APOLLO IMPLANT COMPONENTS

PROFESJONALNE ROZWIĄZANIA DLA IMPLANTOPROTETYKI

EN
INSTRUCTIONS FOR USE OF PRODUCTS
DENTAL ACCESSORIES::
LABORATORY SCREW
TRANSFER IMPRESSIONS
DIGITAL ANALOGS
TOOLS

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.

USERS
IMPLANT COMPONENTS are a medical device intended for professional users, i.e. users with knowledge or professional experience that enable the use of the device in accordance with its intended purpose. The components may only be used by dentists and physicians with experience in the field of dental surgery, including diagnosis and pre-operative planning, in accordance with the scope of indications and on the basis of general rules of conduct in dental surgery, while complying with safety regulations and prevention of accidents in the workplace.

DESIGNATION
IMPLANT COMPONENTS are used in the process of stable and permanent fixation of a crown, bridge or other prosthetic element to the implant. They can be used in patients with partial missing teeth or complete edentulism in the maxilla and/or mandible.

PRODUCT DESCRIPTION
TRANSFER IMPRESSIONS are implant components for taking optical impressions in the patient's mouth, which allow for mapping the correct position of the implant using CAD/CAM technology, thanks to which the information necessary for the correct fitting of the prosthetic work is obtained.

Types of transfer impressions:
- Scanbody GEN II (intraoral scanbody from implant level)
- Scanbody Multi-unit (laboratory scanbody from multiunit level)
- Scanbody SmartFlag by APOLLO Multi-Unit (intraoral scanbody from multiunit level)

DIGITAL ANALOG is an implant component, a physical replica of an implant, with a digital shape library, used in a 3D printed model. The digital analogue plays a key role in the process of digital finishing of implant prosthetic cases.

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Types of digital analogs:
- One Lock Digital Analog
- One Lock Digital Analog Multi-unit

TOOLS are components used to attach the prosthetic case to the implant. They are used both by doctors for clinical work and by dental technicians for laboratory work.

Types of tools:
- multiSHIFT Screwdriver - Screwdriver for components with angulated screw channel up to 36° (L25 or L32)
- Screwdriver Handle - screwdriver handle compatible with multiSHIFT36° Screwdriver

LABORATORY SCREW is a reusable implantology component used for securing prosthetic restorations onto analogs in a dental laboratory.

Types of screws:
- Laboratory Screw (used with abutments at the implant level)
- Laboratory Screw Multi-unitT (used with abutments at the multi-unit level)

INDICATIONS
The target population consists of:
- Patients with partial missing teeth or complete edentulism in the maxilla and/or mandible.
- Patients in whom the stomatognathic system is fully mature.
- Patients who do not have any contraindications related to 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.
- 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.

MATERIAL:
The products are made of biocompatible material:
- Ti-6Al-4V ELI titanium alloy according to ISO 5832-3/ASTM F136
- Medical polimer PEEK according to ISO 10993

DOCUMENTATION
All medical entities are obliged to keep and store medical records in accordance with the law.

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. The compatibility of the device in the form of the implant system code for which they are dedicated is given on the label. The label on the packaging shows the LOT batch number and the REF product reference number, which should be included in the patient file to ensure full traceability of the device used. IMPLANT COMPONENTS are compatible with commonly

used implant systems. A table of systems with which the company's products are compatible is available on the www.apollocomponets.eu website

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.

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 min.

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.

PROSTHETIC PROCEDURES

DIGITAL ANALOG
Inteded use:

1. Unpack the unit pack and remove the ONE LOCK DIGITAL ANALOG
2. Adjust the DIGITAL ANALOG to the model according to the position of the retention groove and anti-rotation surfaces, and slide it into the model.
3. Turn the model over and tighten the ANALOG DIGITAL nut from the bottom with the dedicated wrench until the first resistance is felt.

TRANSFER IMPRESSION
Inteded use:

Intraoral use:

1. Attach the TRANSFER IMPRESSION with the screw to the implant.
2. Use a dedicated screwdriver for your implant system.
3. Check for proper fit and for rotational or vertical IMPRESSION TRANSFER clearances in the implant.
4. Tighten the screw.
5. Make sure that the TRANSFER IMPRESSION position is correct to avoid distortion in the scan/impression image.
6. Start scanning.

Laboratory Use:

1. Attach the TRANSFER IMPRESSION with the screw to the implant analog.
2. Use a dedicated screwdriver for your implant system.
3. Check for proper fit and for rotational or vertical IMPRESSION TRANSFER clearances in the implant analogue.
4. Tighten the screw.
5. Make sure that the TRANSFER IMPRESSION position is correct to avoid distortion in the scan/impression image.
6. Start scanning.

For detailed instructions on the scanning process (DT-02-02-A), please refer to the website – www.apollocomponents.eu

TOOLS
Inteded use:

1. Attach the screwdriver to the handle

2. Use a TOOL/screwdriver with a dedicated multiSHIFT screw
3. Tighten the screw until the recommended torque of 15 Ncm is reached

LABORATORY SCREW
When working with the screw, use a screwdriver dedicated to the specific implant system.

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 artifacts 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.

STORE/REPLACEMENT
All information on the storage of the product and warnings can be found on its label.
Replace the DIGITAL ANALOG/TOOL with a new one when you notice:

- Distortion
- Mechanical damage

Replace the TRANSFER IMPRESSION with a new one when you notice:

- Distortion
- Mechanical damage
- or after 100 sterilization processes

WARRANTY CONDITIONS
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, therefore the 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.

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

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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 Sp. z o.o.
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.*	MD
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.*	REF
Production Batch Code *Indicates the manufacturer's batch code, which allows the identification of the medical device.*	LOT
NON-STERILE *It means that the medical device has not undergone the sterilization process.*	NON STERILE
ATTENTIOM! *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.*	CE
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

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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 FIELD *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 DENTAL ACCESSORIES.
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:

AUSTRIA / BELGIUM / CROATIA / CYPRUS / DENMARK / ESTONIA / FINLAND / NETHERLANDS / IRELAND / NORTHERN IRELAND / LUXEMBOURG / LATVIA / MALTA / GERMANY / POLAND / ROMANIA

Tabela 1. Historia zmian

Data	Wydanie	Identyfikacja dokumentu	Opracowany przez	Opis zmian
30.06.2025	1	DT-10-02-A5	KAROLINA MARKOWSKA	Pierwsze wydanie dokumentu