EN
INSTRUCTIONS FOR USE OF PRODUCTS
IMPLANT COMPONENTS:
SCREWS
IMPLANT ABUTMENTS

Please read this manual thoroughly before use. The surgeon should make sure that he knows the appropriate surgical method. In order to identify and determine the content of the product, the individual label of the product should be checked. Product Part Numbers (REFs) can be found on the www.apollocomponets.eu

The manufacturer is not responsible for complications, injuries, the need for replacement surgery, implantation failure or other damage and adverse effects resulting from circumstances such as inappropriate indications, the use of an inappropriate surgical technique, improper choice of material or its incorrect use, improper use or handling of instruments, use of products after the expiration date, special anatomy of the patient, overload, non-observance of sterility, etc. The operator is responsible for any complications and other consequences. The dentist is responsible for providing the patient with appropriate instructions and information on the operation of the device, its handling and required care, and any known risks associated with the device and the procedure.

INSTRUCTION OF USAGE IN ELECTRONIC VERSION e-IFU:

Availability of instruction for use:
INSTRUCTION OF USAGE (e-IFU) IN ELECTRONIC VERSION e-IFU DT-015 is available on the website https://apollocomponents.eu/ifu.
User of APOLLO IMPLANT COMPONENTS may receive the INTRUCTION OF USAGE IFU DT-01 in paper version, it is necessary to fill the form on website https://apollocomponents.eu/ifu. The producer will provide the document within 7 working days.

MEDICAL DEVICE DESCRIPTION

STANDARD ABUTMENT is a non-sterile, disposable implant component, representing the pillar of prosthetic restoration.

Types of standard abutments:
- STANDARD ABUTMENT (for cemented and screwed cases, single crowns and bridges),
- TITANIUM BASE (for screw-retained cases, single crowns and bridges),
- TITANIUM BASE multiSHIFT36° (for angulated screw-retained cases, single crowns and bridges),
- MULTI-UNIT ABUTMENT (for bridges),
- TEMPORARY ABUTMENT (for temporary restorations),
- PREMILL (is a block-shaped implant component used for milling individual abutments),
- MULTI TITANIUM BASE (disposable implant-prosthetic component, which is the equipment of MULTI-UNIT abutment when prosthetic bridge is made of other material than titanium),
- MULTI TITANIUM BASE multiSHIFT36° (disposable implant-prosthetic component, which is the equipment of MULTI-UNIT abutment when prosthetic bridge is made of other material than titanium, for angulated screw-retained cases).

The medical device is not intended for reprocessing.

CLINICAL SCREW is a non-sterile, single-use implant component used to attach prosthetic restorations to implants. It is included to the abutment.

Types of screws:
- SCANBODY SCREW (screw for scanbody),
- SCANBODY SCREW MULTI-UNIT (screw for scanbody multi-unit),
- TRANSFER IMPRESSION SCREW (screw for transfers),

- CLINICAL SCREW (clinical screw used for abutments),
- CLINICAL SCREW MULTISHIFT (clinical screw used for angulated abutments),
- CLINICAL SCREW MULTI-UNIT (clinical screw used for multi-unit abutments),
- CLINICAL SCREW MULTI-UNIT MULTISHIFT (clinical screw used for angulated, multi-unit abutments).

The medical device is not intended for reprocessing.

DESIGNATION
IMPLANT COMPONENTS are designated to use with dental implant to perform the prosthetic restoration and its support on it. Prosthetic supply done on APOLLO IMPLANT COMPONENTS products may be in the form of single crown/bridge embedded with the usage of cement or restoration composed with denture embedded with the usage of cement that is retention support for removable restoration.

INDICATIONS
IMPLANT COMPONENTS are the pillar of prosthetic restoration and is support. It is a combination: Abutment – dental implant.

POPULATION
Target populations are:

- Patients with partial lack of teeth or complete anodontia in maxilla and/or mandible.
- Patients with fully mature dental system.
- Patients without any contraindications connected with dental implantation.

CONTRAINDICATIONS

- The materials used are biocompatible, but some patients may develop an allergy or hypersensitivity to one of the materials. There are no absolute contraindications to the use of IMPLANT COMPONENTS, except for contraindications applicable to the general principles of implant treatment.
- IMPLANT COMPONENTS cannot be used in patients who have been diagnosed with medical contraindications to the planned treatment.
- Before the procedure patients must be carefully evaluated for all known risk factors and medical conditions that may affect oral surgery and the healing process.
- Treatment with the usage of products is contraindicated in following cases:
    - poor general health of patient,
    - lack of motivation for cooperation and regular follow-up,
    - poor oral hygiene,
    - pregnancy,
    - history of radiation therapy in the facial area,
    - allergy to titanium (material used in the abutment),
    - inadequate bone quality,
    - systemic diseases.

CLINICAL BENEFITS

- Restoration of aesthetics, contributing to patient satisfaction and improvement in physical and mental health, as well as overall health-related quality of life.
- Improvement of impaired masticatory function due to tooth loss.
- Restoration of bite force.

MATERIAL:
The medical devices are made of biocompatible material:

- Ti-6Al-4V ELI titanium alloy made according to ISO 5832-3/ASTM F136

Due to high-quality Ti6Al4V titanium alloy used for production of abutments/screws, it is compatible with implant, provides a guarantee of product long-term durability and minimizes the risk of allergic reactions.

PRODUCT USERS:
The IMPLANT COMPONENTS are medical devices intended for use by qualified professionals who possess the necessary knowledge or experience to ensure proper use according to the intended purpose. Abutments may only be used by dentists or physicians experienced in oral surgery, including diagnostics and pre-

treatment planning, according to indications and based on general principles of conduct in oral surgery, while complying with safety regulations and preventing accidents at workplace.

WARNING

The above description is not sufficient to begin independent use of APOLLO IMPLANT COMPONENTS products. Each component used in oral cavity must be protect against ingestion or entry into the airways. Aa the use of product takes place beyond the control of the manufacturer, any liability for damage caused shall be excluded. All responsibility lies solely with the treating physician. Before using the IMPLANT COMPONENTS it is required to make sure that the tools and support materials needed are complete, efficient and available in the appropriate quantities. Implant-prosthetic components are intended for single use only. Previously used components must not be reused – reprocessing is strictly prohibited, even if the component has not been in contact with tissue. The products described in this manual may be sold only to physicians, dentists and dental technicians.

ADVERSE REACTIONS

During the usage of components and prosthetic accessories, the following reactions were noted:

- Components used in patient's oral cavity either entered the patient's airway or were ingested by him.
- Abutment screw was fractured due to the usage of excessive torque.
- The abutment has not been properly secured due to an incorrect torque.

DOCUMENTATION

All medical professionals are required to maintain medical records in accordance with the law. It is recommended to keep individual patient medical records including: qualification examination results, treatment plan, description of treatment, metrics of implant and prosthetics (type, series number, certificate), photographic and radiological documentation, and patient consent to treatment.

PACKAGING

- The package is a plastic pouch with the attached label that contains three patient labels. This pack contains one non-sterile product unit (IMPLANT ABUTMENT+CLINICAL SCREW or CLINICAL SCREW).
- The label on the packaging includes the batch number LOT and the reference number REF, which shall be included in the patient record in order to ensure full traceability of the product.

TRACEABILITY

In order to ensure that implantable products can be traced and that the manufacturer, product type and dimensions of the product are registered, including for a subsequent new prosthetic restoration, a label with three patient labels is attached to each product pack. They should be used in the office for documentation.

COMPATIBILITY

Compatibility of the product in the form of implant system code dedicated for is provided on the label. APOLLO IMPLANT COMPONENTS are compatible with commonly-used implant systems. A table of compatible implant systems is available on the website www.apollocomponents.eu.

WASHING AND STERILIZATION

- Washing and sterilization

Before use in the oral environment, products labeled NON-STERILE should be washed and sterilized according to the confirmed method described below. The finished product should be washed and sterilized. The implant must be removed from its original unit packaging before cleaning. Patient labels supplied with the implant should be protected from loss or damage.
NOTE: Cleaning/disinfection equipment should meet the requirements of ISO 15883.

STEP 1: WASHING: CLEANING AND DISINFECTING

This manual describes the Apollo validated cleaning and disinfection method. The process should be conducted in accordance with the guidelines below.
ATTENTION! Refer to the safety data sheets for cleaning agent and disinfectant. Follow the instructions provided by the manufacturer of the product regarding temperature, concentration, exposure time and water quality.
ATTENTION! The disinfectant should be replaced every 1 cycle.

Recommended chemicals:

- cleaner – Neodisher MediClean forte 0.5% or similar
- disinfectant – Bomix plus, BODE Chemie 1% or similar

Cleaning steps:

- Wash with a soft brush (outside and inside) in warm tap water (40◦C) until the surface is visibly clean.
- Rinse in cold tap water (<40◦C) for 1 minute.
- Cleaning in an ultrasonic cleaner with a cleaning agent:
  - Frequency: 40 kHz
  - Temperature: 45°C
  - Time: 5 min.
    unless otherwise stated by the manufacturer of the cleaning agent
- Rinse in cold tap water (<40◦C) for 1 minute.

Disinfection steps:

- Soak in disinfectant for 5 minutes (unless otherwise specified by the disinfectant manufacturer); it is important that each part is covered with the center and that no air bubbles appear,
- Rinse in cold tap water (<40◦C) for 1 minute.

Drying stage:

- Dry until completely dry, for a minimum of 15 minutes.

STEP 2: STERILIZATION

ATTENTION!

Before the sterilization process, check whether the product has no mechanical damage.

Cleaned, disinfected and dried product should be packed in packaging intended for recommended steam sterilization. The packaging and packaging process must meet the requirements of the EN ISO 11607 series standards. The product must be packaged in such a way that no re-contamination occurs when removed from the packaging at the time of use. The product should then be steam sterilized in an autoclave under the following conditions:

Sterilization time	*Sterilization temperature*
3 minutes	*134°C*
4 minutes	*132°C*

- Drying time 20 minutes – as part of the autoclave's pre-programmed drying cycle.

IMPORTANT! Use appropriate cleaning and disinfectant products applicable to dentistry. The process should be carried out in accordance with the guidelines of the manufacturer of the products and in dedicated devices.

NOTE!:

a. Sterilization process must be validated and routinely controlled according to requirements of EN ISO 17665-1.

b. The sterilization method described above has been validated and ensures effectiveness and compliance with the requirements of EN 556-1 to meet the required guaranteed sterility LEVEL OF SAL 10-6 (where SAL means Sterility Assurance Level). Any derogation from the above procedure for washing, disinfection and sterilization may result in the non-sterility of the finished product, thereby causing patient infection and further complications affecting health and safety.

c. The implant component cannot be sterilized in the packaging in which it was delivered.

d. An implant contaminated through contact with blood, tissue, body fluids, or biological materials must not be reused. Reprocessing of contaminated devices is not recommended. In such cases, the product must be disposed of.

e. An implant that has not been clinically used but has come into contact with blood, tissues, or body fluids must not be prepared for reuse. In such cases, the product must be disposed of.

f. APOLLO IMPLANT COMPONENTS assumes no responsibility in cases where contaminated implants are subjected to reprocessing.

g. An implant that has not been clinically used but whose packaging was deliberately opened (thus breaking sterility) may be reprocessed (cleaned, disinfected, and sterilized). In such cases, the user assumes full responsibility for desterilization. The implant must be cleaned and sterilized according to the procedures described in the section "WASHING AND STERILIZATION".

PRETREATMENT PROCEDURE

- The doctor is responsible for preparing the patient for the treatment, through an interview with the patient about the state of health, eating habits and lifestyle, and following the patient's post-treatment recommendations.
- It is necessary to inform the patient of the need to maintain oral hygiene standards, treatment plan, possible complications, alternative methods of treatment and the need for dental follow-up.
- A well-diagnosed and compliant patient generally does not need to be concerned about complications or treatment failure, aside from minor swelling, soft tissue bruising, or mild pain in the post-treatment area.

PROSTHETIC PROCEDURES

A necessary preoperative stage is the planning of prosthetic procedure with possible consultation of a prosthetics specialist. The waiting period from implantation to the prosthetic service was 6 weeks for the lower jaw and 8 weeks for the jaw.

Prosthetic procedure includes:

- taking the correct impression of the prosthetic area,
- laboratory process adequate to treatment recommendations, established as final,
- fixing the repair by means of cement and correcting the occlusion and articulation.

How to use:
For screw-retained cases:

1. Produce a crown in the lab.
2. Place the abutment in the implant
3. Apply the cemented crown to the implant
4. Place the screw in the abutment.

Make sure to:

- check that the abutments is properly seated,
- tighten the abutment screw with the force recommended by manufacturer. Do not use excessive force for screwing. Use a dedicated screwdriver.

Recommended torque for screws: The abutment screw meets or exceeds the implant manufacturer's minimum torque requirements. Tighten the screw using the torque recommended by the implant manufacturer. Use the screw included with the APOLLO abutment.

5. Put a crown on the implant.
6. Cement the crown on the abutment according to the cement manufacturer's recommendations

PATIENT'S ORAL CAVITY SAFETY
Products marked NON-STERILE must be cleaned and sterilized prior to use in in the environment of oral cavity. All components used in the cavity must be prevented from being swallowed or entering the airways. Before prosthetic procedure, the patient should carefully rinse the mouth and throat with an antiseptic liquid. Rules of conduct regarding the procedure in accordance with the rules of surgical asepsis.

INFORMATION FOR THE PATIENT AFTER THE TREATMENT
1. It is the dentist's responsibility to provide the patient with appropriate instructions and information regarding the device, its handling and the required care.
2. It is very important for the patient to follow the postoperative instructions and warnings given to him by the doctor during the treatment process, e.g.:

- ✓ taking medications prescribed by a doctor,
- ✓ application of ice packs,
- ✓ avoiding hard and hot foods, do not chew food in the area of the implant,
- ✓ avoiding smoking, drinking hot drinks and alcohol during the treatment process,
- ✓ keeping the area around the implant clean by rinsing with saline after each meal,
- ✓ avoiding exertion (not bending over, not lifting weights, not doing sports, not using the sauna),

- ✓ while sleeping, it is recommended to take a position with the head held high,

3. The patient should be warned about the risks they take if they do not comply with the indications or if they miss follow-up visits.
4. The dentist must instruct the patient to report any unusual changes at the implant site to the physician. If any change in the surgical site is found, the patient needs careful observation. The patient must be adequately warned about the risks and closely supervised.

MRI

The products have not been evaluated for safety or compatibility in a magnetic resonance (MR) environment. They have not been tested for heat, migration, and image artifact in an MRI environment. In non-clinical studies, it has been shown that the products are conditionally safe and compatible during MR Conditional MRI examinations - the test can be performed with the following parameters:

- ✓ static magnetic field with an induction of 3 Tesla or less,
- ✓ magnetic field spatial gradient of 720 Gauss/cm or lower,
- ✓ the maximum specific absorption rate (SAR) of 4W/kg for a given MRI system for a 15-minute scan duration.

Note: It is imperative to read the contraindications and warnings of the manufacturer of the MRI device on which the examination is planned.

STORAGE

The products should be stored in conditions that prevent accidental damage to the packaging, in a dry place, at room temperature, away from sunlight and in their original packaging. All relevant product information and warnings can be found on the product label.

PRODUCT SHELF-LIFE

Non-sterile medical devices manufactured by APOLLO do not have a defined expiration date (shelf-life). The shelf-life of non-sterile products is not limited, as the devices are made from non-degradable materials (titanium alloy Ti6Al4V ELI), which ensures their long-term stability when stored under recommended conditions.

SHELF-LIFE OF THE PRODUCT IN UNIT PACKAGING

The recommended storage period for the product in its individual packaging is 12 months.

TERMS OF WARRANTY

The warranty covers only defects in materials and design and only covers the replacement of a defective product. The warranty does not cover any other costs, in particular the costs of dental work and its follow-up. Temporary parts are excluded from the warranty. Additional claims of any nature are excluded.

DISPOSAL

All used products pose a potential biological hazard, as they may be contaminated with blood, other bodily fluids, bone tissue, or other biological materials. Product disposal of these products must be carried out after decontamination in accordance with local, regional and national regulations.

REPORTING A PROBLEM

Any serious incident related to the Apollo component should be immediately reported to the manufacturer at 95-200 PABIANICE Konopna 16 , iso@apollocomponents.eu and the competent authority of the Member State in which the user or patient has his/her place of residence.

Serious Incident – means any incident that directly or indirectly led, might have led, or might lead to any of the following:
a) the death of a patient, user, or other person;
b) a temporary or permanent serious deterioration in the health of the patient, user, or other person;
c) a serious public health threat.
Incident – means any malfunction or deterioration in the properties or performance of a device made available on the market, including use errors due to ergonomic features, as well as any inadequacy in the information provided by the manufacturer and any undesirable side effects.

ORDER AND DIMENSION INFORMATION

Up-to-date and detailed information on orders of various PRODUCTS can be found in the latest product catalogue. If you have any additional questions, please contact the Customer Service Office: +48 42 225 29 29, Konopna 16; 95-200 Pabianice

SAFETY AND CLINICAL OUTCOME SUMMARIES (SSCPS):
SSCPs for implantable devices covered by this Instructions for Use are available in the European database EUDAMED medical device data, available at: https://ec.europa.eu/tools/eudamed.

MANUFACTURER DATA:

APOLLO IMPLANT COMPONENTS Spółka z ograniczoną odpowiedzialnością
ul. Konopna 16; 95-200 Pabianice, tel. +48 42 225 29 29;

SYMBOLS

For identification purposes, the following graphic markings (pictograms) are used.

Symbol	*Pictogram for applications*
Medical device *It means that the product is a medical device.*	
Producer *It means the manufacturer of the medical device.*	
Production date *Indicates the date of manufacture of the medical device.*	
Part Number *It indicates the manufacturer's catalog number, which allows the identification of the medical device.*	
Production Batch Code *Indicates the manufacturer's batch code, which allows the identification of the medical device.*	
Do not reuse *It means that the medical device is intended for single use only.*	
NON-STERILE *It means that the medical device has not undergone the sterilization process.*	
ATTENTION! *Means that the user must read the instructions for use in order to obtain important warning information, such as warnings and precautions.*	
Number of pieces *Indicates the number in the package.*	QTY
CE mark of conformity with notified body number (0197) *The product complies with the MDR 2017/745 medical device regulation, compliance with the requirements confirmed.*	
Read the electronic instructions for use *Indicates that the user must read the instructions for use.* *Note: e-IFU indicator can be the URL of the manufacturer's website.*	 e-ifuwww.
Unique product identifier *Means a carrier that contains information about the unique identifier of the device.*	
Keep away from sunlight *It means a medical device that must be protected from light sources.*	
Store in a dry place It means a medical device that must be protected from moisture.	
MAGNETIC FIELDS *MR Conditional. Conditionally safe in an MRI environment. A device whose safety in the magnetic resonance imaging environment has been confirmed under certain conditions.*	

The instructions for use apply to IMPLANT ABUTMENT/CLINICAL SCREWS.
It contains detailed information regarding
handling, safety, precautions, indications, and contraindications
necessary for the use of the device.

VERSION OF THE INSTRUCTION FOR USE INTENDED FOR THE EUROPEAN UNION MARKET:

COUNTRY:

APOLLO IMPLANT COMPONENTS
SPÓŁKA Z OGRANICZONĄ ODPOWIEDZIALNOŚCIĄ
95-200 PABIANICE | ul. Konopna 16 | +48 42 225 29 29 | apollocomponents.eu

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Tabela 1. Historia zmian

Data	Wydanie	Identyfikacja dokumentu	Opracowany przez	Opis zmian
19.12.2024	1	DT-01-02-A5	KAROLINA MARKOWSKA	Pierwsze wydanie dokumentu
02.01.2025	2	DT-01-02-A5	KAROLINA MARKOWSKA	Zaktualizowano dokument.