GoldFit™/Plastic Abutments

INSTRUCTIONS FOR USE

(Gold-Plastic Abutments for Adin Implant Systems: Touareg™, Touareg-S™, Touareg-OS™, Touareg CloseFit™, Swell™)

Disclaimer of liability:
These prosthetic components are part of an overall concept and may only be used in conjunction with the associated original products according to the instructions and recommendations of Adin Dental Implant Systems. Use of products made by third parties in conjunction with Adin Dental Implant Systems prosthetic components will avoid any warranty or other obligation, expressed or implied, of Adin Dental Implant Systems.
Users of Adin Dental Implant Systems prosthetic components have the duty to determine whether or not any product is suitable for the particular patient and circumstance.
Adin Dental Implant Systems disclaims any liabilities, expressed or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of Adin Dental Implant Systems products.
The clinician is also obliged to study the latest developments with regards to the Adin Dental Implant Systems products and their applications regularly. In cases of doubt, the clinician must contact Adin Dental Implant Systems. Since the processing and surgical application of this product is under the control of the clinician, it is his/her's responsibility.
Adin Dental Implant Systems assumes no liability whatsoever for damage arising thereof.

Description:
A premanufactured endosseous dental implant abutment directly connected to the Endosseous dental implant is intended for use as an aid in prosthetic rehabilitation.

Indications:
GoldFit™ Engaging are intended for single tooth screw-retained and cement-retained crowns as well as for multiple unit cement-retained implant bridges.
GoldFit™ Engaging Conical Connection 3.0 are intended to be used together with Touareg CloseFit™ NP 3.0 implant to replace a single lateral incisor in the maxilla or central or lateral incisor in the mandible.
The screw-retained solution may be used when the screw access hole is located through the occlusal surface or through the cingulum.

GoldFit™ Non-Engaging are intended for screw-retained multiple teeth prostheses.
This screw retained solution is mainly indicated when the screw access hole are 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.

Contraindications:
It is contraindicated to use GoldFit™ Engaging Conical Connection 3.0 in other positions then for lateral incisors in the maxilla or central and / or lateral incisors in the mandible.
GoldFit™ Engaging Conical Connection 3.0 should not be used for multiple unit restorations.
Instructions for Clinician: We strongly recommend that clinicians, new as well as experienced implant users, attend special training before undertaking a new treatment method. Adin Dental Implant Systems offers a wide range of courses for various levels of knowledge.
For more information regarding courses visit **www.adin-implants.com.**
Always work with an experienced colleague the first time you employ a new treatment method. Adin Dental Implant Systems has a global network of mentors for this purpose.

Procedural Precautions:
Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.
It is especially important to achieve proper stress distribution through passive adaptation and fitting of the bridge to the implant abutments, adjusting occlusion to the opposing jaw, avoiding excessive transverse loading forces, particularly in immediate loading cases.

If the prosthesis metal substructure is made of gold alloy, it should have a high gold content.
Due to the small size of prosthetic components, special care must be taken to insure that they are not swallowed or aspirated by the patient.

Sterility:
GoldFit™ Abutments are co-packed with abutment screw are delivered non-sterile.
Steam sterilize the abutments and the prosthetic kit (if applicable), for 5 min at 135°C/274° F.
Note: Use of non-sterile abutments may lead to infection of tissues or infectious diseases.

Handling Procedures for Clinical Procedures:

1. Place the impression coping implant level onto the implant and take an implant level impression.
2. Connect the healing abutment or temporary restoration.

Laboratory Procedure:

3. Assemble the impression coping and implant replica and position into impression.
4. Fabricate a working model with removable gingival material.
5. Attach the GoldFit™ into implant replica and secure with lab screw.
6. Connect abutment and reduce the plastic sleeve to appropriate height and wax-up a framework.
7. Fabricate the final abutment or framework using standard C&B techniques.

Note: Do not sandblast the seating surfaces.

Clinical Procedure:

8a. For single units: Connect the customized abutment. It is recommended to verify the final abutment seating using radiographic imaging.

8b. For multiple units: Connect the customized abutments or implant bridge/bar. It is recommended to verify the final implant restoration seating using radiographic imaging.

9. Tighten the customized abutment(s) or implant bridge/bar abutment, except for Conical Connection 3.0, to 35 Ncm using Hex or Star Screwdriver and Manual Torque Wrench prosthetic). For Conical Connection 3.0 tighten abutment to 15 Ncm using screwdriver and wrench described above.

Caution:
For Conical Connection 3.0: Never exceed 15 Ncm prosthetic tightening torque for the abutment screw. Over tightening of abutment may lead to a screw fracture.

10. Close screw access hole.
11. For Abutments: Cement final restoration if applicable.

Note: Do not use temporary cement when cementing ceramic crowns and bridges, due to increased risk of micro fractures.

Alloy Recommendations:
The solidus of the gold alloy is 1450°C / 2642°F. It is recommended to use a cast-on temperature of 1390°C/2534°F. A wax burn out temperature of 700-800°C/1292-1472°F, cast on gold alloy at approximately 1390°C/2534°F (torch melted), and then use a porcelain firing temperature of 980°C. Note that the cast-on temperature can impact distortion and softening of any abutment alloy Adin gold alloy is designed to limit both of these, but there will be a limit, and it can depend on the specific abutment design.

Note:
The GoldFit™ abutment alloy is designed for PFM (or C&B) alloys to be cast on it. It is not designed to have porcelain fired directly to it.
All other instructions would be based on the specific cast-on alloy, and porcelain to be used.

For additional information on restorative and dental laboratory procedures please consult treatment guidelines available at: **www.adin-implants.com** or request latest printed version from an Adin Dental Implant Systems representative.

Materials:
GoldFit™: Gold alloy 60% Au, 19% Pt, 20% Pd, 1% Ir. Plastic: POM. Abutment screws: Titanium alloy 90% Ti 6% Al 4%V.
Manufacturer: Adin Dental Implant Systems Ltd.

Caution:
Federal (USA) law restricts the sale of this device to, or on the order of, a licensed physician or dentist.

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

Explanation of Pictograms:

LOT Batch number
Manufacturer
REF Catalogue number
Attention
Non-sterile product

CE 0473 is the Notified Body number for Intertek

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