# Jasper - MIS Spinal Fixation System

**IMPORTANT NOTE**

Before using a product placed on the market by GBS Commonwealth Co. Ltd., the operating surgeon should study carefully the following recommendations, warnings and instructions, as well as the available product-specific information (e.g., product literature, written surgical technique). GBS Commonwealth Co. Ltd. is not liable for complications arising from the use of the device outside of its indicated uses, surgical technique or judgment, product selection, and similar matters outside the control of GBS Commonwealth Co., Ltd.

Compatibility between all GBS Commonwealth Co. Ltd.'s spine product lines, including acquisitions of pre-existing product lines, has not been established. Only authorized combinations of products should be used. Only use as indicated in the Instructions for Use (Package Insert) and/or the Surgical Technique.

**DEVICE DESCRIPTION**

The Jasper MIS spinal system consists of cannulated screws, straight rods, curved rods and set screw components that can be used via percutaneous surgical approach. The components are available in a variety of diameters and lengths in order to accommodate patient anatomy. All products are made of titanium alloy (ASTM F136) and CoCrMo alloy (ASTM F1537) approved for medical use. The implants will be provided non-sterile.

**INDICATIONS**

The Jasper MIS Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine. The Jasper MIS Spinal System can be used in an open approach and a percutaneous approach.

The Jasper MIS Spinal System is intended for the following indications:

- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Curvatures (i.e., scoliosis, kyphosis, lordosis)
- Tumor
- Pseudarthrosis
- Failed previous fusion

**WARNINGS**

The safety and effectiveness of pedicle screw spinal 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 (grades 3 and 4) of the L5-S1 vertebrae, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

The Jasper MIS Spinal System has not been evaluated for safety and compatibility in the MR environment. The Jasper MIS Spinal System has not been tested for heating or migration in the MR environment.

This system should not be used with components of any other systems or manufacturers.

Based on fatigue testing results, when using this system, the physicians /surgeons should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

**PRE-OPERATIVE PRECAUSIONS**

Anyone using GBS Commonwealth products can obtain a Surgical Technique brochure by requesting one from a distributor or from GBS Commonwealth directly. Those using brochures published more than two years before the surgical intervention are advised to get an updated version. GBS Commonwealth devices can only be used by doctors who are fully familiar with the surgical technique required and who have been trained to this end. The doctor operating must take care not to use the instruments to exert inappropriate stress on the spine or the implants and must scrupulously comply with any operating procedure described in the surgical technique provided by GBS Commonwealth. Particular precautions must be taken when using the instruments in pediatrics. Unless otherwise specified on the label, the instruments can be reused after decontamination, cleaning and sterilization.

**CAUTION**

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

**PRECAUTIONS**

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. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

**CONTRAINDICATIONS**

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chances of a successful outcome:

- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis.
- Insufficient quality or quantity of bone which would inhibit rigid device fixation.
- Previous history of infection.
- Excessive local inflammation.
- Open wounds.
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.
- Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage of the operative site.
- Pregnancy.
- A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- Other medical or surgical conditions which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count.
- These contraindications can be relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive.
- Surgeons should warn patients of the above listed potential adverse effects, including the finite service life of the device and the need for post-operative protection of the implant.

**PACKAGING**

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to GBS Commonwealth.

**CLEANING AND DECONTAMINATION:**

**Manual Cleaning procedure**

1. Use the neutral pH enzyme soaking solution that has been prepared.
2. Completely submerge the instrument in enzyme solution and allow it to soak for 20minutes (water temperature: 35-45°C). Use a soft-bristled brush to gently clean the device (particular attention shall be given to crevices, lumens, mated surfaces and other hard-to-clean areas) until all visible soil has been removed. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush).

**Note**: Any assembled instruments such as retractor, please disassemble the parts of retractor both blades, legs and body before submerge. And reassemble it before disassemble.

**Note**: The enzyme solution should be changed on a regular basis in order to ensure its effectiveness.

3. Remove the device from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO,DI and/or distilled) for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas (water temperature: 35-45°C).
4. Prepare the neutral pH cleaning (detergent) solution and place in a sonication unit.
5. Completely submerge device in cleaning solution and sonicate for 10 minutes, preferably at 45-50 kHz.
6. Rinse instrument in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least 3 minutes or until there is no sign of blood or soil in the rinse stream.
7. Repeat Steps 5 and 6 with freshly prepared cleaning solution.
8. Dry the instrument with a clean, disposable, absorbent, non-shedding wipe.
9. Visually inspect the devices under normal room lighting condition to verify all foreign debris has been removed thoroughly clean.
10. Verify that the devices are visually clean.

**Automated cleaning procedure**

Automated washer/disinfector systems are not recommended as the sole cleaning method for complex surgical instruments. These instruments should be cleaned following the manual cleaning procedure above. An automated system may be used as a follow-up method but is not required.

**CAUTION:**

- Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided.
- Visually inspect the devices under normal room lighting condition to verify all foreign debris has been removed thoroughly clean.
- Verify that the instruments are in visually clean.

**GUARANTEE**

The guarantee is only applicable if the device is used in accordance with normal conditions, as defined in this instruction and in conformity with the recommended surgical technique.

**STERILIZATION**

All 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 either wrapped in an FDA cleared sterilization wrap or placed in a rigid sterilization container and placed in the autoclave for sterilization by the hospital using one of the following recommended cycles.

| METHOD | CYCLE | TEMPERATURE | |
|---|---|---|---|
| Steam | Gravity | 270°F (132°C) | 15Minutes (Dry time, 30Minutes) |
| Steam | Pre-Vacuum | 270°F (132°C) | 4Minutes (Dry time, 30Minutes) |

Implants previously implanted should not be re-used. Inspect visually for damage or contamination by biological residue. If damage or biological residue is observed on the implant, it must be discarded.

**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 the distributor or GBS COMMONWEALTH CO. LTD.. Further, if any of the implanted spinal system component(s) ever malfunctions, (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediate. If any GBS COMMONWEALTH CO. LTD.' product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

**SHELF-LIFE**

This product is not sterilized product. The shelf-life is not applicable to our product.

**FURTHER INFORMATION**

Recommended directions for use of this system are available at no charge upon request. If further information is needed or required, please contact GBS COMMONWEALTH CO. LTD. Co., Ltd.

Manufactured For:
GBS Commonwealth Co., Ltd.
#309, WOOLIM LION'S VALLEY C, 168 Gasan Digital 1-ro,
Geumcheon-gu Seoul, Rep. of Korea
TEL : +82-2-6925-4469 FAX : +82-2-6925-4496

Manufactured by : Orthotech Co., Ltd.
78 Yuram-ro, Dong-gu, Daegu Rep. of Korea
Tel : +82-53-314-7016 Fax : +82-53-314-7017

| SYMBOL TRANSLATION | | | |
|---|---|---|---|
| LOT | LOT NUMBER | REF | CATALOG NUMBER |
| | SINGLE USE ONLY | NON STERILE | NON-STERILE |
| | See package insert for labeling limitation | | Consult instruction for use |
| | "DO NOT USE IF PACKAGE IS DAMAGED | | KEEP AWAY FROM SUNLIGHT |
| | KEEP DRY | | USE BY |
| QTY | QUANTITY | | MANUFACTURER |
| | "DATE OF MANUFACTURE | 35°C 1°C | STORE AT ROOM TEMPERATURE |
| Rx Only | Caution : Federal Law(USA) restricts this device to sale, distribution,or use by or on the order of a physician. | | |