

 <b>PRODORTH</b>	<b>INSTRUCTION FOR USE</b>	REF. NO.: FR.7.5.8.2-1 DATE: 23.09.2013
	PRODUCT : DISC PROSTHESIS	REV. NO: 03 REV. DATE: 12.10.2021

### Important Information for the Operation Surgeon!

#### ➤ OBJECTIVE :

Prodorth Cervical Disc Prosthesis is a long-term implant in order to dispose the complaints of the patients which raised because of the pain arising from the herniation at cervical discs, traumas on cervical spine. It provides a 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 each other by a kind of a particular pin. The aim for using cervical disc prosthesis is using a product which can make motions to all directions hence it shows more similar behaviour to an 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 inner mechanism, as well as supporting the shock-absorption.

Prodorth disc prostheses are introduced by anterior approach using special instruments.

Prodorth implants are manufactured of Titanium alloys as well as PEEK material due to their high bio-compatibility. FOR USE ON OR BY THE ORDER OF 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.

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#### ➤ 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)

#### ➤ 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 disability
- Any condition not described in the indications for use
- Obesity

#### ➤ SECONDARY AND POSSIBLE SIDE EFFECTS :

- 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
- HO (heterotopic ossification)
- Anterior displacement of the disc adjacent segment degeneration
- Nonunion or delayed union of the bone
- Bleeding blood vessels
- Bursitis
- Inability to perform daily activities
- Death

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#### ➤ CAUTIONS OF USE :

Never re-use an implant even in 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 of the implant are 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 about surface smoothness, 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.

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**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.

### ➤ HANDLING AND STORAGE :

The handling and the storage of Prodorth disc prosthesis can be at room conditions.

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 prostheses are not supplied sterile. 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 dry 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 and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

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.

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### ➤ STERILIZATION :

Prodorth Cervical Disc Prosthesis as well as its instruments must be sterilized by hospital prior to surgical use. Remove all packaging materials prior to sterilization.

The recommended sterilization method for Prodorth products is steam sterilization in autoclave. The products which are intended to be sterilized should remain in 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 the 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 a improper sterilization by the user.



### ➤ 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. Instruments developed by Prodorth to be used in spinal surgeries of its spinal products, are made of stainless chrome nickel steel, aluminum, and silicone. In case of using other company's instruments, this can 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 set cases, 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.

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### ➤ TRACEABILITY :

There is always a lot number on the label of each package or over implant. This lot number must be attached to the file of the patient in order to trace back for production procedures. Because of traceability reason, distributional documents have to be kept for 30 years.

### ➤ PRODUCT COMPLAINTS :

Any health professional (e.g. surgeon using the products) who has a complaint or is dissatisfied with 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 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.

Please check our website for the most up-to-date versions of Prodorth IFUs.



**RD Medikal Tıbbi Ürünler san. ve Tic. A.Ş**

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PICTOGRAM	EXPLANATION	PICTOGRAM	EXPLANATION
	DO NOT REUSE		EXPIRE DATE
	NON-STERILE		CONSULT INSTRUCTION FOR USE
	NOTIFIED BODY		LOT NUMBER
	DO NOT USE IF DAMAGED		CAUTION
	CATALOGUE NUMBER		MANUFACTURER
	PRODUCTION DATE		KEEP AWAY FROM SUNLIGHT