



## PRODORTH INSTRUCTION FOR USE

Ref. No : 4.2.3-2.F.9  
Date : 23.09.2013 SAYFA: 1/4

**PRODUCT:** PRODORTH POSTERIOR FIXATION SYSTEM

Revision No: 01  
Date: 17.09.2018

### PRODORTH POSTERIOR SPINAL FIXATION SYSTEMS

#### Important Information for the Operation Surgeon !

#### Objective

Prodorth Posterior Fixation 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. Posterior Spine 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.

#### Device Description

The posterior application components of the Posterior Spine System are grouped as below:

1. Pedicular Screws
2. Linear Transverse Connectors
3. Polyaxial Transverse Connectors
4. Rods
5. Nuts
6. Instruments
7. Sterilization Case
8. Pedicle hook
9. Laminar hook
10. Offset hook right
11. Offset hook left
12. Transverse hook right
13. Transverse hook left
14. Posterior sacral screw
15. Posterior sacroiliac screw

Certain implant components from other Prodorth products can be used with the Prodorth Posterior Fixation System.

#### Implant Material

The implantable parts of the Posterior Spine 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.

#### Indications

The specific indications of the Prodorth Posterior Spine System are as follows:

- Degeneration of the disc
- Idiopathic Scoliosis
- Deformities of the spine relating to kyphosis
- Paralytic scoliosis and oblique status of the pelvis, tried to be corrected with anterior instrumentation
- 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

The application area of the Prodorth Posterior Spine System is in between C3 and the sacrum. The fixation levels of the screws are cervical, thoracic and lumbar.

#### Contraindications

- 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
- Congenital abnormality, suspicious spine anatomy, tumor or any condition, which is affecting dependable implant fixation or shortening the life cycle of the device. Any



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kind of condition regarding anatomical structures or physiological performance; including the insufficiency of tissues around the surgical area.

- Pedicular screws with congenital deformity
- Patients who are not obeying precautions or who are not able to.



### Warnings

#### a) Precautions:

- Until now, it is not completely evident, that any fixation system taking advantage of pedicle and screws is promoting spine fusion.
- 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 Spine System should only be implanted by physicians who are familiar with these kind 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 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.

Patient must be warned beforehand about not forcing the implant before a complete fusion.

#### 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 Spine 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.

#### 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.



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- 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.
- Wrong alignment of anatomical structures; including loss of spine slope, reduction and/or height loss.
- Bursitis
- Pain in the area of bone transplantation
- Inability to perform daily activities
- Death

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

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.

### Possible Adverse Events

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

### Attention

Similar products of competitors shall not be combined with the components of the Posterior Spine 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 Spine System implants shall be reused.

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

### 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.

### Cleaning & Decontamination

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.



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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 Posterior Spine System implants as well as the 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.

### 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.

### 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 Spine 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, 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.

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| Pictogram | Explanation                 |
|-----------|-----------------------------|
|           | DO NOT REUSE                |
|           | NON-STERILE                 |
|           | NOTIFIED BODY               |
|           | DO NOT USE IF DAMAGED       |
|           | Catalogue Number            |
|           | Production Date             |
|           | Expire Date                 |
|           | Consult Instruction for use |
|           | Lot Number                  |
|           | Caution                     |
|           | Manufacturer                |



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