TSX®

Immediate Molar Implant System

Surgical Manual

ZimVie

SUPERPOWERS FOR SUPERHEROES
CONTROL
PRECISION
STABILITY
ZIMVIE IMMEDIATE MOLAR IMPLANT SYSTEM

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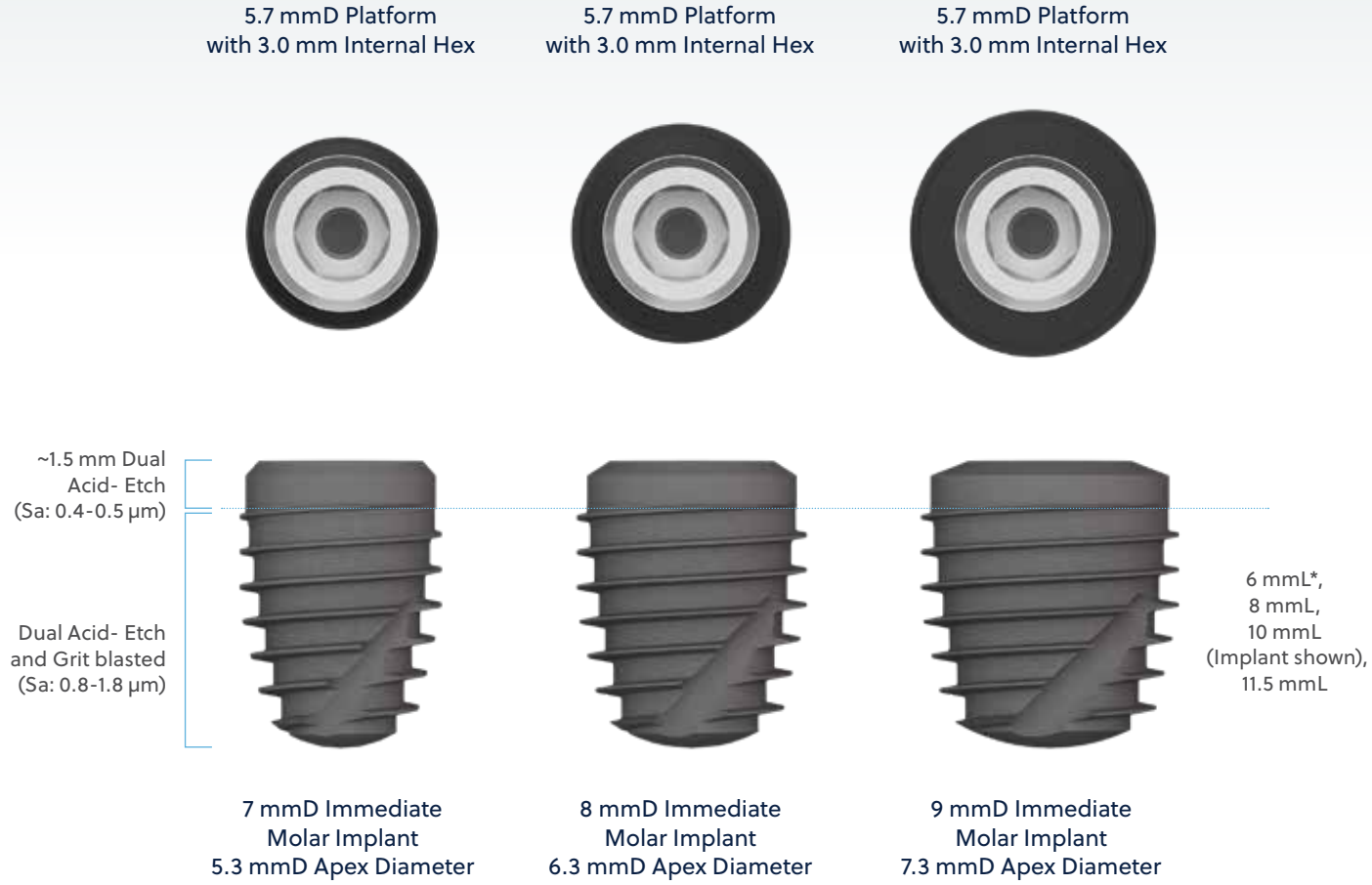
Overview of the ZimVie Immediate Molar Implant System

The ZimVie Immediate Molar Implant System is a collection of implants and surgical protocols specifically designed for immediate placement into a multi-rooted molar extraction socket. The Immediate Molar Implant features a macro design with larger-than-conventional diameters and deep apical threads with the intent of achieving primary stability needed for immediate placement.

The Immediate Molar Implant System features the clinically proven[1] Contemporary Hybrid Surface with the Dual Acid-Etched (DAE) Surface on the implant collar and a rougher microtextured surface on the implant body. The TSX version of the Immediate Molar Implants includes the TSV® Friction-Fit Internal Hex Connection.

TSX Immediate Molar Implant and Specifications



The Immediate Molar Implants are available in three diameters (7, 8, and 9 mmD) with four lengths (6*, 8, 10, and 11.5 mmL). All implants feature a macrogeometry with a unique thread profile, fully tapered core, deep apical threads, and self-tapping flutes designed to achieve the primary stability needed for immediate placement in molar extractions.

The Immediate Molar Implants feature the proprietary TSV Friction-Fit Internal Hex Connection, which has been documented to minimize screw loosening and shield crestal bone from concentrated occlusal forces when utilized with ZimVie's Friction-Fit Abutments.[2,3] The implants feature a coronal platform-switching feature where the outer edge of the implant-abutment interface is repositioned inwardly and away from the outer edge of the implant collar.

*6 mmL is available only in two diameters (7 and 8 mmD)

Indications for Use

The ZimVie Immediate Molar Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed loading, or with a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.

The Immediate Molar Implants may also utilize immediate loading for these indications. The Immediate Molar Implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.

The Immediate Molar Implants may be placed immediately following an extraction or loss of natural teeth provided there is sufficient volume of alveolar bone to provide good primary stability. The Immediate Molar Implants are intended for implantation in the maxillary or mandibular molar region where bone exists and the surgeon has determined that the placement of a narrower diameter implant would increase the probability of failure due to poor primary stability or increased surgical procedures leading to complications.

Anatomical Considerations[4]

The location of molar teeth introduces specific challenges for dental implant placement, owing to the complex anatomy of molar regions and variability in bone quality post-extraction. Achieving initial stability is challenging due to the wide alveolar sockets from molars' multi-rooted nature, necessitating reliance on septal bone and the socket's periphery. Bone quality of molar sockets can also vary and affect stability, particularly in the maxilla. The proximity of molar roots to critical structures like the maxillary sinus and the inferior alveolar nerve also demands precise planning. The morphology of the extraction socket, largely influenced by the tooth’s root structure, determines the implant placement strategy and may sometimes require a delayed protocol for optimal outcomes.

When preparing for dental implant placement in molar extraction sites, it is imperative to give considerable attention to the molar extraction classification. The below classification system provides a comprehensive framework that categorizes the extraction sites based on the amount of bone available and the structural integrity of the socket post-extraction.

Classification of Molar Extraction Site[4]

Molar extraction sockets can be divided into three categories:

The ZimVie Immediate Molar Implant System offers features suitable for immediate placement in most molar extraction sockets (Type A, B, or C), provided basic principles of immediate implant placement are adhered to :

- **Atraumatic or Minimally Traumatic Extraction:** Aims to conserve septal bone in molar regions to maintain optimal bone quality and ensure initial implant stability.
- **Flapless Surgery:** Preserves blood supply to the surrounding tissues and minimizes trauma by avoiding flap elevation.
- **Socket Morphology:** Evaluate the anatomy of the extraction socket to ensure adequate bone availability for implant stability. Some sockets may not provide primary implant stability, necessitating a delayed placement protocol (with or without socket grafting). For instance, when the buccal wall is partially or completely missing, a delayed placement protocol is recommended.
- **Implant Positioning:** Generally, position immediate implants at the lingual or palatal aspect of the extraction socket.
- **Grafting:** If a wide gap exists between the fresh extraction socket and the implant, bone augmentation is carried out at the implant placement site. After placing the bone graft in this gap, a membrane or soft tissue is needed to cover the exposed grafting material.

Fig 1A Type A socket: The coronal section of the implant is fully supported within the septal bone.

Fig 1B Type B socket: The implant is stabilized but not fully contained within the septal bone, leaving a gap between the implant and the inner walls of the socket.

Fig 1C Type C socket: No septal bone is available for implant stabilization. To achieve stability, a wide-diameter implant must engage either the inner walls of the socket and/or the bone apical to the socket.

ZimVie Immediate Molar System's implant macrogeometry includes larger diameters, which are pivotal for achieving primary stability across the diverse anatomical scenarios in extraction sockets. For Type A sockets, the design ensures apical engagement within the ample septal bone. For Type B and C sockets, where bone availability diminishes, the larger diameters crucially engage more peripheral bone or the socket's outer walls, ensuring the implant's stability for immediate placement.

Moreover, the ZimVie System integrates deeper apical threads designed to enhance stability, particularly in Type C sockets where septal bone is minimal or absent. This design maximizes bone engagement in the socket's apical region, a critical factor for securing the implant's initial stability. The introduction of new drills and site preparation instruments aims to minimize operational chatter and maximize cutting efficiency, addressing the need for precision and controlled osteotomy preparation, a strategy particularly vital for Type B and C sockets where the available bone's quality and quantity necessitate meticulous implant positioning.

In conclusion, the design elements of the ZimVie Immediate Molar Implant System—encompassing larger diameters, deeper apical threads, and precision-focused site preparation tools—render it a comprehensive solution for immediate molar implantation within the appropriate anatomical limitations. Addressing the primary stability needs, anatomical challenges, and clinical demands associated with molar replacements, the system equips clinicians with the necessary tools for a broad spectrum of clinical scenarios.

Anatomical Criteria

The diameter and length of implants to be placed will depend on the type of restoration planned as well as the quality and quantity of available bone. Furthermore, diameter selection is based on the distance between buccal and lingual plates, while length selection is guided by root length and maintaining distance from key anatomical structures. Selecting an implant length that allows for apical engagement beyond the tip of the root is recommended. A good quality CBCT scan should be used to determine the appropriate implant length and placement depth.

The following boundaries should be maintained when planning implant location:

Mesial-Distal boundary

- At least 1 mm on either side of the platform is the minimum requirement for restorative contours.
- A distance of 3 mm between implants and a distance of 2 mm between implants and adjacent teeth is recommended for optimal preservation of interproximal marginal bone levels and papillary soft-tissue height.

Buccal-Lingual boundary

- A minimum buccal and/or lingual restoration contour of 1 mm on either side of the platform diameter is needed.
- Restorations require space for sub-structures and substantial veneering materials (i.e., denture).
- Available bone to allow placement such that the occlusal force is axial through the center of the implant body is required.
- It is recommended to create an osteotomy with a biased palatal placement of the implant. Palatal implant placement in anterior extraction sockets commonly results in avoiding dehiscence of the labial plate, allowing sufficient running room for prosthetic components.[6]

Apical-Coronal boundary

- Immediate molars are recommended to be placed 2 mm below the buccal ridge crest or 3 mm below the facial gingival margin.
- Maintaining a distance of at least 2 mm between the maximum osteotomy depth and the superior boundary of the mandibular canal is recommended to avoid impingement of the neurovascular bundle.
- Allow spacing below the floor of the sinus cavity unless sinus grafting procedures are planned.
- Placement of the restorative platform will guide the length and type of implant to be placed.
- A good quality CBCT scan should be used to ultimately determine the appropriate implant length and placement depth.

Surgical Planning

RealGUIDE® UNIVERSAL OPEN SYSTEM

The RealGUIDE® Software Suite, available through ZimVie Digital Solutions, provides clinicians with a comprehensive platform for precise surgical planning. By utilizing the software's innovative features, clinicians can effectively plan Immediate Molar Implant procedures and enhance treatment outcomes. Here's how the RealGUIDE Software Suite can support your practice:

Key Capabilities for Surgical Planning:

- 3D Visualization: Create detailed 3D models from DICOM files, allowing for comprehensive visualization of the patient's anatomy.
- Implant Positioning: Simulate and optimize implant positioning, ensuring accurate angulation and alignment.
- Bone Quality Assessment: Evaluate bone density and identify key anatomical structures to improve implant placement decisions.
- Software-Assisted Treatment Planning: RealGUIDE allows clinicians to seamlessly incorporate implant designs into their surgical planning process using STL files downloadable from ZimVie.com. However, please note that the Immediate Molar Implant System does not support placement in a guided procedure.

Packaging

All Immediate Molar Implants are provided sterile. The implant packaging includes a non-sterile outer box containing a plastic tray with a protective seal. This seal acts as the sterile barrier and must be removed to access an inner sterile tray that holds the implant and the Cover Screw.

Outer Box

Outer Tray Assembly and Patient Chart Labels

Outer Tray Seal (Sterile Barrier)
Peeled to expose the inner tray (sterile content) containing implant and Cover Screw

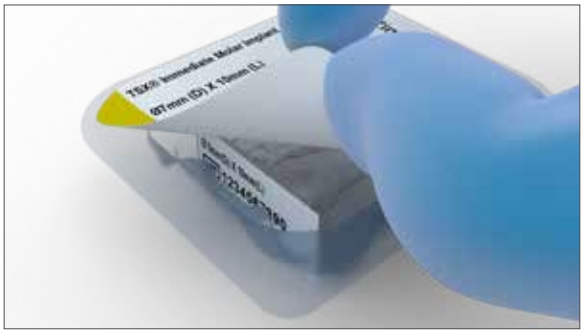
Inner Tray and Lid with Label

Implant and Cover Screw in Inner Tray

The implant sits in a titanium sleeve

Steps to access the implant and Cover Screw

Remove contents from the implant box. The nonsterile assistant peels back the tray lid and drops the sterile Implant Tray onto the sterile field.



Wearing sterile gloves, place the Implant Tray into an empty slot on the Surgical Tray.

The Implant Tray sits in an upright position in the Immediate Molar Surgical Kit to allow for implant staging and no-touch pick up and delivery of the implant.

Peel back the tray lid to expose the implant and Cover Screw.

Place the appropriate insertion instrument over the implant in the inner tray. Engage the implant directly with the insertion instrument.

Lift the implant from the inner vial and carry it to the reception site. Initiate the implant placement into the osteotomy and complete seating with the appropriate instruments.

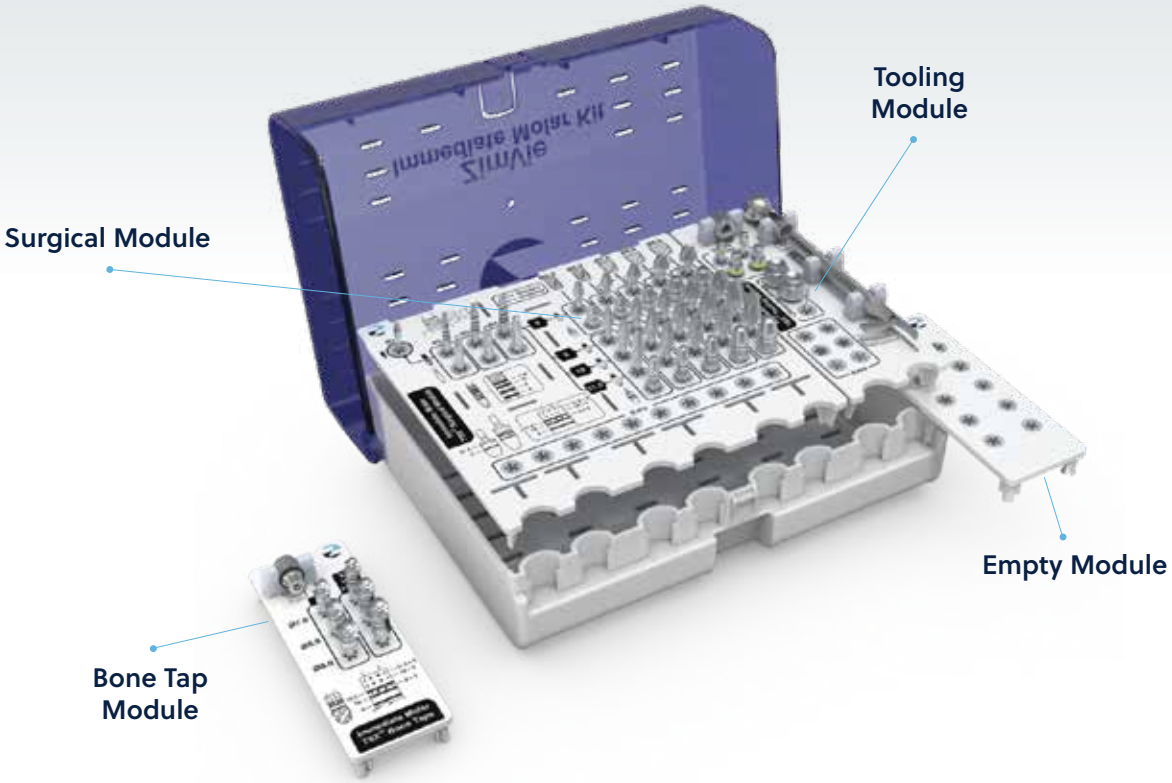
For site preparation and implant placement instructions refer to section "Surgical Procedure."

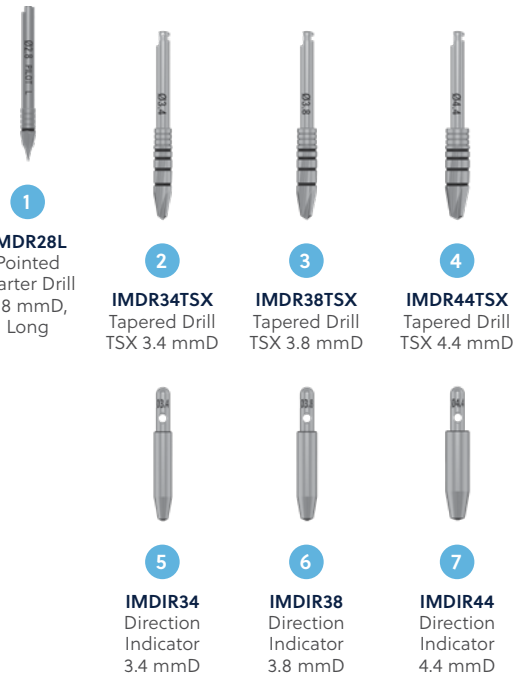
If performing a two-stage surgical protocol, pick up the Cover Screw from the Implant Tray with a Hex Driver and place it onto the implant.

For Cover Screw placement instructions refer to the section titled "Surgical Procedure."

Immediate Molar Kit

The Immediate Molar Kit has a modular, compact design for adaptability, easy access, sterilization, and storage. The kit is organized into modules: the Surgical Module, Tooling Module, an optional Bone Tap Module, and an Empty Module for further customization. Empty grommets allow additional instruments, and visual aids guide users through the site preparation sequence in the Surgical Module.





1 **IMDR28L** Pointed Starter Drill 2.8 mmD, Long

2 **IMDR34TSX** Tapered Drill TSX 3.4 mmD

3 **IMDR38TSX** Tapered Drill TSX 3.8 mmD

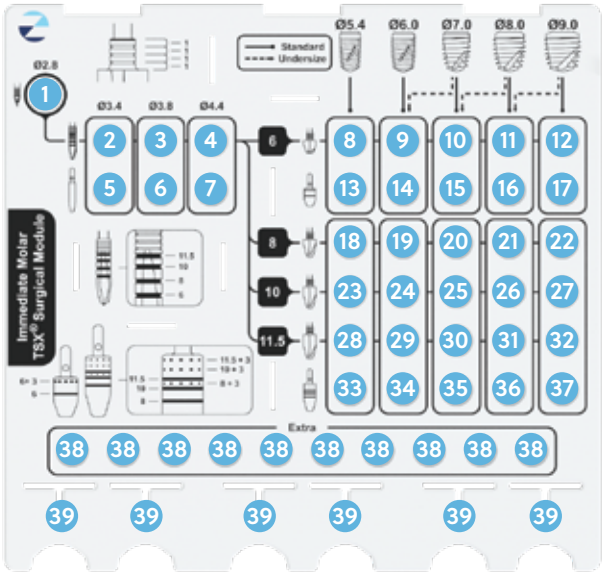
4 **IMDR44TSX** Tapered Drill TSX 4.4 mmD

5 **IMDIR34** Direction Indicator 3.4 mmD

6 **IMDIR38** Direction Indicator 3.8 mmD

7 **IMDIR44** Direction Indicator 4.4 mmD

Surgical Module



38 Empty Grommets

39 Implant Staging Slots

8 **IMDR56** Shaping Drill 5.4 mmD, 6 mmL

9 **IMDR66** Shaping Drill 6 mmD, 6 mmL

10 **IMDR76** Shaping Drill 7 mmD, 6 mmL

11 **IMDR86** Shaping Drill 8 mmD, 6 mmL

12 **IMDR96** Shaping Drill 9 mmD, 6 mmL

13 **IMDI56** Depth Indicator 5.4 mmD, 6 mmL

14 **IMDI66** Depth Indicator 6 mmD, 6 mmL

15 **IMDI76** Depth Indicator 7 mmD, 6 mmL

16 **IMDI86** Depth Indicator 8 mmD, 6 mmL

17 **IMDI96** Depth Indicator 9 mmD, 6 mmL

18 **IMDR58** Shaping Drill 5.4 mmD, 8 mmL

19 **IMDR68** Shaping Drill 6 mmD, 8 mmL

20 **IMDR78** Shaping Drill 7 mmD, 8 mmL

21 **IMDR88** Shaping Drill 8 mmD, 8 mmL

22 **IMDR98** Shaping Drill 9 mmD, 8 mmL

23 **IMDR510** Shaping Drill 5.4 mmD, 10 mmL

24 **IMDR610** Shaping Drill 6 mmD, 10 mmL

25 **IMDR710** Shaping Drill 7 mmD, 10 mmL

26 **IMDR810** Shaping Drill 8 mmD, 10 mmL

27 **IMDR910** Shaping Drill 9 mmD, 10 mmL

28 **IMDR511** Shaping Drill 5.4 mmD, 11.5 mmL

29 **IMDR611** Shaping Drill 6 mmD, 11.5 mmL

30 **IMDR711** Shaping Drill 7 mmD, 11.5 mmL

31 **IMDR811** Shaping Drill 8 mmD, 11.5 mmL

32 **IMDR911** Shaping Drill 9 mmD, 11.5 mmL

33 **IMDI5** Depth Indicator 5.4 mmD, 8-11.5 mmL

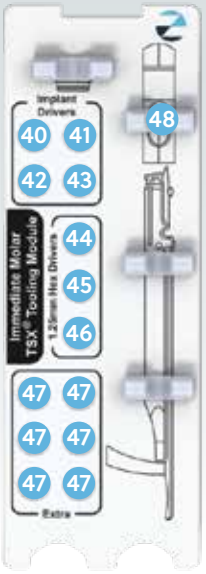
34 **IMDI6** Depth Indicator 6 mmD, 8-11.5 mmL

35 **IMDI7** Depth Indicator 7 mmD, 8-11.5 mmL

36 **IMDI8** Depth Indicator 8 mmD, 8-11.5 mmL

37 **IMDI9** Depth Indicator 9 mmD, 8-11.5 mmL

Tooling Module



40 **RHX3.0DL** Hex Driver, Latch-lock, 3.0 mm (D), 25 mm (L)

41 **RHX3.0DS** Hex Driver, Latch-lock, 3.0 mm (D), 21 mm (L)

42 **RHX3.0RM** Hex Driver, Ratchet, 3.0 mm (D), 22 mm (L)

43 **RHX3.0RS** Hex Driver, Ratchet, 3.0 mm (D), 17 mm (L)

44 **HXLGR1.25** GemLock Hex Driver, Long

45 **HXGR1.25** GemLock Hex Driver, Short

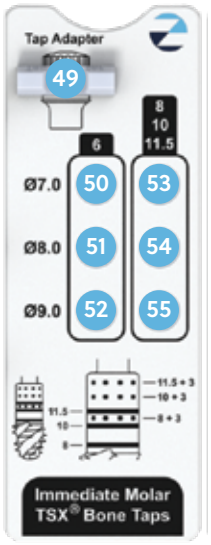
46 **HX1.25D** Latch-Lock Hex Driver, Short, 1.25 mm(D), 23 mm(L)

47 **Empty Grommets**

48 **ZTIRW** High Torque Indicating Ratchet (0-90 Ncm)

Bone Tap Module (Optional)

49 **ISOHEXADPT** High Torque ISO Hex Adapter



50 **IMT76** Bone Tap 7 mmD, 6 mmL

53 **IMT7** Bone Tap 7 mmD, 8-11.5 mmL

51 **IMT86** Bone Tap 8 mmD, 6 mmL

54 **IMT8** Bone Tap 8 mmD, 8-11.5 mmL

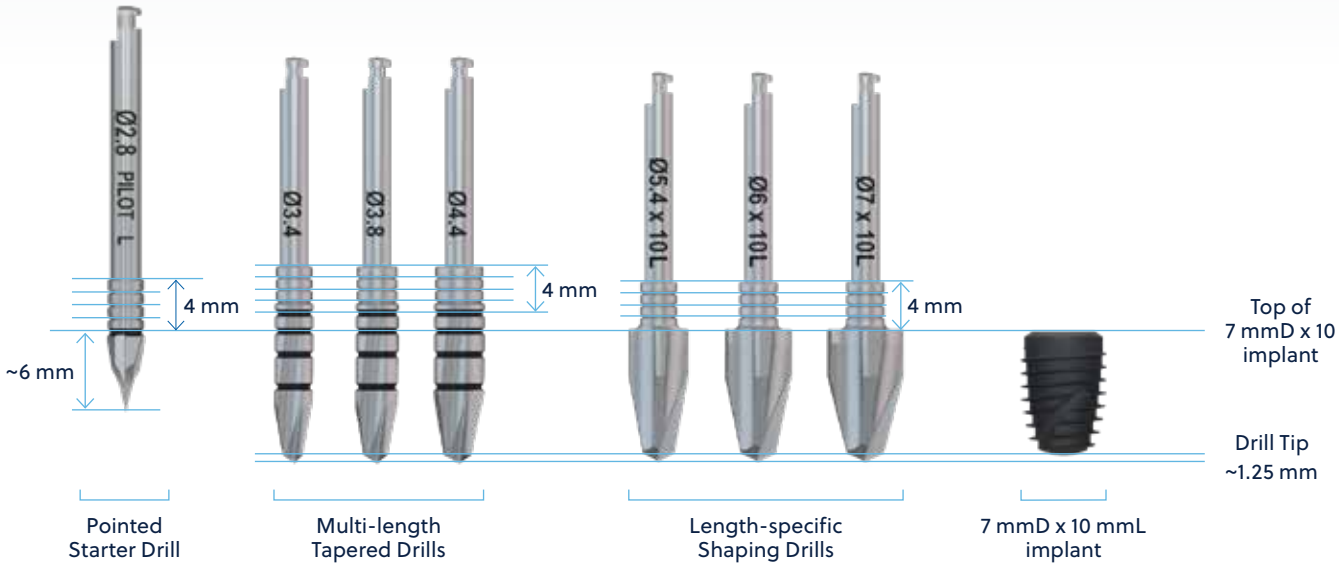
52 **IMT96** Bone Tap 9 mmD, 6 mmL

55 **IMT9** Bone Tap 9 mmD, 8-11.5 mmL

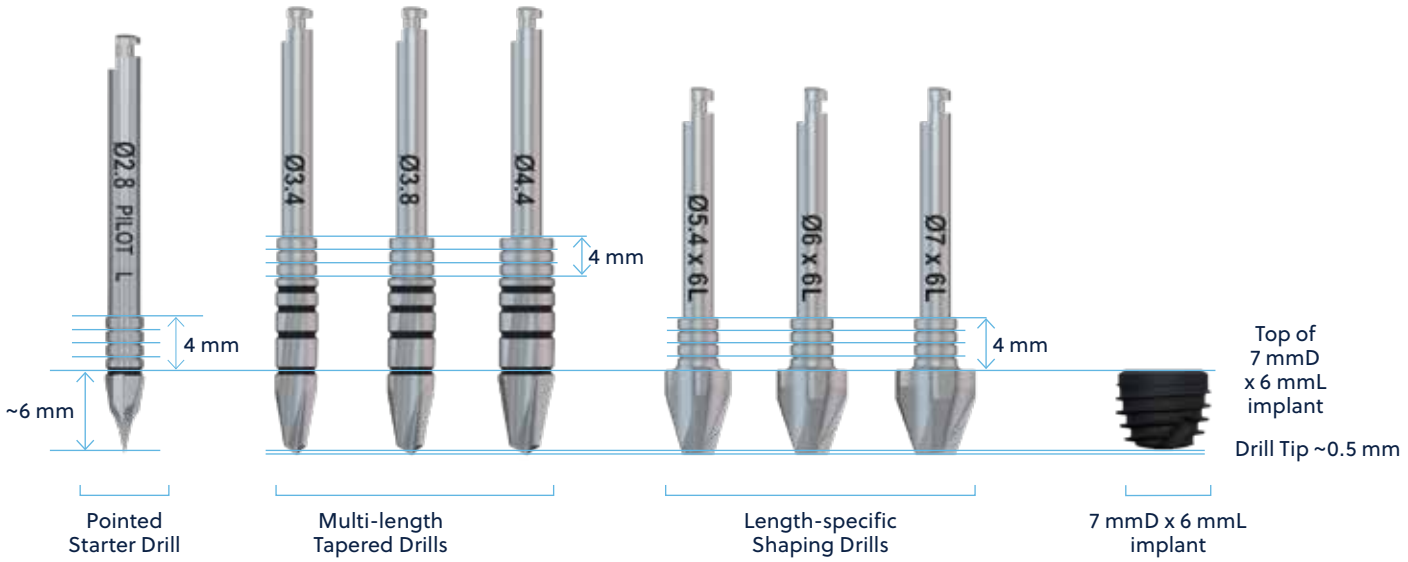
Site Preparation Tools

The ZimVie Immediate Molar System includes various instruments used to prepare the molar extraction site for Immediate Molar Implants. This system includes a range of drills designed for different stages of site preparation, as well as tools like Depth and Direction Indicators and optional instruments, such as Bone Taps. All Immediate Molar Drills have laser-etched lines and/or depth grooves that provide visual depth reference to anatomical structures (e.g. free gingival margin or top of buccal ridge etc.).

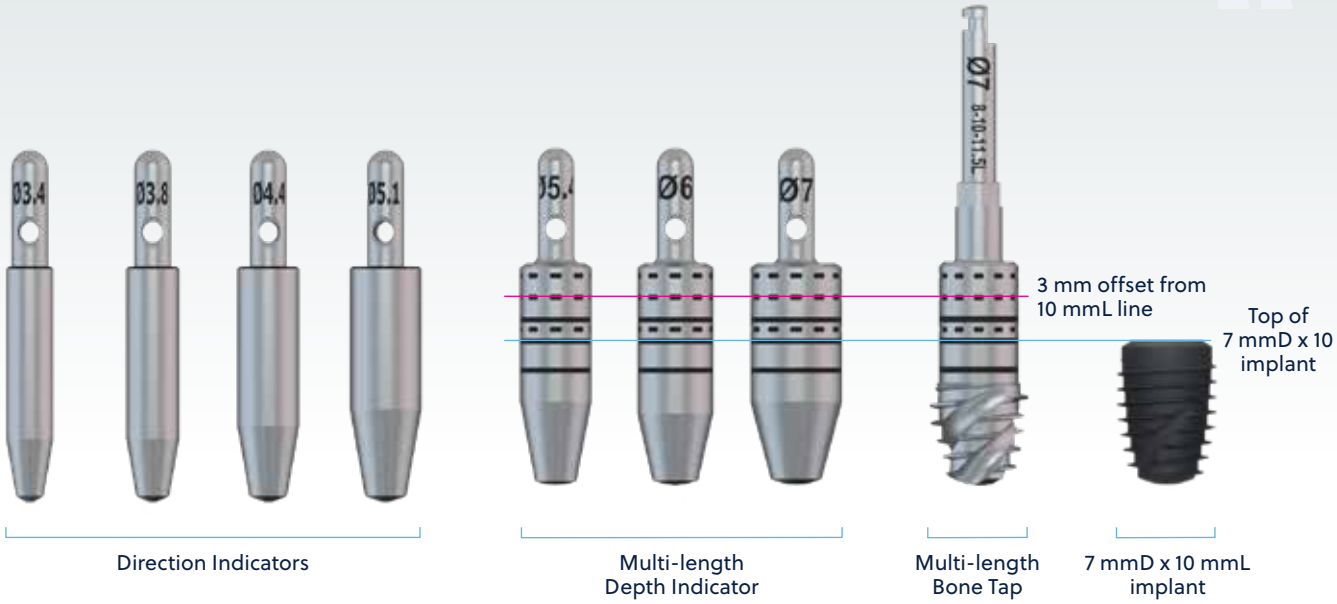
Sytem Depth and Direction Indication



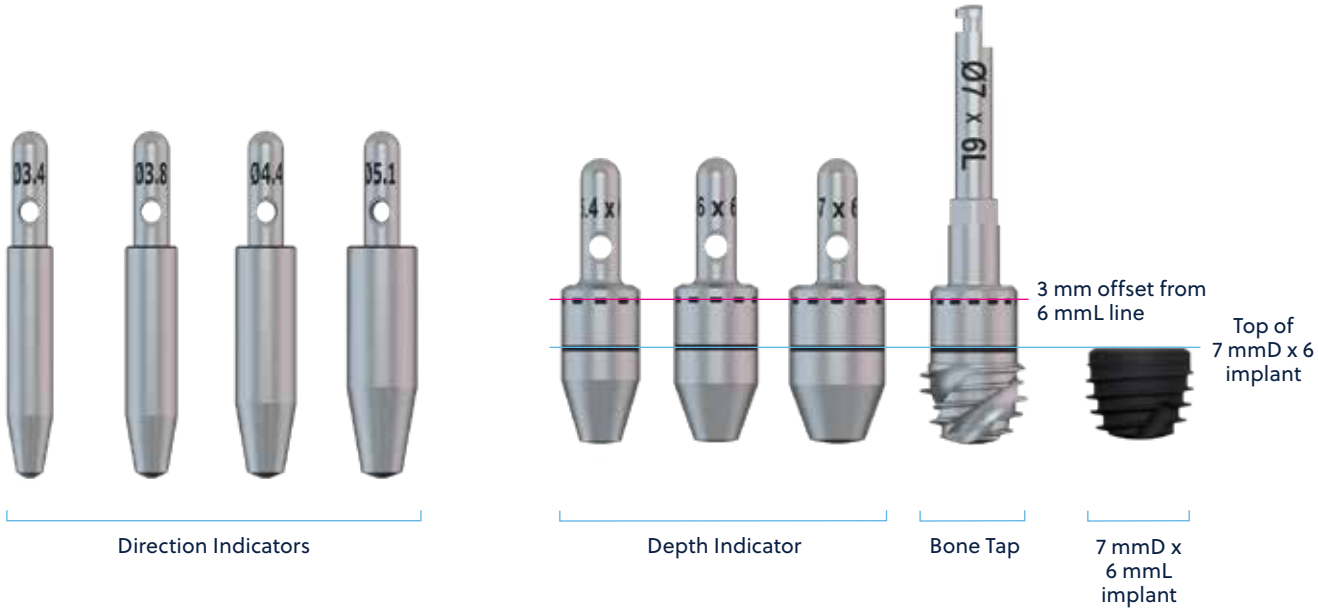
Example TSX Immediate Molar 10 mmL Site Preparation



Example TSX Immediate Molar 6 mmL Site Preparation

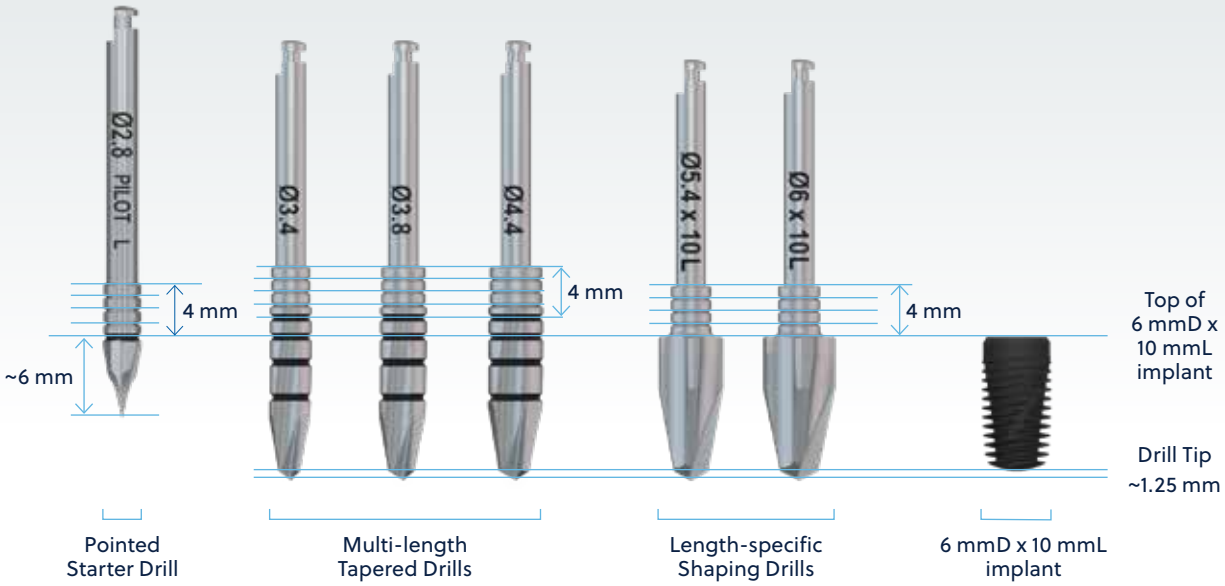


Instruments for 8, 10, and 11.5 mmL



Instruments for 6 mmL

The ZimVie Immediate Molar Site Preparation tools can also be used to place TSX implants with a 5.4 mm and 6.0 mm diameter and 8.0 mm, 10.0 mm, or 11.5 mm length.



Example TSX 10 mmL Site Preparation

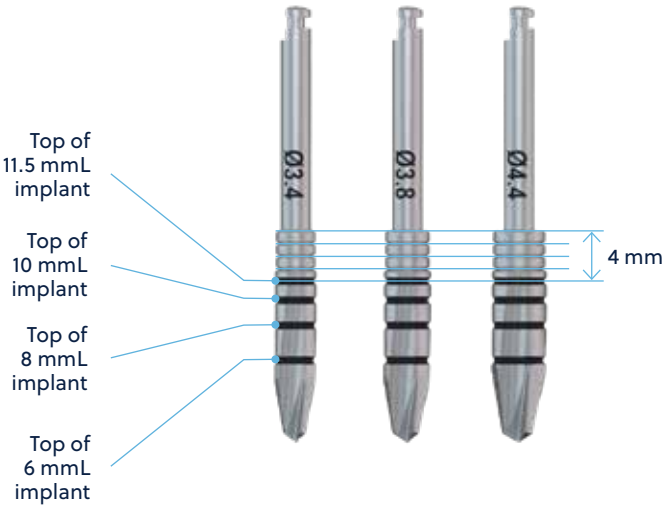
Pointed Starter Drill

The Pointed Starter Drill is used to initiate the osteotomy. This drill creates a nesting hole for the subsequent drills of the site preparation sequence. The Pointed Starter Drill has a laser-etched line to provide visual depth reference for the initial osteotomy. Utilize this drill to a depth where the laser-etched line is at the planned implant platform position. Above the laser-etched line there are four depth markers spaced 1 mm apart to provide additional visual depth reference above the solid laser-etched line.

Tapered Drills

Tapered Drills slowly widen the osteotomy to further prepare the site. Four solid laser-etched lines provide visual depth reference for the implant platform position of an 6 mmL, 8 mmL, 10 mmL, or 11.5 mmL implant at planned depth. Take each Tapered Drill to a depth where the laser-etched line is at the planned platform position of the desired implant length.

Above the cutting portion there are four depth markers spaced 1 mm apart to provide additional visual depth reference.



Note: Each drill is designed with a lead-cutting geometry which prepares an osteotomy approximately 1.25 mm (for 8, 10, 11.5 mmL implants) and 0.5 mm (for 6 mmL implant) longer than the true implant length. For Example:

- 8.0 mmL depth line indicates a 9.25 mmL total cutting length
- 6.0 mmL depth line indicates a 6.5 mmL total cutting length

Length-Specific Shaping Drills

Shaping Drills provide progressive widening and shaping of the osteotomy to ensure an intimate bone-to-implant contact. The Shaping Drills are length-specific instruments.

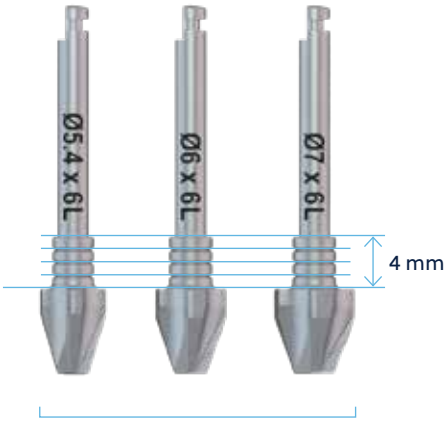
Take the Shaping Drill to a depth where the top of the cutting surface is at the planned implant platform position.

Four depth markers spaced 1 mm apart above the cutting portion provide visual depth references to anatomical structures (e.g. free gingival margin).

Note: The 8-11.5 mmL Shaping Drills are designed with a lead-cutting geometry which prepares an osteotomy approximately 1.25 mm longer than the true implant length. (10 mmL drills feature an 11.25 mmL total cutting length).

The 6 mmL Shaping Drills are designed with a lead-cutting geometry which prepares an osteotomy approximately 0.5 mm longer than the true implant length. (6 mmL drills feature a 6.5 mmL total cutting length).

Length-specific
Shaping Drills
(8-11.5 mmL)



Length-specific
Shaping Drills
(6 mmL)

Direction Indicator

The Immediate Molar Direction Indicator provides osteotomy alignment and paralleling in the early steps of the site preparation sequence.

The drill is shown for reference to highlight that the Direction Indicator shares the same diameter and sufficient length to ensure consistent alignment.

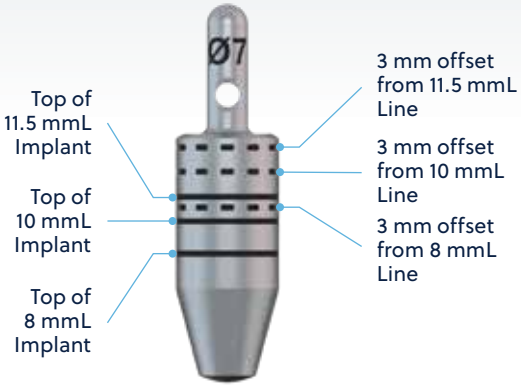
Depth Indicator

The Immediate Molar Depth Indicators are used to simulate implant depth (position) and direction (orientation) in the osteotomy prior to implant placement.

The solid laser-etched lines provide visual depth reference for the implant platform position of a 6 mmL, 8 mmL, 10 mmL, or 11.5 mmL implant at planned depth.

Separate Depth Indicators are used for 6 mmL site preparation and 8 mmL, 10 mmL, 11.5 mmL site preparation.

The dotted lines provide additional visual depth reference for anatomical structures (e.g. free gingival margin). The dotted lines are 3 mm offset from their respective solid lines.



Depth Indicator
(8 - 11.5 mmL)

Depth Indicator
(6 mmL)

Bone Taps

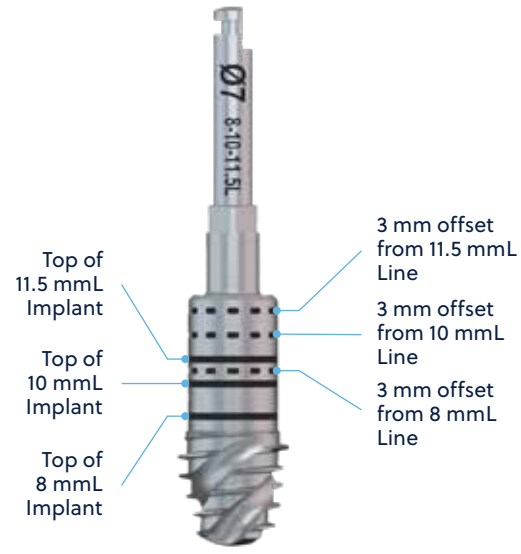
Bone Taps are optional instruments that may be used in dense bone sites to lower insertion torque. These Bone Taps thread the full length of the osteotomy. Please refer to section "Surgical Procedure" for instructions on the use of taps.

The taps can be used directly with a motorized hand-piece or with a manual Ratchet Wrench [ZTIRW] and the adapter [ISOHEXADPT] provided in the Tap Module.

The solid laser-etched lines provide visual depth reference for the implant platform position of a 6 mmL, 8 mmL, 10 mmL, or 11.5 mmL implant at planned depth. Separate Bone Taps are used for 6 mmL site preparation and 8 mmL, 10 mmL, 11.5 mmL site preparation. Take the Bone Tap to a depth where the laser-etched line is at the planned platform position of the desired implant length.

The dotted lines provide additional visual depth reference for anatomical structures (e.g. free gingival margin). The dotted lines are at 3 mm offset from their respective solid lines.

Note: Bone Taps are optional instruments and are not included in the Surgical Kit. The Tap Module can be purchased separately and added to the Immediate Molar Surgical Kit.



Bone Taps
(8 - 11.5 mmL)

Bone Taps
(6 mmL)

Drilling sequence

Protocols for Varying Bone Densities

In general, the bone density can vary in the molar region of the oral cavity and may be influenced by a variety of patient factors such as age.[5] Generally, the density of the cortical bone is typically greater in the mandible than in the maxilla.

The protocols in this Surgical Manual include drilling sequences for both a standard and an undersized osteotomy. The Standard Protocols include using final Shaping Drills sized closely to the corresponding implant profiles and ensure an intimate fit across all implant lengths. The Undersized Protocols are offered for soft bone where the anatomy warrants an undersized osteotomy and may be selected at the clinician's discretion. In a soft bone molar site, an undersized osteotomy may help enhance initial stability of the implant through lateral bone compression.

The final drill for a Standard Protocol is indicated on the Surgical Kit by a solid line emerging from the desired implant graphic. Undersized osteotomies are undersized by one drill diameter size, with the final drill for an Undersized Protocol being indicated on the Surgical Kit by a dotted line emerging from the desired implant graphic.

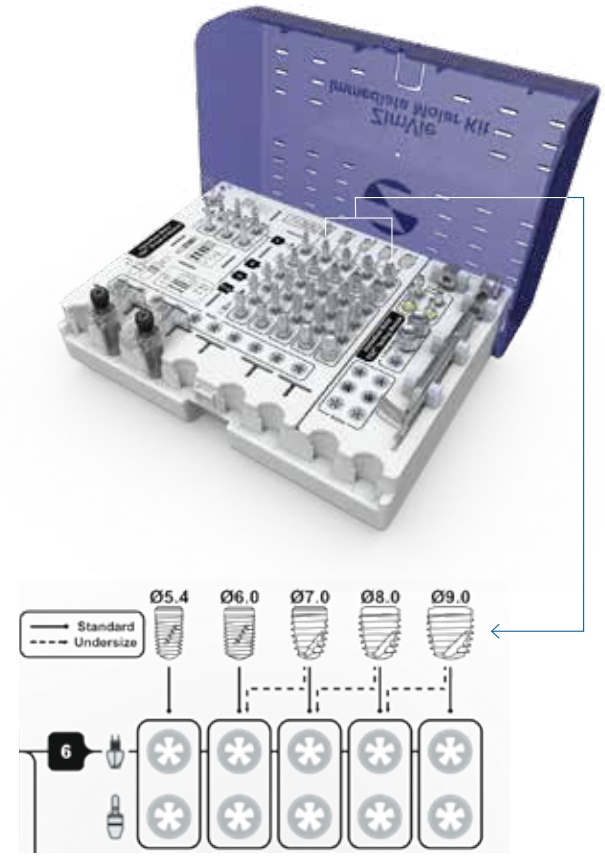
Note: Undersized Protocols are offered for 7 mmD, 8 mmD, and 9 mmD Immediate Molar Implants only.

In addition to Standard and Undersized Protocols, this Surgical Manual describes an optional tapping technique to lower insertion torque, for use at the clinician's discretion. High insertion torque may be common in sites with dense bone structure. Please refer to the section "Surgical Procedure" for tapping instructions.

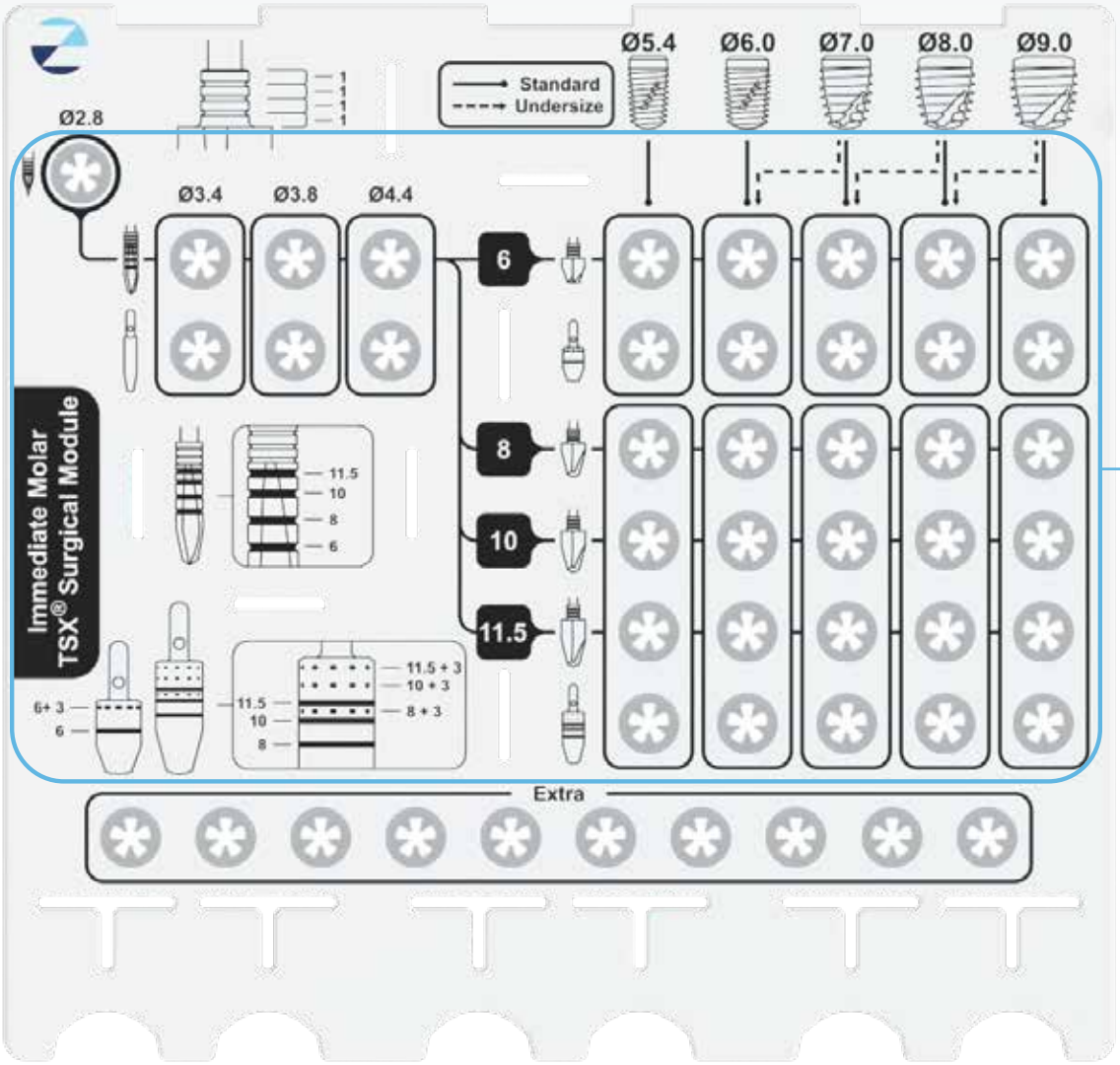
The general drilling sequence of the Immediate Molar Surgical System starts with a Pointed Starter Drill, followed by multi-length Tapered Drills and then the length-specific Shaping Drills. The Surgical Kit is laid out so the site preparation sequence can be traced by following a solid line representative of implant length (6, 8, 10, or 11.5) from left to right on the kit. The image on the right shows the solid line representing 6 mmL.

Mandibular Molar Socket (Dense Bone, Bifurcated)

Maxillary Molar Socket (Soft Bone, Trifurcated)

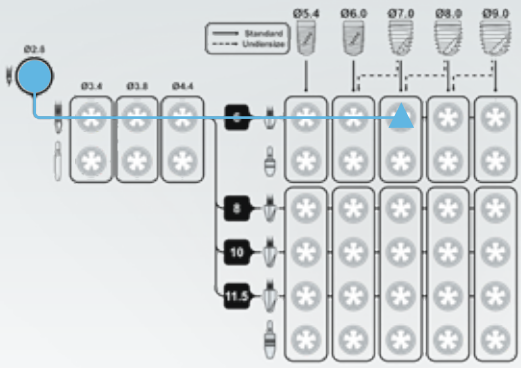


Examples of Drilling Sequence

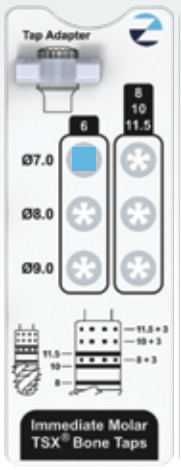


Surgical Module

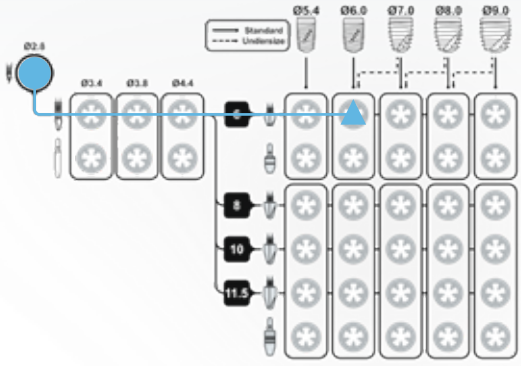
7 mmD x 6 mmL
Standard



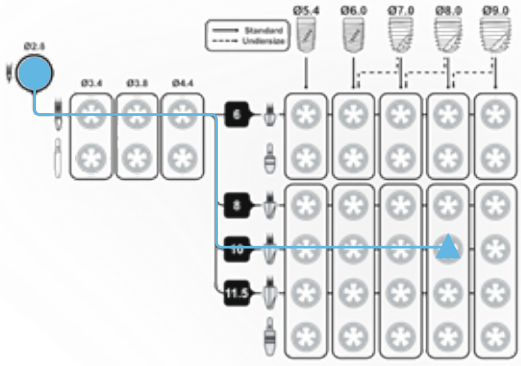
7 mmD
Optional Tap



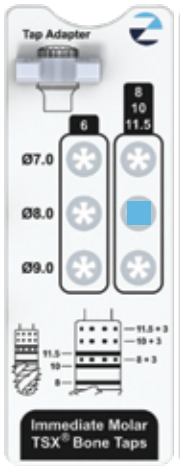
7 mmD x 6 mmL
Undersized



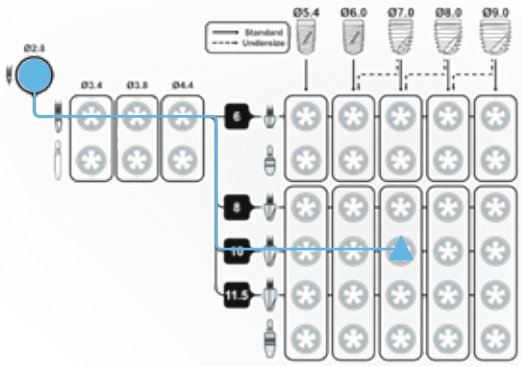
8 mmD x 10 mmL
Standard



8 mmD
Optional Tap



8 mmD x 10 mmL
Undersized



Surgical Procedure

Sterility:

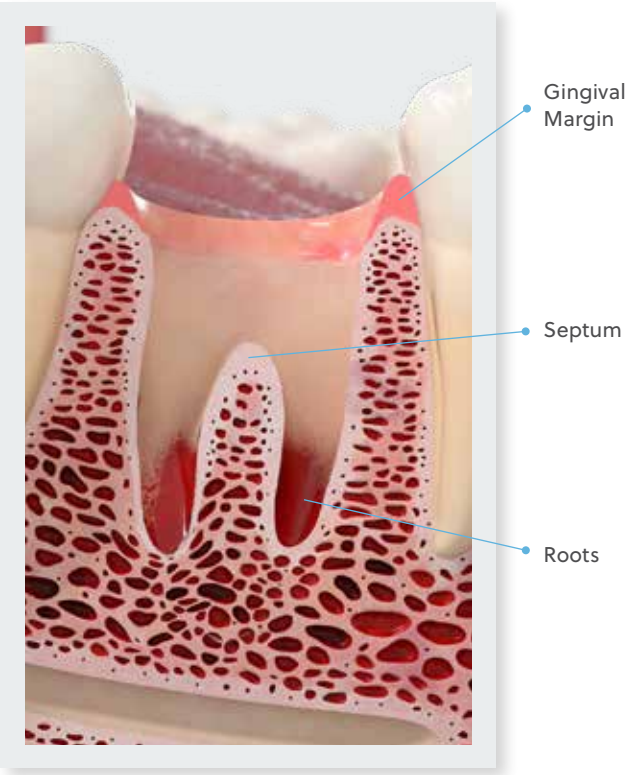
Immediate Molar Surgical Kit trays are sold non-sterile. For Immediate Molar Instruments, refer to specific product labeling for sterility designation. Unless otherwise indicated, instruments and kits are not sterile and must be thoroughly cleaned and sterilized prior to use. For recommended cleaning and sterilization procedures for the Immediate Molar Kits and Instruments, please refer to **Instructions for Use for Kits and Instruments (P-ZBDINSTRP) available at labeling.zimvie.com.**

Surgical drills are reusable and are recommended for up to 15 uses. Surgical drills are susceptible to damage and wear and should be inspected prior to each use. The lifetime of a reusable drill will vary and depends on a variety of factors including bone density encountered, proper handling, cleaning, and disinfection. Over time, repeat uses and reprocessing cycles may affect the instrument's performance and appearance. Cutting edges should present a continuous edge and appear sharp. Check the Latch-Lock shank for wear to ensure the connection is not damaged. If inspection reveals signs of wear, damage, or unrecognizable color identification, replace the drill accordingly.

Note that surgical drills labeled as Single Patient are single use instruments. All other instrumentation in the Immediate Molar Kit, such as Direction/Depth Indicators and reusable Bone Taps, should be inspected prior to each use.

Extract the Tooth

Perform atraumatic extraction of the molar to minimize damage to the surrounding bone and soft tissue. Due to complexity of molar root structures and planned immediate implant placement, particular care should be taken to minimize trauma to the surrounding tissues to preserve bone and soft tissue contours and reduce the risk of infection or delayed healing.



Representation of mandibular molar socket after atraumatic extraction

Initiate the Osteotomy

Please review sections "Anatomical Considerations" and "Site Preparation Tools" prior to initiating the osteotomy.

Initiate the drilling sequence using the Pointed Starter Drill. Place the tip of the Pointed Starter Drill on the center of the planned osteotomy site before initiating drill rotation. Image shown represents an osteotomy precisely on the inter-radicular septum. Gradually initiate drilling, increasing speed to reach the recommended drilling speed between 1200-1500 RPM. Use copious irrigation with sterile water or saline solution to prevent overheating of the bone during high-speed drilling. Continue to advance the drill into the osteotomy until the laser-etched line is at the planned implant platform position.

Note: Take notice of changes in recommended drilling speed through the drilling sequence.

Continue Drilling and Verifying Orientation of Osteotomy

Proceed to the set of Tapered Drills. Place the tip of the Tapered Drill into the center of the initiated osteotomy site and gradually initiate drilling to reach the recommended drill speed. The recommended drilling speed for the 3.4 mmD Tapered Drill is 1200-1500 RPM. All subsequent drills are recommended to be operated between 800-1200 RPM. Continue to advance the Tapered Drills to a depth where the laser-etched line is at the planned platform position of the desired implant length.

After each Tapered Drill, verify orientation of the osteotomy using the provided Direction Indicators. Thread a suture through the hole of the Direction Indicator to prevent accidental swallowing. Verify the orientation of the osteotomy by inserting the wide end of the Direction Indicator into the osteotomy.

Note: Do not pump Immediate Molar Drills, as this may distort the dimensions of the osteotomy. Immediate Molar Drills should be advanced once to full depth and then removed without any pumping action.

Continue Shaping and Verifying Depth of Osteotomy

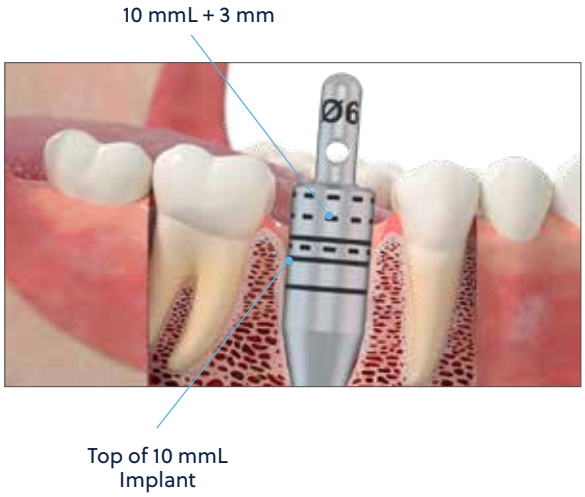
Follow the length-specific path printed on the Surgical Module (representative of the implant lengths: 6, 8, 10, 11.5 mmL) and identify the next set of Shaping Drills. Place the tip of the Shaping Drill on the center of the initiated osteotomy site and gradually initiate drilling to reach the recommended drill speed of 800-1200 RPM. Continue to advance the Shaping Drills into the osteotomy until the top of the cutting surface is aligned with the planned top of the implant platform position, approximately 3 mm below the top of the free gingival margin. There are four depth markers above the drill body that are spaced 1 mm apart and provide visual depth reference up to 4 mm above the top of cutting surface.

Note: Do not pump Immediate Molar Drills, as this may distort the dimensions of the osteotomy. Drills should be advanced once to full depth and then removed without any pumping action.

After each Shaping Drill, verify depth and direction of osteotomy using the provided Depth Indicators. Thread a suture through the hole of the Depth Indicator to prevent accidental swallowing. Verify the direction and position of the preparation by inserting the wide end of corresponding Depth Indicator into the osteotomy.

When increased torque is desired, such as in soft bone sites, the clinician may choose to undersize the osteotomy by one drill diameter and use the final Shaping Drill indicated on the kit by the undersize dotted line emerging from the image of the implant with the desired diameter.

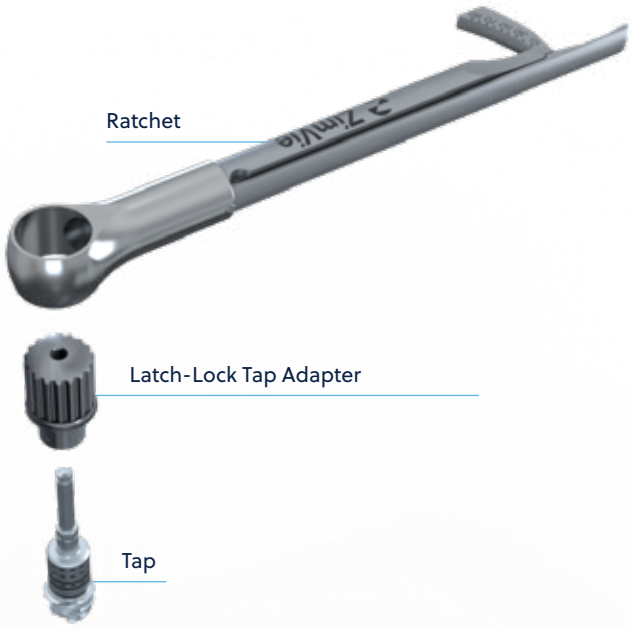
For a Standard Protocol, the final Shaping Drill is indicated on the kit by the Standard Protocol solid line emerging from the image of the implant with the desired diameter.



Optional Tapping

High insertion torque is common in mandibular sites where bone is typically more dense. Tapping the site prior to implant placement aims to lower the insertion torque. Taps can be used directly with a motorized hand piece or a Ratchet Wrench [ZTIRW] using the included adapter [ISOHEXADPT] in the Tap Module. The included adapter [ISOHEXADPT] is only compatible with the Immediate Molar taps and may not be used with other Latch-Lock instruments.

Note: Bone Taps are optional instruments and are not included in the Surgical Kit. Bone Tap Module can be purchased separately and added to the Immediate Molar Surgical Kit.



Using a surgical motorized handpiece, advance the tap into the prepared site at approximately 15 – 20 RPM. Final seating of the Bone Tap may require the use of the Ratchet Wrench [ZTIRW] and Tap Adapter [ISOHEXADPT]. Continue to advance the tap into the osteotomy until the corresponding laser-etched line is at the planned implant platform position.

Please note that the decision to tap the bone during dental implant placement is made by the surgeon based on the individual patient situation and the specific characteristics of the surgical site.

Removing the Implant from the Tray

Refer to section "Steps to access the implant and Cover Screw." Once the implant is staged in the Immediate Molar Surgical Kit, pick up the implant from its tray using the appropriate Implant Driver. Carry the implant to the mouth facing upward to prevent accidental dislodging.

Delivering the Implant to the Site

The following drivers are needed to place the implant:

- [RHX3.0DS] or [RHX3.0DL]- Hex Driver, Latch-Lock, 3.0 mmD (Short 21 mmL or Long 25 mmL) used with a motorized handpiece.
- [RHX3.0RS] or [RHX3.0RM] or [RHX3.0RL]- Hex Driver, Ratchet, 3.0 mmD (Short 17 mmL, Medium 22 mmL, or Long 28 mmL) used with a Ratchet Wrench [ZTIRW]

Deliver the implant to the site using Latch-Lock Implant Drivers [RHX3.0DS or RHX3.0DL] compatible with a motorized handpiece. Place the implant into the site at speeds up to 20 RPM. Do not exceed 80 Ncm of torque with drivers compatible with a motorized handpiece.

If implant placement torque exceeds 80 Ncm, continue implant placement manually using ratchet Hex Drivers [RHX3.0RS, RHX3.0RM, or RHX3.0RL] with a Ratchet Wrench [ZTIRW] to fully seat the implant into the site. Do not exceed 150 Ncm of torque with drivers compatible with a Ratchet Wrench.

Do not exceed 90 Ncm when pulling on the torque-indicating arm of ZTIRW. Alternatively, the ZTIRW body, without pulling on the torque-indicating arm, may be used as a traditional Ratchet Wrench without torque indication and is designed to withstand regular use in this manner up to 150 Ncm. Usage above 150 Ncm may cause accelerated wear.

Post Placement Considerations

The ZimVie Immediate Molars Implants are designed for immediate placement. Immediate loading may be considered when good primary stability is achieved and when the appropriate level of loading is employed for the individual situation. Depending on the primary stability and occlusal forces after placement, the implant may either be a candidate for a single-stage or a two-stage procedure.

Please refer to the Instructions for Use for complete indications.

Single-Stage Procedure[7]

This procedure is often used when there is sufficient primary stability to load the implant. After ensuring the implant is properly and securely positioned, a Healing Abutment or a Provisional Restoration is immediately attached. Provisional Restorations can be used to shape the soft tissue and create an ideal emergence profile for the final restoration. Careful management of the soft tissues around the implant through the use of custom or prefabricated Healing Abutment can enhance the aesthetic outcome. When placing implants, especially immediately post-extraction, there is often a gap between the implant surface and the native bone walls of the socket. Placement of bone grafting material, between the implant and extraction socket may provide support and volume to the hard and soft tissues[7].

ZimVie Immediate Molar Implants are compatible with variety of healing, provisional, and definitive restorative components that can be used during a Single-Stage Procedure. The Healing Components and provisional restorative options cater to different clinical needs, ensuring that Immediate Molar Implants can be managed efficiently with suitable temporary restorations while soft tissue heals and definitive restorations are fabricated.

For complete list of restorative components, please reference the TSX Immediate Molar Catalog.

Two-Stage Procedure

Two-stage surgery is often used in cases where there is inadequate primary stability for loading or when the implant needs time to integrate with the bone (osseointegration) prior to loading. In a traditional two-stage protocol, the Surgical Cover Screw is threaded into the implant over which the tissue is sutured during implant healing.

Locate the Surgical Cover Screw in the cap of the inner vial. Using a Hex Driver [HXLGR1.25 or HXGR1.25], manually engage the Cover Screw and remove from implant plastic tray, carry the Cover Screw to the implant site, and finger-tighten. A Latch-Lock Hex Driver [HX1.25D] may be used to complete Cover Screw seating if desired.

When the gap between the implant and the buccal bone wall of a fresh extraction socket is large, bone grafting is recommended. This grafting helps improve hard tissue healing and reduces marginal bone loss. To facilitate predictable bone regeneration and graft containment, the application of a barrier membrane is recommended.[5]

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5. Lee W. Immediate implant placement in fresh extraction sockets. J Korean Assoc Oral Maxillofac Surg. 2021 Feb 28;47(1):57-61. doi: 10.5125/jkaoms.2021.47.1.57. PMID: 33632979; PMCID: PMC7925164.

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7. Chu SJ, Salama MA, Salama H, et al. The dual-zone therapeutic concept of managing immediate implant placement and provisional restoration in anterior extraction sockets. Compend Contin Educ Dent 2012;33:524–534.

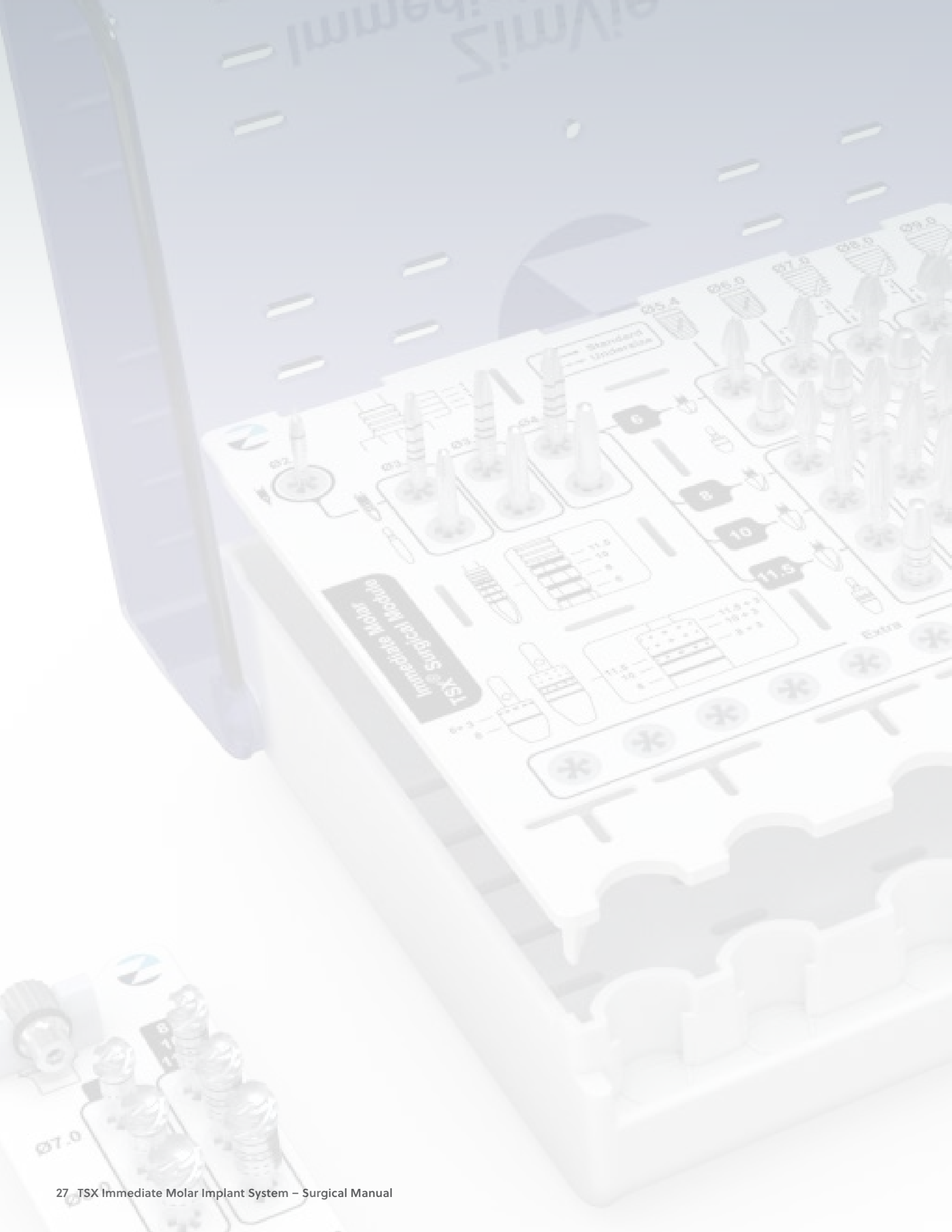
Important Product Information

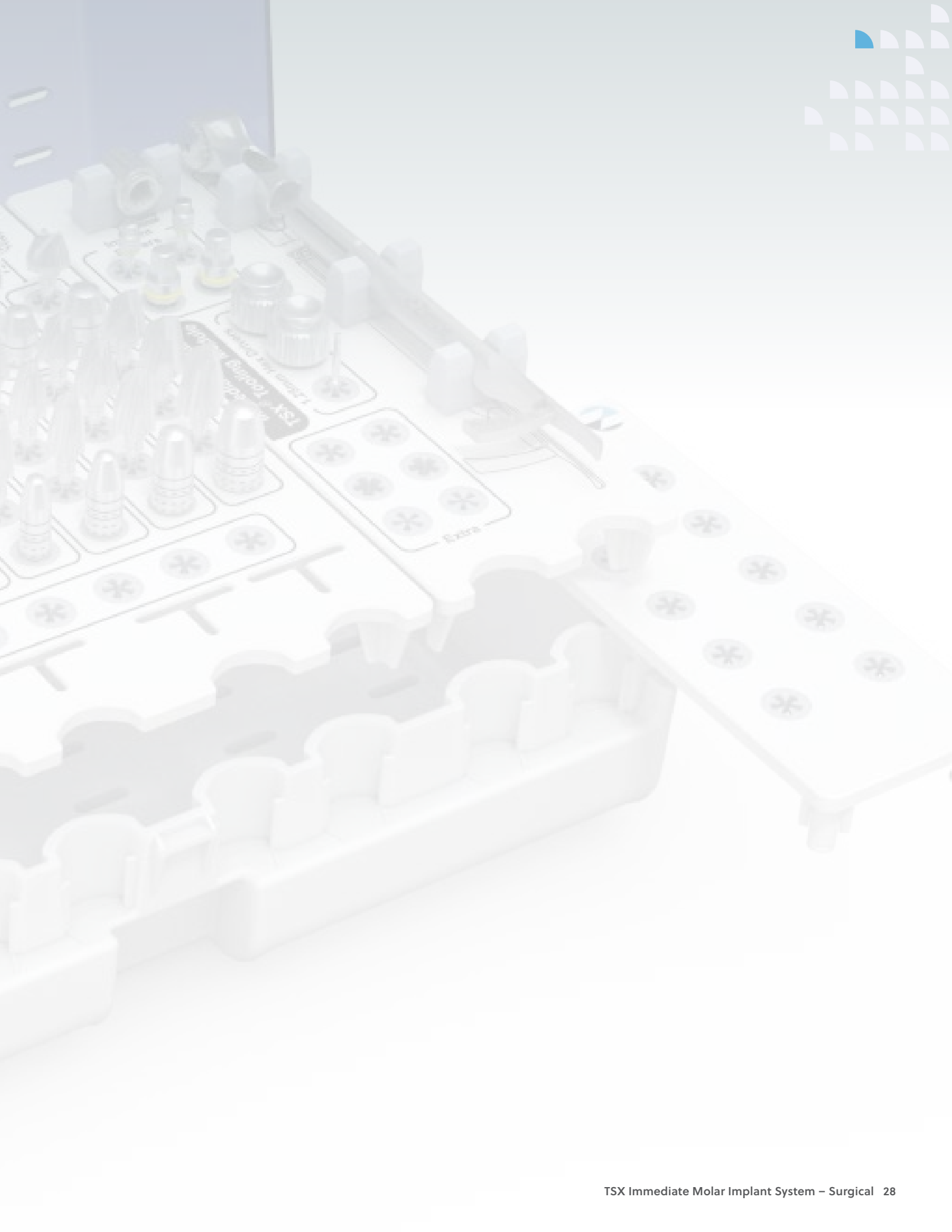
ZimVie Dental Implants

For detailed product information on all ZimVie Dental Implants, refer to the ZimVie Dental Implant IFU [P-IIS086GI] located at labeling.zimvie.com.

ZimVie Kits and Intruments

The recommended procedure for Cleaning and Sterilization of ZimVie Kits and Instruments [P-ZBDINSTRP] is available at labeling.zimvie.com.





Notes

For more information visit ZimVie.com

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