



Adin Guided Surgery System Step by Step Instructions

Surgical Guide Planning



Adin Guided Surgery System and Planning Software

Adin's Guided Surgery System supports both a PARTIALLY guided procedure in which only drilling is done through the guide, with implants being placed freehand after removal of the guide, and a FULLY guided procedure in which both drilling and implant placement are done through the guide.

Adin's Guided Surgery System is an open system and may be used with a variety of planning software programs in which Adin's virtual components and parameters can be embedded.

Note: it is essential that the dentist or dental technician intending to use one of the available planning software programs MUST ensure that all of Adin's virtual components and parameters are embedded in it first, BEFORE using it to plan a guide for Adin's Guided Surgery System.

Warning

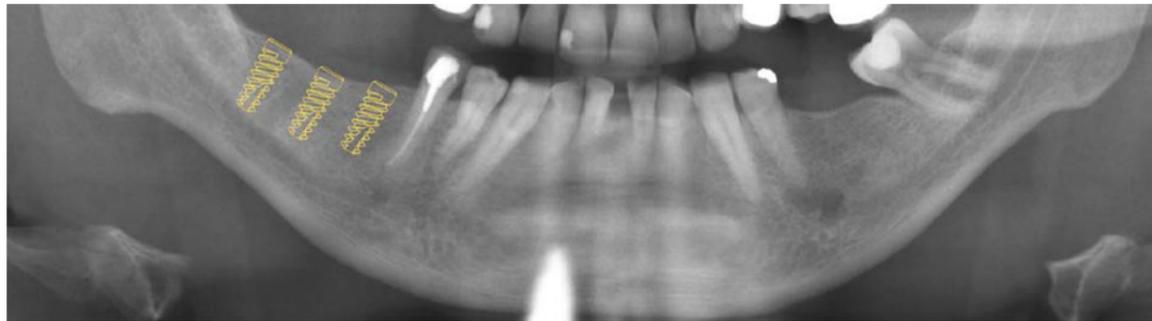
Each implant position should take into account prosthetic and anatomical considerations, including bone limitation, which are listed in detail in Adin's User Manuals, IFUs and Step by Step instructions.

STEP BY STEP Planning Procedure

Doctor's Initial Plan

The dental surgeon needs to formulate a preliminary surgical plan which indicates the number of implants required, their locations and the type of restoration that is planned.

Please plan 3 implants in the mandibular right segment for a screw retained bridge:



Required Data

Ideal planning of implant positions is a top-down process in which implants are positioned according to the type and position of the future restoration. In order to accomplish this the doctor needs to provide radiographs, impressions (physical or scanned), a wax-up (where applicable) and DICOM files of a current CT scan. All of this data is imported to the planning software so that the planning technician can visualize a 3D image of both CT and clinical data of the patient.

Checklist:

- o Doctor's treatment plan:
 - Implant locations
 - Number of implants
 - Restoration type
- o DICOM files
- o Impression of current dental situation (physical or scanned)
- o Wax-up (where applicable)

Doctor's Approval

Note: Although this step is the last one in the planning process, it is important to know that the plan MUST be approved by the oral surgeon prior to undertaking fabrication of the guide.

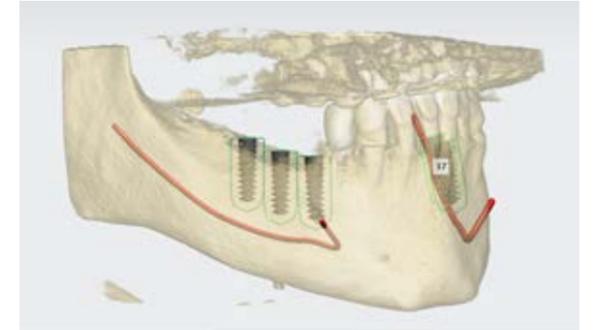
Based on the required initial treatment plan, the planning center produces one or more suggested plans and e-mails them to the doctor. The doctor must then confirm that the suggested surgical plans have been formulated in accordance with the required initial treatment plan, and must verify each implant's position. The doctor then needs to sign (electronically or physically) the approved plan as a preliminary step before fabrication of the guide.

The Planning Software

Data Acquisition

There are many options for planning software approved for use with Adin's Guided Surgery System. The doctor MUST verify that the planning center is using one of these approved software programs.

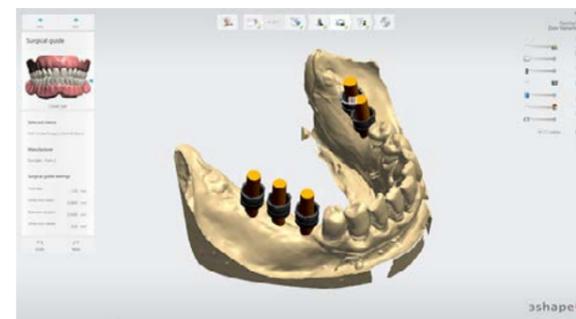
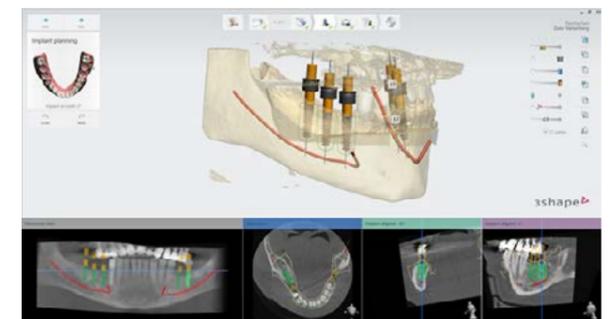
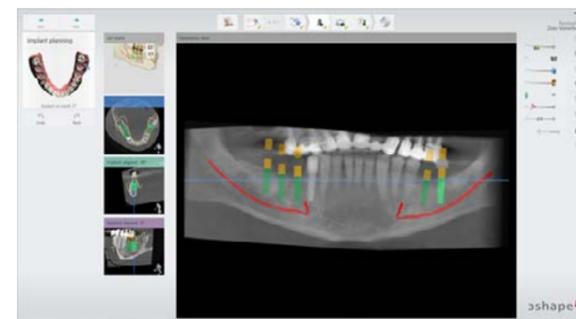
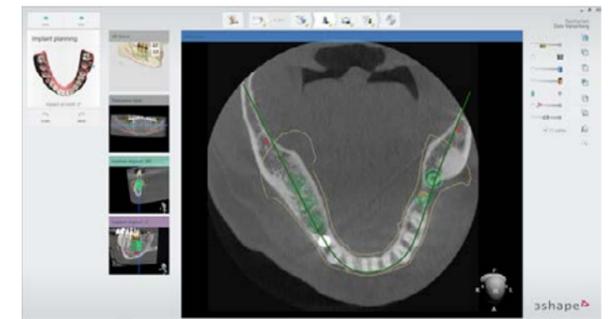
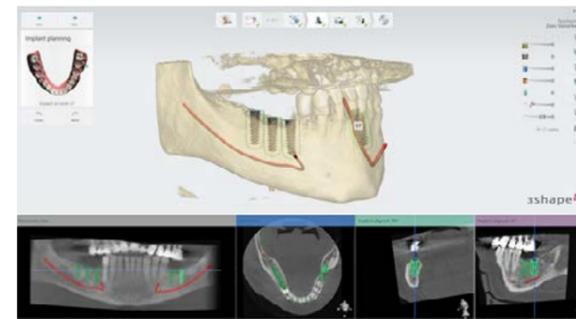
CT scan data (DICOM files), 3D digital data acquired from the oral cavity, and wax-ups are imported to the planning software and aligned with each other in order to ensure a perfect match between the various data sources.



Virtual Implant Positioning

At first each implant is placed arbitrarily, based on the location of the future restoration. The final length, diameter and angulation of each implant are later modified according to the software's ability to provide 3D visualization of each implant and its surroundings, thereby ensuring:

- 1.** Safe distancing from anatomic landmarks (such as nerves, external bony walls etc.).
- 2.** Correct spacing between implants.
- 3.** Parallelism and compatibility with available prosthetic components.
- 4.** Safe placement of guiding sleeves into the fabricated guide.

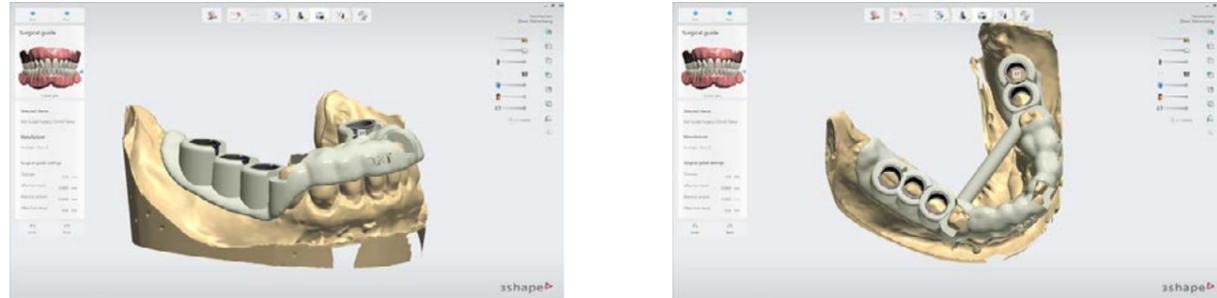


Virtual Guide Planning

Once each virtual implant has been positioned correctly, the software will enable for fabrication of the surgical guide and specific positioning of each guiding sleeve.

The output of the software includes:

1. A printing file for a 3D printer for fabrication of the guide.
2. A PDF file with images of each implant, its position and surroundings as well as the drills and tools recommended for each implant, based on its length and diameter.



Guide Fabrication

Adin's guides are created using 3D printing.

It is critically important to adhere to the specific instructions of the printer and software in order to ensure that the guide is made to the desired accuracy.

Guiding sleeves (GS0020, GS0055, GS003) are later attached to the guide. It is mandatory to ensure that the sleeves fit perfectly in the guide and that excess cement (if used) is not causing a change in the sleeves' position.

Note: Surgical guides are delivered as non-sterile. Follow the disinfection guidelines to ensure that the guide has been disinfected prior to surgery.

Guide Disinfection

Guides MUST be sterilized using steam sterilization.

Immerse the guide completely in a 0.2% Chlorhexidine solution for 10 minutes at room temperature just before surgery. Where applicable, guides should be autoclaved according to the instructions of the guide manufacturer.

Note: Autoclave the guide only if instructed by the guide manufacturer.

When Receiving the Guide

The surgical guide is delivered in a package which contains documents, including the signed and approved treatment plan and a complete surgical protocol for each planned implant.

Note: Make sure that the guide and documentation are related to your patient and that the plan is in harmony with the approved treatment plan.

Guide Try-in

It is highly recommended to try-in the guide before starting the surgical procedure. This try-in evaluation should be performed even if the guide will later be anchored to its position using anchoring pins.

Tooth supported guides should be seated firmly on supporting teeth. They should fit the dentition perfectly and be completely stable.

Soft-tissue supported guides should contact supporting tissues perfectly, with no areas bearing excessive pressure that may dislodge the guides from their correct position.

In rare situations, minor adjustments may be required.

Note: The guide should not be used if major adjustments are necessary.

Guide Positioning

Following the administration of local anesthetic the disinfected guide should be firmly seated in the mouth. It is highly recommended to anchor the guide to position using anchoring pins.

Fixation Screws

These screws are intended for cases in which there are not enough teeth available to stabilize and maintain the guide in place throughout the entire procedure. The use of fixation screws is mandatory for soft-tissue supported cases and highly recommended for distal extension cases.

Drilling

The user must follow the planned surgical sequence, which is specific for each planned implant.

The large cylinder of each drill centers the drill in the guide's sleeves. A stop is located at the top of each drill. In-out movements of the drill during rotation will prevent it from jamming in the sleeves.

The recommended sequence includes the following tools and drills:

Tissue Punch

A tissue punch is used to create a circular incision around each planned implant site.

It is recommended to use 300 rpm for trephining down to bone.

Remove the guide and debride the soft tissue using either a periodontal curette, Orban periodontal knife, scalpel or similar instrument.

Note: Before using the punch make sure that it will cut through attached gingiva only. Where there is a risk of the punch cutting through the free gingival margin it is advisable to raise a small, localized flap to ensure that the implant will be surrounded by attached gingiva.

Note: The punch does not have a built-in stop. Use it with caution.

Pilot Drill

The starter drill is designed so that its active tip will contact tissue only after the larger cylinder has been correctly positioned in the guide's sleeve. Thus, it prepares the initial osteotomy at the correct angulation for subsequent drills while remaining centered in the sleeve precisely.

Recommended drilling speed: 800 rpm.

Drilling sequence

The drilling kit is designed so that each drill row refers to a specific implant length and each drill column refers to a specific implant diameter.

Follow the planned drilling protocol for each individual implant.

Recommended drilling speed: between 800-1200 rpm.

To be certain that the drill to be used is of the correct length and diameter, check the laser marking on the drill and confirm the dimensions by using the measuring tool imprinted on the side of the kit.

Note: To be safe, in case of doubt it is possible to start drilling to a length shorter than planned, using drills shorter than intended. A parallel radiograph can help determine whether to use the planned implant length or to finish the case using a shorter implant length.

Implant Insertion

Adin's Guided Surgery System is designed to allow insertion of mount-less implants through the sleeves of the surgical guide. This ensures accurate 3D positioning of the implants.

The insertion tools allow rigid connection to mount-less implants by means of a holding screw, and delivery and insertion of the implant to its correct position, using either the hand operated ratchet or the handpiece adaptor.

Recommended drilling speed: 50 rpm.

To ensure correct orientation of the Hex or anti-rotational index, the final position of the implant may be fixed either before or after removal of the surgical guide.

Drill Design

Adin's Guided Surgery drills are made so that each one self-centers within the guide's sleeve. Drills are supplied in the following diameters and lengths:

Lengths: 6, 8, 10, 11.5, 13, 16.

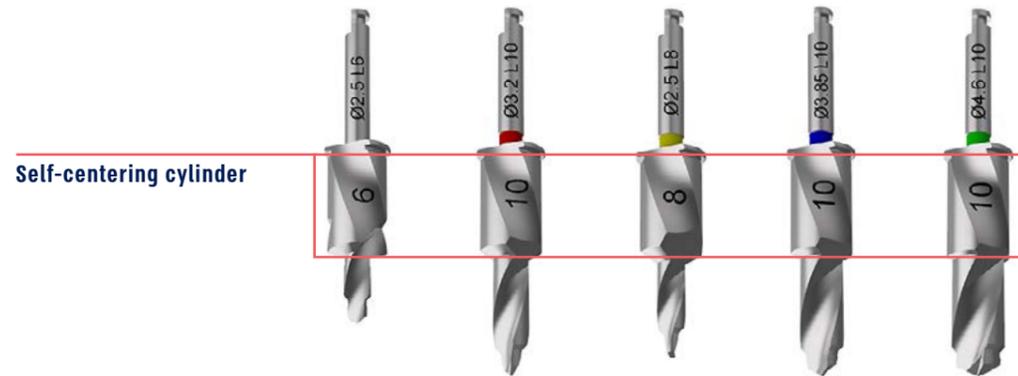
Diameters: 2.5, 3.2, 3.85, 4.6

Each drill is marked with a specific color indicating its diameter, as well as with specific laser markings of its length and diameter.

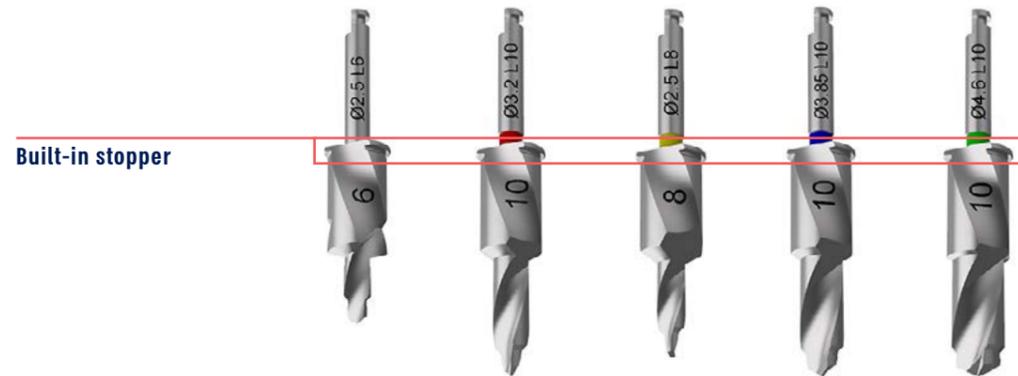
Note: 18mm drills are available separately and are not included in the drill kit box.

Self-Centering Mechanism:

The self-centering mechanism is controlled by a 5.5mm diameter cylinder at the top of each drill. Within each cylinder are unique channels which allow saline coolant to stream through the sleeve while drilling.



At the top of each cylinder is a built-in stop for ensuring that the correct drilling depth has been reached when it contacts the guide's sleeve:



Tissue Punch Design

The tissue punch is designed to make a circular incision of 5mm. The punch is designed to self-center in the same way as with the guided surgery drills.

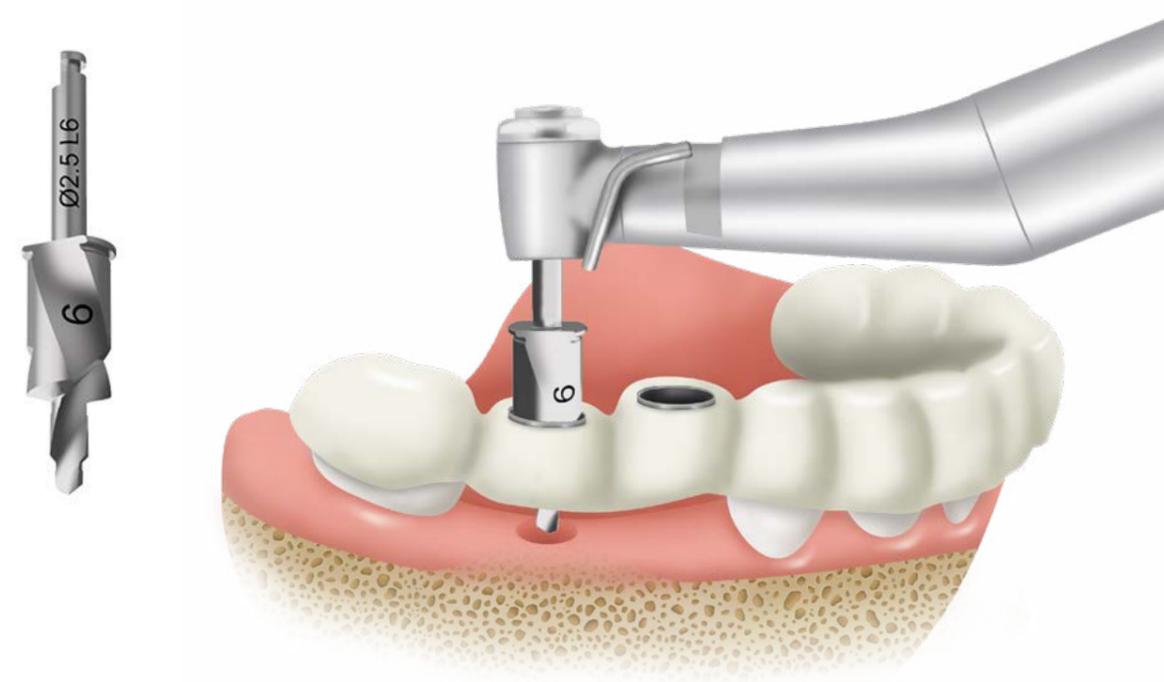
Self-centering cylinder



Note: The punch only makes a circular incision at the planned implant site and does not remove any soft tissue. After punching, take the guide off and remove soft tissue with the aid of either a scalpel, Orban knife, periodontal curette, or similar instrument.

Pilot Drill Design

The pilot drill is used to make the initial penetration into bone. Its design is similar to that of the other guided drills but it also has a reamer that can flatten bone, where applicable. It's active portion is 2.5mm wide and 6 mm long. The surgical guide is designed so that the self-centering cylinder engages the sleeve BEFORE the drill touches bone in order to ensure correct positioning of the drill.



Adin's Guided Surgery System Kits – Design Aspects

Adin's Guided Surgery System comprises several kits, with each one designed for specific procedures and implant types:

- o Drill Kit - Standard
- o Tool Kit – RS
- o Drill & Tool Kit - CloseFit™ NP and UNP
- o Tool Kit - CloseFit™ RP and WP

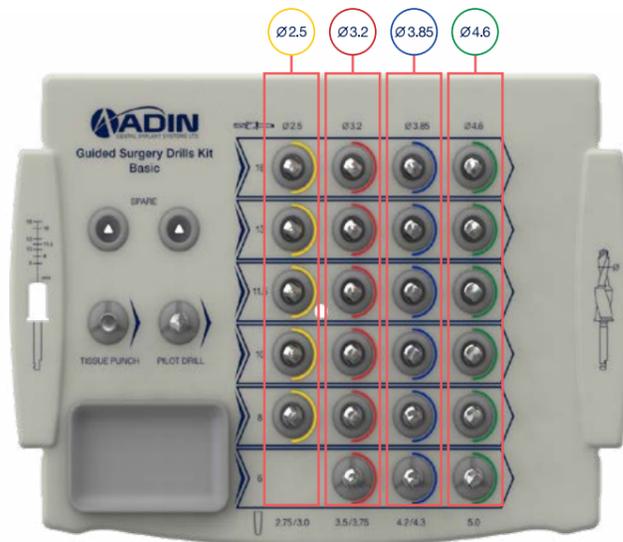
The Standard Drilling Kit

The standard drilling kit is designed to be used with 5.5mm sleeves. The kit is organized in a way that enhances safety and ease of use:

1. The grid is configured to ensure that drilling will follow a left-to-right sequence:



2. All drills in each vertical column are of a specific diameter:



3. The diameter of each drill group refers to the diameter of the center of the drill, as indicated in the drawing on the left:



4. All drills in each horizontal row are of the same length:



5. The safety gauge in the drawing on the right side provides easy verification of the length of the drills by placing their large cylinders in the carved out area:



The RS Insertion Kit

The RS insertion kit is designed to be used with 5.5mm sleeves.

The kit is organized into 6 areas, with each one representing a specific function during implant placement and insertion:

1. Anchoring drill and pins:
used to anchor the guide to its correct position when the guide design calls for such anchoring.



2. Fixture mounts:
used to insert mount-less implants into the planned 3D position while keeping them centered.

3. Screw fixture mounts:
intended for implant insertion and additional anchoring of the guide to its position later on, if needed.



- Note:**
Fixture mounts markings are used to ensure correct alignment of the HEX.



4. Sockets:
used to extend the length of tools whenever the guide's design requires it.



5. Extraction tools:
used for disengaging insertion tools, if needed.



6. Ratchet and surgical driver:
used for implant insertion.





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