

User Manual

Overdenture Restorations

Grip™ Attachment System

Ball Attachment System

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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 manual and the general Instructions for Use (IFUs) should be carefully read prior to use of Adin's implant systems.

Note: Not all products may have been licensed in accordance with the Canadian law.

Product availability may vary between countries

Cleaning, Disinfection And Sterilization

The Overdenture Attachment System, and other restorative components, instruments, and replacement Ball and Grip™ Attachments (sold separately), tools and instruments are supplied NON-STERILE, and should be sterilized prior to use on patients. Ball caps and Grip™ retentions are to be disinfected only.

Cleaning

prior to first use and after each use, proceed with the following cleaning procedure:

Manual Cleaning Using Ultrasonic Cleaner Applicable For All Abutments And Instruments

- Disassemble the devices (if applicable)
- Rinse the devices under running cold water and while keeping them immersed, brush thoroughly away from the body with soft bristle brush.
- Place the devices in an ultrasonic cleaner with 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. (In Germany it is recommended to use cleaning/disinfection solution)
- Sonicate the devices for 10 minutes
- Rinse the devices with tap water for a minimum of two minutes and brush with a soft bristled brush
- Clean the interior cavity of the device (where applicable) with a thin wire to remove any remaining debris
- Inspect the devices visually for any remaining contamination or debris and scrub as necessary

Automated Cleaning Using Automated Washer, Applicable For All Reusable Instruments

- Disassemble the devices (if applicable)
- 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 (In Germany it is recommended to use cleaning/disinfection solution).
- Perform the washing cycle, with following cycle parameters:
 - 4 minutes cold prewash at $30 \pm 5^{\circ}\text{C}$
 - 10 minutes cleaning wash at $55 \pm 5^{\circ}\text{C}$
 - 1 minute rinse at $30 \pm 5^{\circ}\text{C}$
 - 10 minutes rinse at $30 \pm 5^{\circ}\text{C}$ with distilled water
- Inspect the devices visually for any remaining bone fragments or debris and scrub as necessary.

Functional Testing & Maintenance

- Visual inspection for cleanliness should be performed with magnifying glasses.
- If necessary, perform recleaning again until the instruments are visibly clean.

Drying

Dry the devices using paper toweling or dry heat not exceeding 132°C/270°F.

Disinfection

The Ball caps and Grip™ retentions are supplied NON-STERILE, prior to first use proceed with the following disinfection procedure:

Manual Disinfection:

1. Wear disposable gloves.
2. Soak the device in container filled with 70% Ethanol, for 5 minutes.
3. Wipe the device with a damp cloth.
4. Leave the device for complete air dry.

Automated Disinfection:

1. Pre-wash: with cold tap water 25-35 °C, 3 min
2. Main Cleaning: with tap water add Deconex® POWER ZYME Cleaning at 55±5°C, 5 min.
3. Rinse with warm (50°C) DI / RO water, 1 min.
4. Thermal disinfection: with DI- / RO-water at 80°C, 3 min.
5. Drying: 6 min at 100°C.

Post Cleaning Storage

Place the devices in sterilization pouches to protect from contact with contaminated instruments until sterilization by autoclave.

Sterilization

Tools and instruments (excluding the Ball Caps and Grip™ retention) provided non-sterile should be sterilized prior to use on patients. Reusable tools and instruments should be cleaned and sterilized prior to reuse on patients. The retentions may be sterilized using a liquid chemical sterilant as described below. Tools and instruments should be sterilized according to applicable instructions from the device manufacturer. In order to ensure that the inserts are sterilized, all microorganisms including Clostridium sporogeneses and Bacillus subtilis spores are eliminated, the Inserts must be soaked for a minimum of 3 hours in the liquid sterilant at room temperature.

Titanium abutments and stainless steel or other metal instruments may be sterilized by Autoclave sterilization using the following parameters. For gravity cycle, place components in autoclave bag; and for Pre-Vacuum Cycle, wrap the component with autoclave wrap material and secure wrap with autoclave tape.

USA Only: Wrap the components using a wrap that is FDA-cleared for the indicated cycles.

Autoclave Sterilization Parameters are listed below:

Cycle Type	Temperature	posure Time	Drying Time
Gravity	132°C / 270°F	15 Minutes	30 Minutes
Pre-Vacuum	132°C / 270°F	4 Minutes	30 Minutes

Re-sterilizable instruments should be dried completely and stored in a clean and dry location at normal room temperature. Prior to instrument use, the exterior of any sterilized packaging should be inspected for integrity. Care must be exercised in the handling of wrapped or autoclave bagged instrument kits or instruments to prevent damage to the sterile barrier. If damage to the sterile barrier is observed, re-serialization is recommended for reusable devices only. Single Use devices should not be re-sterilised.

Disposal

Dispose of used devices which pose a risk of infection according to facility clinical waste procedures and applicable local and state regulations.

Cleaning Implant Retained Denture

Similar to natural teeth, dental plaque tends to form on the overdenture. The plaque accumulates when it is not properly cleaned.

Dental hygiene is vital to help the overdenture last and function for longer. It is recommended to follow this one simple step daily for cleaning an overdenture:

Fill a bowl with warm water to prevent fracture of the overdenture. Apply non-abrasive toothpaste onto a soft bristle toothbrush brush gently and meticulously every surface of the overdenture.

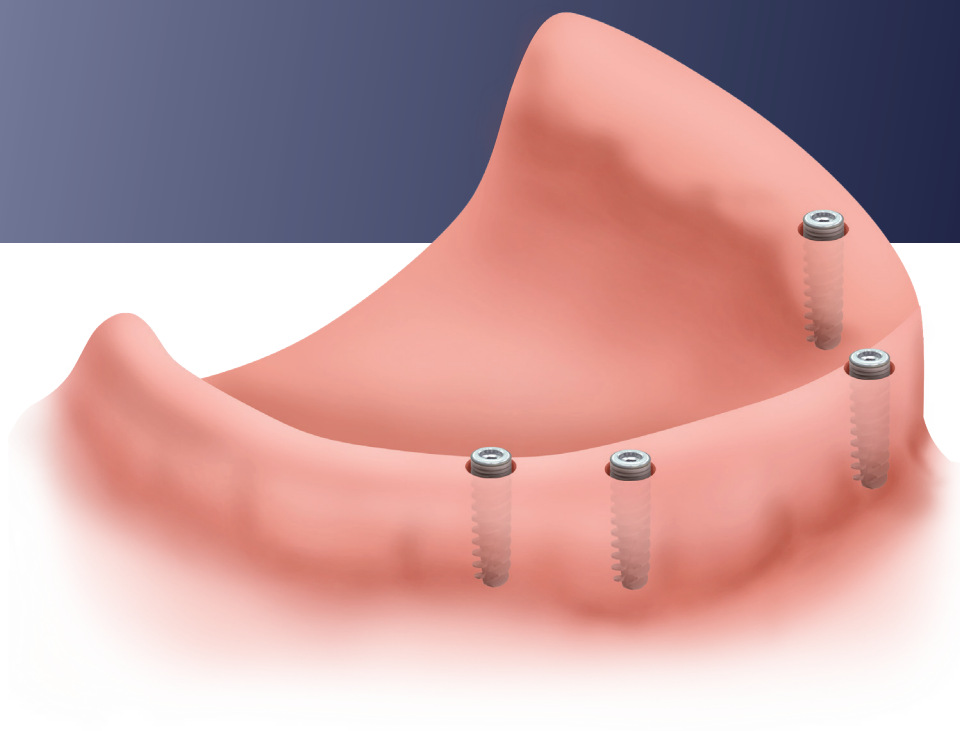
Additional Notes Of Caution

Failure of the patient to follow oral hygiene protocols and appropriately care for the overdenture may also result in inflamed tissue around the implant, leading to the development of peri-implantitis.

Throughout time, peri-implantitis may cause the implant to become mobile and fail. Please ask patients to consider the following when caring for their overdentures:

Avoid using abrasive toothpaste to clean the overdenture. The coarse particles in the toothpaste may scratch the surfaces of the overdenture, enhancing the potential for plaque accumulation.

Grip™ Attachment System



Description

The Grip™ attachment system is a versatile solution, designed to ensure maximum denture retention and stability both for maxillary and mandibular dentures.

The variety of retentive caps allow dentists to choose the required retention level needed for each individual case and can easily be replaced, when needed.

The Grip™ attachment system is available for all Adin's platforms, Internal Hex & Conical Connection (Except UNP and UF), in a range of gingival heights, to enable a reliable, long lasting and cost-effective solution for your patients.

Benefits

The low profile of the Grip™ attachments are ideal for vertical space limitations.

The flexibility of the caps prevents overloading of implants, lowering the risk of damaging the implants.

Grip™ attachments' angle compensation design to enable use in non-parallel implants up to 40°, making it a perfect and flexible solution.

Variety of retentions in different hardness levels to fit any clinical need.

Quick & easy handling of the denture.

Indications For Use

Grip™ Abutment

The Grip™ Abutment Implant Attachment System is designed for use directly on implant to support an overdentures or partial dentures, retained by endosseous implants in the mandible or maxilla.

Grip™ For TMA

The Grip™ Implant Attachment System is designed for use with straight or angled TMA abutment for retaining an overdentures or partial dentures, in the mandible or maxilla.

Grip™ For Bar

The Grip™ for bar is designed for use as a splinted bar attachment connector to support an overdentures or partial dentures, the splinted bridge connected to both straight and angled TMA, other abutments or directly to implant, depending on bar design.

Grip™ Safety Information

To reduce wear on the Grip™ abutments, it is critical to implement a maintenance routine to the Grip™ abutment and the denture components by both the clinician and the patient.

Maintenance Guidelines – For the patients

- Insert and remove of overdenture: to insert the overdenture ensure you can feel denture is positioned above the Grip™ before applying pressure. Use both hands and simultaneously press down on each side to firmly seat the overdenture into place.
- Avoid biting the overdenture into place as this force will result in improper wear of the Grip™ Abutment and may affect its longevity.
- To remove the overdenture place a finger under the left edge and one under the right edge of the overdenture and pull one side upward at a time.
- Once the overdenture is removed clean the components thoroughly.

Contraindications

- Not appropriate where a totally rigid connection is required (e.g. Screw-retain restoration).
- Use of a single implant
- Use on implant with divergence of greater than 20 degrees from vertical is not applicable.
- Use on Ultra Narrow implants
- Bruxism
- Patient not suitable for dental implant placement
- General contraindications associated with elective surgery should be observed.
- Allergic or hypersensitive response to Nylon and Ti-6Al-4V alloy (titanium, aluminum, vanadium).

Warnings And Precautions

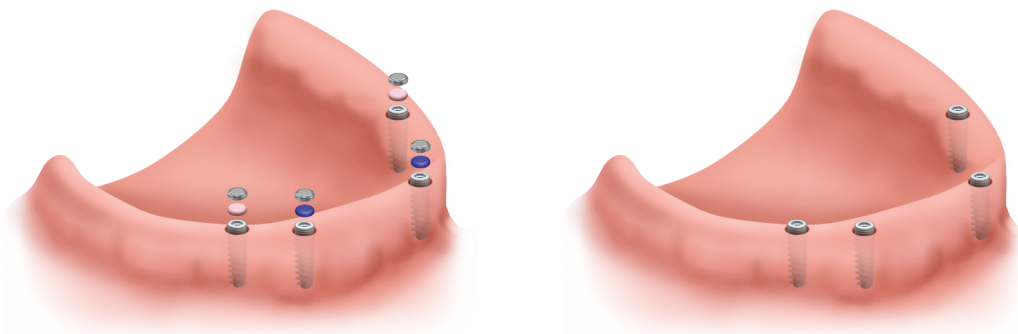
Product should be inspected for integrity prior to use. Product from damaged packaging should not be used on patients. In the event of damaged package, the damaged packaging with the product should be returned to the manufacturer and a replacement will be provided only if damage to packaging is caused by product shipment.

If the Grip™ Implant Abutment is subjected to inappropriate loading conditions, there may be a potential risk of metal fatigue. As surgical instruments are susceptible to damage and wear, they should be inspected before each use. Markings should be visible and legible. Any reusable instrument should be replaced if damage or wear is present to ensure proper functionality. The number of uses will vary and depends on a variety of factors including but not limited to bone density, handling, proper cleaning, autoclave exposure, and storage conditions (tools and instruments must be stored dry). When applicable to the surgical instrument, check the connection feature for wear to ensure the connection is not damaged.

Patient evaluation including the determination of the general health, oral hygiene habits and status, motivation towards good dental care, and anatomical acceptability prior to the placement of the implant attachments as part of restorative process, is critical. Thorough evaluation of the patient's medical status and health history is mandatory. Treatment planning is vital to the success of the implant and prosthesis. The use of each of these attachment systems require that the clinician be thoroughly familiar with the product and the method for its use and application. The clinician must also use reasonable judgment in deciding when and where to use the product.

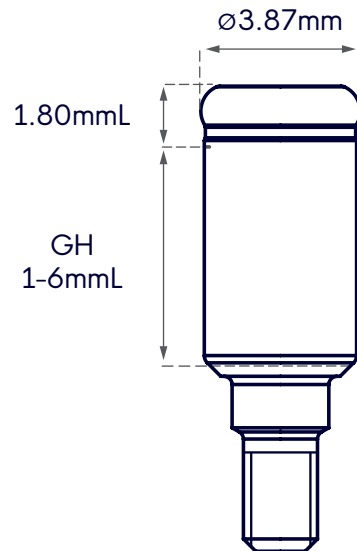
Federal (USA) law restricts this device to sale by or on the order of a licensed dentist only. Any serious incident that has occurred in relation to the device(s) in which this Instructions for Use applies should be reported to the manufacturer identified in this Instructions for Use and the competent authority of the Member State in which the user and/or patient is established.

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



Implant Attachment

The Grip™ Implant attachment resiliency provided by the pivoting action is the leading technology for implant-retained overdentures. Recent studies show, a two implant-retained, tissue-supported overdenture restoration is considered the new elementary standard of care for edentulous patients. It is possible to place more than two implants for an implant-retained overdenture.



Prosthetic Procedures

Grip™ Selection



Touareg™ RS GH: 1-6mm



CloseFit™ GH: 1-6mm



UniFit™ GH: 1-5mm

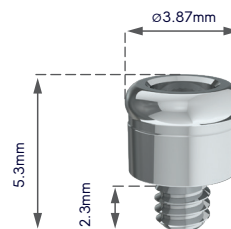
Grip™ for Bar

The Grip™ for Bar is designed for use with overdentures, retained in whole or in part by bar splinted endosseous implants in the mandible or maxilla.

Catalog Number: RS0101

Prosthetic 1.27 hex drivers

Maximum Torque: 35Ncm



Grip™ for TMA

Grip™ for TMA is designed as a splinted bar attachment connector for use with a straight or angled TMA abutment in retaining an overdentures or partial dentures in the mandible or maxilla.

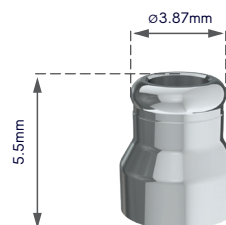
Transition from a screw-retained fixed prosthesis to a removable overdenture can be done with ease by installing a Grip™ for TMA attachment directly to each existing TMA abutment.

Catalog Number: TM0100

Prosthetic Screw: RS3404

Prosthetic Star drivers

Maximum Torque: 15Ncm



Grip™ for Straight TMA



— Grip™ for TMA

— Straight TMA

— Implant

Grip™ for Angled TMA



— Grip™ for TMA

— Angled TMA

— Implant

*Product availability may vary between countries

Grip™ Abutment Tool



Grip Abutment Tool Drivers for Touareg™ RS 1.27 Driver



Grip Abutment Tool Drivers for CloseFit™ implants Star Driver

System Components for Impression and Fabrication



Replica



Impression coping



Block out spacer



Lab Grip™ retention

Prosthetic Procedures

Based on the patient's pre-surgical assessment, the clinician should select and order the appropriate Grip™ Abutment based on clinical consideration such as implant type, diameter, tissue height and angulation. It is imperative that all bone and soft tissue be removed from the superior aspect of the implant body to guarantee complete seating of the Abutment. Using a calibrated torque wrench, tighten the Grip™ Abutment to the recommended torque below is recommended using Adin's designated tools (1.27mm hex or star drivers).

Prosthetic Device	Recommended tightening torque (N.cm)				
	NP	RP	WP	RS	UF
Grip™ attachment - straight			35		
Grip™ attachment - angulated			35		
Grip™ for TMA			35		
Grip™ for BAR			15		

Caution: Don't exceed the recommended prosthetic tightening torque for abutments/ abutment screws. Overtightening of abutment may lead to a screw fracture.

*Product availability may vary between countries

Grip™ Retentions

The Grip™ Implant Attachment System was designed with customizable levels of retention:

Grip™ Retentions		
	Regular Retention	RS6419
	Light Grip™ Retention	RS6418
	Extra Light Grip™ Retention	RS6417

Grip™ Extended Range Retentions		
	Regular Retention	RS6423
	Light Retention	RS6422
	Extra Light Retention Extra Light Retention	RS6421
	Zero Zero Retention Retention	RS6420

Grip™ Metal Housing

The titanium housing is designed to grant additional stability by housing the retention caps whilst allowing pivoting that absorbs the pressure created on the overdenture and reducing potential damage and fractures to the overdenture.



Grip™ Handle

The Grip™ abutment is packed with Grip™ handle, for abutment placement.

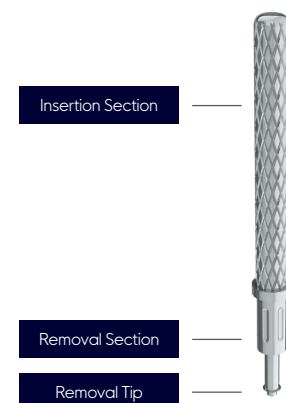
The Grip™ handle is used to carry and place the Grip™ implants attachment abutment onto the implant.

Grip™ Core Tool

Designed for inserting and removing the Grip™ Retentions into and out of the Metal Housings.

Insertion part of the tool – attaches to the retention and uses to place the retention into the Grip™ housing.

Removal part of the tool – attaches to the retention in the Grip™ housing

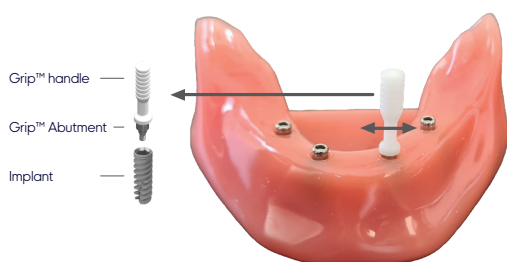


Prosthetic Procedures

Grip Abutment Placement

Step By Step

- 1 After removing the healing cap, use a depth probe to measure gingival height (GH) at its lowest and highest points.
- 2 Select the appropriate Grip™ Abutment according to the measured gingival height (GH).
- 3 Place the selected Grip™ Abutment onto the implant and use the Grip™ Handle to manually screw it in.
- 4 Remove the Grip™ Handle by tilting the tool sideways.



- 5 Use the Adin Torque Driver and Prosthetic Torque Ratchet to tighten the Grip™ Abutment to the implant. Maximum recommended torque: 35Ncm
*Warning: Use of higher torque values than recommended could cause damage to the Grip abutment.



Using The Core Tool

Retention Insertion

1 Unscrew and detach the removal section from the Core Tool.



2 Attach the insertion tool to the Grip™ Retention



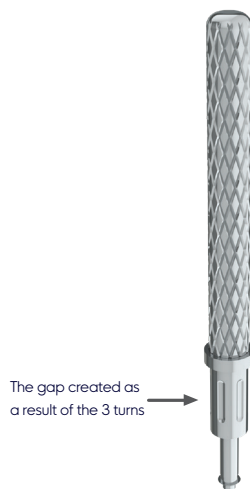
3 Apply moderate force and insert the Core Tool with the Grip™ Retention into the Grip's™ Metal Housing.



Using The Core Tool

Retention Removal

- 1 Loosen the Removal Section of the Core Tool by turning it counterclockwise a full three turns.



- 2 After loosening the Removal Section, insert the Core Tool with the Removal Tip into the Grip's™ Metal Housing.



- 3 Push straight into the bottom of the Grip™ Retention until the sharp edge of the tip engages with the Grip™ Retention.



- 4 Extract the Grip™ Retention from the Grip's™ Metal Housing by pulling the Core Tool sideways.



Disengaging The Grip™ Retention From The Removal Tip

Aim the Removal tip down and away from you. Rotate the Removal section clockwise to tighten it back onto core tool. As it tightens the loose tip will be pushed out and disengage the Retention off of the tool.

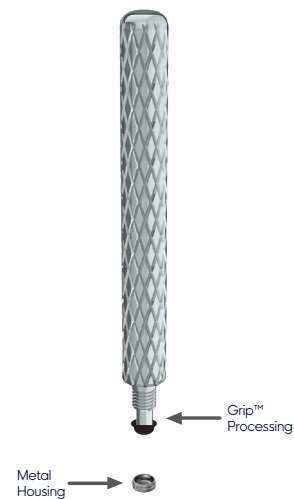


Denture Attachment Housing

- 1 Place a Block-Out Spacer around each Grip™ Abutment and press down



- 2 Use the Core Tool to insert Grip™ Processing into the Grip's™ Metal Housing.



- 3 Seat the Grip's™ Metal Housings with the Grip™ Processing inserts on each Abutment.



- 4 Prepare recesses in the denture for the Grip's™ Metal Housings. There must be no contact between the denture and the Housings to ensure enough space for the acrylic material.



- 5 Use either a chairside light cure acrylic resin or a permanent self-curing acrylic for bonding the Metal Housings to the denture.



- 6 Place a small amount of material:
- Into the recessed area of the denture
 - Around Grip's Metal Housings



- 7 Insert the denture and guide the patient into occlusion while maintaining proper alignment with the opposing arch.



- 8 While the denture material sets, maintain the denture in a passive position, making sure not to compress the soft tissue.



- 9 Remove the denture after the acrylic has cured and fill any voids with acrylic. Remove the excess acrylic from around the Grip™ Metal Housings and the lingual vent-hole, and then polish.



- 10 Remove the Grip™ Processing inserts using the dedicated removal tip in the Core Tool.



Impression And Stone Model Fabrication

- 11** With the Grip™ Abutments torqued in place, snap the Grip™ Impression Copings with the Grip™ Processing inserts on the Abutments until they are firmly seated.



- 12** Inject impression material around and over each Grip™ Impression Coping.



- 13** Place the tray over the Impression Copings and the tissue.



- 14** Once the material has set, remove the impression tray.



- 15** Snap the Grip™ replica into each Impression Coping in the impression tray.



- 16** Capture the Grip™ Abutment orientation in the preferred method for fabricating a stone model.

Denture Attachment Housing

- 17 Initially, replace the Grip™ Processing inserts with the lowest level Grip™ Retention inserts; increase the retention level, if needed.



- 18 Firmly snap the prosthesis into place, ensuring that each insert is fully engaged onto each Grip™ Abutment.

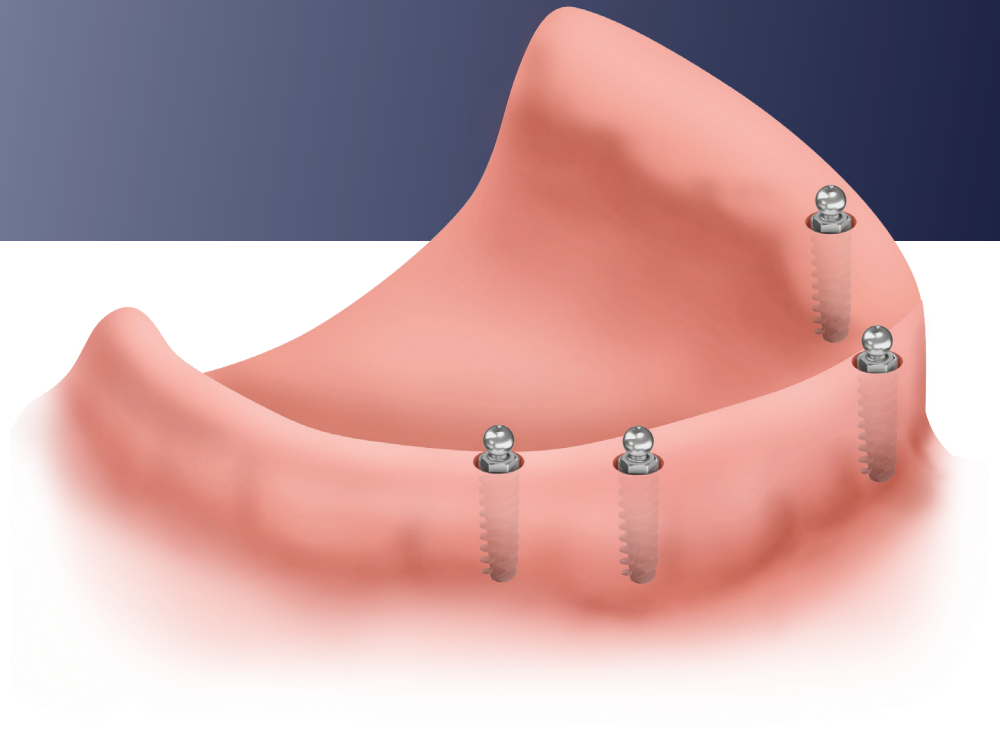


Prosthesis Fabrication – Lab

1. Seat the Grip™ denture attachment housings with the Black processing on each of the abutments.
2. Fabricate the prosthesis.

Note: When delivering the prosthesis, use the lightest retention level inserts for start and increase if needed.

Ball Attachment System



Description

A dental implant abutment connected to the endosseous dental implant used as an aid in full-arch restoration prosthetics.

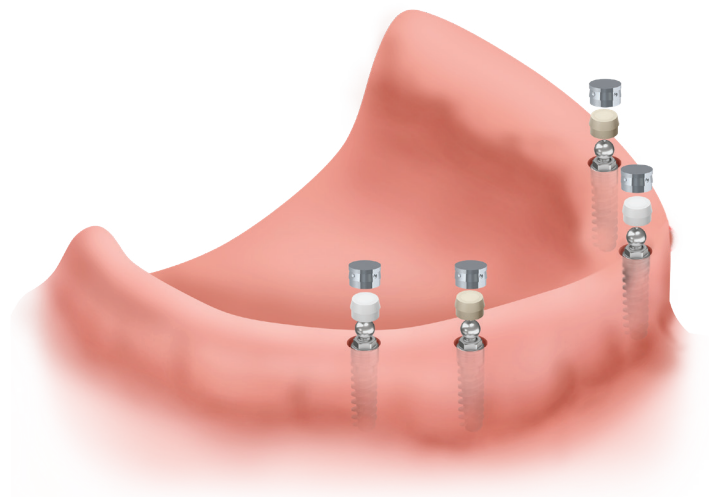
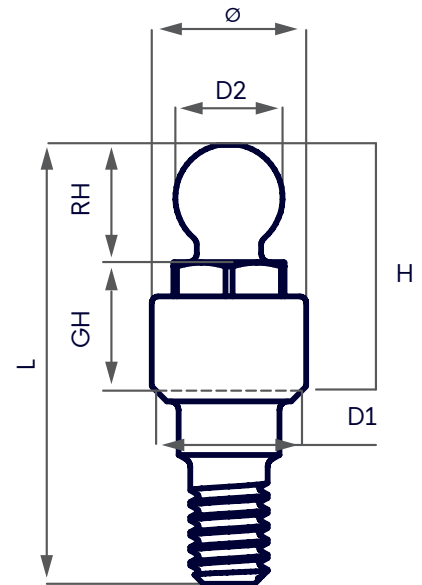
The Ball Attachment System is designed for use directly on implant to support an overdentures or partial dentures, retained by endosseous implants in the mandible or maxilla.

Indications For Use



For fully edentulous jaws retaining tissue-supported overdenture.





Contraindication



- Patients who are medically unfit for oral surgical procedure.
- Compromised manual dexterity.
- Allergy or Hypersensitivity response to nylon, Ti-6Al-4V alloy (titanium, aluminum, vanadium).
- Not appropriate where a totally rigid connection is required (e.g. Screw-retain restoration).
- Use of a single implant
- Use on implant with divergence of greater than 20 degrees from vertical is not applicable.
- Use on Ultra Narrow implants
- Bruxism





Prosthetic Components

Touareg™ RS Platform		
	RS Ball attachment GH: 1-6mm	RS Ball attachment w/ Hex GH: 1-6mm

CloseFit™ Platform				
	UNP GH: 0.5-5mm	NP GH: 0.5-4mm	RP GH: 0.5-5mm	WP GH: 0.5-5mm

UniFit™ Platform		
	UF GH: 0.5-5mm	

Ball Attachment Tool Drivers		
	1.27 Hex Torque Driver	Torque Driver for Ball Attachment

CloseFit™ Platform				
	Replica	Metal Housing	Plastic Ball Cap white (Nylon)	Plastic Ball Cap Pink soft (Nylon)

*Product availability may vary between countries

Ball attachment selection

- Select the proper ball attachment based on the prosthetic platform of the implant and tissue height.
- Measure the tissue thickness from the top of the prosthetic platform to the crest of the gingiva at its highest point.
- Choose the abutment collar height that is 1mm higher than the tissue height. There should be no tissue above the shoulder of the collar.

Note: Due to tissue depth variations, the abutment heights you choose may vary.

Prosthetic Device	Recommended tightening torque (Ncm)					
	NP	RP	WP	RS	UF	UNP
Ball Attachment - straight	35					25

Place The Ball Attachment

- Remove the healing abutments using a 1.27mm hex driver. Confirm that the prosthetic platforms are free of bone debris and soft tissue.
- Irrigate the internal connection of the implants and dry.

Note: In cases of multiple implants, remove one healing abutment at a time and replace it immediately with a ball abutment. This helps prevent the possibility of soft tissue collapsing onto the implant.

- Place the selected ball abutment onto each implant using:
 - R6090 torque driver for ball attachment or RS6080 1.27 Hex torque driver
 - Hand tighten.

Recommended: Take a radiograph along the long axis of the implants to ensure the abutments are seated completely on the implants.

Note: The X-ray tube must be positioned perpendicular to the implant prosthetic platform.

- Tighten the ball abutments using the 35 Ncm torque wrench and the appropriate driver.

Metal Housing

- Place a transferable mark on top of each ball attachment with permanent marker and seat the denture to determine the ideal location for the attachment housings in the denture.
- Prepare recesses in the denture for the housings. There must be no contact between the denture and the housings to ensure enough space for the acrylic material.

Note: Resting the denture on the metal caps will result in excess pressure on the implants, Make lingual vent holes for any excess acrylic to escape.

Seat The Attachment Housings

Insert the pink Plastic ball (soft) lab processing insert into each titanium housing using the insert seating tool. Snap an attachment housing onto each abutment.

Note: Protective discs may be positioned over the ball abutment to protect the soft tissue during the pick-up procedure.

Block Out The Undercuts

Block out any undercuts beneath the housing and soft tissue using material of choice to prevent the acrylic resin from locking the denture onto the abutment. Seat the denture making sure the denture is not touching the housings.

Note: If the undercuts are not blocked out, the denture may lock onto the ball abutments.

Apply The Acrylic

- Use either a chairside light cure acrylic resin or a permanent self-curing acrylic for bonding the ball attachment housings to the denture.
- Place a small amount of material into the recessed area of the denture and around the titanium housings.

Seat The Denture

- Insert the denture.
- Guide the patient into occlusion, maintaining a proper alignment with the opposing arch.
- Maintain the denture in a passive position without compressing the soft tissue while the denture material sets.
- Remove the denture after the acrylic has cured.
- Fill any voids with acrylic and remove the excess acrylic from around the housings and the lingual vent-hole, and polish.

Ball Abutment Overdenture: Chairside Pick-Up Technique Using Existing Denture

- Remove the processing insert from the housing by using a rotary instrument operated at a low RPM. Caution should be taken to prevent damage to the housing during this procedure.
- Place the plastic retention insert using the insert-seating tool to seat the nylon insert into the titanium housing. The insert must seat securely in place and be leveled with the rim of the housing.

Denture Delivery

Seat the overdenture onto the ball abutments. Modify the occlusion and the tissue side of the denture as necessary and polish after making adjustments.

Verify the patient's ability to remove and insert the denture properly.

If the denture retention level requires adjustments, select an insert with a different retention.

Note: If the retention is too great for the patient to remove the denture and an insert with lower retention is not available, the reamer may be used to reduce the retention.

- Insert the reamer into the caps and rotate clockwise for a few rotations. Try in the prosthesis, if retention is still too great; repeat until the proper retention is achieved.
- Instruct the patient on the proper insertion and removal of the prosthesis. This includes inserting the denture using their fingers and not biting the denture into place. When removing the denture, lift it as evenly as possible.

Maintenance

- Do not soak the overdenture in any liquid not designed for use with denture cleaning as these can harm the retentive feature of the retentions, which may ultimately cause additional wear on the Abutment.
- If a denture cleaning solution such as Polident® or Efferdent® is used, it is recommended that the overdenture be soaked for fifteen minutes or less.
- Instruct patients to brush implant attachment Abutments with a soft-bristled toothbrush and visit the dentist for regular inspection and maintenance of the Abutments, retentions and Denture Caps.
- Refrain from picking at the Abutments with toothpicks or other foreign objects.
- Refrain from eating without the overdenture in place as food will scratch the Abutment and may result in failure of the dental implant.
- Oral rinse such as Listerine® mouthwash can be used safely without any negative effect on the Abutments or Replacement retentions.
- Do not wash the overdenture in the dishwasher.

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.

