PRODORTH	INSTRUCTION FOR USE	REF. NO.: TD.01.15.02 DATE: 20.04.2018
	PRODUCT : DISC PROSTHESIS	REV. NO: 06 REV. DATE: 26.10.2022

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

➢ OBJECTIVE :

Prodorth Anterior Cervical Disc Prosthesis is a long-term implant in order to dispose of the patients' complaints which are raised because of the pain arising from the herniation at discs, traumas, or any disorders on the cervical spine. It provides relative mobility at the cervical spine due to its special design which allows axial rotations, translations, flexion-extension and lateral bending. For optimal results, a detailed preoperative evaluation, a meticulous surgical technique and adequate post-operative care are mandatory.
It is important that both the patient and surgeon be fully aware of the risks and possible complications associated with this type of surgery.
Before attempting this technique, the surgeon is advised to attend a training course with a surgeon already experienced with the use of the device.

➢ DESCRIPTION :

Prodorth Cervical Disc Prosthesis is composed of 2 plates working separately and connected to each other by a kind of particular pin. The aim of using a cervical disc prosthesis is to use a product that can make motions in all directions hence it shows more similar behavior to a healthy disc. The PEEK material placed between the titanium plates provides a slippery area with a high scratching resistance which results in the most efficient movement capability of the cervical disc prosthesis in the intervertebral area.
Tube-shaped PEEK material is used as a cover for the inner mechanism, as well as supporting shock absorption.
Prodorth disc prostheses are introduced by the anterior approach using special instruments.
FOR USE BY A PHYSICIAN, SURGEON OR SPECIALIST DOCTOR ONLY.

➢ IMPLANT MATERIAL:

The raw materials used in the Prodorth Cervical Disc Prosthesis are VESTAKEEP PEEK by EVONIK INDUSTRIES as indicated by the symbol "®" (ASTM F-2026) also the titanium alloys (ASTM F-136). Prodorth expressly warrants that these devices are fabricated from a combination of the foregoing material specifications.

➢ INDICATIONS:

Prodorth Cervical Disc Prosthesis is indicated in skeletally mature patients for reconstruction of the disc at only one level from C3-C7:
• Degenerative disc pathologies
• Herniated nucleus pulposus
• Visible loss of disc height compared to adjacent levels
• Spondylosis (defined by the presence of osteophytes)
Note: Patients should be skeletally mature and have had six months of non-operative treatment.

PRODUCT: DISC PROSTHESIS

➢ CONTRAINDICATIONS :

Prodorth Disc Prosthesis should never be used at any condition not described in the indications for use. Contraindications include, but are not limited to:
• Fracture, tumor
• Osteoporosis. Calcium metabolism disorder
• Pregnancy
• Infection
• Recognized allergies to titanium alloys and PEEK material
• Damaged cervical vertebrae from an accident (trauma) at the level of the surgery
• An unhealthy shape (deformity) of the cervical vertebrae at the level of the surgery
• Low bone mineral density, such as osteoporosis or osteopenia
• Severe facet joint disease or degeneration
• Mental tdisability
• Any condition not described in the indications for use
• Obesity
• Open wounds
• Fever or leukocytosis
• Alcohol or drug addiction
• Uncooperative patient or patient with neurologic disorders rendering the patient incapable of following instructions
These contraindications can be relative or absolute and should be considered when physician makes a decision. The above list does not include all possibilities. Surgeons should discuss relative contraindications with the patient.

➢ SECONDARY AND POSSIBLE SIDE EFFECTS :

The patient shall be notified regarding the below mentioned adverse events pre-operatively. A second surgical treatment may be required:
• Pseudarthrosis
• Implant penetration, migration or Implant failure
• Infection
• Tissue or nerve damage caused by improper positioning and placement of implants or instruments
• Paralysis
• Allergy to materials used
• Dysphagia
• Loosening
• Increased neck pain
• Instability
• Hematoma
• c7 palsy
• Hoarseness
• Pain or illness
• Wound infection
• HO (heterotopic ossification)
• Anterior displacement of the disc adjacent segment degeneration
• Bleeding blood vessels
• Bursitis
• Inability to perform daily activities
• Death

PRODUCT: DISC PROSTHESIS

➢ CAUTIONS OF USE :

Never re-use an implant even in a perfect state. Any Implant which has been used, twisted, bent, implanted and then removed even If it appears intact must be discarded.
Use new implants routinely.

Correct selection of the implant is highly important! Use of provided trials is recommended.

Preoperatively:

The surgeon must be fully conversant with all aspects of the surgical technique and know the indications and contra-indications of this type of implant. The surgeon must have acquainted himself before the operation with the specific technique for insertion of the product which is available from the manufacturer.
As part of the pre-operative examination, the surgeon must check that no biological, biomechanical or other factors will affect the correct conduct of the operation and the post-operative period.
Patient must be warned beforehand about not forcing the implant before a complete healing time.
The correct selection of the type of size of implant appropriate to the patient and the positioning ofthe implant is extremely important.
Preoperative planning may be used to estimate the required implant size and to assure that the appropriate range of sizes is available for surgery. All implants and instruments shall be opened, visually controlled for possible damages, cleaned and sterilized preoperatively. If there are some disorders with surface smoothless, do not use the implant and contact to supplier.
A surgical technique for the PRODORTH Cervical Disc Prosthesis is available upon request. This technique is not a substitute for training and is for general informational purposes only.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information provided in this document should be explained to the patient.

Postoperatively: Patients must be informed of the precautions to be taken in their everyday life to guarantee a maximum implant service life. It is recommended that a regular postoperative follow-up be undertaken to detect early signs of failure of the implants and to consider the action to be taken.
Deterioration of the device after bone consolidation cannot be considered to constitute a dysfunction or deterioration in the characteristics of the implant. A suitable rehabilitation program must be designed and implemented.

PRODUCT: DISC PROSTHESIS

➢ HANDLING AND STORAGE :

The handling and the storage of Prodorth disc prosthesis can be in room condition.
The implants must be stored with care. Should these requirements not be followed, reduced mechanical properties may occur, which could lead to implant failure in some cases. Proper function of the surgical instruments specific to the disc prosthesis should be checked prior to use.

➢ CLEANING - DECONTAMINATION :

Prodorth Cervical Disc Prosthesis are not supplied sterile. An appropriate sterilization method should be used.
All packaging and labeling must be removed before the next steps. The cleaning and decontamination must be completed before sterilization.
Cleaning in a machine with products adapted and drying all products which can alter the implants are forbidden.
All instruments and implants must be disassembled (if applicable) and then cleaned and disinfected using neutral cleaners before sterilization and introduction into a sterile surgical field.
Cleaning in a machine with products adapted and drying all products which can alter the implants are forbidden.
Cleaners and disinfectants should be intended to disinfect the medical device and CE certified as well.
Never use metallic brushes for cleaning which may damage the products.

➢ STERILIZATION :

Prodorth Cervical Disc Prosthesis is released to market as non-sterile.
Prodorth Cervical Disc Prosthesis as well as its instruments must be sterilized by hospital prior to surgical use. All packaging materials are removed prior to sterilization. The recommended sterilization method for Prodorth Cervical Disc Prosthesis is steam sterilization in an autoclave.The products which are intended to be sterilized should remain in an autoclave at 134 °C for 18 minutes. There is no other sterilization method PRODORTH recommends.

Note: Due to many variables in sterilization, each medical facility should calibrate and verify the sterilization process (e.g., temperatures, times) used for their equipment.

Use appropriate protective wrapping and add the original stickers preventing the implant from direct contact with the sticker. Care should be taken to protect parts from mechanical damage. The recommendation given is for information only. The manufacturer and distributor assume no responsibility for Prodorth products for improper sterilization by the user.

➢ MRI SAFETY INFORMATION:

Non-clinical testing has shown that Cervical Disc Prosthesis is MR Compatible. A patient with these system parts in his body can safely be scanned in MR systems in case the following conditions are met:
• Only 1.5 and 3.0 Tesla static magnetic fields
• Magnetic spatial drop field up to 970 Gauss/cm (9.7 T/m) or less
• Average specific absorption rate (SAR) for the whole body 2 W/kg (Normal Use Mode) Under the above scanning conditions, after 15 minutes of continuous scanning, our Prodorth Cervical Disc Prosthesis and elements are expected to produce a temperature rise of up to 3°C.

PRODUCT: DISC PROSTHESIS

➢ ATTENTION :

Similar products of competitors shall not be combined with the components of the Prodorth disc prosthesis.
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.
No component of the disc prosthesis implants shall be reused.
The restricted shelf life of the device is 10 years. It should never be used after its expiration date.

➢ DISPOSAL :

Implants removed from the patient at revision surgery should never be reimplanted as the internal structure of the implant cannot be determined by visual examination. Removed implants must be treated as biological hazards and required to be treated or disposed of according to the country's waste regulations, hospital policies and procedures where the implant is removed.

➢ PACKAGING :

Implants and instruments are delivered inside the special trays of instrument boxes,, non-sterile packages or in locked bags. All products shall be controlled and accepted by the receiver. If there is any damage on the outer packaging please return the relating product to RD MEDIKAL INC. immediately.

➢ TRACEABILITY :

There is always a lot number on the label of each package or over the implant. This lot number must be attached to the file of the patient in order to trace back for production procedures. Because of traceability reasons, distributional documents have to be kept for 15 years.

➢ PRODUCT COMPLAINTS :

Any health professional (e.g. surgeon using the products) who has a complaint or is dissatisfied with the quality, identification, reliability, safety, efficacy and/or performance of Prodorth Cervical Disc Prosthesis must 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 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 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.

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

RD Medikal Tıbbi Ürünler san. ve Tic. A.Ş
Karacaoğlan Mah. Bornova Cad. No:9G/1 Bornova İzmir / TURKEY
T: 0090.232.348 4950 (Pbx)
info@prodorth.com

PRODUCT: DISC PROSTHESIS

PICTOGRAM	EXPLANATION
	DO NOT REUSE
	NON-STERILE
CE 2292	NOTIFIED BODY
	DO NOT USE IF DAMAGED
REF	CATALOGUE NUMBER
	PRODUCTION DATE
	EXPIRE DATE
	CONSULT INSTRUCTION FOR USE
LOT	LOT NUMBER
	CAUTION
	MANUFACTURER
	KEEP AWAY FROM SUNLIGHT
	COUNTRY OF MANUFACTURE
	KEEP AWAY FROM RAIN
MD	MEDICAL DEVICE
	MR CONDITIONAL