

EN

INSTRUCTIONS FOR USE SCANBODY smartflag by APOLLO
A set dedicated to the implementation of intraoral scans, for full-arch cases
"All on X"

Read this manual carefully before use. The surgeon should make sure that he knows the appropriate surgical method. The individual label of the product should be checked to identify and determine the product content. Product part numbers (REF) can be found at www.apollocomponents.eu

The manufacturer shall not be liable for complications, injuries, necessity of replacement surgery, failure of implantation or other damage and adverse effects resulting from circumstances such as inappropriate indications, use of inappropriate surgical technique, improper choice of material or its incorrect use, improper use of tools or handling, use of devices after expiry date, specific anatomy of the patient, overload, non-sterile, etc. The operator is responsible for any complications and other consequences. It is the responsibility of the dentist to provide the patient with appropriate instructions and information on the operation of the device, its handling and the required care and any known risks associated with the device and the procedure.

INSTRUCTIONS FOR USE OF THE PRODUCT (E-IFU) IN ELECTRONIC/PAPER FORM:

An electronic version of the manual is available on the website (<https://apollocomponents.eu>).

To receive the instructions in paper version, the form should be completed on the above website. The manufacturer will deliver the document within 7 days.

DESCRIPTION OF THE PRODUCT

A SCANBODY smartflag by APOLLO is an implant component, transfer impression for collecting impressions in the patient's mouth, which allows to map the correct position of the implant using CAD/CAM technology, due to which the information necessary for the correct adjustment of prosthetic work is obtained.

SCANBODY smartflag by APOLLO are compatible with commonly used implant systems. Compatibility chart is available at <https://apollocomponents.eu>. Additionally, the label gives information about the implant system with which the given model of the device is compatible.

INTENDED USE

SCANBODY smartflag by APOLLO is dedicated to perform intraoral scans in order to prepare prosthetic restoration on two or more implants.

INDICATIONS

SCANBODY smartflag by APOLLO is dedicated to cases on 2 or more implants.

POPULATION

The target population shall be:

- The patients with partial tooth loss or complete toothlessness 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.

PATIENTS WITH DISABILITIES

- 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 the device, except for contraindications applicable in the general principles of treatment.
- The products must not be used for patients who have been shown to be medically contraindicated for the intended treatment.
- Before surgery, patients should be carefully examined for all known risk factors and diseases affecting oral surgery and healing.
- Treatment with the use of products is contraindicated in the following cases:
 - poor general condition of the patient,
 - lack of motivation for cooperation and constant control,
 - poor oral hygiene,
 - pregnancy,
 - prior irradiation of the facial area
 - allergy to titanium alloy, the material from which the fastener is made,
 - acute and chronic infectious diseases,
 - the quality of the bones,
 - systemic diseases.

CLINICAL BENEFITS

Facilitate proper alignment, sizing, alignment and implantation of the correct implants.

MATERIAL:

The products are made of biocompatible materials:

SCANBODY	Titanium alloy Ti-6Al-4V ELI (grade 23), according to ISO 5832-3/ASTM
	Medical PEEK polymer according to ISO 10993
LAB. SCREW	Titanium alloy Ti-6Al-4V ELI (grade 23), according to ISO 5832-3/ASTM

USERS OF THE PRODUCT:

SCANBODY smartflag by APOLLO is a medical device intended for professional users, i.e. those who have professional knowledge or experience, enabling the use of the device for its intended purpose.

They may only be used by dentists and doctors with experience in the field of dental surgery, including diagnostics and pre-surgery planning, in accordance with the scope of indications and based on the general principles of dental surgery, while complying with safety and accident prevention regulations at the workplace.

WARNINGS

The above description is not sufficient to start working on your own with Apollo Implant Components products. All components used in the oral cavity should be protected from ingestion or entry into the respiratory tract. As the use of the product is beyond the control of the company, any liability for damage caused is excluded. The responsibility lies solely with the doctor performing the procedure. Before working with FITTINGS, make sure that the tools and support materials you need are complete, functional and available in the correct quantities. The products described in this manual may only be sold to or on behalf of doctors, dentists and dental technicians.

SIDE EFFECTS

During the use of prosthetic components and accessories, the following complications have been reported:

- Components used in the patient's mouth have entered the patient's respiratory tract or been swallowed by the patient.
- The clinical screw has been broken due to excessive torque.
- The component has not been properly secured due to the incorrect torque applied.

DOCUMENTATION

All medical entities are obliged to keep and store medical records in accordance with the provisions of law. It is recommended to keep individual patient medical records including, but not limited to: Results of qualifying examinations, treatment plan, description of the course of treatment, metrics of implants and prosthetic elements (type, series number, certificate), photographic and radiological documentation and patient consent to the treatment.

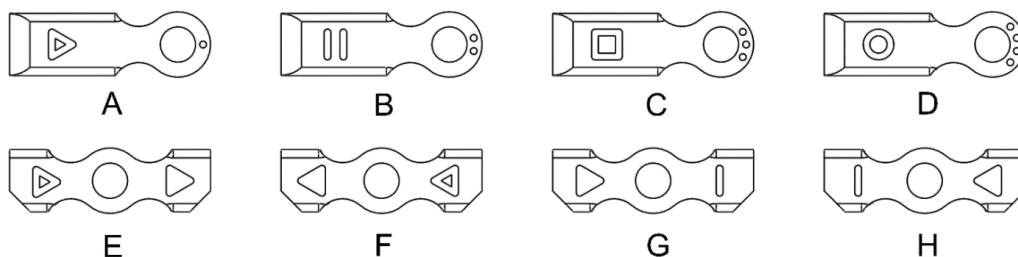
PACKAGING

- The unit packaging is a foil bag with the product label attached. The package contains 1 piece of the product in a non-sterile state.
- The label on the packaging shows the batch number(LOT) and the reference number of the product (REF).

ZESTAW scanbody SmartFlag by APOLLO

Set contains 8 pieces of SCANBODY smartflag by APOLLO®.

- 4 pieces of single-wing
- 4 pieces of double-wing



Scanbody has markings:

- the flat reference part contains:
 - unique marks allowing for a smooth scanning process, without the need to "block" previously scanned scanbodies
- on the side reference part are:
 - designation/abbreviations to identify the system with which the scanbody is compatible, along with the designation of the connection type (implant level/multi-unit level), platform or diameter
 - The letters A, B, C, D for single-wing scanbody and E, F, G, H for double-wing scanbody, identifying different types of scanbody for the same system/platform/MU diameter.

STORAGE/EXCHANGE

SCANBODY smartflag by APOLLO require special storage conditions:

- store separately
- sterilize separately

Replace the SCANBODY smartflag by APOLLO with a new one when you notice:

- distortion
- mechanical damage

TRACEABILITY

In order to ensure traceability of implantable products and to register the manufacturer, the type of product and the dimensions of the product, also for subsequent new prosthetic restoration, a label bearing three patient labels shall be attached to each package of the product. They should be used in the office for documentation.

COMPATIBILITY

The compatibility of the device in the form of the code of the implant system to which they are dedicated is indicated on the label. SCANBODY smartflag by APOLLO are compatible with commonly used implant systems. The compatibility chart is available at www.apollocomponents.eu

WASHING AND STERILIZING

In order to control the kit and its wear, we recommend that you always perform the cleaning and sterilization process for all scanbody in the kit, even if they are not used in the particular scanning process.

- Before use in an oral environment, products with a NON-STERILE label must be washed and sterilized according to the confirmed method described below.
- Before cleaning, remove the component from the original unit packaging.
- Wash and sterilize the finished product.
 - If the screw is integrated with the scanbody, do not disassemble the product during the washing and sterilization process.
 - If the screw is not integrated into the scanbody, remove the screw from the scanbody and wash and sterilize it together with the scanbody.

STEP 1: WASHING: CLEANING AND DISINFECTION

- Note: Cleaning/disinfection equipment shall comply with the requirements of ISO 15883.
- This manual describes the Apollo validated method of cleaning and disinfection.
- Follow these guidelines.
- Note: Refer to the safety data sheets for cleaner and disinfectant. Follow the instructions provided by the manufacturer of the product regarding temperature, concentration, exposure time and water quality.
- NOTE: Disinfection fluid 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:

- Washing with a soft brush (outside and inside) in warm tap water (40°C) to obtain a visibly clean surface.
- Rinsing in cold tap water (<40°C) for 1 minute.
- Ultrasonic cleaning with cleaner:
 - Frequency: 40 kHz
 - Temperature: 45°C
 - Time: 5 minutes.

unless otherwise stated by the manufacturer of the cleaner.

- Rinsing in cold tap water (<40°C) for 1 minute.

Stages of disinfection:

- Immersion in disinfectant for 5 minutes (unless otherwise specified by the disinfectant manufacturer); it is important that each part is covered with the disinfectant and there are no air bubbles,
- Rinsing in cold tap water (<40°C) for 1 minute.

STEP 2: STERILIZATION

- NOTE: Check for mechanical damage before sterilizing the product.
- The cleaned, disinfected and dried product should be packaged in a package intended for the recommended steam sterilization.
- The packaging and packaging process must meet the requirements of the EN ISO 11607.
- The device must be packed in such a way that when it is removed from the packaging, there is no re-contamination at the time of use.
- The product shall then be subjected to a steam autoclaving process under the following conditions:

<i>Time of sterilization</i>	<i>Sterilization temperature</i>
<i>3 minutes</i>	<i>134°C</i>
<i>4 minutes</i>	<i>132°C</i>

Drying time 20 min.

IMPORTANT! Use suitable dental cleaning and disinfecting agents. The process should be carried out in accordance with the guidelines of the manufacturer of the means and in dedicated devices.

NOTE:

- The sterilization process must be validated and routinely controlled in accordance with the requirements of EN ISO 17665-1.
- The sterilization method described above has been validated and guarantees effectiveness and compliance with the requirements of EN 556-1 in order to meet the required guaranteed sterility level SAL 10⁻⁶ (where SAL stands for Sterility Assurance Level). Any deviation from the washing, disinfection and sterilization procedure described above threatens the lack of sterility of the finished product, and thus infection of the patient and further complications affecting his health and safety.
- The product must not be sterilized in the packaging in which it was delivered.
- Re-preparation for use has minimal effect on the devices.
- Scanbody can be used up to 100 times. Every time after washing it, its wear and damage resulting from the intended use shall be checked. In the event of any damage or defects, the product should be disposed of safely.
- The user is responsible for the use of damaged or dirty products.

NOTE: There is no evidence that the cleaning, disinfection and sterilization methods in this manual will destroy prions that are causative agents of Creutzfeldt-Jakob disease (CJD). When used in patients with CJD or variant Creutzfeldt-Jakob disease (vCJD), they should be disposed of appropriately immediately after surgery to prevent their use in other patients.

PROCEDURE

- Select a multi-unit abutment with the appropriate angle so that one insertion path is possible on all implants.
- Choose a scanbody dedicated to the implant system and the level from which the work is planned (multiunit level or implant level).

INTRAORAL USE - placing a scanbody in an implant or on a multi-unit abutment:

- Place the scanbody with the screw to the implant or multi-unit abutment
- Use a dedicated screwdriver for your implant system.
- Check the correct fit and that there are no rotational or vertical scanbody clearances in an implant or on the multi-unit abutment
- Tighten the screw.

LABORATORY USE - placing a scanbody in an implant analog or multi-unit analog:

- Place the scanbody with the screw to the implant/multi-unit analog.
- Use a dedicated screwdriver for your implant system.
- Check the correct fit and that there are no rotational or vertical scanbody clearances in the implant/multi-unit analogue.
- Tighten the screw.

HOW TO USE

POSITIONING/PLACEMENT of the Smartflag:

- choose the type of smartflags depending on the clinical conditions (single or double wing) – adjust their type to the space between the implants
- always use smartflags with different symbols located on a flat reference surface, pay special attention to this when using different implant platforms or different implant systems
- place a smartflag along the appendix, if clinical conditions permit
- place the smartflag so that they do not touch each other (keeping the smallest distance between neighboring smartflags) – check with a dental floss whether the appropriate distances are maintained – the floss should loosely pass between the smartflag
- Tighten the smartflag using a wrench dedicated to the used implant system – the force of tightening is 15 Ncm
- Take an X-ray image to confirm that the scanbody is properly seated

SCANNER SETTINGS:

- use the largest scanner tip available
- turn off the scan assist function – Artificial Intelligence, AI
- set the maximum scan depth
- record the scan – for e.g., by recording the desktop

SCANNING:

- start with a full-arch scan with your smartflags with a seamless motion so they are all scanned and come back scanning with a sweep motion

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- the tip of the scanner must not touch the smartflag
- maintain a balanced scan rate and do not lose sight of the smartflag view from the registration field of the scanner
- be particularly careful when moving from one smartflag to another – make sure that the tip of the scanner covers both the flags in the registration field at the same time
- if the scanning process is interrupted or stopped, restart the process from the location with the characteristic surface registered.
- make sure to register all key reference surfaces of smartflag in the scanning process - Figure 1.
- send the scan film to your lab/milling center

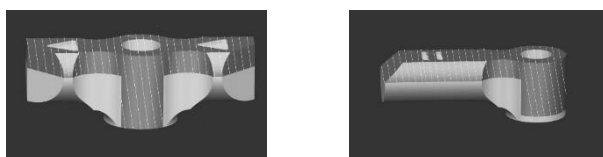


Figure 1. Reference surfaces



SAFETY IN THE PATIENT'S MOUTH

All components used in the oral cavity should be protected against ingestion or inhalation, with particular emphasis on the screw.

MAGNETIC RESONANCE

The products have not been evaluated for safety or compatibility in a magnetic resonance (MR) environment. They have not been tested for heating, migration and image artifact in a magnetic resonance environment. In non-clinical studies, the products have been shown to be conditionally safe and compatible during MR Conditional magnetic resonance imaging tests - 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,
- Maximum MRI specific Absorption Rate (SAR) of 4W/kg for a 15-minute scan duration.

Note: It is essential 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 under conditions that prevent accidental damage to the packaging, in a dry place, at room temperature, in the original packaging. All relevant product information and warnings can be found on the product label.

WARRANTY/GUARANTEE CONDITIONS

The warranty covers only defects in materials and construction and covers only the replacement of the defective product. The guarantee does not cover any other costs, in particular the costs of dental work and its continuation.

Additional claims of any nature are excluded.

DISPOSAL

All the devices used present a potential biological hazard because they may be contaminated with blood or other body fluids, bone tissue or other tissues. Disposal of products must be carried out after decontamination in accordance with local, regional and national laws.

REPORTING PROBLEMS

The user and/or the patient should report any suspicion of a serious incident involving this device by informing the manufacturer or the competent authorities in the region where the serious incident occurred.

INFORMATION ON ORDERS AND DIMENSIONS

Current and detailed ordering information for various PRODUCTS can be found in the latest product catalog.

In case of additional questions, please contact the Customer Service Office: +48 42 225 29 29, ul. Konopna 16; 95-200 Pabianice

MANUFACTURER'S DETAILS:

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 indications (pictograms) shall be used.

<i>Name of the symbol</i>	<i>Pictogram to be used</i>
Medical device <i>Indicates that the product is a medical device.</i>	
Manufacturer <i>Indicates the manufacturer of the medical device.</i>	
Date of manufacture <i>Indicates the date of manufacture of the medical device.</i>	
Part number <i>Indicates the manufacturer's part number that allows the medical device to be identified.</i>	
Batch number <i>Indicates the manufacturer's batch code that allows the medical device to be identified.</i>	
NON-STERILE <i>Indicates that the medical device has not undergone a sterilization process.</i>	
Attention! <i>Indicates that the user must consult the instructions for use for important warning information such as warnings and precautions.</i>	
Number of pieces <i>Indicates the number in the package.</i>	QTY
CE conformity mark <i>Indicates that the product complies with MDR 2017/745 Medical Devices Regulation.</i>	CE
Refer to the electronic IFU <i>Indicates that the user must read the instructions for use. Attention: the e-IFU indicator can be the URL of the manufacturer's website.</i>	 ifuwww.
Unique product identifier <i>Indicates the carrier which contains information about a unique identifier of the product.</i>	
Store away from sunlight <i>Indicates the medical devices that should be stored away from light source.</i>	
Store in a dry place <i>Indicates the medical device that should be protected from moisture.</i>	

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