PRODORTH	INSTRUCTION FOR USE	REF. NO.: TD.03.15.02 DATE: 20.04.2018
	PRODUCT : OCCIPITAL PLATE	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 Occipital Plate System is attached to the spine with hooks and/or screws combined with rods to support the surgical area during the posterior fusion phase of the bone and to provide immobilization and stabilization of spinal segments.
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 Occipital Plate System is designed for cervical posterior stabilization operations. The System is an implantation system used to relieve patients' complaints caused by degenerative disc disease, traumas, or any fixation problems that need to be second operations.
Posterior Occipital Plate System implants are temporary implants and are not able to withstand the forces like healthy bone structures. After the spine is fused, these devices serve no functional purpose and may be removed.
While the final decision on implant removal is, of course, up to the surgeon and patient.
FOR USE ONLY BY A PHYSICIAN, SURGEON, OR SPECIALIST DOCTOR ONLY.

➢ IMPLANT MATERIAL:

The implantable parts of the Prodorth Occipital Plate System are made of titanium alloys, conforming to surgical implants (Ti6Al4V ELI ISO 5832-3 or ASTM F 136). Prodorth expressly warrants that these devices are fabricated from one of the foregoing material specifications.
Titanium alloys provide high bio-compatibility.

➢ INDICATIONS:

The specific indications of the Prodorth Occipital Plate System are as follows:
- Degeneration of the disc
- Idiopatique
- Scoliosis
- Deformities of the spine relating to kyphosis
- Paralytic scoliosis and oblique status of the pelvis
- Lordotic deformities of the spine
- Oblique status of the pelvis and neuromuscular scoliosis
- Vertebral fracture or dislocation
- Tumors
- Spondilolisthesis
- Stenosis
- Pseudoarthrosis
- Nonunion of the bone
- Trauma

- An unhealthy shape (deformity) of the vertebrae at the level of the surgery
- Damaged vertebrae from an accident(trauma) at the level of the surgery

The application area of the Prodorth Posterior Spine System is in craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3).

➢ CONTRAINDICATIONS :

Prodorth Occipital Plate System should never be used at any condition not described in the indications for use. Contraindications include, but are not limited to:
- Infection history; systemic, spine, or localized
- Obesity
- Mental diseases
- Alcohol or drug addiction
- Fever or unusual increase in the amount of leukocyte
- Pregnancy
- Allergic reaction against implant materials
- Serious osteoporosis, osteopenia
- Open wounds
- The congenital abnormality, suspicious spine anatomy, neuromuscular disorder, nerve or vascular diseases, tumor, or any condition, which is affecting dependable implant fixation or shortening the life cycle of the device
- Any kind of condition regarding anatomical structures or physiological performance; including the insufficiency of tissues around the surgical area
- Patients who are not obeying precautions or who are not able to

These contraindications can be relative or absolute and should be considered when a physician makes a decision. The above list does not include all possibilities. Surgeons should discuss relative contraindications with the patient.

⚠ ➢ WARNINGS :

a) Precautions:

Possible risks of the device relating to its use and leading to the renewal of the surgical treatment include: component fracture, loosening of the fixation, nonunion, fracture of the vertebrae, neurological injuries and vascular or visceral injuries, death.
The Occipital Plate System should only be implanted by physicians who are familiar with these kinds of implants and surgical techniques. This device system alone is not able to give the required spine support. Its use before any bone transplantation or bone fusion has been achieved, will lead to the failure of the system. No implant at all is able to withstand the total loading of the body before complete fusion has occurred; acting otherwise will lead to bending, loosening, and fracture.
The proper selection of the size of the implant for the patient will affect the result of the surgical treatment. Smoking patients are facing a delay in bone fusion and they should be warned respectively. Furthermore, patients with morbid obesity, low muscle and bone quality and patients having a nerve paralysis are not suitable.

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b) Pre-operatively :

The surgeon must be fully conversant with all aspects of the surgical technique and know the indications and contraindications of this type of implant.
The Prodorth Occipital 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 Occipital 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. Prodorth occipital plates can be broken when subjected to increased loading associated with delayed union or non-un-ion.
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 are 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 smoothless, do not use the implant and contact to supplier.

c) During surgical treatment :

- Care has to be taken not to damage the spine cord or nerve roots particularly during the attachment of screws and hooks
- Fracture, sliding or mishandling of instruments or implants may cause damage to the patient or the surgical team
- Surfaces of implants shall be protected against impacts and scratches
- All bolts and setscrews shall be tightened one more time before closing the soft tissues
- Implants shall not be reused

d) Post-operatively :

- Loosening or breakage of the implant may occur even after fusion, thus, the surgeon may have to remove the implant after the treatment.
- The patient shall be given a detailed notification regarding risks and restrictions of implants and post-operative rehabilitation.
- The patient shall be advised to take advantage of crutches, walking sticks and other external supports and to limit physical activities. The patient shall further be informed concerning the minimization of rotation and bending moments to keep up his daily life; any kind of support shall be given.

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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➢ SECONDARY AND POSSIBLE SIDE EFFECTS :

Complications and adverse reactions have been reported with the use of similar spinal instrumentation systems. These adverse effects, including the possibility of death, should be discussed with the patient prior to surgery. The patient shall be notified regarding the below mentioned adverse events preoperatively.

- Bending, loosening, or fracture of implants or instruments
- Tissue or nerve damage caused by improper positioning and placement of implants or instruments
- Allergic reactions to metal including possible tumor formation
- Skin or muscle sensitivity in patients with insufficient tissue
- Nonunion or delayed union of the bone or Mal-union
- Infection
- Nervous or vascular damages because of surgical trauma, including loss of neurological functions, paralysis and leakage of spine fluid
- Gastrointestinal, urological or systemic disorders
- Pain or illness
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery
- Bone loss or decrease in bone density
- Bleeding blood vessels
- Wrong alignment of anatomical structures; including loss of spine slope, reduction and/or height loss.
- Bursitis
- Inability to perform daily activities
- Prolongation of the operation time due to malfunction of some instruments during the operation
- Death

Note: Additional surgery can be necessary to correct some of these potential adverse events

⚠ ➢ ATTENTION :

Similar products of competitors shall not be combined with the components of the Posterior Occipital Plate System. 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 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 Posterior Fixation System 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 demonstrated that our Posterior Occipital Plate products are MR Compatible. A patient with these system parts in his body can safely be scanned in MR systems if the following conditions are met:

- 1.5 and 3.0 Tesla static magnetic field only
- Magnetic spatial drop field of 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) Above Under the specified scanning conditions, our Posterior Occipital Plate products and elements are expected to create a temperature rise of up to 3°C after 15 minutes of continuous scanning.

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➢ PACKAGING :

Implants and instruments are delivered inside particular trays in steel container 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 MEDICAL INC. immediately.

➢ HANDLING AND STORAGE :

The handling and the storage of the Posterior Occipital 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 Posterior Occipital Plate should be checked prior to use.

⚠ ➢ CLEANING - DECONTAMINATION :

Prodorth Occipital Plate implants are not supplied sterile. An appropriate sterilization method should be conducted.

All packaging and labeling must be removed before the next steps. The cleaning and decontamination must be completed before sterilization.

Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. 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.

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.

Cleaning in a machine with products adapted and dry all products which can alter the implants are forbidden.

➢ STERILIZATION :

Prodorth Occipital Plate implants as well as the instruments must be sterilized by hospital prior to surgical use. Remove all packaging materials prior to sterilization.

The recommeded 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.

➢ 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.

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➢ 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.

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