

	INSTRUCTION FOR USE	REF. NO.: TD.03.15.02 DATE: 20.04.2018
	PRODUCT : POSTERIOR FIXATION SYSTEM	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 Posterior Fixation System is attached to the spine with screws and/or hooks 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 Posterior Fixation System 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 the lumbar discs, and traumas on the spine. Posterior Fixation Systems are long-term implants, however, they 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. Certain implant components from other Prodorth products can be used with the Prodorth Posterior Fixation System.

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

➤ IMPLANT MATERIAL:

The implantable parts of the the Posterior Fixation 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 provides a high bio-compatibility.

➤ INDICATIONS:

The specific indications of the Prodorth Posterior Spine 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
- Instability of deformity
- Deformities of the spine
- Oblique status of the pelvis and neuromuscular scoliosis
- Vertebral fracture or dislocation
- Tumors
- Spondylolisthesis
- Stenosis
- Pseudoarthrosis
- Nonunion of the bone
- Trauma (i.e., fracture or dislocation)

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- Failed previous fusion

The application area of the Prodorth Posterior Fixation System is in cervical, thoracolumbar and sacral segments.

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

➤ CONTRAINDICATIONS :

Prodorth Posterior Fixation 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
 - Local inflammation, with or without fever or leukocytosis
 - Pregnancy
 - Allergic reaction against implant materials
 - Serious osteoporosis, osteopenia
 - Open wounds
 - Congenital abnormality, suspicious spine anatomy, 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
 - 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
 - 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 preoperatively. A second surgical treatment may be required:

- 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

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- 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.



➤ 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 Posterior Fixation System should only be implanted by physicians who are familiar with this kind of implant 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.

b) Pre-operatively:

- Only patients conforming to the criterions listed under INDICATIONS and are not contradicting to the points under CONTRAINDICATIONS are suitable for implantation
- Implant components should be handled and stored with care (protected against mechanical damage)
- The surgeon has to check the availability of all related implants and instruments preoperatively. Similar products of competitors shall not be combined with the components of the Posterior Fixation System
- 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 Posterior Fixation System is available upon request. This technique is not a substitute for training and is for general informational purposes only

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

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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.
- 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.

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.

⚠️ ATTENTION :

Similar products of competitors shall not be combined with the components of the Posterior Fixation System.

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 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 shown that our Prodorth Posterior Fixation System 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, Prodorth Posterior Fixation System and elements are expected to produce a temperature rise of up to 3°C.

➤ 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 MEDIKAL INC. immediately.

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➤ HANDLING AND STORAGE :

The handling and the storage of the Posterior Fixation System 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 Fixation System should be checked prior to use.

⚠️ CLEANING - DECONTAMINATION :

Prodorth posterior fixation system 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 Posterior Fixation System is released to market as non-sterile. Prodorth Posterior Fixation System 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 Posterior Fixation System 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.

➤ 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 Posterior Fixation 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.



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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