seating of the implant to the desired depth. In some instances, drill length reference lines measure longer than the stated length of the implant. It is recommended that the implant surgeon be thoroughly familiar with the specific measurement system being utilized and provide a suitable safety margin adjacent to any teeth and vital structures. Failure to recognize the difference between the actual length of the drill and radiographic measurements can result in permanent injury to the nerves or other vital structures by drilling beyond the depth intended, potentially resulting in permanent numbness to the lower lip and chin or other injuries.

Each implant system has specific design characteristics for mating implants, abutments, prosthetic components, and instrumentation including surgical kits. Combining instruments, surgical kits, and components that are not configured or dimensioned for correct mating can lead to mechanical failure of components, damage to tissue, or unsatisfactory aesthetic results.

One-hundred percent success cannot be guaranteed no matter a treatment is planned with software or physical models. Lack of adequate quantity and/or quality of remaining bone, infection, inadequate surgical technique, poor patient oral hygiene, and generalized disease are some potential causes for failure of osseointegration, both immediately after surgery or after osseointegration is initially achieved. Pre-operative hard tissue or soft tissue deficits may yield a compromised aesthetic result or unfavorable implant angulation. With respect to children, routine treatment is not recommended until completion of alveolar growth has been verified.

**PROCEDURAL PRECAUTIONS, SURGERY**

The applicability of the surgical guides much be verified before the surgery. Quality assurance effort must be made to ensure the surgical guide is made according to the designed model and to the treatment plan. This includes trying the model onto diagnostic models, and on patient's anatomy. If a guide is found not fitting properly on the patient's anatomy, or cannot be properly secured, it must not be used for the treatment. The surgical guides should be visually inspected and evaluated. Any possible structure that can cause stress concentration should be identified and adjusted.

All efforts must be made to minimize damage to the host tissue. In particular, special attention must be paid to thermal and surgical trauma and to the elimination of contaminants and sources of infection. The surgical procedure requires a high degree of precision and care. Any divergence from the principle of least possible trauma at implant installation increases the risk of failure to establish osseointegration. All
drilling procedures should be performed at maximum 1000-2000 RPM (or follow the manufacturer's instructions) with copious irrigation, with or without surgical guide designed by the system, with or without surgical kits provided by implant manufacturers. The use of sharp drills, sufficient irrigation, an in-and-out drilling motion, short cutting cycles, waiting for the bone to cool, and use of pilot drills in successively increasing sizes are essential. Please refer to our web site for the specific sequence of drills for each implant type and size.

An appropriate follow-up protocol should be followed.

**CAUTION**

The use of this device is restricted to, or by the order of, licensed physicians or dentists, and per the prescriptions of licensed physicians or dentists only.

**MANUFACTURED BY:**

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