

Certain[®] Tapered Navigator[®] System

For Guided Surgery

Laboratory Manual



 **ZimVie**

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Congratulations

on choosing the industry leading instrumentation system in guided surgery!

The Tapered Navigator System for Guided Surgery is designed to allow clinicians to place and provisionalize implants using the CT planning software and surgical guides of their choice. The system is open architecture, meaning it is compatible with most of the currently available software and surgical guide providers on the market.

To utilize the Tapered Navigator System, clinicians will need to obtain the Kit and have access to a Cone Beam Scanner or CT scanning facility. In addition, laboratory technicians will need to obtain the Tapered Navigator Laboratory Kit to fabricate the preoperative master cast.



Treatment Considerations:

Patient Evaluation and Selection

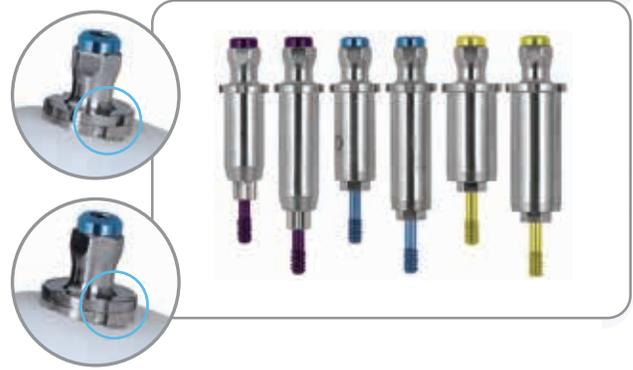
Several important factors must be considered when evaluating a patient prior to implant surgery. The presurgical evaluation must include a cautious and detailed assessment of the patient's general health, current medical status, medical history, oral hygiene, motivation and expectations. Factors such as heavy tobacco use, masticatory function and alcohol consumption should also be considered. In addition, the clinician should determine if the case presents an acceptable anatomical basis conducive to implant placement. An extensive intraoral examination should be undertaken to evaluate the oral cavity for any potential bone or soft-tissue pathology. The examiner should also determine the periodontal status of the remaining teeth, the health of the soft tissue and the presence of occlusal abnormalities such as bruxism or crossbite. The presence of other conditions that could adversely affect any existing natural dentition or healthy soft tissue surrounding the implant should also be evaluated.

Surgical Components

Kit Components

Implant Mounts

Implant mounts are used through the master tubes in the surgical guide to place implants. The implant mounts have the Certain Connection and are available in three diameters (3.4, 4.1 and 5 mm) and two prolongations identified as (S) and (L) for a total of six unique implant mounts. Because a specific implant mount may be required multiple times, four complete sets of implant mounts are available in the kit for a total of 24 implant mounts. The implant mounts must be fully engaged with the implant prior to tightening the implant mount screw using a hex driver. The implant mounts must be advanced as far as possible through the master tube prior to activating the handpiece. The instrument must then be progressed until the flange contacts the master tube. Cutouts on the flange can be used as a visual reference during implant placement to orient the hex connection of the implant. A cutout is aligned with a slot on the Master Tube to ensure accurate transfer of the hex orientation from the preoperative master cast to the mouth.



Tissue Punches

Tissue punches are used through the master tubes in the surgical guide (until bone contact occurs) to remove soft-tissue for flapless surgery. Tissue punches are available in two diameters (4 and 5 mm) and one length. Each tissue punch accommodates two prolongations. The (S) prolongation is designated by the laser line, with the top of the tissue punch representing the (L) prolongation. Depending on the planned depth of the implant (i.e., subcrestal), these references may not coincide with the top of the master tube. Discontinue use of the instrument once the cutting edge of the tissue punch makes bone contact.

The recommended drill speed is 300 rpm.



Cortical Perforators

Cortical perforators are used through the master tubes in the surgical guide to perforate the cortical plate. The cortical perforators are available in two diameters (4 and 5 mm) and two prolongations (S and L). The cortical perforators must be advanced as far as possible so that the guide body (the cylindrical portion of the instrument, which is guided by the master tube) is engaged within the master tube prior to activation. The cortical perforators must then be progressed until the flange contacts the master tube.

The recommended drill speed is 1200 rpm.



Twist Drills

The Navigator Twist Drills are used to prepare the osteotomy for implant placement through the surgical guide. Once the surgical guide is in place, the twist drill with the twist drill positioning handle is inserted into the master tube within the surgical guide. The twist drills are to be inserted as far as possible through the drill positioning handle into the osteotomy prior to activation. The drills are depth-specific and incorporate flanges to stop the drills when contact is made with the twist drill positioning handle. Twist drills are available in one diameter (1.9 mm) and seven lengths (a, b, c, d, e, f and g).

The recommended drill speed is 1200 rpm.



Twist Drill Positioning Handle

The twist drill positioning handle contains two drill guide tubes (4 and 5 mm) that are placed within the respective master tubes of the surgical guide to guide and stop the twist drills at a predetermined depth for preparation of the osteotomy. The twist handle must be fully seated within the corresponding master tube prior to twist drill engagement.



Countersink Drills

Countersink drills are available in three diameters (3, 4 and 5 mm) and two prolongations (S and L). The countersink drills must be advanced as far as possible so that the guide body of the drill is engaged within the master tube prior to activation. The countersink drills must then be progressed until the flange contacts the master tube.

The recommended drill speed is 800 rpm.



Countersink Shaping Drills

Shaping drills are available in three diameters (3.25, 4 and 5 mm), two prolongations (S and L) and five lengths (8.5, 10, 11.5, 13 and 15 mm). In some instances, as specified in the Surgical Plan (for 5 mm implants in dense bone), the 4 mm diameter shaping drills will be used in conjunction with a reduction handle. The shaping drills must be advanced as far as possible so that the guide body of the drill is engaged within the master tube and/or reduction handle prior to activation. The instrument must then be progressed until the flange contacts the master tube and/or reduction handle.

The recommended drill speed is 800 rpm.



Reduction Drill Positioning Handle

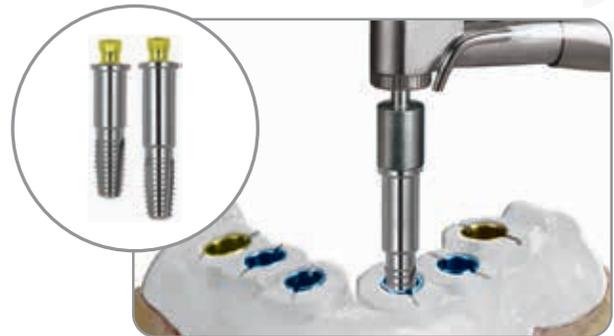
The reduction drill positioning handle contains one drill guide tube that fits into the 5 mm diameter master tube, and is used with 4 mm diameter shaping drills for dense bone. The reduction handle must be fully seated within the master tube prior to starting the shaping drill.



Bone Taps

The bone taps are available in three diameters (3.25, 4 and 5 mm), two prolongations (S and L), and five lengths (8.5, 10, 11.5, 13, and 15 mm). The bone taps must be advanced as far as possible through the master tube prior to activation. The instrument must then be progressed until the flange contacts the master tube.

The recommended drill speed is 20 rpm.



Bone Profilers

Hand-held bone profilers are available to manually remove crestal bone for proper abutment seating after the surgical guide is removed for 3.4, 4.1 and 5 mm diameter implants.



Implant Staging

The Tapered Navigator Kit contains eight implant holder slots to hold the inner packaging of the Tapered Implants. Implants can be manually pre-mounted here in preparation for placement.



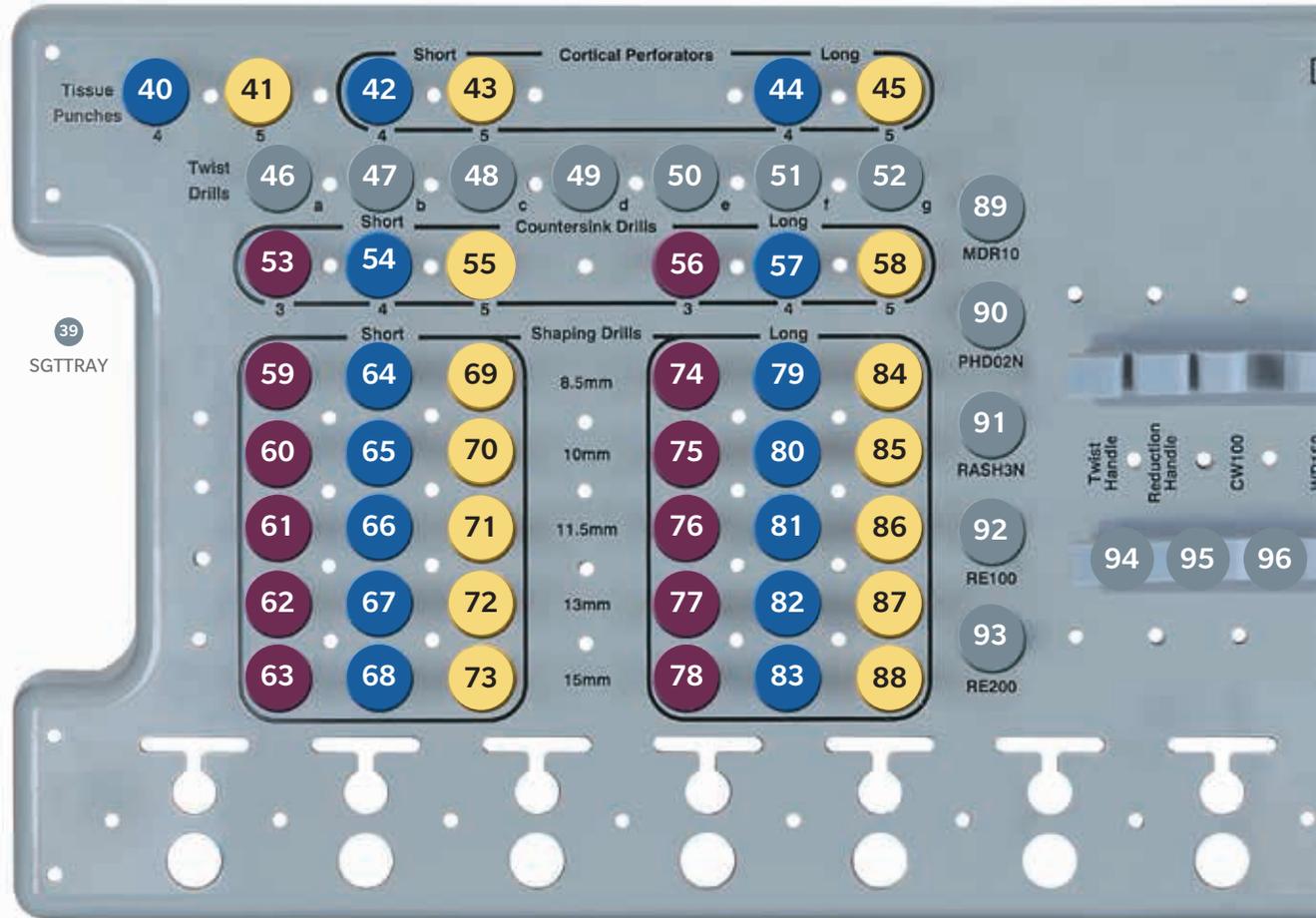
Miscellaneous Tools

Miscellaneous standard drivers and ratchets are included in the system to place Certain Tapered Implants. These tools include the following: PHD02N, RASH3N, MDR10, CW100, WR150, RE100 and RE200.



Surgical Kit Assembly Layout

Surgical Kit (Top Tray)

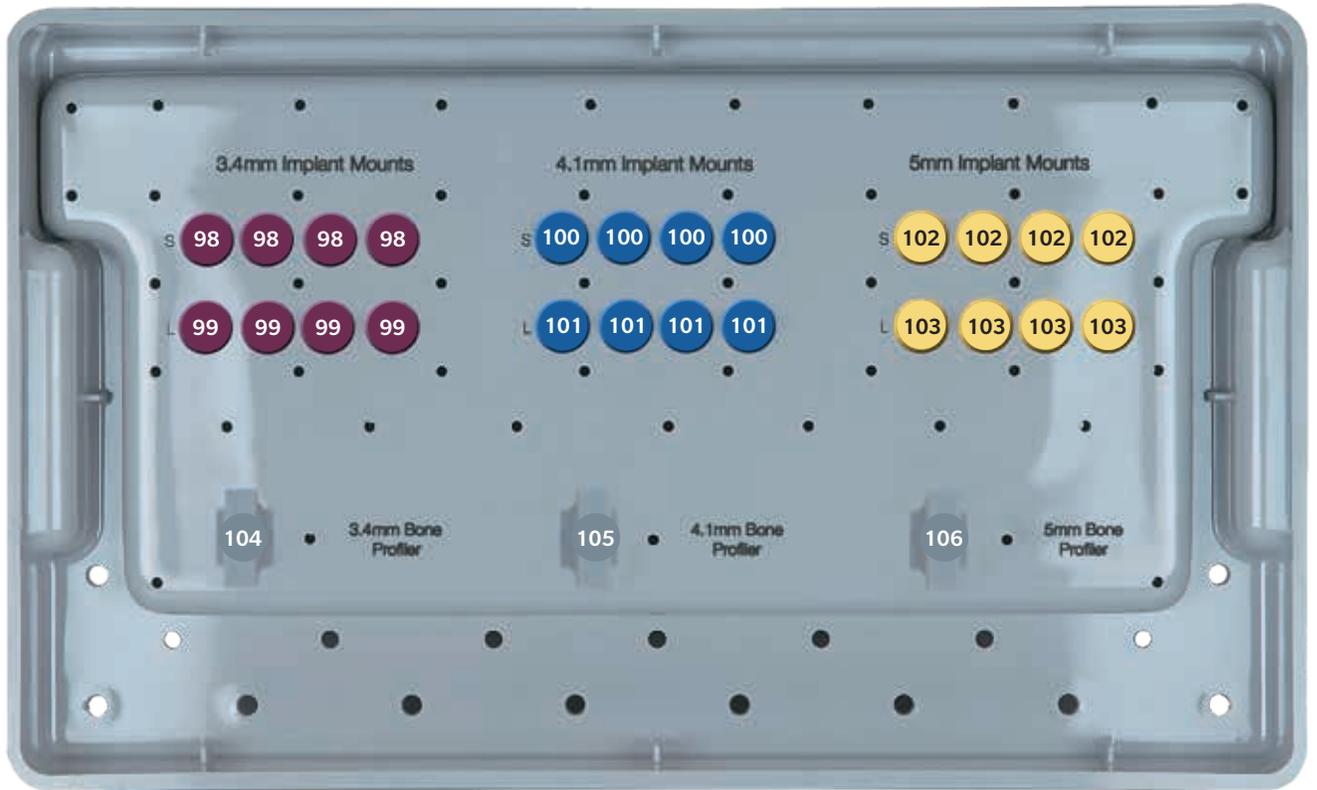




Implant Mount Assembly Layout

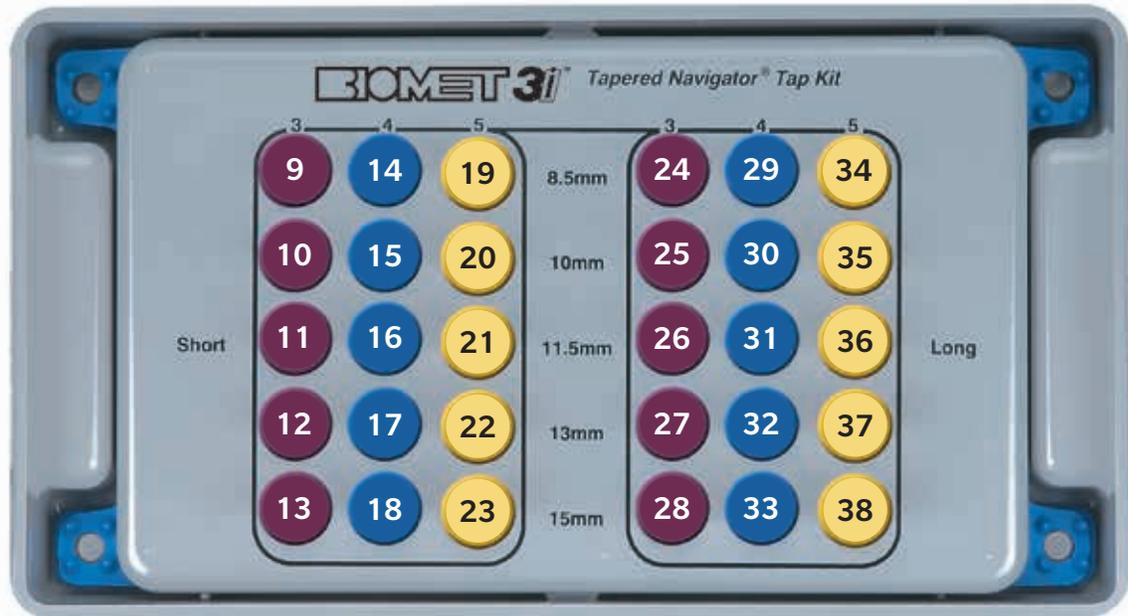
Surgical Kit (Bottom Tray)

39
SGTRAY



Tap Kit Assembly Layout

8
SGTTAPT

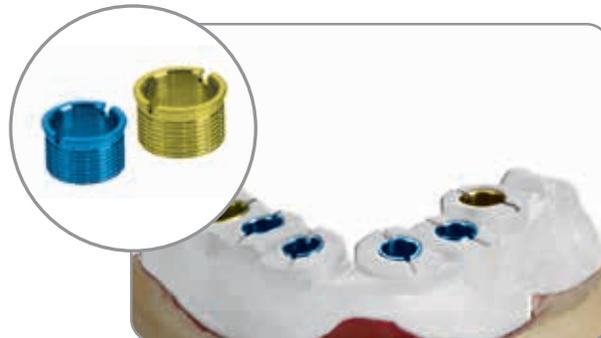


Laboratory Components

Master Tubes

Master tubes guide the instruments and provide depth control through the surgical guide. Instrumentation for the 3.25 mm and 4 mm diameter implants are guided by the blue (4 mm) master tubes, and the yellow (5 mm) master tubes are used for 5 mm diameter implants. The Master Tubes are positioned in the surgical guide by the surgical guide manufacturer.

The "slot" feature on the Master Tubes is used for alignment with the Analog Mounts for analog placement when fabricating the master cast and for alignment with the implant mounts and implants during surgery.



Implant Analog Mounts

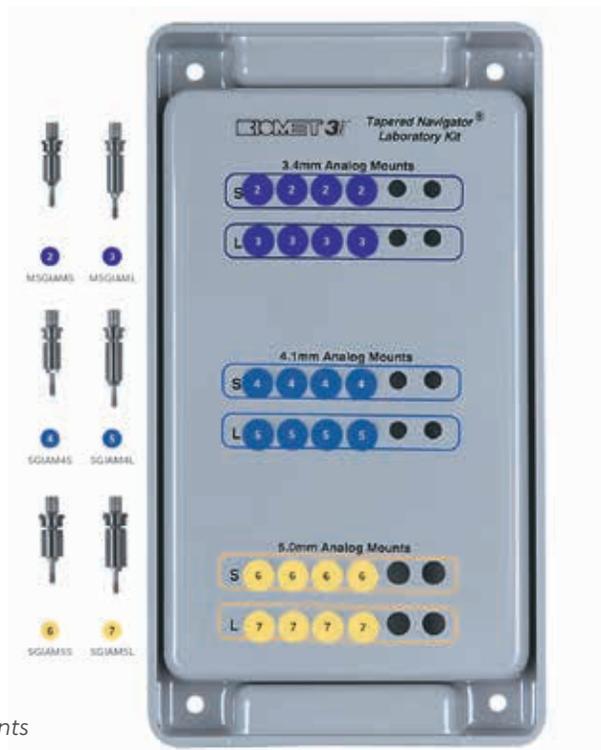
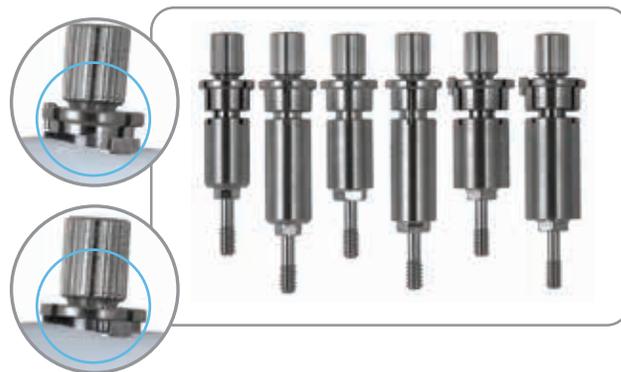
The Tapered Navigator Laboratory Kit is comprised of implant analog mounts used through the master tubes in the surgical guide to position implant analogs into a cast. The laboratory kit, like the surgical kit, contains six unique mounts with the Certain Connection (3.4, 4.1 and 5 mm diameters, and two prolongations identified as (S) and (L)). Because a specific analog mount may be required multiple times, there are a total of 24 (six sets of four) in the laboratory kit. The analog mounts feature a mechanical-locking system to hold the implant analog in place (vertically, laterally and rotationally) within the master tube. A peg on the side of the analog mount engages one of the slots on the master tube to ensure accurate transfer of the hex orientation from the preoperative master cast to the mouth. This feature is what allows clinicians to place and provisionalize implants on the same day.

Place the implant analog onto the analog mount and thread the thumb screw approximately two turns. Place the analog mount and implant analog assembly through the master tube, engage the pin into the slot and tighten the thumb screw using the square driver. Over-tightening the analog mounts outside of the master tubes may damage the analog mounts.

The Tapered Navigator System is also compatible with the implant analog mounts contained in the Navigator Laboratory Kit for Parallel Walled implants [SGLKIT].* The prolongation correlations are as follows:

	SGLKIT	SGTILKIT
Depth/Prolongation	(2)	(S)
Depth/Prolongation	(4)	(L)

***Note:** All other Parallel Walled Navigator Components and instruments are not compatible with Tapered Navigator Surgical Guides.



Procedural Overview

Steps to Success:

1. The scanning appliance may be created from an existing denture or new wax-up to visualize the soft-tissue and tooth position in the third party planning software chosen.
2. A CT scan of the patient is performed by an imaging center or in the clinician's office. Data from the scan is converted into the planning software.
3. The clinician plans the case within the planning software and the case plan is sent to the Surgical Guide manufacturer. Fixation of the Surgical Guide can also be planned at this time.
4. The Surgical Guide manufacturer develops a case-specific Surgical Plan and Surgical Guide.
5. The Surgical Plan and Surgical Guide are sent to the dental laboratory or restorative doctor and used in conjunction with the Tapered Navigator Laboratory Kit (if no immediate provisional restoration is desired, go to step 8).
6. The master cast is poured into the Surgical Guide or the Implant Analogs are placed in the preoperative cast on a partially edentulous case using the Surgical Guide and Navigator Analog Mounts.
7. The abutments are selected and the provisional restoration is fabricated and sent to the clinician.
8. The Surgical Guide and Surgical Plan are sent to the surgeon and used in conjunction with the Tapered Navigator Surgical Kit.
9. The Surgical Guide is placed and may be fixated with 2 mm fixation screws.
10. The clinician will prepare the site(s) with the case-specific Surgical Plan and Surgical Guide for implant placement with the Tapered Navigator Surgical Kit.
11. The implants are placed through the Surgical Guide utilizing the Navigator Implant Mounts.
12. The Implant Mounts and Surgical Guide are removed.
13. If a traditional procedure is desired, a one or two-stage procedure is completed and a traditional provisional restoration – denture/Maryland Bridge/flipper partial – may be delivered.
14. If the case is planned for immediate provisionalization, the abutments and the provisional restoration are delivered.

Surgical Planning

The Tapered Navigator System For Guided Surgery works in conjunction with the surgical plan provided by the CT-planning software company and/or the surgical guide manufacturer/laboratory. Each Surgical Plan is case-specific to provide direction regarding the instrumentation that will be used for each implant site, including the additional steps required for dense bone and the instrument speed recommendations.

Implant Label	#1	#2	#3	#4	#5
Implant Catalog Code	INT515	NIITP4315	INT413	INT3215	NINT3210
Implant Catalog Diameter (mm)	5	4	4	3.25	3.25
Implant Catalog Length (mm)	15	15	13	15	10
Implant Placement					
Prolongation	Short	Long	Long	Short	Long
Tissue Punch	5	4	4	4	4
Cortical Perforator	5(S)	4(L)	4(L)	4(S)	4(L)
Twist Drill / Handle - Side	e / T - 5	g / T - 4	f / T - 4	e / T - 4	d / T - 4
Countersink Drill	5(S)	4(L)	4(L)	3(S)	3(L)
Shaping Drill [^]	4 x 11.5 (S) / R*	3.25 x 13 (L)	3.25 x 13 (L)	-----	-----
Shaping Drill [^]	4 x 15 (S) / R*	-----	-----	-----	-----
Shaping Drill	5 x 10 (S)	4 x 10 (L)	4 x 13 (L)	3.25 x 10 (S)	3.25 x 10 (L)
Shaping Drill	5 x 15 (S)	4 x 15 (L)	-----	3.25 x 15 (S)	-----
Tap [^]	5 x 15 (S)	4 x 15 (L)	4 x 13 (L)	3.25 x 15 (S)	3.25 x 10 (L)
Implant Mount	5(S)	3(L)	4(L)	3(S)	3(L)
Bone Profiler	5	-----	4	3	3
Analog Placement					
Analog Mount	5(S)	3(L)	4(L)	3(S)	3(L)
Analog Type	IILAW5	IMMILA	IILA20	IMMILA	IMMILA

[^]These Additional Steps are Required for Dense Bone. R* Designates that the Reduction Handle Must be Used during this Step.

The prolongation, defined as the vertical relationship between the implant platform and master tube, is determined for each implant site by the surgical guide manufacturer/laboratory. The Tapered Navigator System For Guided Surgery has two prolongations: Short and Long or (S) and (L).

The Surgical Plan specifies the prolongation (S and L) for instruments that pass directly through the surgical guide master tubes including the tissue punches, cortical perforators, countersink drills, shaping drills and bone taps. The tissue punches have landmarks referenced as (S) and (L) that indicate the approximate depth to which this instrument should be used through the master tubes (Figure 1). The tissue punches pass through the master tube until the center of the specified line on the instrument reaches the top of the master tube [Fig. 2]. Depending on the planned placement of the implant (i.e., subcrestal), these references may not coincide with the top of the master tube. Discontinue use of the instrument once the cutting edge of the tissue punch makes bone contact. All other instruments that pass through the guide should progress until the flange contacts the master tube.



The prolongation also determines which implant mount and implant analog mount must be used. The mounts are labeled by diameter and prolongation. Therefore, a 4 mm implant with a short prolongation will be specified as 4(S).

The Tapered Navigator System is also compatible with the analog mounts contained in the Parallel Walled Navigator Laboratory Kit [SGLKIT]. The prolongation correlations are as follows:

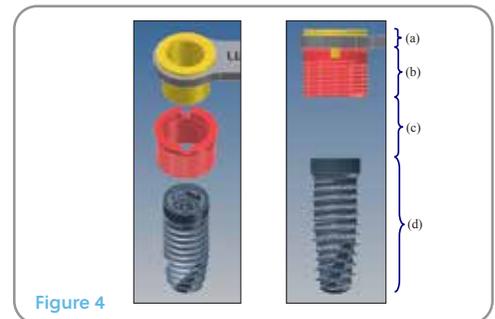
	SGLKIT	SGTILKIT
Depth/Prolongation	(2)	(S)
Depth/Prolongation	(4)	(L)

***Note:** All other Parallel Walled Navigator Components and instruments are not compatible with Tapered Navigator Surgical Guides.

Tips and Techniques

Planning Considerations

- 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. Fixation points planned into the vestibular aspect of the Surgical Guide allow for insertion of the fixation screws while the patient occludes into the bite registration.
- Consider interarch space when planning implant lengths 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.
- When planning implant placement within the planning software, an additional length of 0.6 mm beyond the apex of the implant must be included to accommodate for the additional length of the Twist and Shaping Drill Tips.
- 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.
- Prolongation is defined as the vertical relationship between the implant platform and the Master Tube. 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 (Figure 3 and Figure 4). Please select appropriate implant lengths when treatment planning.
- **Following are the descriptions of dimensions (a), (b), (c) and (d):**
 - (a) Thickness of the Drill Guide Tube flange and Drill Positioning Handle = 1.5 mm
 - (b) Master Tube height = 4 mm
 - (c) Prolongation = 5 mm or 8 mm (Short, "S", or Long, "L", respectively)
 - (d) Implant length = 8.5, 10, 11.5, 13 or 15 mm (catalog length, not actual length)
 - [(b) + (c)] Mount length = 9 mm or 12 mm (Short, "S", or Long, "L", respectively)
 - [(b) + (c) + (d)] Overall cutting length for the final Shaping Drill and Bone Taps
 - [(a) + (b) + (c) + (d)] Overall cutting length for the Twist Drills
- 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.



- 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: 9.0 and 12.0 mm.
- 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) (Figure 5).
- 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, 7.0 mm is needed between 4.0 mm implants, with 8.0 mm needed between 5.0 mm implants (Figure 6).



Figure 5



Figure 6

Preparation for Surgery

- Review the Surgical Plan and identify the respective instruments within each kit prior to surgery. Be aware of the specified prolongation, (S) or (L). Within the Surgical Plan, (S) and (L) specify the prolongation for each implant site.
- Inspect the Surgical Guide for imperfections and reinforce potential weak areas of the Surgical Guide with acrylic resin. Inspect the Master Tube(s) to ensure that no fabrication material remains inside from the Surgical Guide manufacturer.

Quick Tip:

Prior to surgery, try in a Drill Positioning Handle in each Master Tube to determine if the Surgical Guide needs 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 slot position on the Surgical Guide to record the hexorientation landmarks (Figure 7). To verify hex orientation at the time of implant placement, a periodontal probe or curet will confirm alignment of the Implant Mount and Master Tube by engaging the aligned slots.
- To ensure proper guidance of the instrumentation through the Master Tube(s) and Drill Positioning Handle(s), all steps outlined in the Surgical Plan are required, with the exception of the Tissue Punch in cases where a flap is elevated. The Surgical Plan specifies additional steps required in dense bone scenarios.
- 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 Tube(s) in the Surgical Guide provides little tactile confirmation of bone density.

Quick Tip:

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



Figure 7

Surgery

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.

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.

- Orthodontic wire may provide additional Surgical Guide stabilization for tooth-supported cases.
- All instrumentation should be advanced as far as possible through the Master Tube(s) or the Drill Positioning Handle(s) and into the osteotomy prior to activation. This will limit the possibility of damaging either the instruments or the tube(s) (Figure 8).

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(s). Pre-drilling access holes below and/or adjacent to the Master Tube(s) may be considered to promote site irrigation.

Irrigate and suction the osteotomy and tubes to remove debris between each step of the Surgical Plan and prior to implant placement.

Quick 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 applying lateral force on the instrumentation during use, as this may cause damage or premature wear.

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 (Figure 9).

Quick 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.

Figure 8



Figure 9



When using the Implant Mounts and Bone Taps, progress the instruments until the instrument flange contacts the Master Tube. It is recommended to use the WR150 Ratchet Wrench with extension for final rotations of these instruments. Once seated, do not continue to rotate these instruments as this can cause damage to the instrumentation or osteotomy (Figure 10).

The Implant Mounts must be fully engaged within the implant prior to tightening the Implant Mount Screw.

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. For cases requiring more than two (2) implants, removal of the subsequent Implant Mounts immediately following implant placement will reduce divergent forces on the Surgical Guide.

When removing Implant Mounts, remove along the path of insertion and avoid applying lateral force. A slight counter-clockwise torque applied to the Implant Mount with the CW100 may assist with Implant Mount removal.

Quick Tip:

Use a Bone Profiler prior to placing an abutment or any type. Use an oversized Bone Profiler when placing pre-angled abutments.

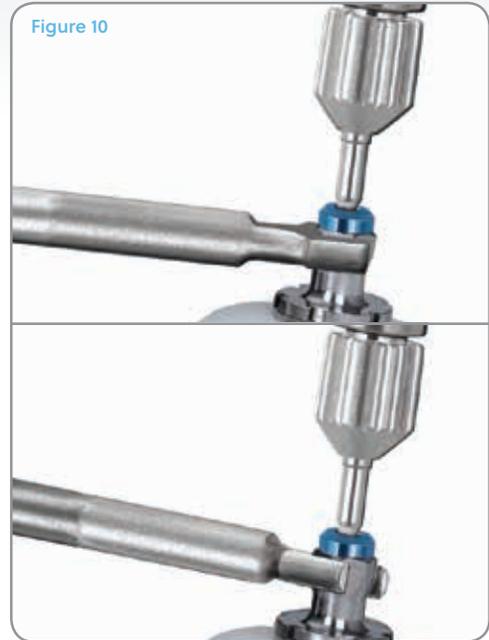


Figure 10

Instrumentation Care

The screw held within the Implant and Analog Mounts is available in two different lengths to accommodate the vertical positions that a Tapered 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 (Figure 11).

All Tapered Navigator Instruments are reusable with required replacement after fifteen (15) implant site uses.

- Due to the close interaction of the Tapered Navigator Instrumentation with the Master Tube(s) and Drill Positioning Handles, 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.

Inspect all instruments under magnification ($\geq 3\times$) 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 instrument resistance is detected within the Master Tube(s) or Drill Positioning Handles during surgery, discontinue use and inspect the components for wear or damage.

Do not use non-Tapered Navigator Drills or components with Tapered Navigator Surgical Guides, as all instrumentation is designed specifically to work with the Tapered Navigator Master Tube(s) to maximize accuracy of preparation and placement of ZimVie Dental Certain Tapered 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 (Figure 12).

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



Figure 11



Figure 12

*Please refer to ART630 for complete instructions on the sterilization and care of stainless steel.

Immediate Provisionalization Option

A key benefit of using the ZimVie Dental Tapered Navigator System For Guided Surgery is the option to use the Surgical Guide to create a preoperative master cast and a fixed provisional restoration in the laboratory prior to the day of surgery. This may allow the clinician to insert a provisional restoration immediately following implant placement using the Surgical Guide to provide the patient with aesthetic and functional teeth the same day.

Pages 20-31 in this manual are designed to guide surgeons, restorative clinicians and laboratory technicians through the process of fabricating a preoperative master cast and a provisional restoration for insertion following the placement of ZimVie Dental Implants using the Tapered Navigator System For Guided Surgery. The CT software company may also offer the option of fabricating a stereolithographic model for use in creating a master cast.

The provisional restoration may be fabricated using a variety of ZimVie Dental Provisional Components. These components and manual guidelines were developed to provide an easy to use way to deliver an accurately fitting provisional restoration on the day of surgery regardless of potential error from CT scan data, cast fabrication or implant placement. When selecting the provisional component to use, it is important to identify the type of definitive restoration and the abutment system that will be used to create it. The chart below includes recommendations that a clinician may want to consider for provisional component selection dependent upon the type of definitive restoration planned.

Provisional Component Selection Guide			
Provisional Component	Seating Platform	Provisional Restoration	Definitive Restoration
PreFormance Posts	Direct To Implant	Cement-Retained	Cement- Or Screw-Retained
PreFormance PEEK Or Titanium Temporary Cylinders	Direct To Implant	Screw-Retained	Cement- Or Screw-Retained
QuickBridge® Provisional Restoration Components	Abutment Level (For Low Profile Abutments Only)	Cement-Retained	Screw-Retained

Fabrication of Dentures and Provisional Restorations

New or Partial Denture and CT Scanning Appliance

1. Clinician

Make impressions of the maxillary and mandibular arches.

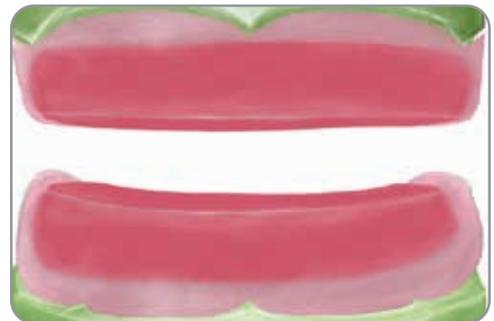
Quick Tips:

- The use of a scanning appliance is required in fully edentulous cases and recommended in all multiple-unit cases.
- The scanning appliance and scanning protocol will be dependent on the planning software utilized.



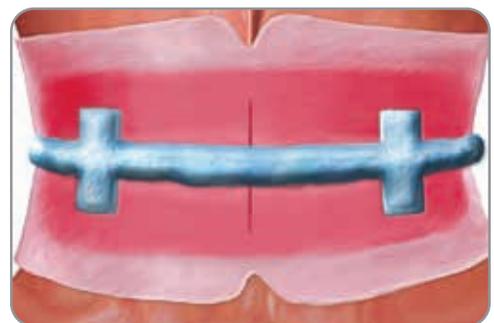
2. Laboratory

Pour the maxillary and mandibular impressions in die stone. Fabricate baseplate(s) and wax occlusal rim(s) on the cast(s).



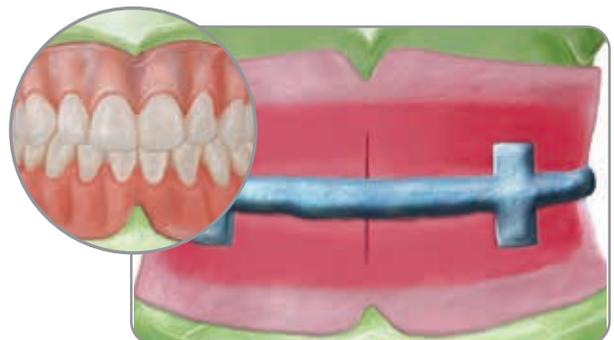
3. Clinician

Place the wax occlusal rim(s) in the mouth, contour appropriately and make an interocclusal registration.



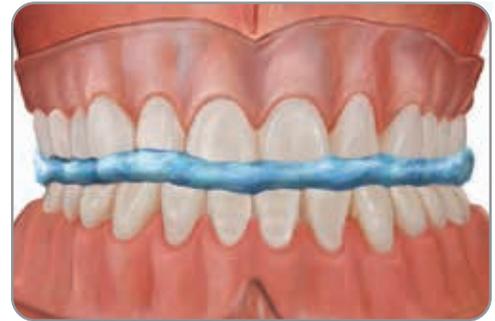
4. Laboratory

Articulate the maxillary and mandibular casts using the interocclusal registration. Set denture teeth on the baseplate(s) and wax for try in.



5. Clinician

Place the wax try-in(s) in the mouth. Verify the occlusion, aesthetics and phonetics. Make any adjustments necessary. If major adjustments are necessary, make a new interocclusal registration.



6. Laboratory

Wax the denture for the arch in which implants will be placed for processing, and flask it. Separate the flask, and boil away the wax. Process, finish and polish the denture. Using a denture duplication flask, mix the duplication material and place it into one side of the flask. Place the patient's existing denture into the material with the soft-tissue side down. Allow the duplication material to set per the manufacturer's instructions. Apply a separator to the surface. Mix the duplication material and place it into the other side of the flask and close the flask over the denture. Allow the duplication material to set. Separate the flask and remove the denture.



7. Create a mixture of 30% barium sulfate and cold-cure acrylic resin. Pour the mixture into the tooth areas only. Allow the acrylic resin to set per the manufacturer's instructions. Create a mixture of 10% barium sulfate and coldcure acrylic resin. Pour the mixture into the flask. Close the flask tightly. Allow the acrylic resin to set.

Quick Tip:

Both single-scan (barium-sulfate scanning appliance) and dual-scan (gutta percha marked scanning appliance) protocols are possible with the Navigator System.



8. Remove the CT scanning appliance from the flask, finish and polish. Place the appliance on the cast. Place the cast on the articulator and make an interocclusal registration. The scanning appliance is returned to the clinician for the CT scan and the occlusal registration is set aside for later use.



CT Scanning Appliance Using an Existing Denture

1. Clinician or Laboratory

Using a denture duplication flask, mix the duplication material and place it into one side of the flask. Place the patient's existing denture into the material with the soft-tissue side down. Allow the duplication material to set per the manufacturer's instructions. Apply a separator to the surface. Verify the occlusion duplication material and place it into the other side of the flask and close the flask over the denture. Allow the duplication material to set. Separate the flask and remove the denture.



2. Create a mixture of 30% barium sulfate and cold-cure acrylic resin. Pour the mixture into the tooth areas only. Allow the acrylic resin to set per the manufacturer's instructions. Create a mixture of 10% barium sulfate and cold-cure acrylic resin. Pour the mixture into the flask. Close the flask tightly. Allow the acrylic resin to set.



3. Remove the CT scanning appliance from the duplication flask, finish and polish.



4. Clinician

Place the CT scanning appliance in the mouth and equilibrate. Make an interocclusal registration. Send the scanning appliance with the patient for the CT scan and set aside the interocclusal registration for later use

Quick Tip:

- Create a bite registration from radiotranslucent material to confirm proper positioning of the scanning appliance during CT scanning.
- Confirm that the seating 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.



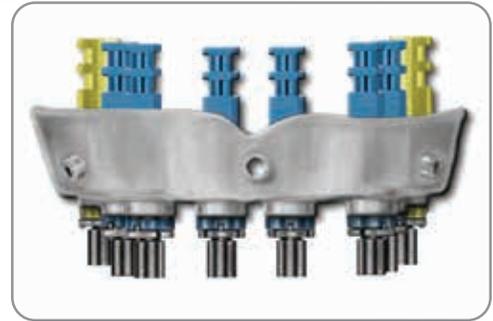
Pre-Surgical of an Edentulous Fixed Provisional Restoration Fabrication of Master Cast, Articulation and Vacuum Formed Template

1. Laboratory

Select the proper diameter and length Analog Mounts for each implant position following the instructions provided by the Surgical Guide manufacturer. Place the Implant Analogs onto the Analog Mounts, line up the hexes and thread the thumb screws into these approximately two turns. Place the Analog Mount/ Analog assemblies through the Master Tubes, engage the rotational positioning pin into the notch and tighten the thumb screws using the Square Driver.

Quick Tip:

Over-tightening the Analog Mounts outside of the Master Tubes may damage the Analog Mounts.



2. Bead and box the Surgical Guide using rope wax. Apply a stone separator around the inside of the guide. Syringe soft-tissue material around the analogs approximately 2 mm apical from the interface of the Analog Mount. Pour stone into the Surgical Guide to create the master cast and allow it to set. Unscrew the thumb screws and remove the Analog Mounts. Carefully separate the Surgical Guide from the master cast.



3. Place the scanning appliance on the master cast and verify the fit and tooth position. Articulate the master cast with the opposing cast using the scanning appliance and the interocclusal registration.



4. Make a vacuum formed template over the scanning appliance on the cast. Remove the template and the scanning appliance and separate those. Continue on to step 5 for abutment selection and provisional restoration fabrication.

Proceed to:

Page 24 for screw-retained PreFormance Temporary Cylinder.

Page 26 for screw-retained Low Profile Abutment and Temporary Cylinder.



Screw-Retained PreFormance® Temporary Cylinder

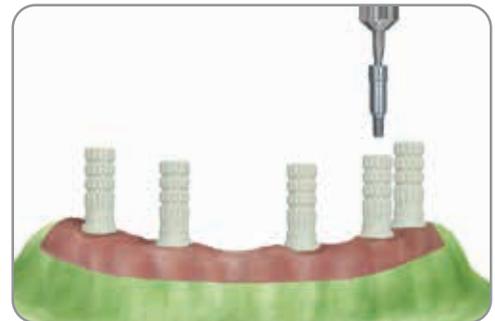
Continued from Laboratory Procedure (Steps 1-4) on page 20.

Abutment Selection

5. PreFormance Temporary Cylinders are designed to allow acrylic resin to be added to develop the desired subgingival and supragingival contour to the restoration. The hexed cylinder is used for single-units and the non-hexed cylinder is used for multiple-unit provisional restorations. Match the color coding of the Implant Analog to determine the platform diameter.



6. Place the selected PreFormance Temporary Cylinders into each Implant Analog. Secure the abutments into place using a Certain Titanium Abutment Screw for hexed cylinders or a large diameter titanium abutment screw for non-hexed cylinders and the Large Hex Driver.

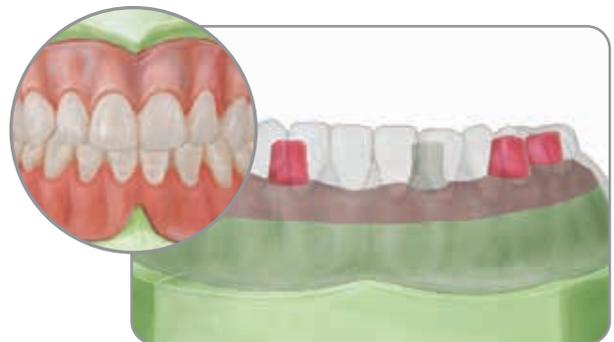


Provisional Restoration Fabrication

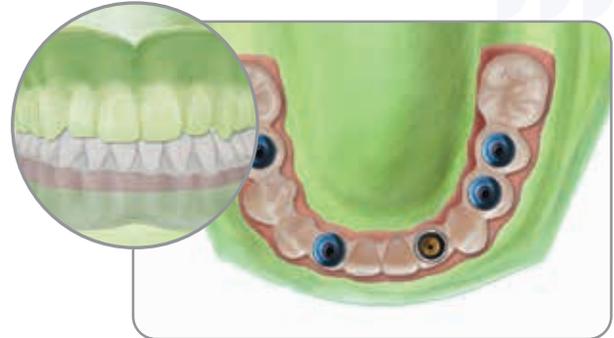
7. Drill holes in the vacuum formed template in the areas of the PreFormance Temporary Cylinders. Place the vacuum formed template on the master cast over the temporary cylinders. Reduce the cylinders as necessary so that these fit within the template using a carbide bur. Seal the cylinder screw access openings with wax or putty. Select one cylinder in an area with dense bone to process it into the provisional restoration. Block out the retention facets on all other cylinders with wax. Place the cast back on the articulator. Add acrylic resin into the retention facets on the selected cylinder and fill the tooth portion of the template with acrylic resin. Fully seat the template on the cast over the temporary cylinders using the articulation. Allow the acrylic resin to set per the manufacturer's instructions.

Or

Duplicate the master cast with the PreFormance Temporary Cylinders in place. Articulate, wax the provisional restoration on the duplicate cast and process it in acrylic resin.



- Clear the cylinder screw access opening and remove the abutment screw from the selected cylinder. Remove the template from the cast over the nonprocessed cylinders with the selected temporary cylinder inside the acrylic resin. Remove the provisional restoration from the template. Remove all excess acrylic resin from around the margin areas of the provisional restoration. Relieve the holes for the other cylinders as necessary so that the provisional restoration can be placed over those and removed easily. Fill in any voids. Finish the restoration to the desired contour and polish.



CT Guided Surgical Implant Placement

9. Clinician

Place the implants using the Surgical Guide and following the Surgical Guide provided by the guide manufacturer. See page 14 for an example of a Surgical Plan.



Post-Surgical Delivery of Provisional Restoration

- Place a PreFormance Temporary Cylinder on the implant that is on the opposite of the arch from the selected lab-processed cylinder. Secure the cylinder into place using an abutment screw and the Large Hex Driver. Seal the screw access opening with impression material. Try in the provisional restoration over the PreFormance Temporary Cylinder and secure it into place by threading an abutment screw through the lab-processed cylinder. Verify that it fits to the cylinder margins properly. Adjust the occlusion as indicated and remove the provisional restoration.



- Place acrylic resin into the retention facets on the PreFormance Temporary Cylinder and into the cylinder area on the provisional restoration. Seat the provisional restoration over the cylinder and secure it into place by threading an abutment screw through the lab-processed cylinder. Have the patient close into centric occlusion. Allow the acrylic resin to set per the manufacturer's instructions. Remove the abutment screws and remove the provisional restoration. Place the remaining cylinders on the implants and lute these into the provisional restoration by repeating the prior steps. Fill in any voids. Remove any excess acrylic resin and polish. Secure the provisional restoration into place with the titanium abutment screws using the Large Hex Driver. Torque the screws to 10 Ncm using the Large Hex Driver Tip and a torque device. Place a temporary filling material into the screw access openings and seal those with composite resin. Adjust the occlusion as indicated. If a flap procedure was used during surgery, suture the soft-tissue around the provisional restoration.

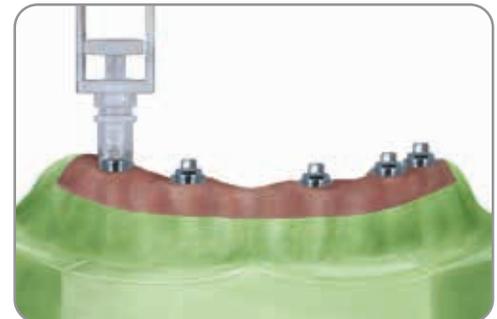


Screw-retained Low Profile Abutment and Temporary Cylinder

Continued from Laboratory Procedure (Steps 1-4) on page 20.

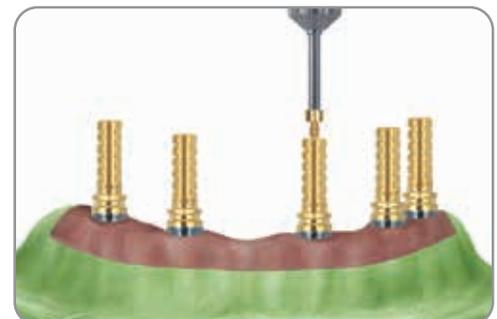
Abutment Selection

- Select the proper Low Profile Abutment collar height for each implant by measuring the soft-tissue depth on the buccal side at each location. If a 1 mm subgingival margin is desired, subtract 1 mm. Next, select the proper abutment angulation; straight, 17° or 30°. Allow approximately 3.5 mm of interarch distance between the top of the abutment and the opposing occlusion. Finally, match the color-coding of the Implant Analog to determine the platform diameter.
- Place the selected Low Profile Abutments into each Implant Analog and press firmly until feeling and/or hearing an audible and tactile click. Secure the abutments into place using the Low Profile Abutment Screws and the Abutment Driver.



Provisional Restoration Fabrication

- Select the appropriate Low Profile Temporary Cylinders for single or multiple units. Place a Low Profile Temporary Cylinder on each of the abutments. Secure the cylinders into place using the Low Profile Titanium Screw and the Large Hex Driver.

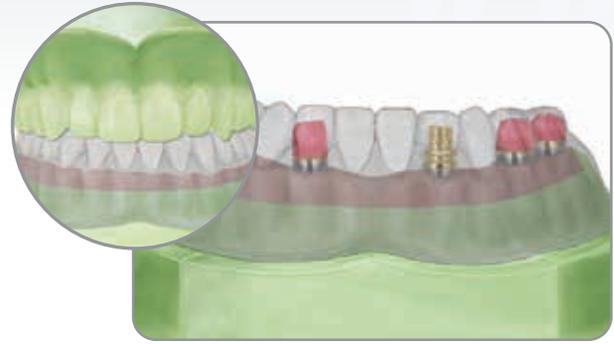


8. Drill holes in the vacuum formed template in the areas of the Low Profile Temporary Cylinders. Place the vacuum formed template on the master cast over the cylinders. Reduce the cylinders as necessary so that these fit within the template using a carbide bur. Seal the cylinder screw access openings with wax or putty. Select one cylinder in an area with dense bone to process it into the provisional restoration. Block out the retention facets on all other cylinders with wax. Place the cast back on the articulator. Add acrylic resin into the retention facets on the selected cylinder and fill the tooth portion of the template with acrylic resin. Fully seat the template on the cast over the cylinders using the articulation. Allow the acrylic resin to set per the manufacturer's instructions.

Or

Duplicate the master cast with the Low Profile Abutments and Temporary Cylinders in place. Articulate, wax the provisional restoration on the duplicate cast and process it in acrylic resin.

9. Clear the cylinder screw access opening and remove the retaining screw from the selected cylinder. Remove the template from the cast over the non-processed cylinders with the selected temporary cylinder inside the acrylic resin. Remove the provisional restoration from the template. Remove all excess acrylic resin from around the margin areas and fill in any voids. Relieve the holes for the other cylinders as necessary so that the provisional restoration can be placed over these and removed easily. Fill in any voids. Finish the restoration to the desired contour and polish.



CT Guided Surgical Implant Placement

10. Clinician

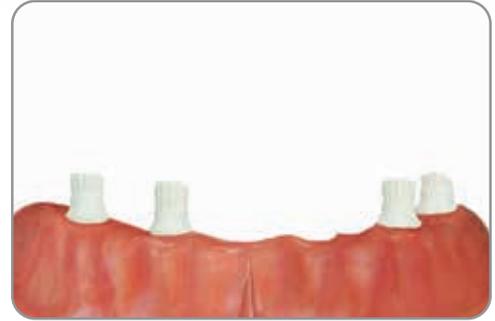
Place the implants using the Surgical Guide and following the Surgical Plan provided by the guide manufacturer. See page 14 for an example of a Surgical Plan.



Post Surgical Delivery of Provisional Restoration

11. Clinician

Place each Low Profile Abutment into the implants, one by one, in the proper locations. Press firmly until feeling and/or hearing the audible and tactile click. Thread the Low Profile Abutment Screws into the implants using the Abutment Driver. Verify an accurate fit of each abutment by visualizing the interfaces or by taking a radiograph. Torque the abutment screws to 20 Ncm using the Abutment Driver Tip and a torque device. Place a Low Profile Temporary Cylinder on an abutment on the opposite side of the arch from the selected lab-processed cylinder. Secure the cylinder into place using the Low Profile Titanium Screw and the Large Hex Driver. Seal the screw access opening with impression material. Try in the provisional restoration over the Low Profile Temporary Cylinder and secure it into place by threading a retaining screw through the lab-processed cylinder. Verify that it fits to the cylinder margins properly. Adjust the occlusion as indicated and remove the provisional restoration.



12. If a flap procedure was used during surgery, suture the soft-tissue around the Low Profile Abutments. Place acrylic resin into the retention facets on the Low Profile Temporary Cylinder and into the cylinder area on the provisional restoration. Seat the provisional restoration over the cylinder and secure it into place by threading a retaining screw through the lab-processed cylinder. Have the patient close into centric occlusion. Allow the acrylic resin to set per the manufacturer's instructions. Remove the Low Profile Titanium Screws and remove the provisional restoration. Place the remaining Low Profile Temporary Cylinders on the abutments and lute these into the provisional restoration by repeating the prior steps. Fill in any voids. Remove any excess acrylic resin and polish. Secure the provisional restoration into place with the Low Profile Gold-Tite® Retaining Screws using the Large Hex Driver. Torque the screws to 10 Ncm using the Large Hex Driver Tip and a torque device. Place a temporary filling material into the screw access openings and seal those with composite resin. Adjust the occlusion as indicated.



Pre-Surgical of a Partially Edentulous Fixed Provisional Restoration Fabrication of Master Cast, Articulation and Vacuum Formed Template

1. Laboratory

Select the proper diameter and length Analog Mounts for each implant position following the instructions provided by the Surgical Guide manufacturer. Place the Implant Analogs onto the Analog Mounts, line up the hexes and thread the thumb screws into these approximately two turns. Place the Analog Mount/ Analog assemblies through the Master Tubes, engage the rotational positioning notches and tighten the thumb screws using the Square Driver.

Quick Tip:

Over-tightening the Analog Mounts outside of the Master Tubes may damage the Analog Mounts.



2. Mark the planned implant locations on the preoperative cast and drill holes for each implant that is slightly larger in diameter than the Implant Analogs. Do not drill through the guide. Insert the Implant Analogs attached to the Surgical Guide into the holes, and seat the guide onto the remaining teeth on the cast. Fixate the analogs in the cast using stone or pattern resin. Unscrew the thumb screws and remove these. Remove the Surgical Guide from the master cast.



3. If a scanning appliance was fabricated on this cast, place it on the master cast and verify the fit and tooth position. Articulate the master cast with the opposing cast using the occlusal registration.



4. Make a vacuum formed template over the scanning appliance or diagnostic setup on the cast. Remove the template and the scanning appliance or setup and separate those.



Cement-Retained PreFormance Post

Continued from Laboratory Procedure (Steps 1-4) on page 20.

Abutment Selection

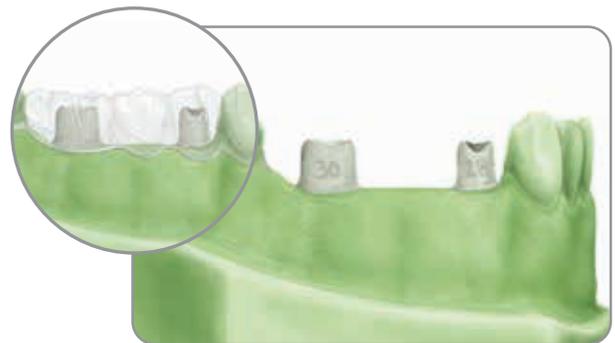
5. Measure the soft-tissue depth in the interproximal areas at each location and select the proper abutment collar height that will allow the margin to be at soft-tissue level or slightly below after preparation. Also, select the desired emergence profile and a straight or 15° angled PreFormance Post. Finally, match the color-coding of the Implant Analog to determine the platform diameter.



6. Place the selected PreFormance Posts into each Implant Analog. Line up the hexes and place the flat side of the post toward the buccal aspect. Press firmly until feeling and/or hearing the audible and tactile click. Secure the abutments into place using a Certain® Titanium Abutment Screw and the Large Hex Driver.



7. Prepare the margin of each PreFormance Post following the gingival contour at soft-tissue level or slightly below and prepare the post area for the proper draw of single or multiple units. A rough diamond bur is recommended. Number each abutment with the tooth position on the buccal side with a bur. Seal the abutment screw access openings with wax or putty.



8. Place the vacuum formed template on the master cast over the PreFormance Posts. Reduce the posts as necessary so that these fit within the template. Block out the undercuts on the adjacent teeth. Place the cast back on the articulator. Apply a separator to the posts and the casts. Fill the tooth portion of the template with acrylic resin. Fully seat the template on the cast over the abutments using the articulation. Allow the acrylic resin to set per the manufacturer's instructions.

Or

Duplicate the master cast with the abutments in place. Articulate, wax the provisional restoration on the duplicate cast and process it in acrylic resin.



- Remove the template from the PreFormance Posts. Remove the provisional restoration from the template. Remove all excess acrylic resin from around the margin areas and fill in any voids. Finish the restoration to the desired contour and polish.

Optional: Relieve each abutment area for the intraoral relinie of the provisional restoration.



CT Guided Surgical Implant Placement

10. Clinician

Place the implants using the Surgical Guide and following the Surgical Plan provided by the guide manufacturer. See page 14 for an example of a Surgical Plan.



Post Surgical Delivery of Provisional Restoration

- Place each PreFormance Post into the implants, one by one, following the tooth position numbers on the buccal aspect. Press firmly until feeling and/or hearing the audible and tactile click. Thread the Titanium Abutment Screw into each implant using the Large Hex Driver. Verify an accurate fit of each abutment by visualizing the interfaces or by taking a radiograph. Torque the abutment screws to 20 Ncm using the Large Hex Driver Tip and a torque device. Seal each screw access opening with a temporary filling material. Try in the provisional restoration over the PreFormance Posts and verify it fits to the margins properly. Adjust the occlusion as indicated and remove the provisional restoration.
- If the provisional restoration did not fit passively, place acrylic resin into each abutment area, seat the provisional restoration onto the abutments and have the patient close into centric occlusion. Allow the acrylic resin to set per the manufacturer's instructions. Remove the provisional restoration and fill in any voids. It may be necessary to remove the PreFormance Posts and place those into the provisional restoration to fill marginal voids. Remove any excess acrylic resin and polish. Place temporary cement into the provisional restoration, seat it on the abutments and have the patient close into centric occlusion. Remove any excess cement from around the margin areas. Allow the cement to set per the manufacturer's instructions. If a flap procedure was used during surgery, suture the soft-tissue around the PreFormance Posts and the provisional restoration.



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