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|  | INSTRUCTION FOR USE | REF. NO.: TD.04.01.15.02 DATE: 20.04.2018 |
| | PRODUCT : CERVICAL PLATES | 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 Cervical Plates System is a long-term implant in order to dispose of the patient's complaints which are raised because of the pain arising from the herniation at discs, traumas, or any disorders on the cervical spine. 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 Plates System is designed for Cervical Anterior Stabilization operations. The system is completely compatible with the body anatomy. There is a locking mechanism that eliminates the risk of screws pull out at the level of each screw on the plate. Prodorth Cervical Plates and cervical screws have lengths and diameters suitable for each level. All these components are supplied in a container (carrying box) or in non sterile packages. Prodorth plates are manufactured of Titanium due to their high bio-compatibility and to the fact that they may be imaged better in such radiological examinations as MR, CT, etc.

FOR USE BY A PHYSICIAN, SURGEON OR SPECIALIST DOCTOR ONLY.

➤ IMPLANT MATERIAL:

The raw material used in the Prodorth Cervical Plate is titanium alloys (ASTM F-136). Prodorth expressly warrants that these devices are fabricated from a combination of the foregoing material specifications.

➤ INDICATIONS:

The Prodorth Cervical Plate Systems are intended for anterior interbody screw fixation of the cervical spine at levels C2-T1. Prodorth Cervical Plate is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity, pseudoarthrosis, and/or failed previous fusions.

WARNING: These devices are not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Note: Patients should be skeletally mature and have had six months of non-operative treatment.

➤ CONTRAINDICATIONS :

Prodorth Cervical Plate System should never be used at any condition not described in the indications for use. Contraindications include, but are not limited to:

- Over infection or distant foci of infections
- Local inflammation, with or without fever or leukocytosis
- Pregnancy

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- Diseases or conditions other than those specifically described in the indications section
 - Use in the posterior elements (pedicles) of the cervical, thoracic, or lumbar vertebrae
 - Where attempted correction exceeds the limits of physiological conditions
 - Metabolic disorders that may impair bone formation
 - Inadequate bone stock to support the device
 - Inability to restrict high activity level
 - Obesity
 - Mental disability
 - Poor prognosis for good wound healing (e.g. decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition)
 - Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia
 - Recognized allergies to titanium or titanium alloys
 - Alcohol or drug addiction
 - An unhealthy shape (deformity) of the vertebra at the level of the surgery
 - 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:

- Paralysis
- Dural tear leading to cerebrospinal fluid fistula or pseudo meningocele
- Other spinal cord injuries not otherwise described due to the positioning of the spinal attachment device
- Laminar erosion
- Epidural bleeding
- Abnormal sensations
- Radiculopathy
- Loosening, bending, breaking, disassembly, and/or migration of the components
- Collapse of a fracture and/or fusion site
- Device failure
- Corrosion at the screw/locking cap interface contributing to breakage, and/or pseudoarthrosis
- Discomfort or pain, soft tissue erosion, or protrusion due to prominent implanted hardware
- Attachment device pullout, especially with short constructs and osteoporotic bone
- Implant or graft extrusion through the skin
- Postural deformities, pain, skin breakdown, or residual neural compression due to kyphosis or lordosis occurring at the top of the segment being instrumented
- Bone loss or fracture due to stress shielding

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- Foreign body reaction to the device including tumor formation, autoimmune disease, metallosis, and/or scarring
 - Non-union or pseudoarthrosis
 - Cessation of growth at the fusion site
 - Discitis, arachnoiditis, and/or other types of inflammation
 - Hemothorax
 - Deep vein thrombosis, thrombophlebitis, and/or pulmonary embolism that may be fatal; may be due to patient position and/or length of the surgical procedure
 - Decubitus ulcer
 - Wound infection, deep or superficial, which may require implant removal and/or other medical interventions
 - Wound dehiscence, delayed wound healing, or hematoma
 - Pain, possibly severe in nature
 - Urinary tract infection
 - Blood vessel damage and/or blood loss or hemorrhage
 - Fracture(s) of the bone
 - Gastrointestinal, urological, and/or reproductive system compromise including sterility, impotency, and/or loss of consortium
 - Bone graft donor site pain
- Inability to resume activities of normal daily living
- Tissue or nerve damage caused by improper positioning and placement of implants or instruments
 - Breathing problems
 - Dysphagia
 - Death



➤ 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!

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 PRODORTH Cervical Plate instrumentation should only be used after the surgeon has had adequate training in this method of fixation and has become thoroughly knowledgeable about the spinal anatomy and biomechanics. A surgical technique for the PRODORTH Cervical Plate is available upon request. This technique is not a substitute for training and is for general informational purposes only.

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.

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Prodorth plates can be broken when subjected to increased loading associated with delayed union or non-union.

The correct selection of the type and the size of the implant, as well as the positioning 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 the supplier.

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 daily 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 Cervical Plate 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 cervical plates system should be checked prior to use.



➤ CLEANING - DECONTAMINATION :

Cervical plate implants are not supplied sterile. Appropriate sterilization method should be used.

All packaging and labeling must be removed before the next steps as 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.

➤ STERILIZATION :

Prodorth Cervical Plates are released to market as non-sterile. Prodorth Cervical Plates as well as their 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 Plate 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.

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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.



➤ WARNINGS :

Prodorth Cervical Plate Systems are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and should be removed. Implant removal, should be followed by adequate postoperative management to avoid fracture or re-fracture. While the final decision on implant removal is, of course, up to the surgeon and patient.



➤ ATTENTION :

Similar products of competitors shall not be combined with the components of the Prodorth Cervical Plate.

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 cervical plate implants shall be reused.

The restricted shelf life of the device is 10 years. It should never be used after its expiration date.

➤ MRI SAFETY INFORMATION:

Non-clinical testing has shown that Cervical Plate 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 (9.7T/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, Cervical Plate and elements are expected to produce a temperature rise of up to 3°C.

➤ DISPOSAL :

Implants removed from the patient at revision surgery should never be re-implanted 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 are delivered in the non-sterile packages or in particular cases in steel containers. Packaged implants must be stored unopened in their original packaging. Protective packaging must be removed only before sterilization.

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The implants must not be mechanically machined or changed in any way. Their instruments are delivered in one container (as a set). Each set must be closed. If the set is used, complete set composition must carefully be checked. All implants and instruments must be checked prior to any use. Damaged products and packages must not be used but they must be returned to RD Medikal.

➤ 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 15 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 Plate 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, fax 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 latest version of this IFU.



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

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