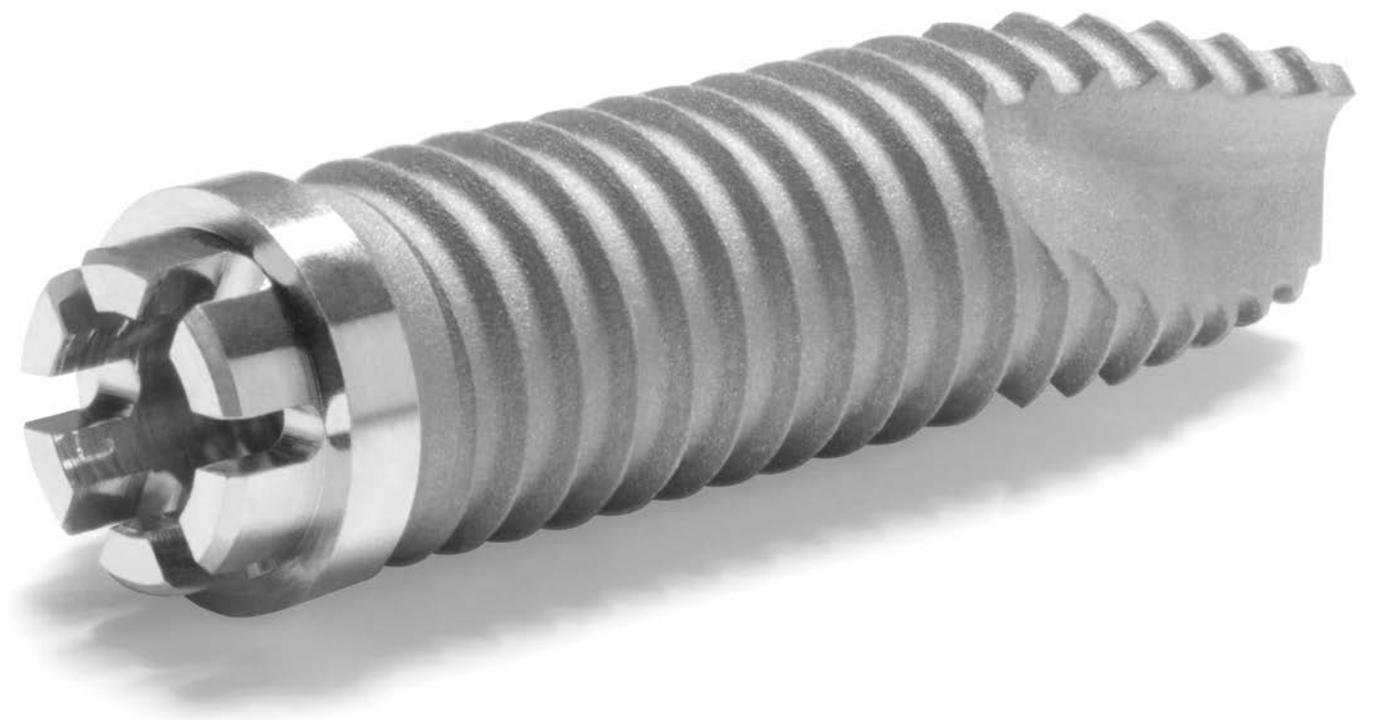


Spline® Implant System

Surgical Manual



Overview

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Spline System Product Color - Coding

Zimmer Biomet Dental's Spline color-coding system is located on the Spline Surgical Kit tray, certain Spline prosthetics and the product packaging. It provides simplicity at a glance by indicating the diameter compatibility of the product based on the stripe found on the package or surgical kit.

The chart indicates which color corresponds to each product interface diameter.

COLOR	PRODUCT DIAMETER COMPATIBILITY
Yellow	3.25 mm
Blue	3.75 mm & 4.0 mm
Green	5.0 mm
Black	Common products that are compatible with more than one diameter (i.e. 3.25 mm & 4.0 mm).

The Surgical Products Manual (SPM) is designed to provide a basic overview of the presurgical and surgical procedures applicable to Spline Implant Systems.

This manual is not intended for use as a substitute for professional training and experience. The clinician should use medically sound treatment planning and procedures appropriate for each patient's individual case for predictable results.

Team Approach

Successful implant treatment requires the coordinated efforts of several dental professionals – the restorative dentist, the surgeon (periodontist, oral surgeon, general dentist), the laboratory technician, and the dental hygienist. By holding a presurgical conference, these individuals are able to develop an appropriate treatment strategy. This provides a balance between esthetic, functional, and surgical goals. In addition, the coordinated approach ensures that treatment is complete, guarding against omission of important technical considerations such as the use of a surgical template for implant location.

Patient Evaluation & Selection

- Take a general medical history
- Undertake a psycho-social evaluation
- Explore indications and contraindications
- Determine anatomical landmark considerations related to implant positioning
- Determine feasible vertical dimensions
- Discuss treatment objectives and patient's expectations
- Perform various radiographic evaluations

Presurgical Planning Considerations

Proper stress distribution is essential to the long-term success of both the prosthesis and the implant. Overload is one of the key contributors to implant failure and is especially important in the cuspid and molar regions.

To minimize excessive loads, the following guidelines apply:

1. Reduce occlusal forces through reduction of the occlusal table width.
2. Distribute occlusal forces optimally by maximizing the number of abutments used to support the prosthesis and placing implants

of the maximum length and diameter allowable.

3. Position and incline the implants properly to ensure good prosthetic design, function, and esthetics.
4. Cantilevering should not be part of a treatment plan due to the force amplification of the resultant moment arm.
5. Strengthen the overall treatment plan in patients with either a heavy muscular profile or whose occlusal analysis indicates a strong bite by using the largest size implants, maximum numbers of abutments, minimizing the use of cantilevers, and placing abutments for the most even distribution of occlusal loads.

Spline Dental Implants require a minimum of 4-6mm of space (rim-to-rim) depending on the restoration. A minimum of 3 mm (not applicable to single tooth cases) is required between a natural tooth and the rim of an implant.

A 1:1 implant-to-natural tooth root ratio should be followed when possible. Eight (8) millimeter implants should never be placed freestanding. The use of implants with a diameter ≥ 3.75 mm is recommended in the posterior.

Presurgical Planning Considerations (continued)

Per Ante's Law, "The total periodontal membrane area of the abutment teeth should equal or exceed that of the teeth to be replaced." The following tables provide the average surface areas of Zimmer Biomet Dental Implants and natural teeth.

Zimmer Biomet Dental Implant Body Surface Area

Implant	Implant Length (mm)	Spline
3.25 mm Spline Reliance Cylinder	8	89
	10	109
	13	140
	15	160
	18	190
4.0 mm Spline Reliance Cylinder	8	111
	10	136
	13	174
	15	199
	18	236
5.0 mm Spline Reliance Cylinder	8	148
	10	182
	13	229
	15	261
3.75 mm Spline Twist Threaded	8	110
	10	145
	13	197
	15	231
	18	282
5.0 mm Spline Twist Threaded	8	170
	10	218
	13	287
	15	331

Comparison of the Root Surface Area of Natural Dentition¹

Tooth	Maxillary		Mandibular	
	Surface Area (mm ²)	Ranking	Surface Area (mm ²)	Ranking
Central	204	6	154	7
Lateral	179	7	168	6
Canine	273	3	268	3
First premolar	234	4	180	5
Second premolar	220	5	207	4
First molar	433	1	431	1
Second molar	431	2	421	2

¹Root surface measurement and a method for x-ray determination of root surface area. Jepsen, A., Acta Odont Scand, 21:35-46, 1963.

Implant Patient Maintenance

- Review clinical hygiene procedures.
- Outline patient's home-care hygiene regimen.
- Follow up on initial design, occlusion, and contouring for function, esthetic and hygienic evaluation.
- Examine patient on a routine recall basis.

Types of Restoration

Number of Implants	Restoration Desired (Design Options)
1 implant	Terminal abutment, pier abutment, single tooth (for molars, 2 implants with a minimum diameter of 3.75 mm or greater should be used if space is available).
2 implants	Implant-supported bridge, overdenture.*
3, 4 implants	Implant-supported bridge, overdenture. Overdenture incorporates multiple bars, attachments, or clips. This produces more than one axis of rotation, requiring prosthesis to be implant supported. Support design should distribute load to soft tissue without producing excessive force to the implants.*
5 or more implants	Implant-supported bridge, overdenture, fixed detachable full arch reconstruction.

*Overdenture using fewer than 5 implants should be supported by tissue or combination of tissue and implant. Designs utilize implant support in the anterior and soft tissue support in the posterior.

Autoclave Tray Drill Sequence

3.25 mm Spline Reliance Cylinder Implant

1. Round Bur
2. 2.3 mm Pilot Drill
3. Parallel Pin(s)
4. 3.0 mm Intermediate Drill
5. Parallel Pin(s)
6. 3.25 mm Countersink Drill
7. 3.25 mm Final Drill
8. 3.25 mm Implant Body Try-in

3.75 mm Spline Twist Threaded Implant

1. Round Bur
2. 2.3 mm Pilot Drill
3. Parallel Pin(s)
4. 3.0 mm Intermediate Drill
5. Parallel Pin(s)
6. 3.25 mm Final Drill
7. 3.25 mm Implant Body Try-in
8. 4.0 mm Countersink Drill
9. 3.75 mm Tap (optional)**

4.0 mm Spline Reliance Cylinder Implant

1. Round Bur
2. 2.3 mm Pilot Drill
3. Parallel Pin(s)
4. 3.0 mm Intermediate Drill
5. Parallel Pin(s)
6. 4.0 mm Countersink Drill
7. 4.0 mm Final Drill
8. 4.0 mm Implant Body Try-in

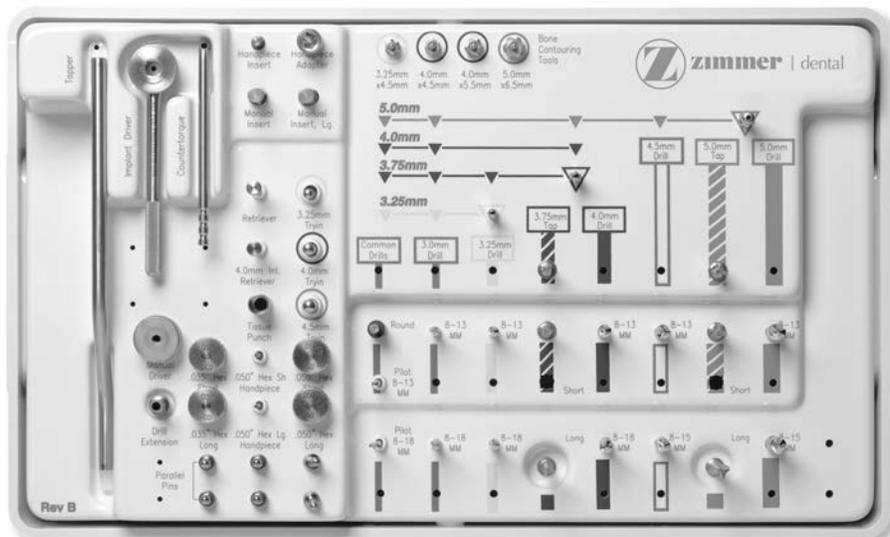
5.0 mm Spline Reliance Cylinder Implant

1. Round Bur
2. 2.3 mm Pilot Drill
3. Parallel Pin(s)
4. 3.0 mm Intermediate Drill
5. Parallel Pin(s)
6. 4.0 mm Final Drill
7. 4.5 mm Intermediate Drill
8. 4.5 mm Implant Body Try-in
9. 5.0 mm Countersink Drill
10. 5.0 mm Final Drill

5.0 mm Spline Twist Threaded Implant

1. Round Bur
2. 2.3 mm Pilot Drill
3. Parallel Pin(s)
4. 3.0 mm Intermediate Drill
5. Parallel Pin(s)
6. 4.0 mm Final Drill
10. 4.5 mm Intermediate Drill
11. 4.5 mm Implant Body Try-in
12. 5.0 mm Countersink Drill
13. 5.0 mm Tap (optional)**

**Use of a Thread Tap for self-tapping implants is not normally necessary. However, in dense bone (e.g. Type 1) pre-tapping the site may be necessary. Thread Taps should be available if needed.



Autoclave Tray Drill Sequence (continued)

Surgical Kit comes with all the instrumentation needed to place 3.25 mm and 4.0 mm Spline Reliance cylinder implants, Part Number 2410A.

3.25 mm and 4.0 mm Spline Reliance Cylinder and Spline Twist Threaded Surgical Kit, P/N 2410A Contents:

Surgical Box and Tray

Round Bur

Pilot Drill, 8-13 mm

Pilot Drill, 8-18 mm

3.0 mm Intermediate Drill, 8-13 mm

3.0 mm Intermediate Drill, 8-18 mm

3.25 mm Countersink Drill

3.25 mm Final Drill, 8-13 mm

3.25 mm Final Drill, 8-18 mm

4.0 mm Countersink Drill

4.0 mm Final Drill, 8-13 mm

4.0 mm Final Drill, 8-18 mm

Drill Extension

Parallel Pins, Straight (Qty 4)

Parallel Pins, 15° (Qty 2)

Try-in, 3.25 mm

Try-in, 4.0 mm

Tapper Handle

3.25 Tapper Tips (Qty 4)

4.0 Tapper Tips (Qty 2)

Implant Body Retriever

Tissue Punch

Hex Driver, .035", Long (0.9 mmD)

Hex Driver, .035", Short (0.9 mmD)

Hex Driver, .050", Long (1.25 mmD)

Hex Driver, .050", Short (1.25 mmD)

3.25 mm x 4.5 mm Bone Contouring Tool

4.0 mm x 4.5 mm Bone Contouring Tool

Bone Contouring Tool Manual Driver

5.0 mm Spline Reliance Cylinder and Spline Twist Threaded Surgical Kit, P/N 2412A Contents:

5.0 mm Countersink Drill

4.5 mm Intermediate Drill, 8-13 mm

4.5 mm Intermediate Drill, 8-15 mm

5.0 mm Final Drill, 8-18 mm

5.0 mm Final Drill, 8-15 mm

4.5 mm Implant Body Try-in

5.0 mm x 6.5 mm Bone Contouring Tool

*Surgical tray and threaded delivery tools not included

5.0 mm Spline Twist Threaded Surgical Kit, P/N 2414A Contents:

5.0 mm Countersink Drill

4.5 mm Intermediate Drill, 8-13 mm

4.5 mm Intermediate Drill, 8-15 mm

4.5 mm Implant Body Try-in

5.0 mm x 6.5 mm Bone Contouring Tool

*Surgical tray and threaded delivery tools not included

Sterilization Guidelines:

Please remove any protective packaging from the surgical tray before sterilization. The following are suggested guidelines for sterilization. Use commercially available chemical or biological monitors to determine the efficacy of the cycle employed.

- Steam Autoclave at 121°C/250°F, 15-20 psig for 40 minutes minimum followed by a 30 minute dry cycle.
- Dry heat at 160°C/320°F, for 2 hours (do not exceed 170°C/338°F).
- Chemclaving and flashclaving is NOT recommended.

Note: Exceeding these sterilization parameters may result in damage to plastic components. Verify the calibration of your unit to ensure recommended temperatures are not being exceeded.

Preoperative Planning Considerations:

Proper treatment planning, as well as the selection of the proper implant length and diameter, are crucial to the long-term success of the implant and restoration.

Before an implant can be selected, the anatomical foundation available to receive the implant must be carefully assessed. Several steps should be taken to complete the evaluation:

1. Clinical examination of the oral cavity can provide important information about the health of the soft tissue at the proposed implant site. Tissue tone and the state of the superficial tissues should be evaluated. In addition, the patient should demonstrate an adequate dimension of attached gingiva or keratinized tissue at the site selected for implantation. In partially edentulous cases, the periodontal status of the remaining dentition should be assessed and interaction between the implant restoration and the adjacent natural dentition should be considered.
2. The bony foundation and ridge need to be clinically analyzed to ensure the presence of proper dimensions and the amount of bone for implant placement. At least one millimeter of bone should be present at the buccal and lingual aspects of the implant following placement. During the planning stage, it is useful to measure the existing bone foundation.

Note: Please ensure as many implants as necessary are used for a fully stable restoration.

CT Scans:

Computed tomography (CT) scans help surgeons view parts of the body with three-dimensional images. Image-guided surgical planning allows surgeons to see anatomical landmarks such as nerves, sinus cavities and bony structures in order to plan for the placement of dental implants and prostheses.

Through the use of CT scans, clinicians are able to more precisely measure the locations of anatomical structures, dimensions of the underlying bone and ascertain bone densities in order to plan and treat clinically demanding cases.

Radiographic Transparencies:

The vertical height of the bone can be determined radiographically. Accurate measurement of the vertical dimension on the radiograph facilitates the selection of the appropriate implant length. This helps to avoid implant placement into the maxillary sinus, the floor of the nose or the mandibular canal, and prevents perforation of the inferior aspect of the mandible. Measurements can be made directly on the panoramic radiograph using a millimeter ruler. Corrections should be made for the degree of enlargement or reduction produced by the particular radiographic equipment.

Radiographic marking balls (RMB30) of a known dimension can be embedded in a plastic template prior to radiographic examination. Once the radiograph is taken and the metal marking balls are visible on the image, measurements can be taken to determine the amount of bone available for implant placement. (See instructions on page 6).

To calculate the distortion factor, a simple formula can be utilized:
 $(5 \div A) \times B =$ the amount of actual bone available.

Formula Key =

- Radiographic marking ball = 5.0 mm in diameter.
- A = Size of marking ball image on radiograph.
- B = Length in millimeters on the radiograph of available bone between the crest of the ridge and the inferior alveolar canal.

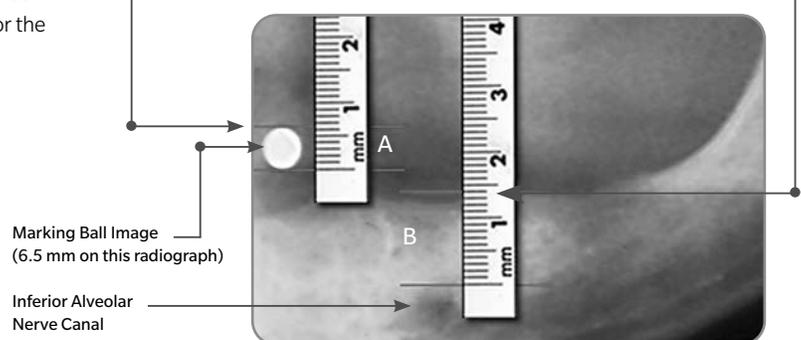
Example:

A = 6.5 mm

B = 14 mm

Therefore: $(5 \div 6.5) \times 14 = 10.76$ mm actual bone available

Note: A 2.0 mm margin of safety, from the apical end of the implant to any adjacent vital structure, should be considered.



Radiographic Transparencies Instructional Steps:

A dental implant radiographic transparency supports the preoperative implant treatment planning process. A radiographic transparency is overlaid onto a radiograph to assist the clinician in the preoperative determination of options for implant length and diameter. It is used in conjunction with a 5.0 mm radiographic marking ball. Representations of the implant and the 5.0 mm radiographic marking ball are shown on the radiographic transparency at 100% and 125% scales.

Visually inspect the transparency before each use for damage. The transparency should not be used if damaged or deteriorated. The following steps outline the proper use of the radiographic transparency in conjunction with the 5.0 mm radiographic marking ball(s) during preoperative planning:

1. Overlay the 100% and 125% scaled 5.0 mm circular radiograph ball outline found on the transparency over the 5.0 mm radiographic ball image on the radiograph and determine which outline is closest to the diameter of the radiographic ball image on the radiograph. If the radiographic ball image on the radiograph extends outside the circular border of the radiographic ball outline on the 100% scale, use the 125% scale for measurement estimations. If the radiographic ball image extends outside the circular border of the radiographic ball outline on the 125% scale, DO NOT use this radiographic transparency and refer to the Radiographic Marking Balls procedure to determine approximate bone height (See section on calculation of distortion factor on page 5).

Note: The radiographic ball should maintain its spherical shape on the radiograph, otherwise distortion that cannot be measured may have occurred. If this happens, it is recommended that a new radiograph be taken.

2. Select the scale (100% or 125%) to use based on which circular radiograph ball outline best matches the diameter of the radiographic ball image on the radiograph.

3. To determine an approximation of available vertical bone height at the proposed implant site, align the zero mark on the selected ruler (100% or 125%) to the crest of the edentulous ridge and measure the length between the crest and anatomical structures in the proposed implant site including the floor of the maxillary sinus, the floor of the nose and the mandibular canal.

Note: A minimum of 2.0 mm margin of safety, from the apical end of the implant to the adjacent vital structure, should be considered.

4. Overlay the implant silhouette corresponding to the selected scale (100% or 125%) onto the proposed implant site to visually estimate if adequate vertical bone height is present for the selected implant length.

Note: The intended use of this device is exclusively for preoperative planning and to be used as a guide. Implant length and diameter should not be determined solely by relying on the radiographic transparency.

General Surgical Procedure Considerations

It is important that the implant procedure be performed under aseptic conditions. Irrigation technique should be reviewed to ensure that compressed coolant air is not introduced into the surgical site via a drill. All instruments must be clean and sterile. Please note that the surgical instrumentation used to place dental implants is provided non-sterile and therefore must be sterilized prior to use. The sterilization chart on page 8 provides specific sterilization instructions.

Handling

Only powder-free gloved hands or non-metallic instruments should be used to handle the implant. Implants are packaged to protect the product from damage during transit and storage.

Cleaning

Use the following guidelines for cleaning components:

Surgical Drills - Rinse with cool to lukewarm water for two-and-one-half minutes. Use a 25-gauge or 30-gauge* needle to clean the lumen, making sure to flush water through the needle. Place in an ultrasonic cleaner with an enzymatic detergent mixed with tap water per the manufacturer's guidelines. Sonicate for 10 minutes. Rinse with tap water for three minutes.

Prosthetic Components - Disassemble two piece components. Rinse in cool to lukewarm water for two-and-one-half minutes. Place in an ultrasonic cleaner with an enzymatic detergent mixed with tap water per the manufacturer's guidelines. Sonicate for 10 minutes.

Surgical and Prosthetic Tools - Rinse with cool to lukewarm water for two-and-one-half minutes. Wipe with cotton gauze moistened with tap water. Use multipurpose soft bristle brush to remove excess soil. Wipe with a two percent glutaraldehyde solution. Let tool sit for five minutes. Rinse with tap water for three minutes.

Surgical Tray and Second Stage/Prosthetic Tray - Remove all parts from the surgical tray, then remove the tray insert. Rinse the tray and tray insert thoroughly with cool to lukewarm (43°C/110°F or less) tap water. Use a damp cloth to wipe and remove any excess soil from each part. After rinsing, wipe each part with a cloth that has been dipped in an enzymatic detergent solution diluted to manufacturer's specifications. Wipe parts until all visible contamination has been removed. To eliminate all residual enzymes and detergent, thoroughly rinse (minimum of three minutes) the cleaned parts with tap water. **Note:** This procedure should be performed after an instrument used during a surgery comes into contact with the surgical tray or second stage/prosthetic tray.

Sterilization

Sterile products have been gamma radiation sterilized and are for single use only. Only HA-Coated implant bodies may be resterilized. Resterilize once (HA-Coated implants can be sterilized by autoclaving or dry heat) if the sterile packaging has been opened, but only if the implant has not been contaminated in any manner. If resterilization is needed, remove the cap, healing screw, and any implant driver mounts from the body. Place the healing screw, implant, and any implant driver mount in an appropriate container for sterilization. Do not sterilize the implant body with the healing screw in place. Do not sterilize the cap or vial. Repeated autoclaving is not advised.

Zimmer Biomet Dental Spline surgical instrumentation and prosthetic components are provided non-sterile and must be sterilized prior to use. Remove instrumentation or prosthetic components from packaging prior to sterilization. Refer to the following table for instrumentation sterilization guidelines. **Note:** Two-piece components should be disassembled prior to sterilization to ensure maximum efficacy.

*All drills 2.8mmD or smaller will require a 30-gauge needle to clean the lumen.

Sterilization Technique/Surgical Instrumentation

Product	Autoclave ¹	Dry Heat
HA-Coated Implants	yes ² (only once)	yes ² (only once)
Pilot Drill	yes	yes ⁴
Round Bur	yes	yes
Intermediate Drills	yes	yes ⁴
Countersink Drills	yes	yes ⁴
Final Drills	yes	yes ⁴
Spline Bone Contouring Tools	yes	yes
Manual Driver - Spline Bone Contouring Tools	yes	no
Drill Extension	yes	yes
Thread Taps	yes	no
Implant/Tap Driver	yes	no
Handpiece Adapter	yes	yes
Manual Mount Driver	yes	yes
Latch-Lock Mount Driver	yes	yes
Countertorque Tool	yes	yes
Healing Screws	yes	yes
Parallel Pins	yes	yes
Implant Body Try-ins	yes	yes
Prosthetic Torque Wrench	yes	no
Hex Drive Seating Tool	yes	yes
Tapper/Tapper Tips	yes	yes ⁴
Implant Body Retriever	yes	yes
Tissue Punch	yes	no
Temporary Gingival Cuffs	yes	yes
Autoclave Tray (Cat. No. 2309)	yes	yes ⁴
Suggested Parameters (guidelines only) ³	121°C/250°F 15-20 psig 40 minutes minimum followed by a 30 minute dry cycle	160°C/320°F 2 hrs

¹ A standard autoclave bag should be used. Check trays, autoclave interior, and water supply for cleanliness. The autoclave should have a drying cycle.

² Implant body must not be contaminated.

³ Use commercially available chemical or biological monitors to determine the efficacy of the actual cycle employed.

⁴ Due to the melting point of the plastics used in these products, dry heat sterilization should not exceed 170°C/338°F.

Bone Preparation

Make a mesiodistal incision along the buccal side of the alveolar crest through the mucoperiosteum and attached gingiva to the bone. (Flap and incision designs may vary due to clinician preference.) The incision should be long enough to permit adequate reflection and a broad field of view without tearing the tissue. (Occasionally, vertical releasing incisions may be employed.) Using a periosteal elevator, carefully lift the periosteum to expose the alveolar bone only as necessary to provide an adequate surgical working area (**Fig. 1**).

Place retractors or sutures to hold the tissues. Remove any spinous ridges or other bone irregularities using the round bur or a Rongeur Forceps to create as flat a bone plateau as possible (**Fig. 2**).

Keep bone removal to a minimum. (Insufficient bone height/width and abnormal defects or contours not previously detected may now contraindicate placement of the implant.) Ridge width should allow at least 1 mm of bone to remain buccal and lingual to the implant after placement. Maintain 4-6mm of space (rim-to-rim) between implants or 3 mm (not applicable to single tooth cases) from any adjacent natural dentition. Allow 1mm of bone circumferential and 2mm of bone apical to the implant when inserted (e.g., 10mm of alveolar bone is required to insert an 8mm length implant body). Ridge contour should be adequately palpated to estimate an angle of insertion which will achieve parallelism with other implants and natural tooth abutments where indicated.

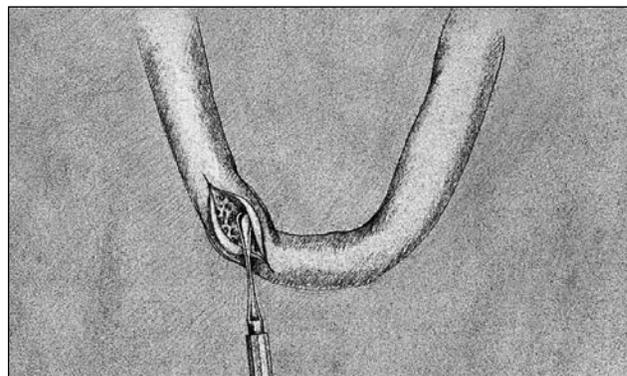


Figure 1. A mesiodistal incision with adequate reflection will provide a broad field of view for implant placement.

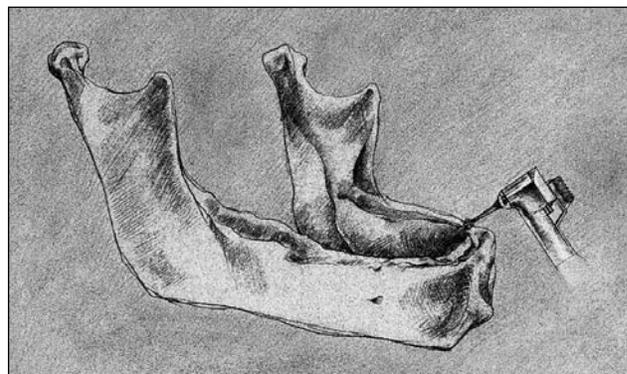


Figure 2. Bone irregularities are removed to provide a flat plateau.

Components



Round Bur



Pilot Drill



Parallel Pins



Drill Extension



Intermediate and Final Drills



Countersink Drill



Implant Body Try-in

General Instructions for Implant Bed Preparation

Bone cutting procedures involving the Pilot, 3.0 mm Intermediate, and 3.25, 4.0, 4.5 and 5.0 mm drills require a low speed (600-850 rpm), high-torque, internally irrigated handpiece. This will minimize excessive heat generation and preserve the vitality of bone which is in contact with the implant. The Thread Taps do not accommodate internal irrigation and external irrigation is required. If the Thread Taps will be operated in a handpiece, a contra-angle that operates at less than 50 rpm is required and the handpiece must be capable of high torque operation.

Irrigation techniques should be reviewed to ensure that compressed coolant air is not introduced into the surgical site via a surgical bur. Because profuse internal irrigation is required to keep the drill from clogging, avoid splitting or diverting the drill's internal irrigation for external purposes. Accommodate external irrigation by utilizing a sterile, water-filled syringe.

Perform all drilling, particularly with 2.3 mmD Pilot, 3.0, 3.25, 4.0, 4.5 and 5.0 mm drills, with a straight, up-and-down motion in order to avoid creation of an oval-shaped osteotomy site.

When additional drill length is required, a Drill Extension is available that extends the effective cutting length of the drill by 10mm. The Drill Extension should be used when additional length is required due to interference caused by adjacent teeth. The Drill Extension has a standard latch-lock shank with a cylindrical shaft to lock any Zimmer Biomet Dental latch-lock type drill into the extension with a set screw. Do not use with drills other than the standard latch-lock type. In addition, do not use excessive drilling speeds (i.e., speeds greater than 850 rpm) with the Drill Extension. The Drill Extension allows for internal irrigation. **Note:** The Drill Extension is not used with the Thread Taps or Driver Extension.

Drill Extension Procedure

- A. Insert any Zimmer Biomet Dental latch-lock drill into the internal bore.
- B. Rotate the drill until it seats positively inside of the bore.
- C. Using the 1.25 mmD (0.050") Hex Tool, tighten the set screw. **Note:** Tightening the set screw requires that the drill be positively engaged. Failure to engage may strip the set screw.
- D. To remove the drill from the extension, loosen the set screw one-half to three-quarters of a turn and remove the drill. **Note:** The drill extension is provided with a positive mechanical stop to prevent the set screw from being removed from the drill extension body. Do not use excessive force when loosening the screw.

Note: Clean drill heads often to remove debris and ensure a sharp cutting surface. A 25-gauge or 30-gauge needle can be used to clean the drill's irrigation hole. Due to the density of bone commonly found in the symphysis region, use newer drills. Rotate these drills for use in the maxilla or where more porous bone is found (Type II or III). **A maximum of 20 uses per drill is recommended.**

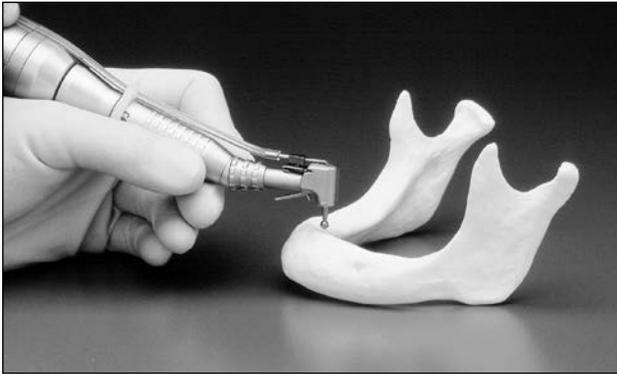


Figure 3. Round Bur creates dimple on the alveolar crest to accommodate tip of Pilot Drill.

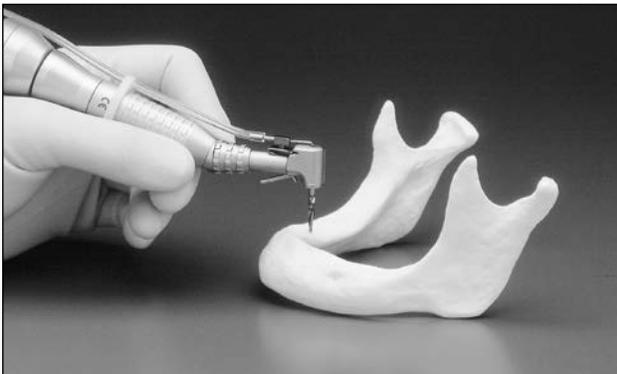


Figure 4. Pilot Drill creates a hole to the depth of implant length selected.



Figure 5. Parallel Pin inserted into the pilot hole allows visual inspection of angulation.

Surgical Drilling Guidelines

Please refer to the additional surgical drilling guidelines below before following the surgical charts. These guidelines correspond and provide additional information to the surgical sequencing found in the charts.

Explanation of Depth Bands

The bands on the Pilot, 3.0 mm, 3.25 mm, 4.0 mm, 4.5 mm, and 5.0 mm diameter drills are cutting depth markings indicating implant length. The depth markings are machined and laser etched for increased visibility. Also note the addition of a depth band to indicate the placement of the 11.5mm Spline Twist Implant. The bands are located 1 mm longer than the implant abutment junction. (For example: The 13 mm band is dimensioned 14mm from the tip of the drill.) This length should be chosen on a case by case basis taking into account bone irregularities at the crest. Always take into account vital anatomical structures when allowing for additional length during surgical site excavation.

- A. Use copious external irrigation with the Round (Rosette) Bur when creating a 1-1.5mm dimple in the dense ridge crest (**Fig. 3**).
- B. Use the Pilot Drill to create a pilot hole to the depth of implant length selected using the depth marks on the drill (**Fig. 4**). Flush the hole to remove debris.
- C. Use Parallel Pins to check proper angularity before proceeding with 3.0 mm diameter drill. The narrow end of the pin corresponds to the diameter of the Pilot Drill and the large end corresponds to the 3.0 mm diameter drill. Insert the appropriate pin end into the corresponding diameter hole (**Fig. 5**). Repeat for additional implants, referring to the angularity and draw requirements established by prior sites. Floss may be threaded through the hole on the Parallel Pins for retention to prevent patient aspiration.
- D. Drills 3.25 mm, 4.0 mm, 4.5 mm, 5.0 mm. **Important:** Use the appropriate length and diameter drill for each step (**Figs. 6 and**



Figure 6. The Intermediate Drill is used to increase diameter of the osteotomy.

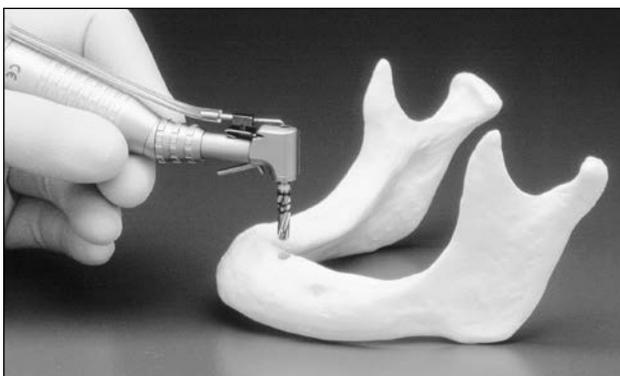


Figure 7. The Final Drill is used to complete the desired diameter of the osteotomy.*

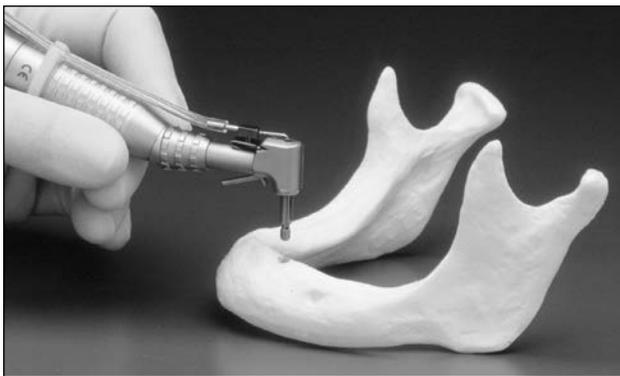


Figure 8. The Countersink Drill creates a recessed area in the cortical bone.**

7).

E. Use the appropriate diameter countersink drill to create a recessed area in the cortical bone (Fig. 8). **Note:** For Spline Twist Threaded Implants the countersink is also used to create a proper contour in the bone that matches the coronal flare of the implant and healing screw.

F. Confirm the exact implant body size selection by trial fitting an appropriate diameter Implant Body Try-in into the prepared site. **Note:** The concentric rings on the Implant Body Try-in correspond to the exact lengths of the implant from the apical end to the implant-abutment junction. Floss may be threaded through the hole for retention to prevent patient aspiration.

Optional:

G. Taps 3.75 and 5.0 mm: Use the appropriate length and diameter Thread Tap for Spline Twist Threaded Implants. Refer to **Tapping The Surgical Site 3.75 mm & 5.0 mm Spline Twist Threaded Implants** for complete instructions. **Note:** The Thread Taps do not accommodate internal irrigation and external irrigation is required. Use of the Thread Tap is contraindicated in soft maxillary bone.

*Use of a Thread Tap for self-tapping Spline Twist Threaded Implants is not normally necessary. However, in dense bone (e.g., Type I) pre-tapping the site may be necessary. Thread Taps should be available if needed.

Note: Use a surgical template as a guide. Refer to **Surgical Drilling Guidelines** first, then refer to table for recommended drilling sequence corresponding to implant(s) being placed and available instrumentation.

**Please refer to the charts on the following pages for surgical drill sequencing.

Surgical Autoclave Kit Driva™ Drilling Sequence

Drill Speed	Drill or Thread Tap	3.25 mm	3.75 mm	4.0 mm	5.0 mm	5.0 mm
		Spline Reliance Cylinder Implant	Spline Twist Threaded Implant	Spline Reliance Cylinder Implant	Spline Reliance Cylinder Implant	Spline Twist Threaded Implant
600-850 rpm	Round (Rosette) ^a	1	1	1	1	1
	Pilot ^b	2	2	2	2	2
	Parallel Pins ^c (narrow end)	√	√	√	√	√
600-850 rpm	3.0 mm Intermediate ^d Drill	3	3	3	3	3
	Parallel Pins ^c (large end)	√	√	√	√	√
600-850 rpm	3.25 mm Countersink Drill ^e	4				
	3.25 mm Final Drill ^d	5	4			
	3.25 mm Implant Try-in ^f	√	√			
600-850 rpm	4.0 mm Countersink Drill ^e		5	4		
	4.0 mm Final Drill ^d			5	4	4
	4.0 mm Implant Try-in ^f			√		
600-850 rpm	4.5 mm Intermediate Drill ^d				5	5
	4.5 mm Implant Try-in ^f				√	√
600-850 rpm	5.0 mm Countersink Drill ^e				6	6
	5.0 mm Final Drill ^d				7	
50 rpm	3.75 mm Tap ^{g,h} See: Tapping the Surgical Site – 3.75 mm & 5.0 mm Spline Twist Threaded Implants for additional instructions		6			
50 rpm	5.0 mm Tap ^{g,h} See: Tapping the Surgical Site – 3.75 mm & 5.0 mm Spline Twist Threaded Implants for additional instructions					7
N/A	See: Implant Placement for Spline Reliance Cylinder Implants	6		6	8	
N/A	See: Implant Placement for Spline Twist Threaded Implants		7			8

Note: √ indicates should be used in drilling sequence.

Components

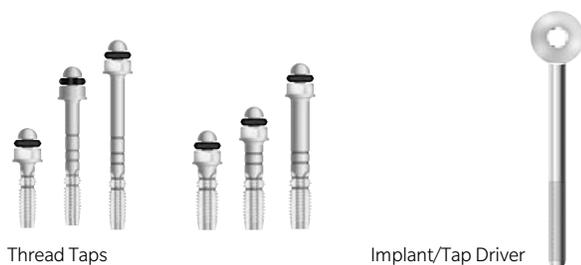


Figure 9. Thread Taps can be operated manually in the Implant/Tab Driver or used in a handpiece via the Handpiece Adapter.

Tapping the Surgical Site - 3.75 mm & 5.0 mm Spline Twist Threaded Implants

Note: Use of a Thread Tap for self-tapping Spline Twist Threaded Implants is not normally necessary. However, in dense bone (e.g., Type I) pre-tapping the site may be necessary. Thread Taps should be available if needed.

The surgical site may be tapped with either a surgical handpiece or Manual Tap Driver (Fig. 9). When tapping by hand, insert the appropriate length Thread Tap into the bottom broach of the driver head so the driver rotates freely in a clockwise direction. Place the tip of the Thread Tap into the drilled implant site. Rotate the thumb wheel in a clockwise direction while applying moderate apical pressure to engage the Thread Tap into the surgical site. Ratchet the driver in a clockwise direction while applying moderate pressure (Fig. 10). Avoid any lateral movements when tapping. Thread the hole to the desired depth reference notch (also marked by a laser band). Grab hold of the superior portion of the tap and disengage the driver from the tap. Flip the driver over and re-engage the Thread Tap; the driver should now ratchet in a counterclockwise direction. Ratchet the driver in a counterclockwise direction to back the tap out. **Do not pull on the bone tap.** Use of the Thread Tap is contraindicated in soft maxillary bone.

When using the handpiece, place the appropriate length Thread Tap in the Handpiece Adapter. The Handpiece Adapter will fit



Figure 10. Thread Tap is ratcheted clockwise to the appropriate depth reference notch.

Components

Spline Reliance Cylinder Implants



3.25 MP-1*

4.0 MP-1

5.0 MP-1



Figure 11. The cylindrical implant is initially delivered to the site via the vial cap.

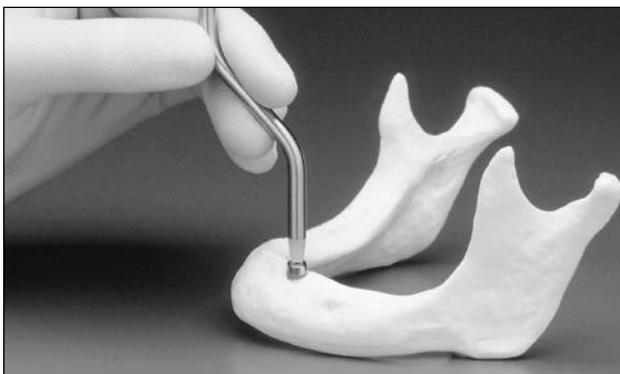


Figure 12. The Tapper may be used to facilitate final seating of cylindrical implants.

any latch-lock handpiece. Place the tip of the Thread Tap into the drilled implant site. The rotational speed for the tapping procedure should be below 50 rpm. This may require a change in contra-angle, capable of low speed, high torque operation. Apply firm pressure and begin rotating the Thread Tap slowly. When the threads engage, allow the Thread Tap to feed without pressure. Thread the hole to the desired depth reference notch (also marked by a laser band). Switch the handpiece to the reverse mode and back the Thread Tap out. **Do not pull on the Thread Tap.** Use of the Thread Tap is contraindicated in soft maxillary bone. After site has been tapped reference: **Implant Placement For Spline Twist Threaded Implants.**

Implant Placement for Cylinder Implants

- A. Irrigate the completed implant receptor site with additional sterile water.
- B. While holding the plastic cap, seat the implant into the prepared site (Fig. 11) until firm (at least halfway).
- C. Remove the plastic cap by applying a steady pressure to the cap perpendicular to long axis of implant in a mesial or distal direction. The cap will “snap” off. Fully seat the implant (the top of healing screw flush or slightly above crest of alveolar bone) using a gentle tapping action with a rubber mallet on the plastic-tipped Tapper (Fig. 12). Check the healing screw for tightness with the hex drive seating tool.
- D. A radiographic check of implant placement should be performed at this time.
- E. Carefully reposition the mucoperiosteal flap for maximum tissue adaptation, and then suture.

Components

Spline Twist Threaded Implants

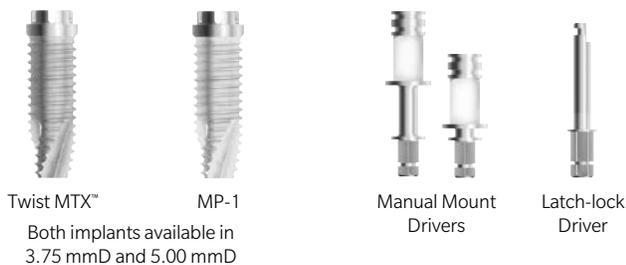


Figure 13.



Figure 14.



Figure 15.

Implant Placement for Self Tapping Spline Twist Threaded Implants

A. Irrigate the completed implant site with additional sterile water.

B. The vial is opened by rotating the cap forward, away from the vial clip. (The cap remains secured to the vial by the hinge on the front of the vial.) The vial can be fastened to the front of the surgical tray utilizing the clip on the back of the vial (**Fig. 13**).

C. The implant may be driven either manually or with the use of a Latch-Lock Driver. The Manual Mount Driver is inserted into the bottom broach of the Implant/ Tap Driver Wrench so that the driver rotates freely in a clockwise direction. The Latch-Lock Mount Driver engages directly into the handpiece. The Mount Driver's male hexagon is inserted into the female hexagon of the implant driver mount. The retaining clip on the Mount Driver provides mechanical retention to the implant driver mount. To remove the implant from the vial, engage the Mount Driver to the driver mount and lift out (**Figs. 14 and 15**). **Note:** The use of mount drivers without retaining clips is not recommended for use with this delivery system. Screw the implant into the prepared site using the handpiece or the Manual Driver Wrench (**Fig. 16**). The implant must be driven into the site at less than 50 rpm. This requires a contra-angle capable of low speed, high torque operation. After the implant is seated, disengage the Mount Driver from the implant driver mount by pulling up in an axial direction.

Note: Life expectancy of tools with retaining clip is 25 sterilization cycles.

D. After the implant is seated at the desired level, unscrew the implant driver mount by disengaging the retaining screw with the 1.25 mmD (0.050") Hex Tool. The driver mount Counter torque Tool may be used to prevent rotation of the implant during driver mount removal (**Fig. 17**). The external hex of the Counter torque Tool engages the hex socket of the driver mount. A hole in the end of the Counter torque Tool allows the long Hex Drive Seating Tool to be passed through the Counter torque Tool and engage the retaining screw. While holding the Counter torque Tool in a fixed position, disengage the retaining screw by turning the Hex Drive Seating Tool in a counterclockwise direction. Remove the driver mount from the implant body. Both the driver mount and the retaining screw are disposable products.

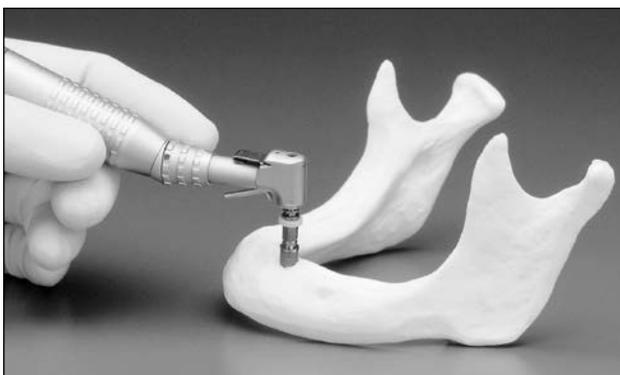


Figure 16.

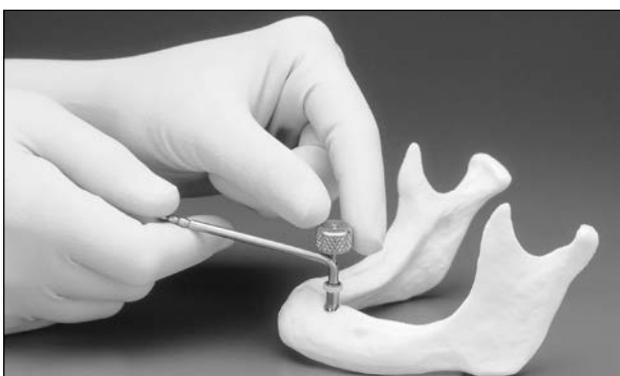


Figure 17.

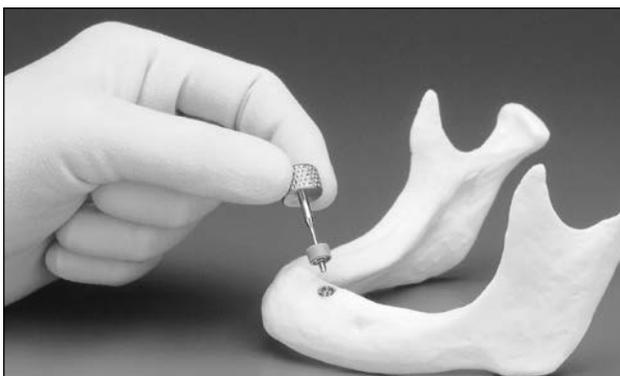


Figure 18.

E. To remove the healing screw from the implant vial cap, place the 0.9 mmD (0.035") Hex Tool through the rubber retaining boot, engage the female hex, and turn counterclockwise. The boot secures the healing screw to the hex driver.

F. Flush the implant to remove debris before seating the healing screw onto the implant body and tighten with the 0.9 mmD (0.035") Hex Tool (Fig. 18). After tightening is completed, withdraw the Hex Drive Seating Tool from the oral cavity and remove the rubber boot. The rubber boot is a disposable product.

G. A radiographic check of the implant should be taken at this time.

H. Carefully reposition mucoperiosteal flap for maximum tissue adaptation, and then suture.

Post-Operative Course

Instruct the patient to follow a post-surgery regimen including cold packs for the initial 24 hours. An antibiotic may be prescribed. Sutures may be removed after one week. Relieve any removable prosthesis resting on the implant and reline using a soft tissue conditioner reline material.

Allow a healing period of approximately three to four months for the mandible and five to six months for the maxilla. It is important to leave the implant unloaded during this healing period. Periodically monitor the proper healing of the soft and hard tissues.

Optional First Stage Impression for Splines Twist Threaded Implants Only

An impression can be taken at this time using the appropriate

diameter Impression Post (reference section entitled **Impression Posts** in the Prosthetic Manual). **Note:** If the implant has been countersunk it may be necessary to utilize the Bone Contouring Tool first before an impression can be made; reference section entitled **Bone Contouring**. After the impression has been made continue with the single or two-stage implant placement steps.

Caution: After the impression has been made, irrigate and flush the site to remove any impression debris.

Single-Stage Procedure for Spline Twist Threaded Implants Only

A. After the removal of the driver mount from the implant body, use the appropriate Bone Contouring Tool that matches the cuff diameter of the Temporary Gingival Cuff being placed (reference section entitled **Bone Contouring**).

B. When finished, remove the tool from the site. Flush and aspirate the Spline interface and internal threads to remove debris.

An impression can be taken at this time using the appropriate diameter Impression Post (reference section entitled **Impression Posts** in the Prosthetic Manual). After the impression has been made continue with step C.

Caution: After the impression has been made, irrigate and flush the site to remove any impression debris.

C. Place the appropriate Temporary Gingival Cuff using the 1.25 mmD (0.050") Hex Tool and carefully reposition the mucoperiosteal flap for maximum adaptation around the Temporary Gingival Cuff, ensuring that no greater than 0.5mm-1mm of the cuff is exposed supragingivally and then suture.

D. Relieve any removable prosthesis resting on the Temporary Gingival Cuff and reline using a soft tissue conditioner reline material. It is important to leave the Temporary Gingival Cuff unloaded during this healing period.

E. A radiographic check of the implant should be taken at this time.

Caution: The implant's Temporary Gingival Cuff must not be in occlusion during the healing period.

F. Irrigate the completed implant site with additional sterile water.

Placement Into Extraction Sockets

A. Ensure that the socket is free from infection, purulent drainage, remaining tooth structures, and soft or granulation tissue. Gently curette to remove any soft tissue remnants.

B. Ensure that the socket size is small enough that bone-to-implant contact is achieved after use of the final drill.

Note: Bone must be present apical to the tooth socket to achieve initial stabilization.

C. Countersink the implant by 2mm. **Note:** This may require the use of drills (Intermediate and Final Drills) that are longer than the length of the implant being placed.

D. Achieve primary closure after implant placement.

Postoperative Course

Instruct the patient to follow a post-surgery regimen including cold packs for the initial 24 hours. An antibiotic may be prescribed. Sutures may be removed after one week. Relieve any removable prosthesis resting on the implant and reline using a soft tissue conditioner reline material. Allow a healing period of approximately three to four months for the mandible and five to six months for the maxilla. It is important to leave the implant unloaded during this healing period. Periodically monitor the proper healing of the soft and hard tissues.

Components



Temporary Gingival Cuffs



Figure 19. The Temporary Gingival Cuff adapts the soft tissue for the final restoration.

Exposure of Implants – Temporary Gingival Cuffs

Description

Second-stage healing screw with variable cuff heights.

Note: Spline cuffs do not engage their respective implant's anti-rotational feature. Each implant platform has its own variety of cuff heights and diameters available.

Indications

For use at second stage surgery to allow healing of the soft tissue to coincide with the flare of the abutment cuffs for suitable emergence profile of the final prosthesis (**Fig. 19**). Cuff should protrude through the soft tissue by at least 2mm (0.5 mm – 1 mm when used in a single stage procedure, Spline Twist Threaded only). **Note:** Cuffs do not engage their respective implant's anti-rotational feature.

Contraindications

Not to be used as an impression transfer component or temporary abutment.

Note: Spline only - If a single stage surgery was done, the Temporary Gingival Cuff was placed at first stage surgery. Unscrew the Temporary Gingival Cuff using the 1.25 mmD (0.050") Hex Tool and reference the section entitled

Spline Interface Abutment General Guidelines in the Prosthetic Manual (Part Number 4789).

Procedure

Following the healing period, uncover the implant healing screw. The location can be determined by palpation of the soft tissue or use of a periodontal probe. Expose the healing screw using a scalpel, taking care to preserve an adequate amount of keratinized gingiva. Remove the healing screw with the appropriate Hex Tool. Choose a Temporary Gingival Cuff that has a maximum diameter matching the abutment planned for the case. Remove all bone and soft tissue from the superior aspect of the implant body to guarantee complete seating of the Temporary Gingival Cuff. The presence of tissue or bone fragments between the implant and abutment can lead to abutment loosening. Do not use a bur or other drilling instrument, which may compromise the integrity of the implant or its coating. Screw the Temporary Gingival Cuff into the implant using the appropriate Hex Tool. Allow the soft tissues to heal.

Note: For Spline Implants only: The Bone Contouring Tool may be used to facilitate removal of bone and soft tissue at the interface. Use the appropriately flared Bone Contouring Tool that matches the diameter of the Temporary Gingival Cuff being placed. When using the narrow (3.25 mm x 3.75 mm) Temporary Gingival Cuff, utilize the 3.25 mm x 4.5 mm Bone Contouring Tool. Reference: **Bone Contouring - Spline Dental Implant System Only**.

Components



Bone Contouring Tools



Hex Drive Seating Tool Kit, 0.035"



Manual Driver



Figure 20. The Bone Contouring Tool is oriented axially parallel to the implant trajectory.

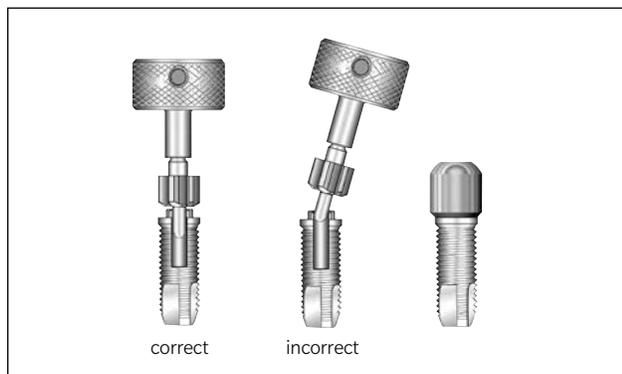


Figure 21. Use of the Bone Contouring Tool with the Manual Driver.

Bone Contouring – Spline Dental Implant System Only

Description

A series of specially designed Bone Contouring Tools of various diameters, operated either manually or in a handpiece. The bullet nose on the Bone Contouring Tool is inserted into the thread opening on the implant. The Bone Contouring Tool is not internally irrigated.

Indications

Used to remove bone from the coronal aspect of an implant body to assist the seating of the Temporary Gingival Cuff and/or abutment.

Contraindications

Not to be used as a countersink drill.

Note: If a single stage surgery was done, bone contouring was performed during implant placement. Unscrew the Temporary Gingival Cuff using the 1.25 mmD (0.050") Hex Tool and proceed to the **Spline Interface Abutment General Guidelines** in the Prosthetic Manual.

Procedure

- A. Remove the implant healing screw with the 0.9 mmD (0.035") Hex Tool.
- B. The Bone Contouring Tool may be operated either manually in the Manual Driver or in the handpiece by engagement of the Latch-Lock.
- C. When using a Manual Driver, insert the appropriate flared bone contouring that matches the diameter of the Temporary Gingival Cuff being placed. Place the tip of the Bone Contouring Tool into the internal thread of the implant body. The Bone Contouring Tool should be oriented such that it is axially parallel to the implant trajectory (Figs. 20 and 21). Turn the driver in a clockwise direction while applying moderate axial pressure. Continue until enough bone is removed to seat the Temporary Gingival Cuff flush with the implant interface.
- D. When using the handpiece, choose the appropriate flared Bone Contouring Tool that matches the diameter of the Temporary Gingival Cuff being placed. Place the tip of the Bone Contouring Tool into the internal threads of the implant body. The rotational speed for the contouring procedure should be between 50-100 rpm. Apply light axial pressure until enough bone is removed to seat the Temporary Gingival Cuff flush with the implant interface. Maintain proper angularity of the Bone Contouring Tool during use. **Note:** Use of excessive force and duration may cause damage. External irrigation must be used during this procedure.
- E. Remove the tool from the site. Flush and aspirate the Spline interface and internal threads to remove debris. A Temporary Gingival Cuff or abutment can now be placed.

Contraindications

Zimmer Biomet Dental Implants should not be placed if there is insufficient alveolar bone width and height to surround the implant. Implants placed in the maxilla should not perforate the sinus. Insufficient availability of bone (minimum 1mm circumferential and 2mm apical), poor bone quality, poor patient oral hygiene, heavy smoking or use of chewing tobacco, and generalized diseases (diabetes, etc.) may contribute to lack of integration and subsequent implant failure. Severe bruxism, clenching, or overloading may cause failure of abutments and implants. Psychologically unstable patients may not be good implant candidates. Clinicians should select patients who they feel will be satisfied psychologically, as well as esthetically and functionally, with the restoration. Exposure to magnetic resonance imaging, radiation, and chemotherapy may impact the viability of the implant. Dental implant patients should be instructed to consult with their physician prior to undergoing such treatment options.

Warnings

Surgical techniques required to place dental implants are highly specialized and complex procedures. Specialized training is strongly recommended. Practitioners should attend courses of study to prepare them in established techniques of oral implantology. Improper technique can cause implant failure and loss of bone.

Irrigation technique should be reviewed to ensure that compressed coolant air is not introduced into the surgical site via a surgical bur. Zimmer Biomet Dental Implant Systems are intended to be used only with Zimmer Biomet Dental's specially-designed bone drills and prosthetic abutments. Implants placed at severe angles relative to existing dentition or multiple implants placed in a convergent/divergent manner can result in complex restorations that may overload the implants, potentially leading to implant failure. Templates or surgical guides should be used when possible to help ensure proper angulation.

Excessive mobility, bone loss, or infection may indicate that the implant is failing. Any implant which appears to be failing should be treated or removed as soon as possible. If removal is necessary, curette any soft tissue from the implant site and allow the site to heal as though it were an atraumatic extraction.

Side Effects

By carefully following the instructions for use and utilizing good surgical technique, complications can be kept to a minimum. The following complications may occur: dehiscence, delayed healing, paresthesia, hyperesthesia, edema, hemorrhage, hematoma, infection, inflammation, and local and generalized allergic reaction.

Changes in Performance

It is the responsibility of the clinician to instruct the patient on all appropriate contraindications, side effects, and precautions as

well as to seek the services of a trained dental professional if there are any changes in the status of the implant (e.g., looseness of the prosthesis, infection or exudate around the implant, pain, or any other unusual symptoms that the patient has not been told to expect). If these conditions occur, the patient should be instructed to see a trained dental professional immediately.

Precautions

Adequate palpation and direct visual inspection of the prospective implant site are necessary to determine the anatomy of available bone. The location of anatomical features to be avoided should be established prior to use of Zimmer Biomet Dental Implants. Care must be taken to evaluate the quality and quantity of the residual bone prior to placement of the implant and after an implant failure.

Hygiene & Maintenance

Long-term health of the implant can be directly related to the quality of oral hygiene. Potential implant candidates should establish an adequate oral hygiene regimen prior to implant therapy. Following implant placement, the clinician should instruct the patient on proper tools and techniques to ensure long-term maintenance of the implant(s). The patient should also be instructed to periodically visit their dental professional for professional cleanings and evaluation.

Caution

Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed dentist.

Cleaning

Cleaning of reusable products should be performed according to current dental standard practices. Select a suitable method of cleaning that removes all visible contamination from the product. After cleaning, package the product appropriately and then sterilize according to the guidelines for sterilization (see pages 5 and 6).



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