GENESIS
GUIDED SURGICAL MANUAL

A Keystone Dental Group Brand
SCIENCE MEETS AESTHETICS
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Product specifications are subject to change without notice.
Items illustrated are not to scale.
INSTRUCTIONS FOR USE

This manual provides guidelines for surgical and restorative clinicians as well as laboratory technicians for use with the GENESIS® Guided Surgery Kit. The success of any dental implant system depends upon proper use of components and instrumentation. This manual is not intended for use as a substitute for professional training and experience.

INDICATIONS
GENESIS® implants are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including cement-retained, screw-retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. GENESIS® Implants are threaded internal-connection implants intended for placement following natural tooth loss or for immediate placement into an extraction socket, and can be restored with a temporary prosthesis in single and multiple-tooth applications when good primary stability is established and appropriate occlusal loading is applied.

SOFT-TISSUE HEALING AND TEMPORIZATION
Following the placement of a GENESIS® implant, soft tissue can be contoured using a titanium healing abutment or a custom-fabricated temporary abutment. A temporary abutment can be placed at this time for immediate temporization. The acrylic portion of the temporary abutment bonds with dental composite/acrylic, allowing for custom aesthetic contouring directly to the temporary abutment.

PATIENT EVALUATION AND SELECTION
Successful implant treatment requires the coordinated efforts of the implanting surgeon, the restorative dentist, and the
dental laboratory technician. Proper patient selection is important for long-term function of a dental implant.

The following factors should be considered prior to implant surgery: general medical history, oral hygiene, patient’s expectations, general dentistry and product indications and contraindications, anatomical landmarks related to implant positioning, interocclusal clearance (the space available between the alveolar crest and opposing dentition), ridge width in relation to the implant diameter.

**IMPLANT SELECTION**
Implant selection should be made in accordance with the required prosthetic result and anatomical bone volume. Selecting implants in this manner aids in maximizing biomechanical stability and proper contouring of the soft tissue. Choosing an implant with a slightly smaller platform than the emergence of the tooth being replaced will provide support of the surrounding soft tissue and optimize the aesthetic result.

Implant placement and healing abutment selections should be based on the following:
- Emergence profile of the restoration in relation to the prosthetic platform diameter
- Height and diameter of the crown as it emerges through the tissue
INSTRUMENT CARE

PRECLEANING
Instruments must be cleaned and sterilized prior to first use and after each use, based on established procedures. Proper instrument care is an important part of successful implant dentistry. Instruments should be soaked immediately after use in instrument-cleaning solution to avoid the drying of blood, saliva, and tissue residue. Surgical trays, must be cleaned with a suitable disinfectant. Multiple-part instruments must be disassembled prior to cleaning and sterilization. Internal debris/residue on instruments must be removed with a soft brush. Instruments should be inspected, cleaned separately and discarded if damaged.

PRINCIPAL CLEANING
Best results are achieved if surgical instruments are cleaned by material type. Instruments and trays can be cleaned and disinfected by hand, followed by an ultrasonic bath with a detergent appropriate for surgical instruments. Instruments and trays must be rinsed and dried thoroughly. Automated washers should not be used as it may reduce the life of the instruments.

STERILIZATION
Instruments and the surgical tray should be autoclaved with a sufficient drying cycle to avoid instrument corrosion. Instruments should be placed in the tray and wrapped in sterilization paper or sterilization packs with indicating tape and date of sterilization.
• Autoclave (prevacuum): 134°C/273°F 4-minute exposure / 40-minute drying time
• Autoclave (gravity cycle): 134°C/273°F 20-minute exposure / 40-minute drying time
• Always use the drying cycle
Keystone Dental does not recommend chemiclave sterilization procedures, as they may damage surgical trays and/or instruments.

**SURGICAL MOTOR AND HANDPIECE**
Cleaning and maintenance instructions for NSK handpieces refer to manufacturer’s instructions for use. Additional information can be found at www.nskdental.com.

**SOFTWARE COMPATIBILITY**
GENESIS® Guided Surgery requires access to compatible implant-planning software, cone-beam CT scan (CBCT), and intraoral scan or optical scan information. Software training is essential for clinicians, technicians, or implant-planning service providers involved in the treatment-planning process.

The GENESIS® Guided Surgery Kit facilities the precise placement of GENESIS® implants through a custom-made surgical guide when used in conjunction with compatible guided surgery software and 3D manufacturing (milling or printing). In addition, the implant-planning file may be exported to compatible prosthetic software, thus enabling the manufacturing of an immediate provisional bridge prior to the surgical procedure.

Note: Please refer to the Keystone Dental website for software partner updates. (www.keystonedental.com)
GUIDED SURGERY

IMPLANT PLANNING AND SURGICAL PROGRESSION

The following is the general process for implant planning and surgical guide fabrication. Follow the manufacturer’s instructions for the implant planning software and other systems used in this process.

1. Patient examination, medical history, preliminary treatment protocol.

2. Collection of digital data (CBCT, intraoral scans clinical images) completion of Rx form with patient details and requirements.

3. In partially edentulous cases, it is recommended to have intra-oral scans of both jaws plus occlusal relationship in addition to the CBCT. This digital information will enable a “virtual tooth setup” in the required zone of interest without the need for a physical diagnostic setup.

4. In fully edentulous cases, it is recommended to follow the “dual scan” protocol using a radiolucent denture with scan markers.

5. Creating a 3D diagnostic treatment plan: Import the CBCT scan data into the treatment-planning software and align the intratoral scans (in partially edentulous cases) or the radiolucent denture scan (in fully edentulous cases). Special care must be taken to ensure correct alignment of digital data to DICOM. Only on completion of this step is it possible to continue with implant planning.
6. Implant planning: Following the instructions on the Rx form and in accordance with the desired prosthetic outcome/virtual tooth set-up, the implant planning may be completed. Care must be taken to ensure the correct safety zone of the implants to surrounding structures (i.e., adjacent implants, root anatomy, inferior mandibular nerve, maxillary sinus).

7. Surgical guide design: Following final approval of the implant planning by the implant surgeon, the surgical guide is designed. When designing a guide, utilizing compatible implant planning software for Keystone Dental, important factors include: selection of the appropriate guide sleeve and position; minimal thickness of guide to ensure proper retention of the sleeve in the guide; inspection windows to verify guide is properly seated by the clinician; and strengthening bars as needed. These parameters can be modified/added in the software by the designer.

8. Surgical guide manufacturing: The surgical guide is manufactured using 3D printing technology. Care must be taken to follow the 3D printer’s manufacturer guidelines. On completion, the guide cylinders should be introduced into the surgical guide.

9. Guided Surgery: The implants are positioned using the custom surgical guide and the dedicated GENESIS® Guided Surgery Kit following the surgical and drilling protocols.
COMPREHENSIVE SURGICAL KIT

A VIRTUAL PLANNING FOR THE IDEAL AESTHETIC RESULT

Continuous direct irrigation on the drill

Designed to accommodate limited interarch space

No implant drill guide keys required

Designed to prevent direct contact between drill flutes and guide sleeve, thus minimizing the potential of metal shavings entering the osteotomy

Guide sleeves in three diameters for ideal implant spacing

Covers implant platforms Ø 3.5/3.8, Ø 4.5, and Ø 5.5

Includes drills with a fixed offset

Drill length = Implant length
INNOVATIVE CONCEPT

HANDPIECE-BASED GUIDANCE
The innovative Digital Guidance Sleeve (DGS) guides the handpiece through the surgical guide to accurately position the implant drills. There is a window on the side of the DGS to allow for direct irrigation on the drill.

The DGS system can be used even when there is minimal interarch distance, such as in the posterior maxilla and mandible. The DGS design allows the drill to enter the guide sleeve at an angle and is only uprighted when the drill enters the bone.

The guide sleeves are available in Ø 4.1, Ø 5.1, and Ø 5.8 diameters.

- Sleeve Ø 4.1
- Sleeve Ø 5.1
- Sleeve Ø 5.8
GUIDED SURGICAL KIT OVERVIEW
<table>
<thead>
<tr>
<th></th>
<th>Item Description</th>
<th>Image</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NSK HANDPIECE</td>
<td><img src="path" alt="Image" /></td>
</tr>
<tr>
<td>2</td>
<td>DGS (DIGITAL GUIDANCE SLEEVE) (Ø 4.1, Ø 5.1, Ø 5.8)</td>
<td><img src="path" alt="Image" /></td>
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<tr>
<td>3</td>
<td>SHORT PILOT DRILL</td>
<td><img src="path" alt="Image" /></td>
</tr>
<tr>
<td>4</td>
<td>TISSUE PUNCH (Ø 3.4, Ø 4.2, Ø 5.1)</td>
<td><img src="path" alt="Image" /></td>
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<tr>
<td>5</td>
<td>DRILLS</td>
<td><img src="path" alt="Image" /></td>
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<tr>
<td>6</td>
<td>IMPLANT DRIVERS</td>
<td><img src="path" alt="Image" /></td>
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<td>7</td>
<td>TORQUE RATCHET</td>
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<tr>
<td>8</td>
<td>TORQUE RATCHET ADAPTER</td>
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<td></td>
<td><em>For Implant Insertion with the Torque Ratchet</em></td>
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<tr>
<td>9</td>
<td>QUAD DRIVER</td>
<td><img src="path" alt="Image" /></td>
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<td>10</td>
<td>FIXATION PIN DRILL</td>
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<tr>
<td>11</td>
<td>FIXATION PINS</td>
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PLANNING THE SURGICAL GUIDE

During the design phase of the treatment, the desired sleeve (Ø 4.1, Ø 5.1, Ø 5.8) should be selected by the digital planner from the sleeve library. Use compatible implant planning software. Once the design is approved by the clinician, the surgical guide is manufactured with the selected guide sleeve.
Step 2

SEATING THE SURGICAL GUIDE
The surgical guide is seated intraorally and checked for passive fit. The proper seating of the surgical guide is confirmed by evaluating the close contact of the guide with adjacent teeth/soft tissue. Specially designed “inspection windows” located on both sides of the guided surgery sleeve help validate correct seating. The DGS must fully engage with the top of the sleeve. If necessary, remove acryllic to avoid interference with seating of the DGS.

Step 3

INSERTION OF THE DGS INTO THE HANDPIECE
The appropriate Digital Guide Sleeve (DGS) is selected, inserted into the handpiece. Once the DGS and appropriate drill are fully inserted into the handpiece the latch is closed to secure them both. Closing the latch locks the components into the handpiece.
Step 4

CREATING THE INITIAL OSTEOTOMY
The osteotomy is initiated by placing the DGS into the guided surgery sleeve with the Short Pilot Drill. The pilot osteotomy is complete when the DGS fully engages the sleeve. Use a drill speed of 600-800 rpm.

(Optional)

OPTIONAL
Using the tissue punch to create the initial osteotomy (Can replace Steps 3-4) For flap-less surgery, the Tissue Punch is used to initiate the osteotomy, replacing steps 3 & 4.

The Ø 3.4 tissue punch engages the 4.1 Sleeve.
The Ø 4.2 tissue punch engages the 5.1 Sleeve.
The Ø 5.1 tissue punch engages the 5.8 Sleeve.
Step 5

REMOVAL OF THE SHORT PILOT DRILL
The Short Pilot Drill is removed by opening the latch, while the DGS remains in place.

Step 6

DRILLING PROTOCOL REVIEW
The osteotomy is completed by following the drilling sequence listed in the drilling report.

- Drill length = Implant length
- Drilling is continued until the DGS is fully engaged in the surgical guide sleeve
- Drills are color-coded, and the dimension is marked on the drill shank
Step 7

CREATING THE FINAL DEPTH OSTEOTOMY USING THE Ø 2.0 / 2.9 MM DRILL

The initial guidance of the Ø 2.0 / 2.9 mm drill (in accordance with the implant length) is achieved by ensuring that the apex of the drill engages the pilot osteotomy and the DGS engages the guide sleeve.

Drilling is continued until the DGS is flush with the guide sleeve to achieve final depth position. The drill can be introduced into the guide sleeves at an angle where inter-arch space is limited, but must not be activated until the DGS engages the sleeve.

For example, in the event the 13 mm implant length was chosen and the DGS does not engage the sleeve, we recommend choosing a shorter drill ensuring engagement to the DGS and then continuing with the appropriate length drill in accordance with the implant.
Step 8

EXPANDING THE OSTEOTOMY TO THE IMPLANT DIAMETER USING SHAPED DRILLS

The process is continued until reaching the right diameter drill in accordance with the drilling protocol.

Note: Depending on bone density, it is recommended to adapt the drilling protocol accordingly. For example, in cases of soft bone, you may choose not to use the final diameter drill.
Step 9

**CHOOSING THE IMPLANT DRIVER**

The correct implant driver is chosen, in accordance with the implant platform and matching the guide sleeve diameter.

- The SD drivers are available for the (Ø 4.1, Ø 5.1, Ø 5.8) sleeves enabling functionality for SD implants with all sleeve diameters.
- The RD drivers are available for the (Ø 5.1, Ø 5.8) sleeves enabling functionality for RD implants with both sleeve diameters.
- The WD drivers offers functionality for (Ø 5.8) sleeve diameter.

Step 10

**IMPLANT INSERTION**

The GENESIS® implant is carefully removed from the sterile packaging and can be inserted with the handpiece at 15 rpm or manually with the Torque Ratchet. Recommended insertion torque is 30-70 Ncm*

*When insertion torques are higher than 70 Ncm, it is recommended to use a surgical tap. When tapping the site, remove the guide to tap the site. The guide can be replaced for insertion of the implant through the guide.
CONTINUED
The GENESIS® implant is properly seated in the Implant Driver when the laser mark is no longer visible.

IMPLANT DELIVERY WITH THE IMPLANT DRIVER
The Implant Driver has a fixed offset. The “Stop” of the Implant Driver must be flush with the guide sleeve to achieve final depth position.
CONTINUED
The correct implant orientation is achieved by aligning the grooves and flat on the Implant Driver with the grooves and flat of the guide sleeve. The Implant Driver must not be rotated beyond its final position.

Step 12
SEATING OF PROSTHETIC COMPONENT
Once fully seated and in correct position, a Cover Screw, Healing Abutment or Temporary Abutment can be seated utilizing the Quad Driver.

Please see Prosthetic Manual for torque values.