Spinamer®

CE 1014

INSTRUCTIONS FOR USE

Important Information — Please Read Prior to Use

Device System Name: Ortovia Spinal System.

Description:

Ortovia Spinal System is temporary, multiple component systems comprised of a variety of non-sterile, single use components, made of titanium, that allow the surgeon to build a spinal implant construct. The systems are attached to the vertebral body and ilium by means of screw or hook. Ortovia Spinal System consists of an assortment of rods, multi-axial and mono-axial pedicle screws, set screws, lateral offsets, bone screws, screw bodies, hooks, iliac connectors, spinal cages. Ortovia Spinal System components may be used in pediatric patients. These components consist of a variety of screws ranging in diameters from 3.0mm to 7.5mm and lengths ranging from 15mm to 60mm. Ortovia Spinal System implants are not compatible with components or metal from any other manufacturer's system.

Indications for Use:

Ortovia Spinal System is intended for posterior, pedicle, and non-pedicle fixation (T1-S2 and Ilium). The system has pediatric and cervical application models. Ortovia Spinal System is intended to be used as an adjunct to fusion using autograft or allograft. The device is indicated for all of the following indications:

1. Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
2. Spondylolisthesis,
3. Trauma (i.e., fracture or dislocation),
4. Spinal stenosis,
5. Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
6. Tumor,
7. Pseudoarthrosis, and
8. Failed previous fusion

When used for fixation to the ilium, the offset connectors of Ortovia Spinal System must be used in conjunction with pedicle screws placed at the S1 or S2 spinal level.

Spinal corpectomy cages is indicated in case of corpus reconstruction. Interbody cages are used between the corpus in disc space for anterior support and fusion.

Ortovia Spinal System components are used with certain components of the Ortovia Spinal cages.

Ortovia Pedicle screw selection must be done according to the table below:

Pedicle screw diameter (mm)	cervical	Pediatrck System (<15kg) T1 - L5	Pediatric System (15-30 kg) T1-T10	Pediatric System (<30 kg) T1 – L5	Adolescent Adult T1 - T10	Adolescent Adult T11 – L5	Adolescent Adult Sacrum	Adult Revision	Adolescent Adult İlium
3.0	X	X							
3.5	X	X	X						
4.0	X	X	X	X					
4.5			X	X	X				
5.0				X	X	X			

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5.5				X	X	X	X	X	
6.0					X	X	X	X	
6.5						X	X	X	
7.0						X	X	X	X
7.5								X	X
8.0									X

Tablo 1: Table for Ortovia Spinal System Pedicle screw selection according to age, weight and anatomic region of the patient.

Contraindications :

include, but are not limited to:

1. Morbid obesity
2. Mental Illness
3. Alcoholism or drug abuse
4. Pregnancy
5. Metal sensitivity/allergies
6. Severe osteopenia
7. Patients unwilling or unable to follow post-operative care instructions
8. Use of the Ortovia Spinal System offset connectors for fixation to the ilium is contraindicated when the sacrum is absent or insufficient for implantation of pedicle screws at the S1 or S2 spinal level.
9. Any circumstances not listed under the heading indications.

Potential Adverse Events:

1. All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events includes, but is not limited to:
2. Inability to use pedicle screw fixation due to anatomic limitations (pedicle dimensions, distorted anatomy)
3. Pedicle screw mal positioning, with or without neurological or vascular injury
4. Proximal or distal junctional kyphosis
5. Pancreatitis
6. Pedicle screw fixation, such as screw or rod bending, breakage, or loosening, may also occur in pediatric and cervical patients and in pediatric and cervical patients may be at increased risk for device-related injury because of their smaller stature.
7. Device component fracture
8. Loss of fixation
9. Non-union
10. Fracture of the vertebra
11. Neurological injury
12. Vascular or visceral injury
13. Early or late loosening of any or all of the components
14. Disassembly and/or bending of any or all components
15. Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, straining, tumor formation, and/or auto- immune disease
16. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain
17. Post-operative change in spinal curvature, loss of correction, height, and/or reduction
18. Infection
19. Pain, discomfort, or abnormal sensations due to the presence of the device
20. Hemorrhage

21. Cessation of any potential growth of the operated portion of the spine
22. Death
23. Note: Potential risks identified with the use of the device system may require additional surgery.

Warnings and Precautions:

1. The growing rod of the system can be used in conjunct with Ortovia Spinal System in limited time period.
2. The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screw mal positioning and neurological or vascular injury. Patients who are not skeletally mature undergoing spinal fusion procedures may have reduced longitudinal spinal growth, or may be at risk for rotational spinal deformities (the "crankshaft phenomenon") due to continued differential growth of the anterior spine.
3. The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients because this is a technically demanding procedure presenting a risk of serious injury to the patient.
4. Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection of placement of the implants are important considerations in the successful utilization of the system in pediatric patients.
5. The selection of proper size, shape and design of the implant for each patient is crucial to the safe use of this device in pediatric patients (see the table for the screw selection).
6. The safety and effectiveness of pedicle screw systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are: significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to spondylolisthesis, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other condition are unknown.
7. Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
8. Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury.
9. Single use only.
10. Non-sterile; the screws, hooks, rods, dominos, lateral offsets, cages, locking nuts, cross connectors, and instruments are sold non- sterile, and therefore must be sterilized before use.
11. To facilitate fusion, a sufficient quantity of autologous bone or other appropriate material should be used.
12. Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
13. Excessive torque applied to the screws may strip the threads in the bone.
14. DO NOT REUSE IMPLANTS. Discard used, damaged, or otherwise suspect implants.
15. The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
16. Based on fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
17. Mixing of dissimilar metals can accelerate the corrosion process. Do not use the titanium alloy or cobalt chrome alloy components of this system with implants of other material composition or components from different manufacturers unless specifically stated.
18. Ortovia Spinal System have not been evaluated for safety and compatibility in the MR environment, nor have the

Ortovia Spinal System been tested for heating or migration in the MR environment.

19. Reuse of the devices labeled as single-use could result in injury or re-operation due to breakage or infection. Do not attempt to re-sterilize single-use implants that come in contact with body fluids.
20. When using the offset connectors to connect the Ortovia Spinal System construct to the ilium, pedicle screws must be used at the S1 or S2 level of the spine. Do not use the offset connectors to connect the ilium without this intermediate screw fixation.
21. The safety, efficacy and performance of the system have been established for conditions in which the system is used as intended and when used as identified in the Indications for Use. Performance of the system has not been evaluated for use that is contrary to the Intended Use, Indications for Use or for use that in contraindicated. Failure to use the system as indicated could detrimentally affect the performance of its components.
22. Other adverse effects related to pedicle screw fixation, such as screw or rod bending, breakage, or loosening, may also occur in pediatric patients. Pediatric patients may be at increased risk for device-related injury because of their small stature.
23. The correct handling of the implant is extremely important. Implants should not be excessively or repeatedly bent, notched or scratched. These Operations can produce defects in surface finish and internal stress concentrations, which may become the focal point for eventual failure of the device.

MRI Compatibility Information:

The Orthofix Ortovia Spinal System have not been evaluated for safety and compatibility in the MR environment. Ortovia Spinal System have not been tested for heating or migration in the MR environment.

Cleaning:

Ortovia Spinal System implants are provided clean, but not sterile. Once an implant comes in contact with any human tissue or bodily fluid, it should not be re-sterilized and used. Please discard all contaminated implants.

All instruments must be thoroughly cleaned after each use using the manual or automated cleaning method validated by the hospital.

From Point of Use:

Whenever possible, do not allow the blood, debris or body fluids to dry on instruments. For best results and to prolong the life of the surgical instrument reprocess immediately after use.

Cleaning may be done using validated hospital methods.

Prior to cleaning please disassemble the modular. All other instruments within the system do not require disassembly prior to cleaning.

Preparation for Cleaning:

Any instruments with moving parts (i.e. knobs, triggers, hinges) should be separated and activated to open position to allow better access of the cleaning fluid to the difficult to clean areas. Use a soft cloth or plastic bristle brush to remove any visible soil from the instruments.

Soak the instruments for a minimum of 10 minutes in sterile water prior to the manual or automated cleaning process.

Use a soft cloth or a soft plastic bristle brush to remove any visible soil from the instruments.

Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage, particularly instruments; these solutions should not be used. Note: Visually inspect instruments after cleaning and prior to each use. Discard or return to Spinamer if instruments are broken, discolored, corroded, have cracked components, pits, gauges, or otherwise found defective. Do not use defective instruments.

Storage and Transport:

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Ortovia Spinal System instruments and implants are provided in a modular case specifically intended to contain and organize the system components. The system instruments are organized into trays within the modular case for easy retrieval during surgery. These trays also provide protection to the system components during shipping. Additionally, individual instruments and implants will be provided in sealed poly bags with individual product labels attached to them.

Sterilization:

Ortovia Spinal System implants and instruments are supplied NON-STERILE. Prior to use, all implants and instruments should be placed in the instrumentation / implant case which will be wrapped in an CE or FDA approved sterilization wrap and placed in the autoclave for sterilization by the hospital using one of the following recommended cycles:

Method	Cycle	Heat	Exposure time	Drying time
Steam method.1	gravity	132 °C (270 °F)	15min	30min
Steam metho.2	Pre vacuum (min 4puls)	132 °C (270 °F)	4min	30min

Sterilization in Rigid Sterilization Containers:

When using rigid sterilization containers, clean, inspect and prepare the rigid sterilization container according to the manufacturer's instructions.

Select the appropriate rigid sterilization container. The following sterilization cycle was validated:

Method	Cycle	Heat	Exposure time	Drying time
Steam	Pre vacuum (min 4puls)	132 °C (270 °F)	4min	30min

Patient Information:

The temporary internal fixation devices used in your recent spinal surgery are metallic implants that attach to the bone and aid in the healing of bone grafts. These implants have been shown to be valuable aids to surgeons in the treatment of bony fusions. These devices do not have the capabilities of living bone. Intact living bone is self-repairing, flexible and occasionally breaks and/or degrades. The anatomy of the human body places a size limitation on any artificial fixation device used in surgery. The maximum size limitation increases the changes of the mechanical complication of loosening, bend, or breaking of the devices. Any of these complications could result in the need for additional surgery. Accordingly, it is very important that you follow the recommendations of your physician. Use braces as instructed. By following these instructions, you can increase your chances of a successfully result and reduce your risk of injury and/or additional surgery.

Packaging:

Packages for each of the components should be intact upon receipt. If a consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for damage prior to use. Damaged packages or products should not be used and should be returned to Spinamer.

Product Complaints:

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Spinamer using the contact details below:

SPİNAMER Sağlık Ürünleri Sanayi ve Teknoloji Ltd.

Metroport Busidence No 705
D100 Yanyol Sok 14B
34180 Bahcelievler Istanbul
Tel:+90 212 4416444 www.spinamer.com

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Further information:

A recommended surgical technique for the use of this system is available upon request from Spinamer at the numbers provided above.

CAUTION

Federal law (U.S.) restricts this device to sale by or on the order of a physician.

Traceability:

There is always a lot number on the label of each Ortovia Spinal System product. This lot number must be attached to the file of the patient in order to trace back production procedures. Because of traceability reason, distributional documents have to be maintained for 10 years.

Notification:

The following must be assured.

1. Delivery:

Particular requirement for active implantable medical devices and implantable medical device;

The supplier shall ensure that the name and address of the shipping package consignee is included in the quality records (see 2).

2. Control of quality records:

Particular requirements for all medical devices;

The supplier shall retain the quality records for a period of time at least equivalent to the lifetime of the medical device which is defined as the time of expected treatment time, and shelf life is defined as 10 years. Spinamer will retain the documents for 10 years.

3. Ordering Information:

Ortovia Spinal System can be ordered from your distributor or contact with Spinamer

4. Removal and disposal:

Ortovia Spinal System is advised to be removed after the healing and disposed as medical wast according to regulation of local authority.

5. Symbols:

LOT	Batch code	NON STERILE	Non-Sterile
REF	Catalogue number		Consult instructions for use
	Do not reuse		Consult instructions for use
	Manufacturer		

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Spinamer Sağlık Ürünleri Sanayi ve Teknoloji Ltd. Şti.
Merkez: Metroport Busidence No 705, D100 Yanyol Sok No14B 34180 Bahcelievler-İstanbul
Fabrika : Sanayi Mah. 1715 Sk. No: 32-34
Esenyurt - İSTANBUL Tel: +90 212 441 64 44
Mail: info@spinamer.com, www.spinamer.com

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