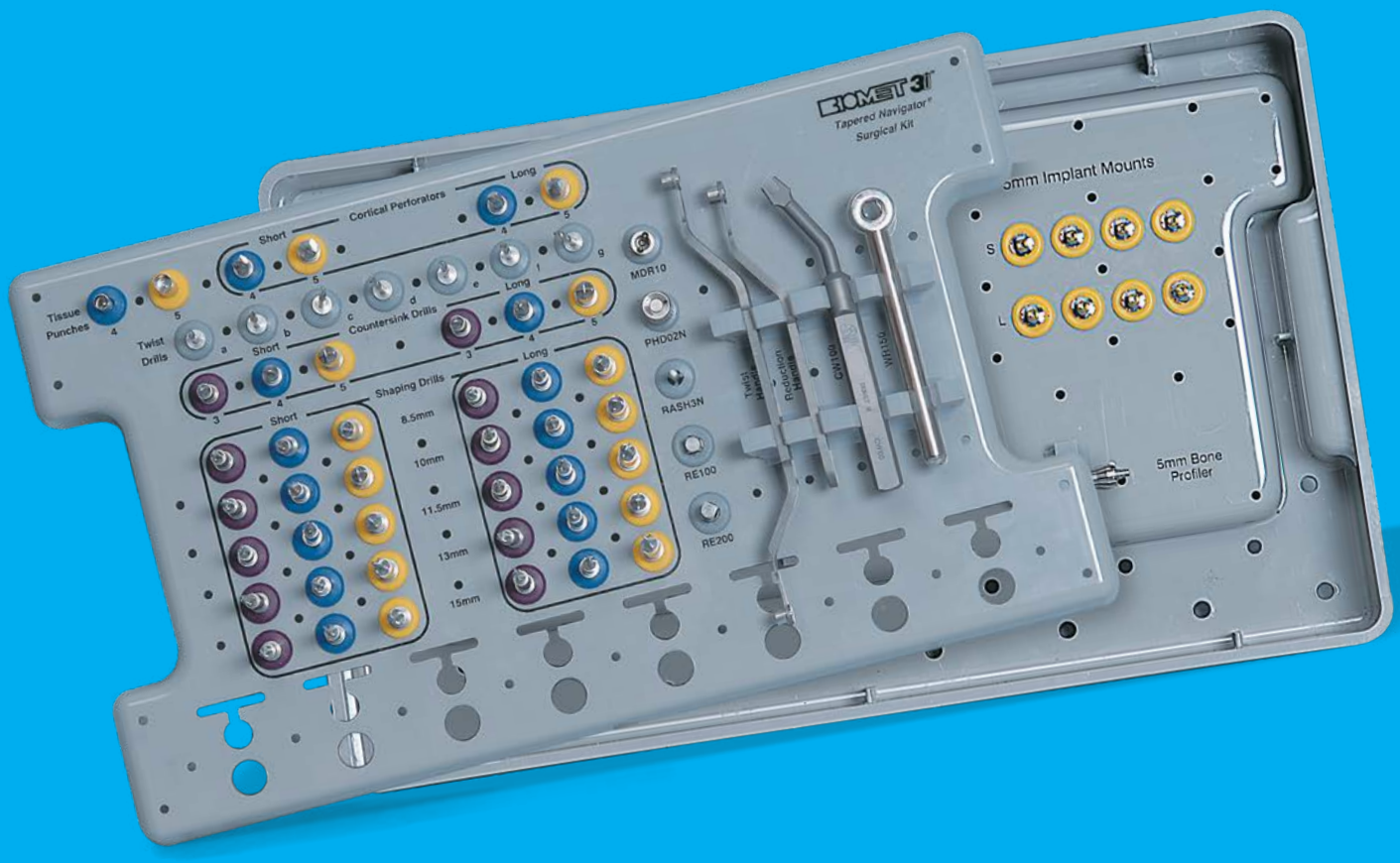
The Navigator® System For Guided Surgery

Technical Considerations



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Guided Implant Treatment

Planning

It is important for users to become familiar with the capabilities and limitations of guided surgery systems. Each type of technology works within certain parameters. Clinicians must ensure that the treatment plan is created in such a way that it will be clinically executable on the day of surgery. As a result, the following should be considered along with the Parallel Walled Navigator System Manual when treatment planning and performing dental implant cases.

The use of a scanning appliance is required in fully edentulous cases and recommended in all multiple-unit cases [Fig. 1].

Fig. 1

- The scanning appliance and scanning protocol will be dependent upon the planning software utilized.
- Both single scan (barium-sulfate scanning appliance) and dual scan (gutta percha marked scanning appliance) protocols are possible with the Navigator System.
- Create a bite registration from radiolucent material to confirm proper positioning of the scanning appliance during CT scanning.

Confirm that the CT scanning appliance fits in the mouth and is seated completely before the scan is performed. Failure to confirm a stable fit of the scanning appliance may result in a poorly fitting Surgical Guide, which will affect the outcome of the procedure.

TIP: Download the most recent version of planning software including implant libraries. The treatment plan must include dental implants that are compatible with the Parallel Walled Navigator System [Fig. 2].

Currently, the Parallel Walled Navigator System is compatible with the following Zimmer Biomet Implants:

- Certain® Internal Connection 3.25, 4.0 and 5.0 mm Parallel Walled Implants
- Prevail® 3/4/3, 4/5/4 Implants and Osseotite XP® 4/5 Implants
- Straight Collar Prevail 4/3 and 5/4 Implants

Currently, the following implants are NOT compatible with the Parallel Walled Navigator System:

- Tapered Implants
- 6.0 mm implants or implants that have a 6.0 mm diameter collar (Prevail 5/6/5)
- 7.0, 18.0 and 20.0 mm length implants
- External hex connection implants
- Certain Internal Connection 5.0 mm Parallel Walled and Straight Collar Prevail 5/4 Implants in 15.0 mm lengths

Presently, Parallel Walled Navigator Instrumentation does not support subcrestal placement of 3.25 mm diameter implants.

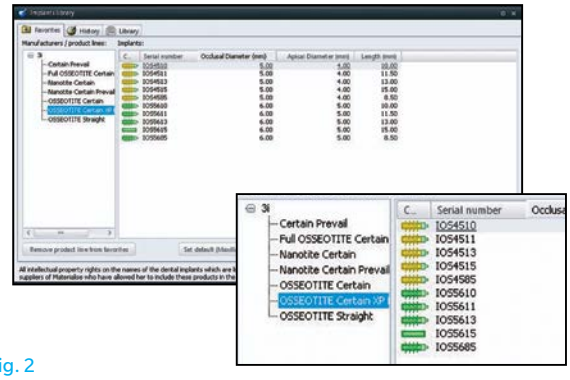


Fig. 2

Zimmer Biomet Dental Implant Selection Screen in SimPlant® Software; courtesy of Materialise Dental.

Surgical Guide fixation is required for tissue-supported cases and recommended for tooth- and bone-supported cases to minimize Surgical Guide movement during surgery.

- 2.0 mm bone screws assist with the stabilization of the Surgical Guide. Points of fixation can be planned into a Surgical Guide during treatment planning within the software.
- Use of a bite registration in occlusion is required for tissue-supported cases to ensure proper positioning of the Surgical Guide during bone screw fixation.

TIP: Fixation points planned into the vestibular aspect of the Surgical Guide allow for insertion of fixation screws while the patient occludes into the bite registration.

Consider interarch space when planning in the posterior. All systems that utilize Surgical Guides will require long drills to accommodate the additional vertical length required to pass through the Surgical Guide and soft tissue. The length of the drill specified is a factor of the implant length selected by the clinician, with the position of the Master Tube determined by the Surgical Guide manufacturer [Fig. 3]. Please select appropriate implant lengths when treatment planning.

Fig. 3

The Surgical Guide manufacturer determines the distance that the Master Tube is positioned above the implant platform. The distance between the top of the Master Tube and the implant platform is variable at the following lengths: 7.5, 9.0, 10.5 and 12.0 mm.

With the Parallel Walled Navigator System, implants are guided into position through the Surgical Guide with Implant Mounts. Guided placement of the implants to the intended depths may not be possible if implants are planned too deep. A maximum depth of 12.0 mm through the Surgical Guide to the seating surface of the implant is possible. Please keep this in mind during case planning.

TIP: Orthodontic wire may provide additional Surgical Guide stabilization for tooth-supported cases. When working in tight interdental spaces, provide sufficient space for the Master Tube to fit between existing dentition or closely planned implants. For a single-unit case, a clinician will need spacing of at least 7.5 mm for a 4.0 mm Master Tube (5.5 mm for the tube itself with 1.0 mm of space on either side) and 8.5 mm for a 5.0 mm Master Tube (6.5 mm for the tube itself with 1.0 mm of space on either side) [Fig. 4].

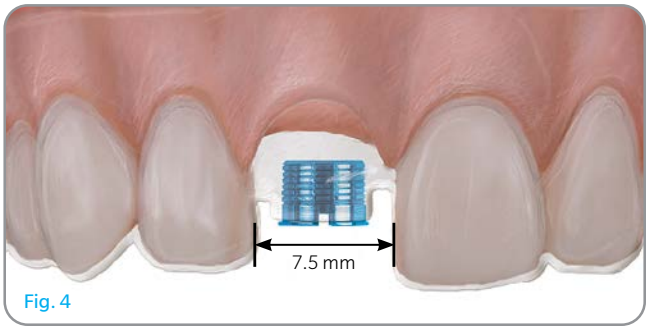


Fig. 4

For multiple-unit cases, you must consider mesial distal inter-implant spacing. Measuring from the center of a planned implant to the center of an adjacent implant, 7.1 mm is needed between 4.0 mm implants, with 8.0 mm needed between 5.0 mm implants [Fig. 5].

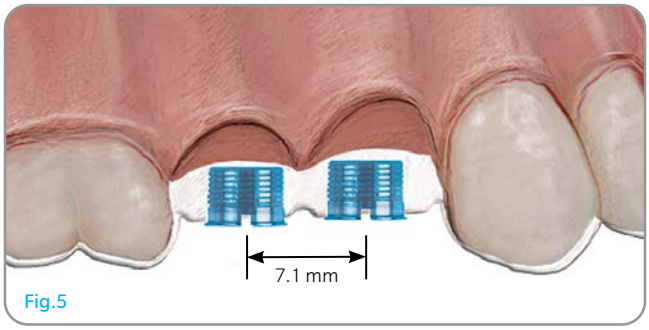


Fig.5

The 4.0 mm Master Tube is used for implants with collar diameters of 3.4 and 4.1 mm. The 5.0 mm Master Tube is used for implants with a collar diameter of 5.0 mm.

When planning to immediately provisionalize Navigator Cases, consider the following factors that may help to indicate primary implant stability:

- Bone density readings (in Hounsfield Units) from a CT scan.
- Potential implant length and position relative to the restoration.
- The use of screw-retention in combination with a full arch cement-retained restoration. The screw-retained sites should be planned at locations with the highest anticipated initial stability.

Preparation

Inspect the Surgical Guide for imperfections and reinforce potential weak areas of the Surgical Guide with acrylic.

Prior to surgery, try-in a Drill Positioning Handle in each Master Tube to determine if the Surgical Guide needs adjustments to allow the Drill Positioning Handles to fully seat once the Surgical Guide is positioned intraorally. Inspect the Master Tubes to ensure that no fabrication material remains from the Surgical Guide manufacturer.

Score the Master Tube notch position on the Surgical Guide to record the hex-orientation landmarks [Fig. 6].

To verify hex orientation at the time of implant placement, a periodontal probe or curette will confirm alignment of the Implant Mount and Master Tube by engaging the aligned slots.

Fig. 6

Preparation of a master cast may be advised to confirm the planned position and restorative considerations of the implants prior to surgery.

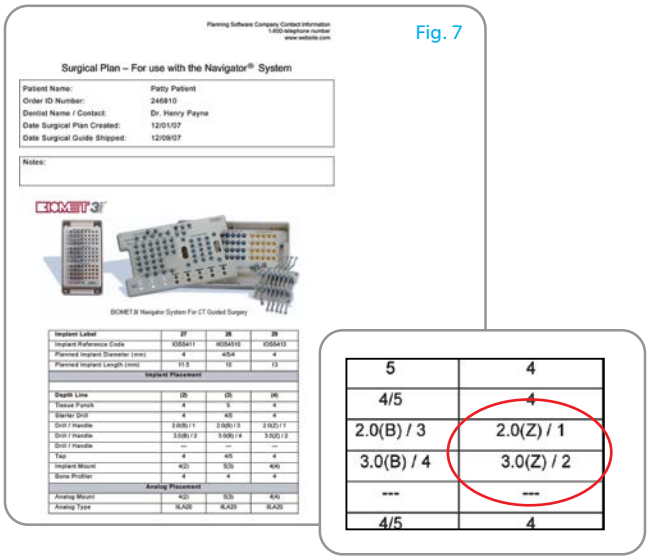
Review the CT scan data for bone density to anticipate areas of poor quality bone and areas where implant stability may be compromised. During use, drilling and placing the implants through the Master Tubes in the Surgical Guide provide little tactile confirmation of bone density.

A limited number of cases will require the use of a Twist Drill(s) in a length(s) that is not included within the Parallel Walled Navigator Surgical Kit. These drill lengths are specified as Y and Z drills [Fig. 7]. If your treatment plan requires one of these drills, your case will be put on hold and the Surgical Guide manufacturer will contact you. You may modify the case plan by changing the length of the implant selected or repositioning the implant to fit within the parameters of the drills included in the Navigator Surgical Kit (drills A-E).

When changing implant length, a size longer or a size shorter implant will be compatible with the system.

If modifying the case is not preferable, you may purchase the required Y or Z Drills by contacting your local sales representative or Zimmer Biomet Dental Customer Service at 1-800-342-5454 or outside the U.S. at 1-561-776-6700.

Fig. 7



The Parallel Walled Navigator Surgical Plan, which specifies the use of (Z) length Twist Drills.

If the Surgical Guide manufacturer receives a plan that is not compatible with the parameters of the Parallel Walled Navigator System, the Surgical Guide manufacturer will place the case on hold and contact the customer. As a result, the customer may be required to modify and re-submit the treatment plan to the Surgical Guide manufacturer. Please note that if the Surgical Guide manufacturer places the case on hold, there may be a delay in the original shipment schedule.

If changing the case plan is not possible, an alternative Surgical Guide may be created for where the Master Tube (guide) for that specific site is excluded from the Surgical Guide.

Clinical Use

For flapless cases, use a Tissue Punch prior to fixation of the Surgical Guide. Remove the Surgical Guide and the tissue plugs. Then replace and fixate the Surgical Guide. The Tissue Punch should not be used at speeds greater than 300–500 rpm.

The Tissue Punch and Starter Drill should not be used beyond the prescribed depth line, as this may reduce the cutting efficiency of the instrument or compromise the osteotomy. All instrumentation should be advanced as far as possible through the Master Tube(s) or the Drill Positioning Handle Guide Tube and into the osteotomy prior to activation. This will limit the possibility of damaging either the instruments or the tube(s).

Use copious irrigation on instruments prior to and during use to provide lubrication and cooling when passing through the Master Tube(s) and/or Drill Positioning Handle. Pre-drilling access holes below and/or adjacent to the Master Tube(s) may be considered to promote site irrigation.

TIP: "Pumping" the Twist Drills in conjunction with irrigation, aides in the removal of debris from the Master Tube, while increasing irrigation access into the osteotomy.

Avoid lateral pressure on drills and other instruments, as this may cause damage to the Guidance Tube(s) and instrumentation.

If the clinical scenario permits, insert the Twist Drill into the Drill Positioning Handle prior to inserting it into the Master Tube(s) of the Surgical Guide. The Twist Drill/ Handle Assembly will reduce the vertical space required for instrument delivery, while reducing the likelihood of exerting lateral pressure on the Twist Drill. [Fig. 8].

Fig.8

The final drill diameters specified on the Parallel Walled Navigator Surgical Plan are recommended for use in medium bone densities. In soft- or dense- bone scenarios, the clinician should size the osteotomy to be in line with the standard drilling protocols for those bone types. The corresponding Navigator Drill and Handle Combination should be selected accordingly. For further information regarding drilling protocols by Zimmer Biomet Dental , please refer to the Surgical Manual.

NOTE: The Parallel Walled Navigator System does not support a soft- bone protocol for Prevail 4/5/4 and Osseotite XP 4/5 Implants.

Sequence the placement of implants in an alternating cross arch pattern, moving from one side to the other so as to not compress soft tissue.

TIP: Place all implants close to the final vertical position with the Handpiece, then use the Hand Ratchet to achieve final vertical position and hex orientation.

During implant placement, once the flange of the Implant Mount contacts the Master Tube, do not continue to torque the Implant Mount.

For cases requiring three (3) or more implants, removal of the Implant Mounts immediately following implant placement may assist with passive Implant Mount removal. If performed, place two (2) implants with Implant Mounts in a cross arch configuration to assist with stabilization of the Surgical Guide. Removal of successive Implant Mounts will reduce divergent forces applied to the Surgical Guide.

When removing Implant Mounts, remove along the path of insertion and avoid applying lateral force.

Use a Bone Profiler prior to placing an abutment of any type.

TIP: Use an oversized Bone Profiler when placing pre-angled abutments.

Fig. 9

The screw held within the Implant and Analog Mounts is available in four (4) different lengths to accommodate the four (4) vertical positions that a Navigator Master Tube can be placed. If disassembling the screw from the Implant or Analog Mount, ensure reassembly of the correct screw length with the appropriate mount body [Fig. 9].

During kit sterilization, allow for completion of a full dry cycle.

- Ensure that water does not pool into components that hold water (ie. MDR10).
- Take care to remove any blood or debris prior to sterilization.

All Navigator Instruments are reusable with required replacement of the Starter Drill and Twist Drill after ten (10) osteotomy preparations. Replacement of Tissue Punches, Implant Mounts, Bone Profilers and Bone Taps is recommended after 15 implant site uses.

- Due to the close interaction of the Navigator Instrumentation with the Master Tube and Drill Guidance Tube, instrumentation wear may be accelerated as compared to non-guided drills and components.
- Wear is also dependent on additional factors, including sterilization and bone densities.

Drill Positioning Handle replacement is recommended at the time of Twist Drill replacement to ensure optimal instrumentation performance, but should be used for no more than 15 osteotomy preparations.

Inspect all instruments under magnification (≥ 3x) for wear or damage prior to and following surgery. In the case of wear or damage, component replacement is necessary.

In the case that increased resistance is detected between instruments during surgery, discontinue use and inspect the components for wear or damage.

Do not use non-Parallel Walled Navigator Drills or Components with Navigator Surgical Guides as all instrumentation is designed specifically to work with the Navigator Master Tubes to maximize accuracy of preparation and placement of Zimmer Biomet Dental Implants.

Navigator Master Tubes (the Surgical Guide) should not be used for guidance when drilling into a stone or acrylic model, as this may damage the Master Tubes [Fig. 10].

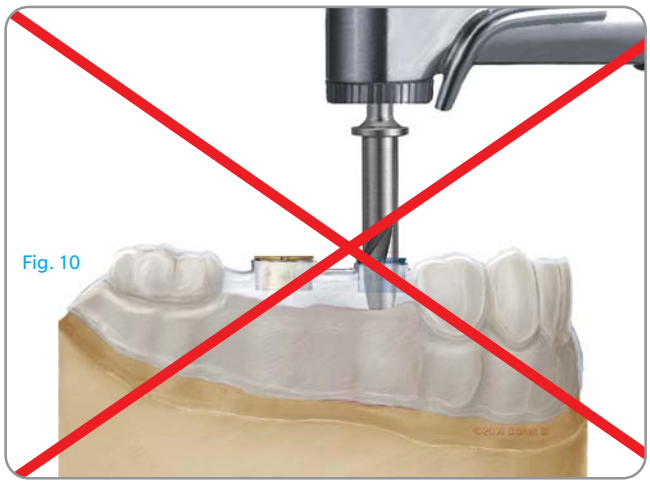


Fig. 10

Do not use the Navigator Drills on anything other than bone.

Looking for the latest in accurate implant treatment?

Try the **Navigator System** for guided surgery!

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Contact us at 1-800-342-5454 or visit

zimmerbiometdental.com

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