Instructions for Use

CENTAUR® SPINAL SYSTEM

This instruction for use is not intended

for distribution outside of Australia.

Manuals are subject to change:

the most current version of each

manual is always available online.

www.prismsurgical.com.au

Please read the instructions for use and the corresponding surgical techniques carefully before use. Ensure you are familiar with the appropriate surgical technique.

Material

Material	Standard
Titanium Alloy ELI	ASTMF136, ISO5832
Cobalt Chrome-Mo	ASTMF1537

Intended use

Centaur Spinal System is intended for permanent implantation to provide immobilization and stabilization of spinal segments and as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine. The Centaur Spinal System is intended for posterior noncervical pedicle fixation.

Performance characteristics

Centaur Spinal System consists of various components such as rods, screws, connectors and set screws that are used collectively to internally support, stabilize and/or correct alignment of the non-cervical spine.

Centaur screws are preassembled and consist of a screw shaft, a saddle/screw retainer and a screw head (tulip).

Centaur screws are available in different lengths are diameters.

Centaur rods are available pre-bent or straight and in different lengths. Centaur rods are 5.5mm in diameter.

Centaur setscrews are assembled in situ and function to lock the rod to the screw.

Centaur cross connectors connect transversely from one rod to another and are intended to provide construct rigidity, where required.

Non-clinical testing of the worst-case scenario has demonstrated that the implants of the Centaur Spinal System have been designed to withstand anticipated loads until fusion occurs or up to 2 years in-vivo (whichever occurs first).

Patient target group

The Centaur Spinal System is intended for use in skeletally mature patients. These products are to be used with respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

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, and/or lordosis
- tumour
- pseudarthrosis
- failed previous fusion in skeletally mature patients

Contraindications

- Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices.
- Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation.
- Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other spinal instrumentation system.
- Any entity or condition that totally precludes the possibility of fusion.

Potential adverse effects

The adverse effects may include but are not limited to:

Bending, loosening or fracture of implant; Metal sensitivity or allergic reaction to a foreign body; Infection, early or late; Nonunion, delayed union, pseudoarthrosis; Subsidence; Pain, discomfort, or abnormal sensations due to the presence of the device; Neural, soft tissue damage due to surgical trauma and/or presence of the device; Paralysis; Hematoma, thrombosis, emboli; Dural tears experienced during surgery could result in the need for further surgery for Dural repair, a chronic CSF leak or fistula, and possible meningitis; Death; Vascular damage, bleeding, due to surgical trauma or presence of the device. Vascular damage could result in catastrophic or fatal bleeding; Screw back out, malposition, device migration possibly leading to construct, device failure, and/or reoperation/revision for device removal; Spinal cord impingement or damage; Fracture of bony structures; Adjacent Segment Disease

Intended conditions of use

These instructions for use alone do not provide sufficient information for direct use of the device or system. Surgery is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out correctly. It is strongly advised that the surgery is performed only by operating surgeons who have acquired the appropriate qualifications, are experienced in spinal surgery, are aware of general risks of spinal surgery, and are familiar with the product-specific surgical procedures.

This device is intended to be used by qualified health care professionals who are experienced in spinal surgery e.g., surgeons, physicians, operating room staff, and individuals involved in preparation of the device. All personnel handling the device should be fully aware that these instructions for use do not include all the information necessary for selection and use of the device. Please read the instructions for use and surgical technique guide carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Perioperative Planning

A thorough clinical evaluation of the patient must occur prior to undertaking surgery. Radiological and diagnostic scans must be taken to allow preoperative planning and to allow assessment of the bony anatomy and pathology.

The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant. At the time of the operation, the corresponding implantation instruments in addition to a complete set of implants must be available. It is important to determine preoperatively whether the patient is allergic to any of the implant materials.

Patient Information

In addition to the contraindications for use, precautions, and possible adverse effects, it is critical that the patient is aware that some activity, particularly but not exclusively, prior to bony fusion, increases the risk of loosening, deforming, or breaking of the implant. The likelihood of successful bone healing is increased by appropriate postoperative care and the patients' ability and willingness to adhere to the surgeon's recommendations.

A patient information leaflet is available electronically at www.prismsurgical.com.au → Patients and Caregivers.

Warnings

It is strongly advised that Centaur Spinal System components are implanted only by spinal surgeons with specific training who are familiar with posterior fusion spinal surgery and who are able to master the product-specific surgical techniques. Implantation is to take place with the instructions for the recommended surgical procedures. The surgeon is responsible for ensuring that the operation is carried out properly.

The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.

Non-sterile device

Centaur Spinal System components are supplied in a non-sterile condition and must be cleaned, and steam sterilised prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilisation, place the product in an approved implant caddy or container. Follow the cleaning and sterilisation instructions given within this brochure. Detailed instructions for processing and reprocessing of reusable surgical instruments, instrument trays and cases are described in document IFU-1 PS Reusable Instrumentation IFU (QMS-IFU-005).

Single-use device

Do not reuse. Products intended for single use must not be re-used or re-implanted.

Reuse may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness, or death. Furthermore, reuse of single-use devices may create a risk of contamination. e.g., due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user. Implanted or used devices must not be reprocessed. Any Prism Surgical implant that has been contaminated by blood, tissue, and/or body fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Storage prior to use

Store implants in their original protective packaging and do not remove them from the packaging until before use. Store open implants in provided implant caddies. Prior to use, check the product and verify the integrity. Do not use if damaged. Refer to the Packaging & Storage section of this document for storage during and after use.

Combination of medical devices

Prism Surgical has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Magnetic Resonance environment

Refer to MRI-1 Prism Surgical Spinal Fusion Implantable Devices - MRI Safety Information Manual

Processing Prism Surgical Centaur Spinal System components

These recommendations are for processing Prism Surgical non-sterile Centaur Spinal System components. The information provided applies to unused and unsoiled Centaur components only. Explanted Centaur components must never be reprocessed and should be disposed of according to hospital protocol upon removal. Any implant that has not been used, but has become soiled, should be handled according to hospital protocol.

Cautions	-Prism implants should not be lubricated. -Do not use a Prism implant component if the surface has been damaged. - Do not use steel wool or abrasive cleaners on Prism implant components. - Prism spinal implant components should not be processed or transported with any type of soiled or contaminated materials. Prism spinal implant components are critical devices and must be terminally sterilized prior to use. -The sterilization parameters are only valid for devices that are adequately cleaned. -The parameters listed are only valid for properly installed, maintained, calibrated and compliant reprocessing equipment in accordance with relevant guidelines and standards. -Consult national regulations and guidelines for additional information. Compliance is additionally required with internal hospital policies and procedures and recommendations of manufacturers of detergents, disinfectants, and any clinical processing equipment.
Limits on reprocessing	-Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on Prism spinal implant components. -Prism spinal implant components should be inspected for corrosion, damage such as scratches and notches, debris, discoloration, or residue. -A discoloration has no adverse effect on titanium or titanium alloy implants. The protective oxide layer is fully maintained. -Any implant with corrosion, scratches, notches, residue, or debris should be discarded and reported to the manufacturer. -Thorough inspection of reprocessed spinal implant components are recommended for each processing cycle.
Point of use care	–Implants should remain covered until needed to avoid becoming soiled or contaminated. Only those to be implanted should be handled. –Minimal handling of implants is necessary to prevent damage to the surface.

Containment and transportation	–Implant components should not come in contact with soiled devices and/or equipment. –Avoid cross contamination of spinal construct/components with soiled instruments during transport. -Spinal construct/components should always be housed in provided caddies/trays during transportation
Cleaning - Manual	-Inspect visually for damage or the presence of blood or tissue. If blood or tissue is observed on the implant, it must be thoroughly cleaned manually using a soft brush and neutral pH detergent or discarded. -Avoid impact, scratching, bending or surface contact with any materials that might affect the implant surface or configuration. NOTES: Special attention shall be paid to recesses since both chemicals and rinse water may be entrapped in them. -Prism Surgical recommend the manual removal of visible debris using an enzymatic cleaner or detergent solution. -An ultrasonic cleaner can be utilised for the manual cleaning of Prism spinal components. Follow the manufacturer's directions, relevant standards and hospital policy for manual cleaning and decontamination recommendations of titanium implants with an ultrasonic cleaner. -The additional use of automated cleaning is required following all manual cleaning methods
Cleaning - Automated	-Prepare a neutral pH enzymatic detergent per manufacturer's recommendation -Fully immerse the devices into the prepared detergent solution and allow them to soak for 1 minute. -After the soak time, use a soft-bristled brush to brush the devices to remove all visible soil. A lumen brush may be used to aid in soil removal. -Remove the devices from the detergent solution and rinse them under running tap water to remove detergent residuals. -Prepare a neutral pH detergent (low foaming) or equivalent per detergent manufacturer's instruction for use in a sonication unit. -Fully immerse the devices into the prepared detergent and agitate them to remove all air bubbles. Allow them to sonicate for 2 minutes. -Remove devices from the prepared detergent and rinse them under running tap water to remove detergent residuals. -Select the cycle and ensure the following set of cycle parameters are properly programmed.

PHASE	RECIRCULATION TIME (MINUTES)	TEMPERATURE	DETERGENT TYPE
Pre-wash 1	02:00	Cold tap water	N/A
Enzyme Wash	02:00	Hot tap water	Neutral pH enzymatic detergent per detergent manufacturer instruction for use.
Wash 1	02:00	65.5°C	Neutral pH detergent (low foaming) per detergent manufacturer instruction for use.
Rinse 1	01:00	Hot tap water	N/A
Drying	07:00	90°C	N/A

	-Remove the devices from the washer following the cycle.
Inspection	–Implant components should be thoroughly inspected after processing, prior to sterilization. –Any implant component with corrosion, scratches, flaws, residue, or debris should be discarded. Report any issues to the manufacturer.
Packaging & Storage	-Place cleaned, dry implants into the proper location in the Prism Surgical case or caddy. Use an appropriate sterilization wrap such as individually wrap tray/caddy in two layers of 1-ply polypropylene wrap (e.g., Kimguard KC600) using sequential envelope folding techniques. -Wrapping and packaging should be in accordance with ISO 11607. -Care should be taken to protect implants from contact with other objects that may damage the surface. -If not stored in sterile, wrapped state, implants should be stored in dry, clean surroundings at room temperature, in their original sealed packaging or sterilisation tray/caddy, respectively.

Sterilisation	The following are recommendations for the sterilisation of the Prism Surgical Centaur Spinal System components. Sterilizer type: Pre-vacuum Preconditioning Pulses: 4 Minimum Temperature: 134°C Full Cycle Time: 3 minutes Minimum Dry Time: 30 minutes Note: Drying time is subject to variation depending on machine load. Dry times may be highly variable due to differences in packaging materials (e.g., nonwoven wraps), environmental conditions, steam quality, implant materials, total mass, sterilizer performance and varying cool down time. The user should employ verifiable methods (e.g., visual inspections) to confirm adequate drying. –The autoclave manufacturer's operating instructions and recommended guidelines for maximum sterilization load should be followed. The autoclave must be professionally installed, maintained, and calibrated. Only legally marketed, sterilization barriers (e.g., wraps, pouches, or containers) should be used by the end user for packaging terminally sterilized devices.
Additional information	-The recommendations provided above have been validated by the medical device manufacturer as being capable of cleaning and sterilizing non-sterile Prism Spinal Plates prior to surgical use. It remains the responsibility of the processor to ensure that the processing is performed using equipment, materials, and personnel in the reprocessing facility, and achieves the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the recommendations provided should be rigorously evaluated for effectiveness and potential adverse consequences. - Cleaning Agent Information; The following cleaning agents were used during validation of the cleaning and sterilisation recommendations; neutral pH detergent (low foaming) (Valsure® Neutral Detergent) and neutral pH enzymatic detergent (Enzol® Enzymatic Detergent). –The cleaning and sterilization information is provided in accordance with EN ISO 17664-1, EN ISO17665-1, AAMI TIR 30, EN ISO 14630, EN ISO 15223-1and EN ISO 20417
Manufacturer contact	

	PSM Pacific Pty Ltd 15/43 Lang Parade MILTON QLD 4064 AUSTRALIA P: +61 7 3720 8882 F: +61 7 3102 9371 www.prismsurgical.com.au

Limited Warranty/Liability

PSM Pacific Pty Ltd. products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. PSM Pacific Pty Ltd. shall not be liable for any incidental or consequential loss, damage, or expense, directly, or indirectly arising from the use of this product. PSM Pacific Pty Ltd. neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product. PSM Pacific Pty Ltd. intends that these instruments should be used only by physicians appropriately trained in orthopaedic surgical techniques.

Product Label and IFU Symbol Reference

	Symbol for consult Instructions for Use.
	Symbol for batch code/lot number. The symbol is accompanied by the manufacturer's batch code.
	Symbol for date of manufacture. This symbol is accompanied by a date.
	Symbol for manufacturer. This symbol is accompanied by the name and address of the manufacturer.
	Symbol for nonsterile. This symbol should be used only to distinguish between identical or similar devices sold in both sterile and nonsterile conditions.
	Symbol for do not reuse. Single use device.
	Symbol for catalogue, reorder, or reference part number.
	Symbol for MR conditional - an item with demonstrated safety in the MR environment within defined conditions.