PRODORTH	INSTRUCTION FOR USE	REF. NO.: TD.05.01.15.02 DATE: 25.05.2023
	PRODUCT : SURGICAL INSTRUMENTS	REV. NO: 00 REV. DATE:

This IFU is valid for all our brands: PRODORTH, PRD+, S33+
Important Information for the Surgeon!

➢ INTENDED USE :

These instruments, herein referred to as "devices", is part of a kit dedicated to placement of a specific product in the PRODORTH range of implants.
The devices are re-usable, re-sterilizable and must be handled by healthcare professionals trained in its conditions for use. It must be handled with care at all stages of use, storage and maintenance.

➢ INDICATIONS :

These devices belong to PRODORTH product range defined by a nomenclature described in the surgical technique provided with the implants and/or instruments of the product range.
These devices can be used only with the PRODORTH implants.

➢ CONTRAINDICATIONS :

• Using outside of its planned scope of application.
• Allergies, intolerances and/or hypersensitivity to the component materials of the instrument.

➢ IMPLANT MATERIAL :

The raw material used in the Prodorth Surgical Instruments are 304, 4057, 4542 Quality Stainless Steel and Silicone. Prodorth expressly warrants that these devices are fabricated from a combination of the foregoing material specifications.

➢ CAUTIONS OF USE :

Instrument cleaning instructions which are recommended by PRODORTH must be applied to surgical instruments before reutilizing them and product should be sterilized. Protect instruments against scratching and nicking, such stress concentrations can lead to failure.
Correct selection of the implant is highly important for performance of surgical instruments.

➢ INSTRUCTIONS FOR USE :

Instructions for placement of implants are detailed in the surgical technique. If you have any concern of using, cleaning, decontamination, sterilization or disposal contact the supplier.

PRODUCT: SURGICAL INSTRUMENTS

a) Before the operation :
• Carefully read the instructions for use of the PRODORTH implants to be used in association with the PRODORTH instruments, along with the surgical technique.
• Carefully read the documents provided with the instrumentation kit.
• Prepare all implants and instruments required for the procedure and ensure that nothing is missing.
• Check their cleanliness, integrity and functionality.
• PRODORTH instruments, designed and provided by PRODORTH, should only be used with the PRODORTH implants.
• Before first implantation, the surgeon and their surgical team should practice handling the instruments to become familiar with the equipment.

b) During the operation :
• The procedure should be performed by a surgeon who has been trained properly.
• Observe every single step described in the surgical technique.
• Do not use this device for any purposes other than described in intended purpose. (see the surgical technique)
• The implantation must be performed only with the instruments provided for this purpose and according to the indications of the surgical technique.

c) After the operation :
• All materials must be cleaned and decontaminated immediately before transport.
• Discard any products which have not functioned properly and ask for a replacement
• Disassemble the product if necessary according to the assembly/disassembly instructions, clean and decontaminate it, then sterilize it before returning it or putting it back into service.

➢ INSTRUMENT CLEANING INSTRUCTIONS :

Surgical instruments which are provided by PRODORTH must be cleaned according to below instruction before reutilizing. After the surgical procedure, surgical instruments must be taken to the cleaning area inside a closed box to prevent any organic residual subsidence on their surfaces. Devices should be prepared and their integrated part should be disassembled. After that, pre-cleaning should be applied. Organic wastes like blood, dirt and tissue residuals on the surface of products should be cleaned under the pressurized water manually. In this step, a soft brush should be used for integrated part to clean cannulated or rough surfaces of the products. Products should be cleaned using the ultrasonic cleaning or disinfection processes after the pre-cleaning process are carried out.

Ultrasonic Processing: (Equipment: Ultrasonic cleaner, Disinfectant: It should include wide microbiological spectrum free of phenol and aldehyde and should include a corrosion inhibitor.) The devices which will be used in this process should be large enough for placing the surgical instruments. Prepare a solution using warm tap water and detergent (or cleaner). Follow recommendations of the detergent supplier during the solution preparation, pay attention to the correct exposure time, temperature, water quality, and concentration. Immerse pre-cleaned products inside the solution. Clean surgical instruments ultrasonically 20 minutes. Rinse products 5 minutes with pressurized water after the ultrasonic cleaning to remove residuals of cleaning solution. Dry the products with a compressed air for 5 minutes and pay attention to not to leave the product wet.

PRODUCT: SURGICAL INSTRUMENTS

Processing in Washing Machine: (Equipment: Washer or disinfector) Disinfectant should be convenient to automated cleaning disinfection machine. Disinfectant which has the ability to clean organic wastes (protein, blood, soil or tissue residual etc.) should be an alkaline cleaner and include corrosion inhibitor. Follow recommendations of the manufacturer company for the amount of the disinfectant. Prepare the disinfectant cleaner according to recommendations of the manufacturer company and place the product with paying attention not to contact of the products with each other. Start the disinfectant cleaner loop. If it is necessary, dry the products with compressed air after the disinfectant cleaning process.

Warnings & Precautions : Decontamination of instruments or accessories should be done immediately after the surgery before allowing them to dry. Blood or debris should be wiped off to prevent them from drying on the surface. All users should be qualified staff with certified evidence of training and competency. Training should contain current applicable guidelines and standards and hospital policies. Surgical instruments must be dried thoroughly to prevent rust formation, even if manufactured from high grade stainless steel. All instruments must be inspected for cleanliness of surfaces, joints, and lumens, proper functioning, and wear and cracks prior to sterilization. Every single surgical instruments should be controlled visually and mechanically to check the proper functionality and whether the parts are working with each other smoothly at least once every 3 months. Likewise, tip sharpness and dimensional controls of surgical instruments should be done at least once every 3 months.

WARNING :
Do not use metal brushes scouring pads during manual cleaning process. Use cleaning agents with low foaming surfactants in order to observe instruments in the cleaning solution. Cleaning agents must be easily rinsed from instruments to prevent any residual. Mineral oil or silicone lubricants should not be used for cleaning process of PRODORTH instruments. Neutral pH enzymatic and cleaning agents are recommended for cleaning reusable instruments. It is very important that alkaline cleaning agents are thoroughly neutralized and rinsed from instruments. Anodized aluminum must not come in contact with certain cleaning or disinfectant solutions. Avoid using strong alkaline cleaners and

➢ HANDLING AND STERILIZATION :

Instruments provided non-sterile must be sterilized according to the validated steam autoclaving process of hospital in an appropriate protective wrapping. If necessary, components must be cleaned prior to sterilization in compliance with hospital validated cleaning process or instructions and recommendations of the chemical detergent supplier. All instruments must be stored in a clean, dry environment and protected from sunlight and extreme temperatures.
The following process parameters are validated by PRODORTH and recommended for sterilization.
Steam autoclave should be performed at 134 °C and 18 minutes.
These recommendations have been obtained and validated using specific equipments. Due to variations in environment and equipment, the sterilization results can vary as well.

PRODUCT: SURGICAL INSTRUMENTS

➢ MAINTENANCE :

PRODORTH Surgical Instruments have a limited lifetime. Therefore, before and after each use, reusable instruments must be inspected for sharpness, wear, damage, proper cleaning, corrosion and integrity of the connecting mechanisms if applicable. Particular care should be taken to drivers, drill bits and instruments used for cutting or implant insertion. Please take into consideration the warnings which are given in instruction for use.

➢ SHIPMENT OF THE PRODUCT :

Surgical Instruments are transferred placing inside a container box or in protective packages with labels. Containers are produced from SS-304 stainless steel. Sets are sterilized before the surgery. Sterilized container should be opened when it arrives to operating room. Cleanliness of sterile materials, presence of any damage on the container box and content of the set should be controlled for each consignment.

➢ DEFINITIONS :

Symbols and abbreviations are given on the package label. The table at the bottom of this paper provides the definitions of these symbols and abbreviations.

➢ WARNINGS :

The surgeon must be familiar with these types of instruments as well as the method of application, and the recommended surgical technique for safe and effective use of any PRODORTH instrument. Before attempting this technique, the surgeon is advised to attend a training course with a surgeon already experienced with the use of the device.
*Instrument failure or damage, as well as tissue damage, can occur when an instrument is subjected to overloads, overspeeds, dense bone, improper use or unintended purpose.
*Additionally, instrument must be cleaned for surgical usage after the sterilization. Please read Surgical Technique documents which is provided by PRODORTH for using the correct instrument properly during the surgery.
*The patient must be warned, preferably by written consent regarding the risks associated with these types of instruments.

➢ ATTENTION :

Prodorth implants and instruments should only be used with Prodorth instruments. In case of using other company's instruments, this might result in galvanic corrosion, incompatibility between the products as well.
The restricted shelf life of the device is 10 years. It should never be used after its expiration date.

PRODUCT: SURGICAL INSTRUMENTS

➢ PACKAGING :

Surgical Instruments are delivered in non-sterile packages or in particular boxes in steel containers. Packaged surgical instruments must be stored unopened in their original packaging. Protective packaging must be removed only before sterilization.
The instruments should not be machined or changed in any way. They are delivered in a container box (as a set) which is provided as closed. If the set is used, set composition must be carefully checked in case of any missing parts. Damaged products and packages should not be used and returned to RD Medikal.

➢ TRACEABILITY :

There is always a lot number on the label of each package or on the surgical instrument. This lot number must be attached to the file of patient in terms of traceability procedures. Due to traceability procedures, documents belongs to the patient and the products have to be kept for 15 years.

➢ PRODUCT COMPLAINTS :

Any health professional (e.g. surgeon using the products) who has a complaint or dissatisfaction with quality, identification, reliability, safety, efficiacy and/or performance of Prodorth Surgical Instruments should inform either Prodorth (or the distributor). If there is a serious adverse event or risk of such, liable to cause death or having caused death or serious problem in the state of a patient or patient's health, Prodorth (or the distributor) must be informed immediately by phone or e-mail. All complaints must be accompanied by the product name, ref. number and lot number of the component. The person formulating the complaint should state the name, address and the nature of complaint, giving as many details as possible.

➢ FURTHER INFORMATION :

In case of complaint, or for supplementary information, or further directions for use of this system, please see the address listed below.

PRODUCT: SURGICAL INSTRUMENTS

Please check our website for the latest version of this IFU.

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PICTOGRAM	EXPLANATION	PICTOGRAM	EXPLANATION
	CONSULT INSTRUCTION FOR USE		LOT NUMBER
	NON-STERILE		CAUTION
	NOTIFIED BODY		MANUFACTURER AND COUNTRY OF MANUFACTURE
	DO NOT USE IF DAMAGED		KEEP AWAY FROM SUNLIGHT
	CATALOGUE NUMBER		MR CONDITIONAL
	PRODUCTION DATE		KEEP AWAY FROM RAIN
	EXPIRE DATE		MEDICAL DEVICE