AURORA® SPINAL SYSTEM

This instruction for use is not intended

for distribution outside of Australia (AU).

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	ASTM F136, ISO 5832-3

Intended use

The Prism Surgical Aurora Spinal System is an anterior spinal fusion device designed to promote arthrodesis and stabilization at one motion segment and is intended for use in the lumbar spine (L2-S1). The Aurora Spinal System is designed to restore stability and increase spinal rigidity after total discectomy of the intervertebral disc and placement of an interbody fusion device (with graft material) to achieve a solid arthrodesis via an anterior or anterolateral surgical approach. The Aurora Spinal System is indicated for use with both open and minimally invasive surgical techniques (MIS).

Performance characteristics

Aurora Spinal System is a low profile, 4-hole anterior lumbar plate and screw fixation system intended to maintain a rigid to semi-rigid construct in-vivo under normal loads.

Aurora plates are supplied with four preassembled locking cams to prevent screw back-out and maintain construct rigidity.

Aurora plates are available in different lengths.

Aurora screws are available in different lengths and diameters.

Non-clinical testing of the worst-case scenario has demonstrated that the implants of the Aurora 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 Aurora 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

- Arthrodesis required at any paired vertebral bodies in the lumbosacral spine
- Degenerative disc disease confirmed by history and radiographic studies.
- Spinal deformities or curvatures (i.e., scoliosis, kyphosis and/or lordosis)

- Spondylolisthesis
- Previous failed fusion
- Trauma (i.e. fracture or dislocation)
- Tumour
- Pseudarthrosis

Contraindications

- Osteoporosis.
- Active systemic infection or infection localised to the site of proposed implantation.
- Any entity or condition that totally precludes the possibility of fusion.
- Extensive calcification of the great vessels
- Retroperitoneal fibrosis
- High grade spondylolisthesis (defined as Meyerding grade 3, 4 or 5[1])
- Tumour or Trauma necessitating multiple vertebral segment stabilisation
- Condition that may place excessive stresses on bone and implants, such as obesity and pregnancy. The decision to use these devices in such conditions must be made by the physician.

Adverse effects

Adverse effects may include but not limited to: Bursitis; Decrease in bone density due to stress shielding; Subsidence; Degenerative changes or instability of segments adjacent to fused vertebral levels; Fracture of bony structures; Implant material sensitivity, or allergic reaction to a foreign body; Infection, early or late; Nerve damage due to surgical trauma or presence of the device; Neurological difficulties including bowel and/or bladder dysfunction; impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paraesthesia; non-union, delayed union; Discomfort or abnormal sensations due to the presence of the device; Paralysis; Spinal cord impingement or damage; Vascular damage could result in catastrophic or fatal bleeding; Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late post-operative period; Bending or fracture of the implant; Loosening of the implant; Dural tears experienced during surgery could result in need for further surgery for dural repair; Chronic CSF leak or fistula, and possible meningitis; Death; pulmonary complications; revision/reoperation for device removal.

Preoperative Planning

A thorough clinical evaluation of the patient must occur prior to undertaking surgery. Radiological scans must be taken to allow preoperative templating and to allow assessment of the bony anatomy for possible deformities. 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 Aurora Spinal System components are implanted only by spinal surgeons with specific training who are familiar with anterior 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

Aurora 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

Implants 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 (with the exception of Aurora Spinal System reusable instrumentation manufactured by Signature Orthopaedics) and assumes no liability in such instances.

Magnetic Resonance (MR) environment

Non-clinical testing has demonstrated the Aurora Spinal System implant is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3.0 T
- Maximum spatial field gradient of 181.2 T/m (18120 G/cm) for 1.5 T system and 90.6 T/m (9060 G/cm) for 3.0 T system.
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of <2 W/kg (normal operating mode)

Under the scan conditions defined above, the Aurora implant is expected to produce a maximum temperature rise of <2°C following 20 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the device extends approximately 26.6 mm from the Aurora implant when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

Processing Prism Surgical Spinal Plates

These recommendations are for processing Prism Surgical non-sterile Aurora Spinal System components. The information provided applies to unused and unsoiled Aurora components only. Explanted Aurora 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	-Any Aurora Spinal System component that has not been used, but has become soiled with blood, tissue and/or bodily fluids/matter, should be handled according to hospital protocol. -Aurora plates and screws should not be lubricated. -Do not use an implant if the surface has been damaged. - Do not use steel wool or abrasive cleaners on Prism implants. - Aurora plates and screws should not be processed or transported with any type of soiled or contaminated materials. -Aurora plates and screws 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 steam sterilization have minimal effects on Prism spinal plates and screws. -Aurora plates and screws 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 Aurora components is required before each use.

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	–Aurora components should not come in contact with soiled devices and/or equipment. –Avoid cross contamination of Aurora™ components with soiled instruments during transport. -Aurora 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/mechanical washer method	-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	–Aurora Spinal System components should be thoroughly inspected after processing, prior to sterilization. –Any Aurora components 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 Aurora Spinal System components. Sterilizer type: Pre-vacuum Preconditioning Pulses: 4 Minimum Temperature: 132°C Full Cycle Time: 4 minutes Minimum Dry Time: 40 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 properly 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 actually 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 properly 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.

	
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Limited Warranty/Liability

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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.

Prior document format QMS-IFU-012 (AU) Version: 9.0.

1 Lak, A. , Abunimer, A. , Rahimi, A. , Tafel, I. , Chi, J. , Lu, Y. , Groff, M. & Zaidi, H. (2020). SPINE, 45 (20), 1451-1458