User Manual

(adin | USA

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This user manual was prepared with the professional assistance and supervision of Dr. Nachum Samet.

Adin Dental Implant Systems

General

Adin Dental Implant Systems Ltd. designs and manufactures advanced solutions for dental implantology. Adin's dental implant systems include implants, abutments and restorative components for dentists and dental technicians, and all required instruments and accessories for the fabrication of implant supported prostheses. This User Manual relates to all Adin's dental implant types: Swell[™], Touareg[™]-S, Touareg[™]-OS, CloseFit[™], UniFit, Triple[™] and One[™]. This manual and the general Instructions for Use (IFUs) should be carefully read prior to use of Adin's implant systems.

Indications for Use

 Adin Dental Implant System is intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges or overdentures in fully or partially edentulous patients in order to restore a patient's masticatory function. Dental Implants may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading.

Adin short implants (6 mmL) are intended to be used only with straight abutments

All digitally designed custom abutments for use with Ti Base abutments or Pre-milled Blank abutments are to be sent to an Adin Dental validated milling center for manufacture.

Use of Abutments

- Abutments are intended for use as accessories to endosseous dental implants to support a prosthetic device in a partially or completely edentulous patient. A dental abutment is intended for use to support single and multiple tooth prosthesis in the mandible or maxilla. The prosthesis can be screw or cement retained to the abutment.
- Flat Connection Abutments are intended for use in conjunction with Adin implants in partially or fully edentulous mandibles and maxillae, in support of multiple-unit screw-retained restorations.
- Healing abutments and cover screws are intended for use with the implant system to protect the inner configuration of the implant and maintain, stabilize, and form the soft tissue during the healing process.
- Temporary abutments are intended for use with dental implant for temporary restoration of single crowns and bridges in the anterior and posterior region for use up to six months.
- UCLA Abutments (TitanFit Abutments) are intended for use in conjunction with Adin implants in partially or fully edentulous mandibles and maxillae, in support of single-unit or multiple-unit screwretained or cement-retained restorations.

Engaging UCLA abutments are intended for single tooth screw-retained and cement-retained crowns as well as for multiple unit cement-retained implant bridges.

Non-Engaging UCLA abutments are intended for screw retained multiple teeth prostheses. This screw retained solution is mainly indicated when the screw access hole is located through the occlusal Surface or through the cingulum as well as for limited inter occlusal space. Indicated for implants with less than 40° overall divergences to allow path of insertion.

- Cement-retained abutments are used to support permanent or temporary prosthetic restoration. In this prosthetic rehabilitation process each abutment is screwed into the implant and a restoration is cemented to it (no occlusal access hole).
- The screw-retained solution may be used when the screw access hole is located through the occlusal surface or through the cingulum.
- The TMA are indicated for multiple-unit, screw-retained restorations, and may be used in combination with an implant level framework design.
- Single TMA abutments are indicated for single unit restoration only. Configuration designated for single crown screw retain solution, available in straight and up to 30° angulation.
- Ball Attachments are designed for use directly on implant to support an overdentures or partial dentures, retained by endosseous implants in the mandible or maxilla.
- Titanium base (Ti Base) is intended for fabricating custom CAD/CAM abutments for single and multiunit prostheses (abutment or directly bolted crown). Ti Bases are attached to an implant for the adhesion of superstructure (abutment or crown) made of Zirconium and/or metal alloys such as CoCr to restore function and aesthetics in the oral cavity. Ti Bases are intended for single use only.

Contraindications

- Dental implants should not be placed in patients who are considered medically unfit for general or oral surgical procedures.
- Special attention, and a thorough evaluation of potential risks and benefits should be given to patients who exhibit underlying medical factors that might affect bone or soft tissue healing processes (e.g., bone or connective tissue disorders, steroid treatments, radiation therapy, cigarette smoking).
- Special accommodation should be practiced in patients with relative contraindications.
- The placement of dental implants is not recommended in children and under-aged patients, until growth has stopped and epiphyseal closure is completed.
- Local infections or pathologies, inadequate bone volume and/or quality as well as general diseases and treatments affecting bone and soft tissue healing may result in osseointegration failure, both immediately after surgery or at a later stage.
- Narrow platform implants (UNP&NP) are contraindicated for use at molar, premolar, and canine restorations.
- Flat Connection Abutments are contraindicated to support of single-unit restoration.
- UCLA abutments are contraindicated to support of single-unit restoration.
- Allergic or hypersensitive response to Ti-6AI-4V alloy (titanium, aluminum, vanadium) and CoCr28Mo alloy (Cobalt, Chromium, Molybdenum).

Note: Current best practices, clinical manuals, textbooks and publications should always be consulted for upto-date information related to medical evaluation, treatment and planning the surgical procedures of patients undergoing implant placement procedures.

Preoperative Considerations and Precautions

- Prior to any surgical procedure, patients must be carefully examined and evaluated to determine their medical, psychological and physical status. Attention should be given to factors that may put the patient at risk or factors that may affect bone or soft tissue healing.
- Panoramic radiographs, as well as CT scans and other individual radiographs must be obtained to enable a complete evaluation of the dental and periodontal status, as well as for the evaluation of available bone for future implant placement.
- A comprehensive dental treatment plan, including the locations, number and sizes of planned implants should be formulated based on a comprehensive clinical and radiographic evaluation.
- Constant communication and collaboration between the dental surgeon, the restorative dentist and the dental laboratory technician are critical to ensure optimal outcomes.
- Whenever applicable, a wax-up and a surgical guide should be used, to ensure correct positioning of dental implants.
- Sufficient residual bone volume is necessary in order to achieve high primary and long-term success of dental implants. In cases of inadequate bone volume, bone augmentation procedures should be considered.
- The number of implants and their diameters, lengths and positions in a specific case must take into account the planned prosthetic type and each individual's specific conditions and habits, such as bruxism or unfavorable jaw relations. Incorrect planning and implant placement may result in compromised esthetic results, undesirable restorative outcome, and increase risk of implant overload or mechanical failure.

Intraoperative Considerations and Precautions

- The surgical placement of dental implants requires a high degree of precision and care.
- Surgical procedures must always be performed using sterile instruments and tools.
- All efforts must be made to minimize damage to both the soft and bone tissues during the surgical phase. Trauma, thermal injury and infection may result in implant failure or damage to the surrounding tissue.
- Any divergence from the established surgical protocols increases the risk of osseointegration failure.
- Loading and healing timing protocols should be determined based on bone quality and the implant's initial stability.

Prosthetics Considerations and Precautions

- Adin implant systems support all established dental implant restorative options.
- Successful restorative and esthetic outcomes require proper planning related to the number and position of the implants. Treatment planning should also take into account mechanical stress and occlusal force distribution, to prevent excessive transverse loads (particularly in immediate loading cases).
- Passive fit of the prosthesis over implants and abutments is mandatory.
- The use of abutments or other components not manufactured by Adin may damage Adin's implants. This, in turn, may lead to undesired prosthetic and/or esthetic results, and even to implant failure and damage to bone and soft tissues.
- Adin short implants are to be used only with straight abutments.

Implant Packaging

- Adin implants are delivered in an outer cardboard box and internal double vial package.
- A label on the outer package includes the following information: implant type, diameter and length, lot number, catalog reference number, manufacture date and expiration date. Four peel-off labels with identical information are included inside each implant package for easy and simple documentation in patients' charts.
- The outer implant vial cap is color coded for easy identification of the implant platform size.
- Never use implants if package is damaged or contaminated in any way.
- Mounted implants are attached to a stainless-steel carrier. Mountless implants are attached to a deliver adapter which is made of titanium.

Carrier and or adapter are intended for transfer to the prepared to the aseptic surgical site without risk of contact contamination.

In terms of product identification, the mountless-packaged implants are differentiated from the mounted ones by the addition of 'ML' to catalog number, item description and printing of the word 'MOUNTLESS' on the implant single unit box.



Product Sterility and Maintenance

- Adin implants are provided sterile (by gamma radiation), and are intended for single use only.
- Never reuse a dental implant and never use implants after their expiration date (indicated on the outer package label) or if package is damaged or contaminated. Such use may result in implant failure and damage to surrounding tissues.
- Adin abutments are supplied non-sterile and must be sterilized prior to use.
- Adin surgical and prosthetic kits are supplied non-sterile.
- Kits and abutments must be steam sterilized using autoclave sterilization for for 4 min at 132°C/270° for the Pre-Vacuum cycle or for 15 min at 132°C / 270°F For the Gravity Cycle.

Hazards

- To prevent aspiration or swallowing, attach a long dental floss to small instruments and pay special care while using them in patients' mouths.
- The Use of improper techniques during implant placement or during the restorative phase can result in implant failure and a substantial loss of surrounding bone.
- Dental implants should never be reused.
- Cover screws, healing abutments, temporary abutments and abutments should also not be reused, due to potential cross contamination. Reuse of these components may also result in product failure, as functionality cannot be guaranteed.
- Incorrect treatment planning, and the use of wrong implant sizes, insufficient amount of implants and/or improper implant positioning may lead to mechanical failures of implants, components or restoration.
- The use of narrow implants (NP and UNP implants) in the posterior region is contraindicated.

Warnings

- The label "Rx Only" refers to the following caution text: "Federal (USA) law restricts the sale of this device to, or on the order of, a licensed physician or dentist".
- Before use, read carefully the instructions for use and surgical manual.
- Improper technique can contribute to implant failure and/or loss of bone. Adin's dental implants are intended for use only in the indicated applications and must not be altered in any way.
- Abutments are provided non-sterile and must be cleaned and sterilized before use in order to prevent contamination. Detailed instructions for use cleaning and sterilization are provided in Adin's User Manual.
- Used uncleaned and unsterile devices may pose a biological hazard due to tissue contamination. To prevent risks associated with such hazards, when necessary, dispose used devices in accordance with applicable local laws and regulations or according to institutional protocol.
- For short implants (shorter than 7 mm), immediate restoration or loading on a single implant in such situation has not been studied and is not recommended for a terminal molar in an arch nor cantilevering more than one pontic off a single implant.

a. Because of the reduced surface area for anchorage in the bone, implants shorter than 7 mm length should be used with caution because they present greater risks to failures compared to standard implants, and are recommended for the following situations:

i. As an additional implant together with longer implants to support implant-borne reconstructions.

ii. As an auxiliary implant for implant-borne bar constructions supporting full dentures in a seriously atrophied mandible.

b. When a short implant is the treatment of choice consider a two-stage surgical approach, splinting of implants, and placement of the widest possible implant. For short implants (strictly shorter than 7 mm), clinicians should closely monitor patients for any of the following conditions: peri-implant bone loss, changes in the implant's response to percussion, or radiographic changes in bone to implant contact along the implant's length. If the implant shows mobility or greater than 50% bone loss, the implant should be evaluated for possible removal. Allow longer periods for osseointegration.
c. Short implants (strictly shorter than 7 mm) should not be placed in patients who

demonstrate untreated occlusal parafunction, such as bruxism or clenching.

 All digitally designed custom abutments for use with Ti Base abutments or Pre-milled Blank abutments are to be sent to the following Adin Dental validated milling center for manufacture: Pittman Dental Laboratory, 2355 Centennial Circle, Gainesville, GA US 30504.

Tel: +1-800-235-4720, e-mail: support@pittmandental.com

For the current list of validated milling centers, see https://www.adin-implants.com/user-manual/

MRI Safety Information



MR Conditional

Warning: The RF safety of the device has not been tested. The patient may only be imaged by landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the RF coil. **Note:** Instruct the patient to carry the patient label / card, especially when undergoing MRI procedure.

Devices which are composed of material that have a known and acceptable MR induced displacement force and torque profile, may be safely imaged by positioning the patient, such that the device is at least 30 cm from the isocenter of the MRI magnet. This is also referred to as landmarking the patient at least 30 cm below the device. This landmarking will ensure that the device will be outside the high RF exposure zone to mitigate RF heating risk.

Published literature was used to determine that the Titanium material used for Adin's implants and abutments is safe from an MR-induced displacement force perspective for a given apatial gradient and also from an MR-induced torque perspective) Scientific rationale based on published literature may be used to determine if the material used is safe from an MR-induced displacement force perspective for a given spatial gradient and also from an MR-induced torque perspective (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): (783-79)).

Device Name	Adin Dental Implant System	
Static Magnetic Field Strength (B0)	≤ 3.0 T	
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)	
RF Excitation	Circularly Polarized (CP)	
RF Transmit Coil Type	For body transmit coil, landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the coil. Extremity T/R coils permitted. Excludes Head T/R coil.	
Operating Mode	Normal Operating Mode in the allowed imaging zone	
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)	
Maximum Head SAR	Not evaluated for head landmark	
Scan Duration	No specific constraints due to implant heating	

A patient with this device can be scanned safely in an MR system under the following conditions:

Training and Education

- Adin strongly recommends that dental professionals, both beginners and experienced implantologists, always keep up-to-date and current with published data and knowledge related to surgical and prosthetic treatment using dental implants and abutments.
- Adin offers a wide range of courses at various levels, and provides support through a global network of experienced experts.
- Please contact your local Adin representative for more information regarding certified training centers.

Five types of implants:

CloseFit™ Implant System: 0 UNP CloseFit™ 0 Ultra Narrow Platform & 3.0mm & 4.3/5.0mm & 4.3/5

• Diameter and length range:

		Diameter/s	Lengths
UNP	Ultra-Narrow Platform	2.75mm	10, 11.5, 13, 16, 18
NP	Narrow Platform	3mm	10, 11.5, 13, 16, 18
RP	Regular Platform	3.5mm	8, 10, 11.5, 13, 15, 18
WP	Wide Platform	4.3mm	8, 10, 11.5, 13, 15, 18
		5mm	8, 10, 11.5, 13, 15, 18

CloseFit[™] implants' restorative platforms are identified by specific colors, which is consistent for all surgical and restorative components and tools:

- Titanium- 2.75mm Ultra Narrow Platform
- • Yellow- 3mm Narrow Platform

- • Pink- 3.5mm Standard Platform
- Blue- 4.3/5mm Wide Platform

Five types of implants:

Touareg[™]-S and Touareg[™]-OS Implant Systems:

Standard internal hex connection (RS) for all implant diameters.
 Touareg[™]-OS - OsseoFix[™] surface.

• Touareg[™]-S - Alumina oxide blast/Acid etched surface.





• Diameter and length range:

		Diameter/s	Lengths
Int Hex	Standard Internal Hex	3.5mm	8, 10, 11.5, 13, 16, 18
Int Hex	Standard Internal Hex	3.75mm	8, 10, 11.5, 13, 16, 18
Int Hex	Standard Internal Hex	4.2mm	6.25, 8, 10, 11.5, 13, 16, 18
Int Hex	Standard Internal Hex	5mm	6.25, 8, 10, 11.5, 13, 16
Int Hex	Standard Internal Hex	6mm	6.25, 8, 10, 11.5, 13

UniFit implant system:

UniFit implant system offers bone level implants that are designed for high primary stability and immediate loading procedures. This system simplifies surgical and restoration procedures by offering a unified single implantabutment connection for all UniFit implants and UniFit prosthetic components. The system offers wide range of implant diameters: Ø3.5, Ø3.75, Ø4.3, Ø5.0, Ø6.0 [mm]. UniFit system offers a unified internal connection for various implants sizes with external shapes design that is based on Touareg CloseFit[™] implants.

- UniFit conical star connection for all available diameters
- OsseoFix™ surface

		Diamete	er and length range:		
	surface treatment				
1	eat			Diameter/s	Lengths
	ce tr	UF	Standard conical star connection	3.5mm	8, 10, 11.5, 13, 16, 18
	rfac	UF	Standard conical star connection	3.75mm	8,10,11.5,13,16,18
	X™ SU	UF	Standard conical star connection	4.3mm	6.0, 8, 10, 11.5, 13, 16, 18
÷	OFix	UF	Standard conical star connection	5mm	6.0, 8, 10, 11.5, 13, 16, 18
lin)sse	UF	Standard conical star connection	6mm	6.0, 8, 10, 11.5, 13
,	()				



All UniFit implants have the OsseoFix™ surface:

uses calcium phosphate to achieve the desired surface roughness and cleanliness levels.

Swell[™] Implant System:

- Standard internal hex connection (RS) for all implant diameters
- Alumina oxide blast/Acid etched surface
- Diameter and length range:



		Diameter/s	Lengths
Int Hex	Standard Internal Hex	3.3mm	10, 11.5, 13, 16, 18
Int Hex	Standard Internal Hex	3.75mm	8, 10, 11.5, 13, 16, 18
Int Hex	Standard Internal Hex	4.2mm	6.25, 8, 10, 11.5, 13, 16, 18
Int Hex	Standard Internal Hex	5mm	6.25, 8, 10, 11.5, 13, 16
Int Hex	Standard Internal Hex	6mm	6.25, 8, 10, 11.5, 13

Triple[™] Implant System:

- Standard internal hex connection (RS) for all implant diameters.
- Alumina oxide blast/Acid etched surface.
- Diameter and length range:



		Diameter/s	Lengths
Int Hex	Standard Internal Hex	3.5mm	8, 10, 11.5, 13, 16, 18
Int Hex	Standard Internal Hex	3.75mm	8, 10, 11.5, 13, 16, 18
Int Hex	Standard Internal Hex	4.2mm	6.25, 8, 10, 11.5, 13, 16, 18
Int Hex	Standard Internal Hex	5mm	6.25, 8, 10, 11.5, 13, 16
Int Hex	Standard Internal Hex	6mm	6.25, 8, 10, 11.5, 13, 16

One[™] Implant System:

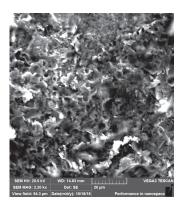
- One-piece type implants.
- Alumina oxide blast/Acid etched surface.
- Diameter and length range:



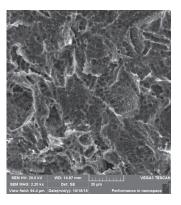
	Diameter/s	Lengths
One piece	3mm	10, 11.5, 13, 15
One piece	3.3mm	10, 11.5, 13, 15
One piece	3.6mm	10, 11.5, 13, 15
	4.2mm	10 11 5 12 15
One piece	5mm	10, 11.5, 13, 15

Surface Types

Adin Dental Implants are available in two surface types:



• OsseoFix[™] surface: uses calcium phosphate to achieve the desired surface roughness and cleanliness levels.



• AB/AE surface: uses alumina and acid etching technology to achieve surface topography and roughness.

Implant Connection Types

Adin offers two implant designs, with similar external design but different internal connection:

Internal Hex Implants

all diameters share one prosthetic platform.

CloseFit™

Close-Fit implants: with a unique conical connection for narrow platforms, standard platforms and wide platforms.

UniFit™

UniFit implants: with a unique conical star connection. All diameters share a single connection for all prosthetic components







Package Color Coding

CloseFit[™] System

- • White 2.75mm Ultra Narrow Platform
- • Orange 3mm Narrow Platform
- • Red 3.5mm Standard Platform
- Blue 4.3mm Wide Platform
- Green 5mm Wide Platfor

UniFit System

- • Yellow 3.5mm
- • Red 3.75mm
- • Blue 4.3mm
- • Green 5mm
- O White 6mm

Internal Hex System

- • Yellow 3.3 & 3.5mm
- • Red 3.75mm
- • Blue 4.2mm
- • Green 5mm
- O White 6mm

One[™] System

- • White 3mm
- • Yellow 3.3mm
- • Red 3.6mm
- • Blue 4.2mm
- Green 5mm

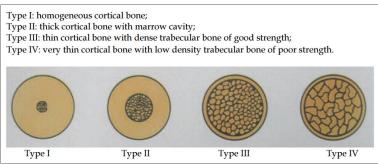
Surgical Procedures

Surgical Treatment Planning

- The number of implants is determined as part of a comprehensive treatment planning process, based on the planned restoration type.
- Bone dimensions, as well as the distances from adjacent teeth and other critical anatomical structures are determined based on up-to-date radiographs and CT scans.
- The use of a surgical guide is highly recommended to ensure correct position and angulation of each implant.
- Adin implant systems include a wide range of implant diameters and lengths, enabling clinicians to
- place and stabilize implants even in minimal bone volume.

Bone Quality and Quantity

- Dense, compact (Type I) bone provides better initial stability for implants, when compared to porous (Type IV) bone.
- Treatment planning and loading protocols should be decided upon based on individual bone conditions at each specific placement site.
- A minimum of 1.5mm of bone should surround each implant.
- A minimal distance of 2mm from critical anatomical structures (e.g., nerves) should be planned and maintained to avoid damage to these structures.



Lekholm U, Zarb GA (1985)

Shape and Design Considerations

Specific features of the unique design of Touareg-S[™], Touareg-OS[™], CloseFit[™], UniFit[™], One[™] and Triple[™] implants:

- The large range of diameters and lengths allows solutions even in sites with limited bone volume.
- The distinct narrowing of the UniFit implant's collar s designed to support optimal ridge adaptation, especially when crestal ridge width is limited.
- The active apex and sharp threads are designed to assist in angulation changes during placement, to enable correct final positioning of each implant.
 Caution: Due to the active apex, implants may not stop at the bottom of the osteotomy. This requires full attention by the surgeon to prevent damage to surrounding structures.
- The unique thread design is crafted for anchorage and initial stabilization in various bone types.

Implant Size and their Recommended Sites

• Narrow platform (NP) and Ultra Narrow platform (UNP) implants should only be used for fixed partial denture restoration for the replacement of maxillary lateral incisors or mandibular incisors. In all other sites,

NP and UNP implants should only be used when connected to other, larger diameter implant fixed partial denture restorations.

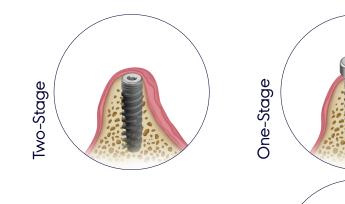
- All other implant platforms can be used for the restoration of fixed or removable partial dentures, in all sites of the mandible or maxilla.
- Clinicians should take into consideration occlusal forces as well as harmful habits when planning their cases, so that adequate implant diameter and length are used.
 Important: determine local anatomy and suitability at the available bone for implant placement. Adequate radiographs direct palpation and visual inspection of the implant site are necessary prior to treatment planning and use of Adin implants.

Adin implants can be inserted manually or using a contra-angle at speeds not exciding 25-30rpm. • The maximum insertion torque should not exceed 50Ncm.

The use of a Surgical Torque Ratchet or a drilling-unit can help avoid excess torqueing forces. **Caution:** Excess torque may damage implant connection, and may compromise healing and osseointegration. Adin's Implants should not be angled more than 30°.

Two-stage and One-stage Surgical Approaches

- Adin implants may be implanted with the two-stage or one-stage surgical approach or following the One-Stage surgical approach. The decision as to which approach to use lies completely in the hands of the surgeon.
- In the two-stage surgical approach, implants are covered by gingival tissues and are completely submerged below the gingiva during the healing phase. After placement, a cover screw which is supplied with each implant, is used to block the implant's connection, and the soft tissues are sutured. A second surgery is performed once osseointegration is achieved (hence the term "two-stage") to expose the connection of the implant and a healing cap or an abutment is used to fabricate an interim restoration and replace the cover screw, and the soft tissues are sutured.
- In the one-stage surgical approach, implants are not covered by gingival tissues after placement. Instead of a cover screw, a healing abutment is attached to the implant, and the soft tissues are sutured around the healing abutment. In the one-stage approach there is no need for a second surgery to expose the implant. However, attention must be given to the following important concerns:
- Implant should have high primary stability to use this approach.
- Healing abutment should extend about 2mm above gingival margins, to ensure that soft tissues do not cover the healing cap during the healing phase.





- Adin implants may be placed utilizing the flapless technique.
- However, since this technique prevents direct view of the bone, it requires meticulous planning and execution, and should only be considered for use with computerized-based guided surgery techniques.

Drilling Protocols

Drills Intended Use

• Adin's drills are bone cutting instruments intended for the preparation of dental implant sites in the maxilla or the mandible, prior to the insertion of dental implants.

Drills Description and Characteristics

- Adin's drills are made of surgical stainless steel and are used with external irrigation.
- Drills are available in two lengths: Short 6-13mm and Long 8-18mm.

Depth Measurement System

• Each Adin drill is marked with a unique line sequencing pattern to ensure correct measurement of the desired drilling depth.

Dental practitioners must review and become thoroughly familiar with Adin's measurement system to avoid damage to adjacent anatomical structures.

- The marks indicate actual millimeter lengths and correspond to the top of the implant.
- **Caution**: The drills are marked so that preparation is up to 1mm longer than the actual length of the corresponding implants.
- Caution: Failure to properly analyze desired drill depth for each implant, and/or failure to drill to the planned depth can result in permanent damage and injury to nerves and other anatomical structures.



Adaptation of Drilling Protocols to Different Bone Conditions

- Drilling protocols proposed by Adin cannot replace the professional knowledge and clinical judgement of the performing surgeon.
- Standard drilling protocols that are published in Adin's catalog are for full bone conditions, i.e.: for cases in which placed implants are completely covered with bone.
- Following these protocols in type 1-3 bone will result in implants stable enough for immediate loading, when this treatment modality is indicated. Note: The success of immediate loading procedures does not only rely on the stability of dental implants, but also on prosthetic procedures that are the complete responsibility of the performing dentist.
- In soft bone conditions, it is recommended to consider a reduction of one drill size (relative to standard drilling protocols), to ensure adequate implant initial stability. The self-tapping features and the conical shape of the implants allow for smooth insertion coupled with bone condensation during placement into undersized osteotomies. In such cases, it is also recommended to drill 1–2mm less than the total length of the desired implant. The active apex will enable further bone cutting into the final depth.
- Caution: This procedure requires surgeons to pay special attention in order to prevent damage to surrounding structures.
- In dense bone conditions, it is recommended to prepare an osteotomy that is 1mm longer than the length of the planned implant. In such conditions, the implant's self-drilling properties should not be utilized.
- NEVER exceed 50Ncm of torque when placing Adin dental implants.
- All drilling and pre-tapping procedures should be performed using sharp instruments, under constant and profuse irrigation.

Step-by-Step Drilling Procedure

- Stable In-and-out vertical movement of the drill is critical to allow irrigation and flushing away of debris while penetrating the bone.
- Drill to bone contact should not exceed a few seconds, while pushing the drill further into the bone up to the pre-determined length. Replace drills and proceed drilling as indicated for the desired implant diameter, paying attention to adjustments that may be required due to bone quality at the specific site.
- Drilling should be performed at low speeds (800rpm -2000rpm).
- Pre-tapping (threading of the bone) and implant placement procedures should be accomplished at very low speed (25-30rpm) or manually.
- The use of drill stoppers is highly recommended to enable easier control of drill penetration to the correct depth.
- Drilling sequence: The recommended drilling sequence for specific implant diameters is illustrated in the following table:

	Bone Type D-IV	Bone Type D-II-III	Bone Type D-I
2.75mmD	1. 2.5 For all bone types	1. 2.5 For all bone types	1. 2.5 For all bone types
3.0mmD	1. 2.0	1. 2.0 2. 2.8	1. 2.0 2. 2.8
3.3mmD	Swell [™] implants: 1. 2.0 2. (2.8) One [™] implants: 1. 2.0	Swell [™] implants: 1. 2.0 2. (2.8) 3. (3.2) One [™] implants: 1. 2.0 2. (2.8)	Swell [™] implants: 1. Three Step* One [™] implants: 1. 2.0 2. (2.8)
3.5 / 3.6mmD	1. Three-Step*	1. Three-Step* 2. (3.2)	1. Three-Step* 2. (3.2)
3.75mmD	1. Three-Step*	1. Three Step* 2. (3.2)	1. Three-Step* 2. 3.2
4.2 / 4.3mmD	CloseFit [™] , Touareg [™] -S/OS, UniFit, Triple [™] and One [™] 1. Three-Step [*] 2. (3.6) Swell [™] implants: 1. Three Step [*] 2. 3.2	1. Three-Step* 2. (3.6)	1. Three-Step* 2. 3.6
5.0mmD	1. Three-Step* 2. 3.6 3. (4.2)	1. Three-Step* 2. 3.6 3. 4.2 4. (4.6)	1. Three-Step* 2. 3.6 3. 4.2 4. 4.6
6.0mmD	CloseFit [™] , Touareg [™] -S/ OS, UniFit, Triple [™] 1. Three-Step [*] 2. 3.6 3. 4.2 4. (5.2) Swell [™] implants: 1. Three-Step [*] 2. 3.6 3. 4.2 4. 4.6 5. (5.2)	CloseFit [™] , Touareg [™] -S/OS, UniFit, Triple [™] 1. Three-Step* 2. 3.6 3. 4.2 4. 5.2 5. (5.6) Swell [™] implants: 1. Three-Step* 2. 3.6 3. 4.2 4. 4.6 5. 5.2 6. (5.6)	CloseFit [™] , Touareg [™] -S/OS, UniFit, Triple [™] 1. Three-Step* 2. 3.6 3. 4.2 4. 5.2 5. 5.6 Swell [™] implants: 1. Three-Step* 2. 3.6 3. 4.2 4. 4.6 5. 5.2 6. (5.6)

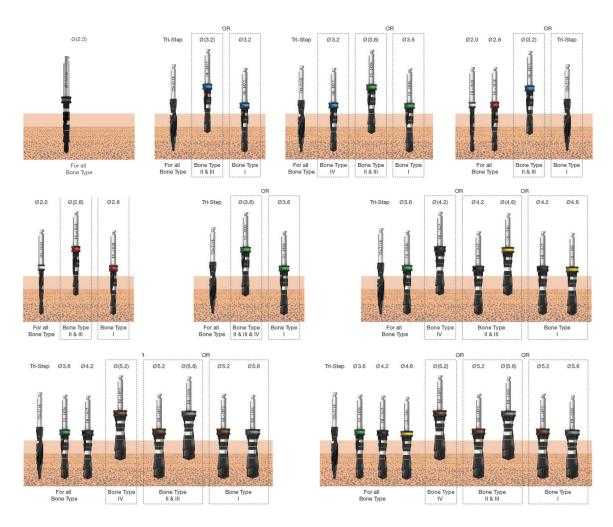
 * A series of 2, 2.8 and 3.2 drills may be used as an alternative to Three-Step drills.

Important:

• All measurements are in mm.

Caution:

- The drills are marked so that preparation is up to 1mm longer than the actual length of the corresponding implants.
- Drill diameter in parenthesis (x.x) indicates a recommendation to drill to the depth of the cortical bone only.



Drilling Accessories

Drill Extension Shaft

A Drill Extension Shaft is used to enable elongation of the regular drill shaft to enable access of Twist Drills between or near teeth/restorations. The elongated shaft requires adjustment of the irrigation mechanism to ensure that a constant flow of saline reaches the drill.

Caution: Extension shafts are not intended for use with any tool other than drills.

Parallel Implant Positioning

Implants placed in each edentulous area should be placed parallel or with a mild angulation between each other. Parallel Pins are supplied in all surgical kits, and are used during the surgical phase to indicate implant position and angulation.

A parallel pin should be placed into the first osteotomy, and based on its angulation, the next osteotomies should be prepared. Placement of parallel pins into each osteotomy will ensure parallelism among a series of implants.

Attention: Bone anatomy and adjacent anatomical structures should be taken into account, and either deviation from parallelism or the use of shorter implants should be considered to prevent damage to vital structures. Radiographic evaluation of the implant sites is highly recommended, using the parallel pins to ensure correct implant placement.

Drill Cautions and Warnings

- Adin drills should only be used by a licensed dentist who has the knowledge, skills and training related to the surgical placement and restoration of dental implants.
- Dental practitioners must review and become thoroughly familiar with Adin's measurement system to avoid damage to adjacent anatomical structures.
- Adin drills are supplied non-sterile. The drills must be cleaned and sterilized prior to first use and before each reuse. Cleaning and sterilization instructions are described in the relevant instructions for use.

- Prior to use, drills should be inspected for any wear and/or damage. Defective drills must not be used.
- Do not exceed the maximum speeds published by Adin.
- Excessive drilling speed and/or drilling duration may cause overheating and may compromise healing and osseointegration.

Note: Dental professionals must review and become thoroughly familiar with Adin's systems and instructions prior to use to avoid damage to patients.

Cleaning and Sterilization

Cleaning

Note: The following cleaning procedure should be performed prior to first clinical use and immediately after each surgery, and are applicable to all of Adin's drills and instruments:

Manual cleaning using ultrasonic cleaner

- Disassemble the entire kit, including all drills and components that were not used.
- Remove residual blood, soft or hard tissue debris using running tap water immediately after use. Brush each instrument thoroughly with a soft bristled brush, away from your body, for a minimum of two minutes.
- Clean the interior lumen using a thin brush (where applicable).
- Note: Do not use hot or boiling water.
- Clean each instrument-holding silicone tube separately to ensure removal of all blood or debris.
- Use an ultrasonic cleaner for 10 minutes using a neutral or mild pH enzymatic detergent (e.g. deconex® POWER ZYME) diluted with purified water as 1ml/liter or as per the manufacturer's instructions.
- Clean kit's plastic components thoroughly using a mild detergent, and then rinse in running tap water.
- Inspect each tool or component for any remaining visible debris and repeat the cleaning process if needed.

Automated cleaning using automated washer, applicable for all reusable drills and instruments

- Disassemble the entire kit, including all drills and components that were not used.
- Remove residual blood, soft or hard tissue debris using running tap water.
- Place the instruments in an automatic washer with neutral or mild pH enzymatic detergent (e.g. deconex® POWER ZYME) diluted per the manufacturer's instructions
- Perform a washing cycle, using the following cycle parameters:
 - 1. 4 minutes cold prewash at 30 ± 5°C
 - 2. 10 minutes cleaning wash at $55 \pm 5^{\circ}$ C
 - 3.1 minute rinse at 30 \pm 5°C.
 - 4. 10 minutes rinse at 30 \pm 5°C with distilled water
- Inspect each tool or component for any remaining visible debris and repeat the cleaning process if needed.

Sterilization

- Prior to reassembly and sterilization, all components should be rinsed in running tap water to remove any residual detergent or cleaning solution.
- All components MUST be completely dry prior to steam-sterilization, to prevent corrosion. Dry the devices using paper toweling or dry heat not exceeding 132°C/270°F.
- Place assembled kits or individual tools and instruments in FDA-cleared sterilization bags or wrap them in sterilization level single-use wrapping material for these intended autoclave sterilization cycles. Kit's type and date of sterilization should be marked on the outside using a permanent marker.
- Adin recommends the use of steam sterilization using the following autoclave sterilization parameters:

Cycle Type	Temp.	Exposure Time	Drying Time (min.)
Gravity Displacement	132°C/270°F	15 Minutes	30 Minutes
Pre-Vacuum	132°C/270°F	4 Minutes	30 Minutes

• Storage

• Sterile kits should be stored in a clean cabinet/drawer at room temperature.

Note: Kits remain sterile for a limited period of time, based on the specifications provided by sterile bag/ wrap manufacturer.

Prosthetic Procedures

Restorative Options

- Cement-retained restorations: utilize pre-fabricated or laboratory made abutments to create units that are similar to prepared teeth. Each abutment is screwed onto the implant, and a restoration is cemented to it.
- Screw-retained restorations: are either screwed directly to an implant, or are screwed to a pre-fabricated abutment. In this type of restoration, an access hole remains in the occlusal surface of the restoration.
- Overdentures: can gain support and retention using ball attachments, which are connected onto the implants, or by using a bar which is connected to a few implants.

Main indications, benefits and concerns to take into account for each option:

Cement-Retained Restorations

Main indications:	Single or multiple restorations.	
Benefits:	A fixed solution. Resembles standard crown and bridge procedures. Stable occlusion. Better esthetics (no occlusal access holes).	
Concerns:	Cement removal may be difficult. Difficult to retrieve.	Cores Cores

Screw-Retained Restorations

Main indications:	Multiple-unit restorations.	
Benefits:	A fixed solution. Easy to retrieve.	
Things to keep in mind:	Occlusal stability may be compromised due to screw access holes.	s s

Full Arch Restorations

Main indications:	Totally edentulous jaw.	
Benefits :	Increased quality of life due to better retention and stability of the denture. Simple and easy cleaning and maintenance. Low cost.	
Concerns:	At least two implants are required. Implants should be placed parallel.	

Impressions

Impression types: There are two impression types in implant dentistry:

• Implant-Level Impressions

Transfers the accurate location and 3D position of each implant to the laboratory.



• Abutment-Level Impressions

Transfers the accurate location and 3D position of each abutment to the laboratory.



Model

Model

Each one of these impression types can be captured using one of three impression techniques:

- Closed tray impression technique- is similar in many ways to conventional crown and bridge impression techniques. An impression coping is attached to each implant, and an impression tray filled with impression material records the oral structures. After setting, the impression tray is taken out of the mouth, each impression coping is attached to an analog, and then re-installed into its own position in the impression.
- Open tray impression technique- in this technique, holes are made in the impression tray above each impression coping (hence the name "open tray"). As the impression tray filled with impression material is placed, the tips of the impression copings or their long screws must extend out of the tray and be visible to the dentist.
- **Digital impressions** this technique utilizes specially made scan bodies, that should be recognizable by the specific digital system, to capture the correct three-dimensional position of each implant and the surrounding oral structures.

Basic impression type comparison table:

Open Tray

Impression component	Long Impression component with retentions	in the second
The outcome	Impression components remain embedded within the impression material when tray is taken out of the mouth	H. Con

Closed Tray

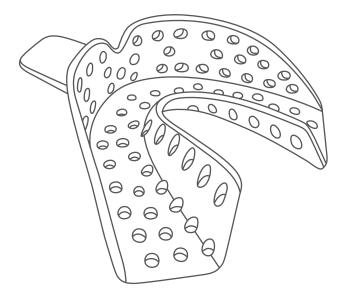
Impression component	Short impression component, with no retentions	NO DE LA COMPANY
The outcome	Impression components remain attached to the implants when tray is taken out of the mouth, and later are re-installed into the impression material	Lator Con

Digital

Impression component	Scan body	
The outcome	3D digital data	0000

Closed Tray Impression Technique

Step By Step





Remove healing cap or provisional restoration.





Fill an impression tray with impression materials.





Attach a closed-tray impression coping to each implant. Ensure correct and complete placement of each coping.





Inject a light or medium body impression material around each impression coping and the surrounding structures.



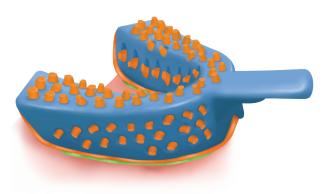


Place the impression tray into the mouth to take the impression.





Hold tray in place until materials set. Impression transfers will remain attached to each implant when tray is removed from the mouth.





Once impression material completely sets, remove impression from the mouth.

8

Remove each impression coping and connect it to an analog.







Re-install each coping-analog assembly to its original place within the impression.



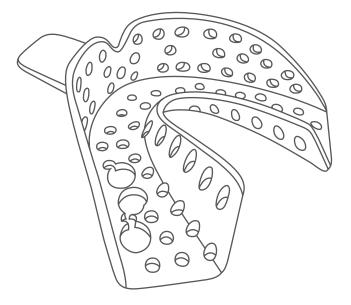


Fabricate a working model.



Open Tray Impression Technique

Step By Step





Remove healing cap or provisional restoration.





Create 5mm diameter holes above each impression coping.



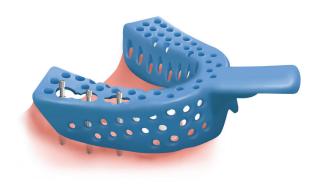


Attach an open-tray impression coping to each implant. Ensure correct and complete placement of each coping.





Make sure that the long screws are visible through the tray when it is placed in position.

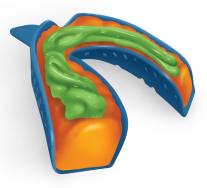


5

Fill an impression tray with impression materials.



Inject a light or medium body impression material around each impression coping and the surrounding structures.





Place the impression tray into the mouth to take the impression.



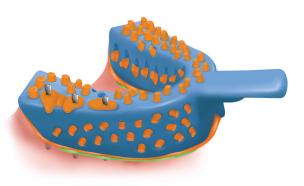




10

Ensure that each long screw is visible through the impression material. Hold tray in place until materials set. Unscrew each screw prior to removing tray.

Embedded transfers will remain embeded within impression material.





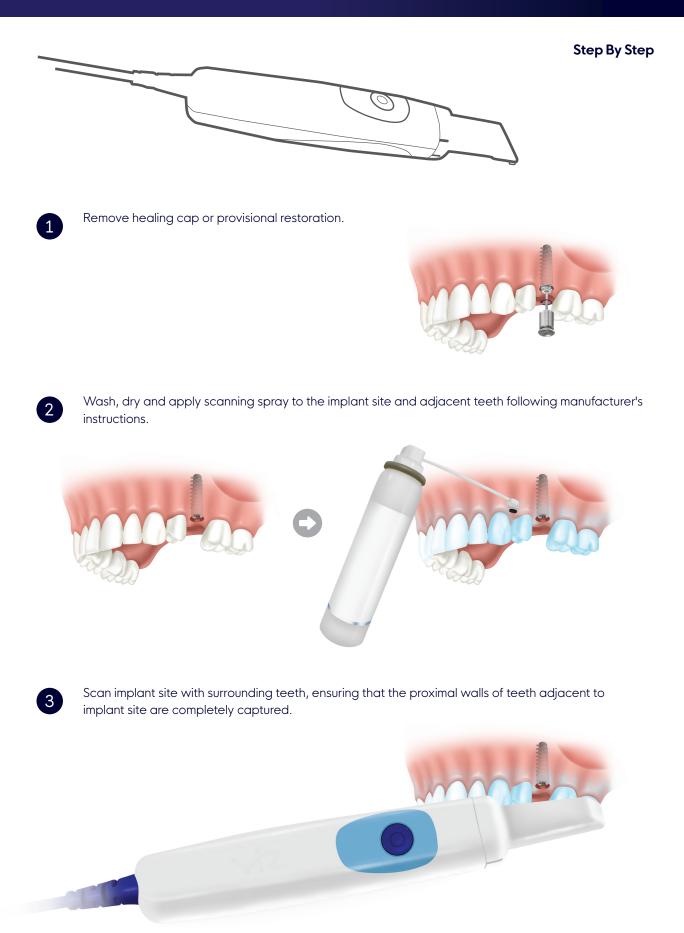
Once impression material completely sets, remove impression from the mouth.

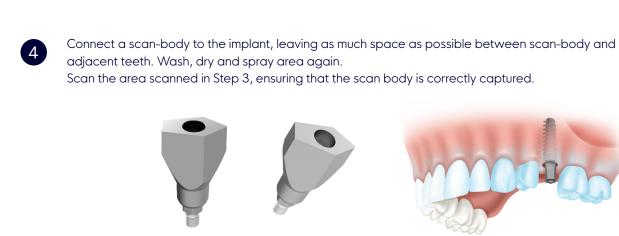




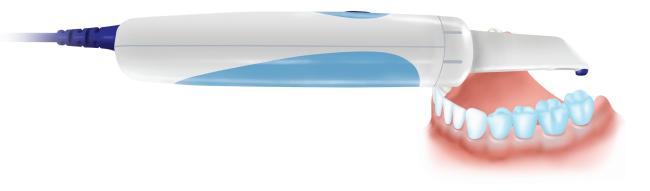
Fabricate a working model.

Digital Impression - Dental Implants









Remove scan-body. Wash, dry, spray and ensure that patient is in full occlusal contact. Scan the buccal aspect of the dentition in an area similar to the scanned area in Step 3 and 4.





5

6

Reconnect healing abutments or provisional restoration.



Abutment for Fixed Restorations

There are three main abutment types for the fabrication of fixed restorations:

- Abutments for cement retained restorations are long, straight or angulated abutments, with or without a chamfer. Fixed restorations are cemented onto these abutments like standard crowns or bridges.
- TMA abutments for screw retained restorations are short, conical shaped abutments. Fixed restorations that are held by screws adhering to TMA abutments.
- Abutments for direct screw retained restorations are long sleeves with or without a pre-fabricated metal implant connection, that are casted in the laboratory to fabricate restorations that are held by screws adhering directly to implants.
- Note: Provisional abutments are available for screw retained restoration types. They share the main characteristics of the corresponding final abutments.

	Cement retained abutments	TMA abutments	Direct, screw retained abutments
Description	Long (UniFit 12.5mmL) straight or angulated abutments, with or without a chamfer	Short, conical, straight or angulated abutments	Long, straight abutments, with or without a pre- fabricated metal implant connection
Angulated abutment options	15°, 25°	*17°, 30°	None
Available gingival heights	1-4mm	1–5mm (Straight TMAs only)	(GH:1,2,3,4)
Main benefits	Most similar to standard crown and bridge procedures Can be modified chairside or in the dental laboratory	Retrievable	Low vertical height
Concerns	Abutment restorative portion should not be shorter than 4 mm	Access holes through occlusal surfaces	Access holes through occlusal surfaces May overload implant connection

Basic Abutment Type Comparison Table:

- Dental drills, tools and accessories are used for implantation and restoration procedures.
- 2.4 ADIN's surgical tools are used for the preparation of osteotomy, for implant placement or removal (compatibility with existing ADIN's products should be checked).
- 2.5 ADIN's prosthetic tools and accessories are used in impressions coping and in rehabilitation with prosthetic devices (compatibility with existing ADIN's products should be checked).



Straight Abutments





Cement Retained Fixed Restorations

Step By Step

Abutment selection:

Note: Abutment selection is easiest when done on an accurate master model, not in patient's mouth.

1

Measure the depth of the gingiva from the head of the implant. Select abutments that are about 1mm bellow gingival margins, if restoration is within the esthetic zone or if margins should not be visible. Otherwise, it is easier if margins are within gingival level or supra-gingival. **Note:** Cement removal may be impossible if restoration's margins are located deep sub-gingival. Remained excess cement has been reported to cause damage to peri-implant tissues.



2

Choose angulated abutment/s when required. When fabricating a multiple unit fixed restoration, it is advisable to choose all abutments, straight and/or angulated abutments before continuing.







Laboratory steps:

Shorten and modify abutments as needed, ensuring retention and resistance are not lost:

- Do not shorten abutments so that their restorative portion height is less than 4 mm.
- Do not over-reduce abutment walls so that retention and wall strength are compromised.





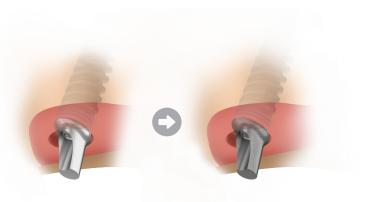
Fabricate a key that will enable easy placement of the abutments within the mouth or the master model. The key is a resin based skeleton which surrounds each abutment so that each abutment has a single position within it, while allowing access to the adhering screws. This key is of outmost importance when multiple angulated abutments are used.





Follow standard crown and bridge fabrication steps to fabricate the desired cemented restoration. Note: It is recommended that abutments

are sandblasted prior to delivery, to ensure adequate retention of the cement.





Remove healing caps and connect each abutment to its corresponding implant. Use the pre-fabricated key, if available, to ensure correct seating of the abutments.

Follow standard crown and bridge procedures to ensure proper seating of the restoration.

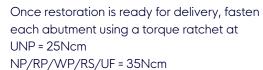




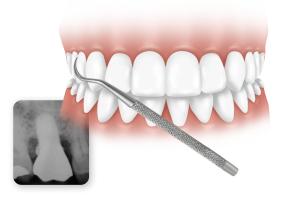
Adjust occlusion, making sure that there is no overloading of the implant-supported restoration in static and dynamic occlusal excursions.







Fill screw access holes with a sealer or with a cotton ball to ensure that cement does not fill this hole. Use a cement of your choice, making sure to remove all excess cement from around the margins. Reassess occlusal adjustment after cementation.



Screw Retained, TMA Abutments Fixed Restorations

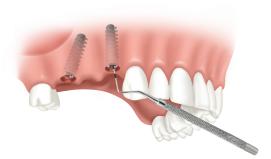
Step By Step

Abutment selection:

Note: Abutment selection is easiest when done on an accurate master model, not in patient's mouth.

1

Measure the depth of the gingiva from the head of the implant. Select abutments that are about 1mm bellow gingival margins, if restoration is within the esthetic zone or if margins should not be visible. Otherwise, it is easier if margins are within gingival level or supra-gingival.



2

Choose angulated abutment/s when required. When fabricating a multiple unit fixed restoration, it is advisable to choose all abutments, straight and/or angulated abutments before continuing.



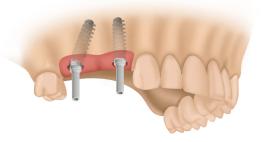


Laboratory steps:

- Attach TMA casting sleeves to each abutment, then shorten and modify the sleeves as needed.
- Alternative option: Scan master model using a 3D scanner.

Follow standard crown and bridge fabrication steps to fabricate the desired restoration, making sure that access holes are left for TMA screws.







5

Remove healing caps and connect each abutment to its corresponding implant.





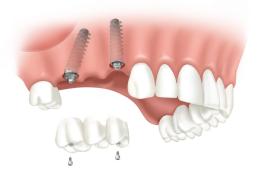
Place restoration on TMA abutments, to assess passive fit. When a multiple unit restoration is fabricated, screw the most distal screw on one side, and ensure complete seat of the restoration on each TMA abutment.Subsequently, repeat this procedure using the most distal screw on the other side to ensure passive fit.



Adjust occlusion, making sure that there is no overloading of the implant-supported restoration in static and dynamic occlusal excursions.



Once restoration is ready for delivery, fasten each TMA abutment using a torque ratchet at 35 Ncm, and fasten restoration's screws at 15 Ncm. Cover each screw with a sealer or with a cotton ball, and fill each access hole with a composite material. Reassess occlusal adjustment.







Direct Screw Retained Fixed Restorations

Step By Step

Ti Bases:

Notes:

- Ti Base units are used to ensure adequate implant-restoration connection.
- They can be used for the fabication of either custom CAD CAM abutments or direct screw retained restorations.
- Direct screw retained restorations are meant for use for single restorations, and can be used for multiple unit restorations only when impaints are completely parallel one to the other.
- All Ti Base abutments are to be sent to the following Adin Dental validated milling center for manufacture (Steps 2-4): Pittman Dental Laboratory, 2355 Centennial Circle, Gainesville, GA US 30504.Tel: +1-800-235-4720 | e-mail: support@pittmandental.com
 For the current list of validated milling centers, see: https://www.adin-implants.com/user-manual/



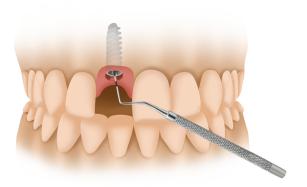
Take an implant level impression.







Choose a Ti Base that is at least 2mm shorter of gingival margins.





Attach Ti Base to each implant analog. Minimal adjustments to Ti Base components is possible but not recommended. **Note:** For single unit restoratoions ONLY use ENGAGED components.





Follow CAD CAM crown and bridge fabrication steps to fabricate the desired restoration. Make sure that access holes are left open for the fastening screw when cementing the restoration onto the Ti Base units.





Clinical steps:

Remove healing abutment/s and connect the restoration to the implant/s.





Screw restoration into implants using recommended torque. Adjust occlusion, making sure that there is no overloading of the implant-supported restoration in static and dynamic occlusal excursions.



Once restoration is ready for delivery, fasten restoration's screws at UNP = 25Ncm NP/RP/WP/RS/UF = 35Ncm Cover each screw with a sealer or with a cotton ball, and fill each access hole with a composite material. Reassess occlusal adjustment.



Every business starts with a vision. Ours is simple: We want to create the best possible dental implant solutions that offer uncompromising quality at an affordable price. It's our people that help our business thrive and grow. That's why we place so much importance on building strong personal relationships that enable us to meet our doctors' and distributors' needs. Understanding that their success is our success, we're focused on providing professional, high quality and affordable solutions and exceptional service that help them grow.



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