HealthShare Victoria

Statement of Requirements

ITS Number:	HPVITS2021-126
ITS Name:	Spinal Prostheses
Closing Date and Time:	12 October 2021 14:00 AEDT

Table of Contents

STATEMENT OF REQUIREMENTS

1. Participating Health Services

a. The Participating Health Services for this ITS are:

- Monash Health
- Melbourne Health
- Alfred Health
- Austin Health
- The Royal Children's Hospital.

2. Scope

a. HealthShare Victoria is seeking responses to the Invitation to Supply (ITS) participating Health Services in the Public Sector with Spinal Prostheses. This is a resourcing event (brownfields) for an existing category in the sector. The envisaged Term of Agreement is two years plus two optional one-year extension periods (2 +1 + 1).

b. The scope of this ITS includes:

(i) the supply of spinal prostheses products, including implants for Minimally Invasive Surgery (MIS);

(ii) Support for the supply of spinal prostheses products referenced in 2.b.(i), including the following:

- goods consignment service;
- service requirements;
- education and training; and
- company representative clinical attendance.

c. The scope of this ITS excludes:

(i) MIS reusable surgical instruments; and

(ii) operating room and wound drainage consumable items.

d. Indicative volumes are listed in Part 7 – Tender Response Worksheet. Respondents are to note that any usage figures provided are indicative only and are provided to assist Respondents with the preparation of their submissions.

3. Product Categories

a. A complete range of Spinal Prostheses is required for treatment of patients across Victorian Public Health Services

b. The categories required include:

CATEGORY NUMBER	CATEGORY NAME
1	Screws and Caps
2	Cages and Spacers
3	Rods, Crosslinks and Connectors
4	Plate and Screw Sets, Endplates and Staples
5	Hooks
6	Wires, Cables and Tapes
7	Miscellaneous
8	Spine-specific Bone Substitutes

Please note that a further ninth category for “Enabling Technologies” is not part of this ITS, but HSV intends to run another sourcing event for this product category in 2022.

c. The Respondent may offer products in one, some or all categories.

d. HSV reserves the right not to consider any additional products offered.

e. For a full list of product categories and subcategories, refer to Appendix 1 - Product List.

4. Product Offering

a. Respondents are to list a direct match to the part and part number listed on the Tender Response Worksheet.

b. If a direct match is not possible, list alternative or best match with the alternate part number.

c. HSV may not consider any product that is subject to a current HSV Agreement, other than those listed below:

   (i) HPVC2017-126

d. Respondents will ensure that each product is offered in only one subcategory. It is the Respondent’s responsibility to ensure that each product is submitted in the most appropriate subcategory.

5. Clinical Trials

a. Participating Health Services may, at their discretion, research or trial new technology or use non-contracted products to perform clinical trials at any time during the Term of any resulting Agreement.

Product Requirements

6. Standards and Compliance

a. All items offered must comply with relevant Australian Standards, Orders, Legislation and Regulations (collectively 'Compliance Requirements') or their equivalent International Compliance Requirements. Refer to Appendix 2 – Compliance Requirements for a list of the minimum Compliance Requirements.

b. All therapeutic goods offered must be approved by the Australian Therapeutic Goods Administration (TGA), unless exempt. The Respondent must provide evidence of this (i.e. full ARTG certificates) in its response. HSV recommends the use of products in accordance with TGA registered indications.

c. The successful Respondent must provide evidence of full ARTG certification to Participating Health Services upon request.

7. Packaging and Labelling

a. Sterile products will be packaged in a manner that protects the contents from contamination during transportation, storage and handling.

b. All labels must comply with the *Therapeutic Goods Act* 1989 and the *Therapeutic Goods (Medical Devices) Regulations* 2002.

c. Items will be delivered in accordance with the manufacturer's instructions.

d. As per the TGA regulations stated in point7.b, product packaging must indicate (where applicable):

   (i) if the product is sterile

   (ii) use-by date

   (iii) if the product is MRI compatible (implantable products)

   (iv) if the product (or packaging) contains latex or is latex-free and

   (v) tracking labels.

8. Infection Control

a. Where applicable, all items must meet the requirements of the *Australian Guidelines for the Prevention and Control of Infection in Healthcare* (2021) and for reusable items must meet the disinfection standard of AS/NZS 4187.

b. Upon request by Participating Health Services, successful Respondents must provide cleaning details for all reusable products.

9. Substances of Concern

a. Preference will be given to products (including their accompanying packaging) that are latex-free, unless otherwise stated.

b. Preference will be given to products that are free of diethylhexyl phthalate (DEHP).

10. Product Information

a. The Respondent will submit a copy of relevant product diagrams, specifications or brochures to assist with accurately identifying products offered.

b. Where research papers or relevant scientific information is available, this should be submitted with the Response.

c. All product information submitted should:

(i) be in electronic format

(ii) be in English, in accordance with the TGA guidelines on product information and labelling

(iii) be specific to the product offered

(iv) contain the Respondent's company name

(v) include the product code

(vi) include a detailed specification of the product

(vii) include clear diagrams/pictures of the product.

d. To assist with managing this material, all product information submitted should be labelled with the relevant HSV category and subcategory number.

e. Electronic copies should include the HSV category and subcategory numbers in the filename or identifying metadata.

f. HSV may not consider unlabelled submissions.

g. Product information will not be evaluated but is necessary to assist with accurately identifying the products offered.

h. HSV reserves the right to exclude products from evaluation when the product is unidentifiable and provided information is:

(i) Not labelled as per clause 10.d above; or

(ii) Is incomplete as to clause 10.c.

i. Product samples are not to be provided unless specifically requested by HSV.

j. The Respondent should not submit information related to products which are not called for in this ITS.

11. Consignment Stock

a. Respondents should indicate if they are providing any of the Deliverables on a consignment basis.

b. Respondents should nominate a Representative to undertake consignment duties.

c. Terms relating to Consignment Stock are set out under Part 5 Draft Deed of Standing Offer Agreement clause 3a.2 Consignment Stock and/or under any relevant Service Level Agreement.

12. Provision of Trolleys and Storage Systems

a. Respondents should indicate in the ITS Response their ability to provide and maintain specialised trolleys and storage systems to facilitate the safe and efficient handling of Spinal Prostheses products, tools and equipment, consignment stock, loan sets and instrument trays.

b. Specialised trolleys and storage systems should be provided free of charge.

c. Trolleys, storage systems and transport containers should be designed and constructed in a manner that facilitates hospital compliance with the standards provided in Appendix 2 – Compliance Requirements.

d. The successful Respondent should ensure that the trolleys are always maintained in a working condition.

13. Loan Sets and Instrument Trays

a. Respondents must indicate the availability of loan sets and instrument trays to support the implantation of offered devices with their response.

b. All instrument trays will be provided with tray lists.

c. Instrument trays must be suitable for sterilisation in line with AS/NZS 4187.

d. Instrument trays (including all contents) will weigh less than five (5) kilograms.

e. Respondents should include the manufacturer's processing and reprocessing instructions for reusable components for product sterilisation.

f. Terms relating to loan sets are set out in clause 3.9 Loan Sets of Part 5 Draft Deed of Standing Offer Agreement.

14. Screw Banks

a. Respondents should advise the availability of screw banks to facilitate the management of screw inventory. Where screw banks are available, Respondents should advise the following information in the ITS response:

   (i) all conditions associated with their provision

   (ii) any limitations to their provision

   (iii) information regarding the installation and ongoing management of the system, including infection control / prevention requirements for decontamination and sterilisation

   (iv) the ability to provide validation of processing (e.g. NATA certification). Copies of certification will be available in hardcopy or electronic format upon request from HSV or health services

   (v) the availability of and any conditions associated with vendor management of screw banks.

b. Provision of screw banks should be provided free of charge.

c. Preference will be given to Respondent who are able to provide sterile screw banks.

15. Warranty

a. Warranty on implantable or consumable products covered in this ITS are to be issued a warranty up to the expiry date specified on the product packaging. This must be stated as part of your response to this ITS.

b. Loan sets and instrument trays are to be issued a warranty for the full duration of the loan, from the delivery date for normal use.

c. In the event of product breakage or failure once implanted, the relevant Supplier must disclose the details and findings of their investigation, including but not limited to the frequency of product failure for that product range.

d. Upon request, the successful Respondent will provide information (printed or electronic) explaining product warranty process.

e. The repair or replacement of any item under warranty will be at no cost to the Participating Health Service.

f. The cost of any pickup or delivery associated with a repair or replacement under warranty will be borne by the successful Respondent.

g. It is highly desirable that successful Respondents provide Participating Health Services with a replacement or suitable loan item at no cost until the repaired item is returned.

16. Recall Process

a. All recalls must be managed in line with the *Uniform Recall Procedure for Therapeutic Goods* (URPTG) (V2.1, February 2019).

b. Within three (3) months of agreement commencement, all recalls and/or hazard alerts will be completed using GS1 Recall Health.

c. Class 1 recalls (as defined by the TGA's *Uniform Recall Procedure for Therapeutic Goods* (URPTG) (V2.1, February 2019)) must also meet the requirements under Part 5 clause 11 Warranties where applicable.

Pricing

17. Price Variation

a. HSV mandates that Pricing must be submitted on the basis that it will be fixed for the duration of this Agreement.

18. Sole and Panel Pricing

a. HSV may choose to award a single supplier for this ITS (Sole Supply) or a panel of suppliers (Panel Supply).

b. In the Response Worksheet, Respondents are to list price options for both Sole Supply and Panel Supply. Note sole supply ensures all contracted purchases by health services for a subcategory the subject of a sole supply award.

c. Where HSV elects to award panel supply, health services may choose to purchase from any or all contracted suppliers.

Delivery

19. Electronic Data Interchange

a. The Participating Health Services prefer to exchange orders, payments, acknowledgements, invoices, remittance notices and other records (Data) electronically, in place of tangible documents. Successful Respondents are required to work with the Participating Health Services to achieve this outcome.

20. Delivery

a. Products within the scope of this ITS will be delivered to the location(s) specified by Participating Health Services within the shortest possible timeframe; however, this must not exceed two (2) Business Days from receipt of order unless otherwise agreed with the Participating Health Service.

b. All deliveries are bound as per the Deed of Standing Offer Agreement, Part 5 clause 9 Acceptance and Rejection of Deliverables.

21. Urgent Deliveries

a. For the purposes of this section, urgent deliveries refers to urgent requests placed by an individual Participating Health Service, and does not include state-wide emergency situations.

b. Preference will be given to Respondents which are able to receive and action urgent delivery requests 24 hours a day, 7 days a week.

c. Urgent deliveries should be received by Participating Health Services within 24 hours from receipt of order or as agreed as per the Service Level Agreement (SLA).

d. Any additional costs associated with Urgent Deliveries shall be clearly outlined in the User Guide tab of the Tender Response Worksheet and shall be discussed and agreed with the ordering health service prior to acceptance of any urgent order SLA with the individual Participating Health Service.

Support

22. Training

a. Upon request by a Participating Health Service, successful Respondents will deliver a training package and/or training materials to facilitate the introduction of their product offering on contract to clinicians in their operating environment.

b. Training requirements may include (but are not limited to):

   (i) face-to-face training at Participating Health Service sites (i.e. in-service training)

   (ii) off-site study days for clinicians

   (iii) updates and refresher training on new products and/or equipment and surgical techniques

   (iv) training on cleaning and sterilisation to nominated personnel and the Participating Health Services' CSSD and SSU (for reusable instruments)

   (v) training materials.

23. Customer Service and Support

a. The successful Respondent must be able to deliver 24-hour, 7-day customer service and support to Participating Health Services.

b. The successful Respondent will provide Participating Health Services with representatives that are:

   (i) inherently familiar with the contracted products

   (ii) appropriately qualified

   (iii) technically/clinically knowledgeable about the contracted products

   (iv) available to respond to Participating Health Services' queries 24 hours a day.

c. It is desirable that nominated Representatives have a clinical background or experience.

d. The level of customer service and support required of Representatives is expected to include (but is not limited to):

   (i) liaising with clinicians to recommend products and solutions

   (ii) promptly answering clinicians' queries (including after hours)

   (iii) liaising with various hospital departments (for example: operating theatre, Nurse Unit Managers)

   (iv) providing on-site clinical support during cases (if requested)

   (v) providing informational materials

   (vi) providing education and in-service training upon request.

e. Representatives must comply with Participating Health Services' local policies regarding engagement with Participating Health Service staff.

Award

24. Key Performance Indicators

a. Refer to Part 5 Draft Deed of Standing Offer Agreement clause 5 and Schedule 1 – Supply Schedule, Item 17.

25. Service Level Agreement

a. Participating Health Services may enter into a Service Level Agreement (SLA) with the successful Respondent(s). The SLA may cover arrangements including, but not limited to:

   (i) the provision of products on consignment

   (ii) requirements for stock management and rotation

   (iii) loan set requirements

   (iv) arrangements for ordering, invoicing and delivery

   (v) clinical support, including attendance requirements for Representatives in relation to education and training

   (vi) communication arrangements for product recalls and safety alerts (refer to Part 4 clause 16 Recall Process).

b. The SLA will be in addition to the Agreement between the successful Respondent(s) and HSV and will not alter any terms of the Agreement.

c. HSV will not be responsible for monitoring compliance with any SLA. This is a matter of agreement between the parties to the SLA.

d. Successful Respondent(s) will provide a copy of all Service Level Agreements to HSV within 1 week of being finalised.

26. Contract Panel of Suppliers

a. The capability of each Respondent will be assessed using the information submitted with their response to this sourcing event HPVITS2021-126 for product categories 1 to 8.
b. Only successful Respondents will be added to the Contract Panel of Suppliers for the supply of Spinal Prostheses as described in this Statement of Requirements under the new agreement.
c. Once the Contract Panel of Suppliers has been established, the Panel will remain closed for the full term of the contract (four years) from the date upon which the contract is established.
d. The Contract Panel will remain closed subject to any actions which HSV takes in relation to Market Dynamics as stipulated in Part 5, Draft Deed of Agreement, Clause 3.7.

27. Product Evaluation and Award to Contract

a. The award of products to contract will be the result of their suitability based on both their commercial and technical attributes.
b. Only products of Suppliers will be considered for evaluation and award to Contract.

c. Only Suppliers will be allowed to submit new products across all Product Categories for consideration for evaluation and addition under the contract variation request process referenced in Part 5, Draft Deed of Agreement, Clause 3.7 over the term of the new contract.

28. Patient Implant Cards and Patient Information Leaflets

a. Suppliers need to supply patient implant cards and patient information leaflets in accordance with the guidelines stipulated in Clause 13A of Schedule 1 of the Therapeutic Goods (Medical Devices) Regulations 2002 (the MD Regulations).
b. Suppliers will be required to provide confirmation that their products will be supplied with patient implant cards and patient information leaflets as part of their response to this ITS.

Category 1 – Screws and Caps

a. A range of screws and caps is required, including:

(i) fixed/monoaxial pedicle screws

(ii) polyaxial/multiaxial pedicle screws

(iii) MIS pedicle screws

(iv) single inner set screws/end caps/blockers

(v) reduction/dual inner set screws

(vi) monoaxial lateral mass screws (posterior c-spine)

(vii) polyaxial lateral mass screws (posterior c-spine)

(viii) uniplanar screws.

b. Variations include:

(i) full range in size, diameter, length and tulip size

(ii) material

(iii) partially or fully threaded

(iv) type of tip

(v) cannulated or non-cannulated

(vi) fenestrated or non-fenestrated

(vii) extended or non–extended screw head

(viii) sterile, individually wrapped or non-sterile

(ix) instrument – single-use or reusable

(x) loan set and instrument tray contents

(xi) additional components.

c. Product description:

For each screw and cap offered, respondents shall include the following attributes in the product description of the response worksheet:

(i) brand name

(ii) item description (e.g. polyaxial pedicle screws, reduction screws, etc)

(iii) sterile, individually wrapped or non-sterile

(iv) materials of manufacture (e.g. titanium, stainless steel etc)

(v) dimensions, specified in millimetres

(vi) for screws:

- fenestrated – cannulated or non-cannulated (where applicable)
- partially or fully threaded (where applicable)
- type of screw head (where applicable)
- type of tip (where applicable)

- any additional components (where applicable).

(vii) for instrumentation:

- single-use or re-useable
- contents of loan sets and trays (where applicable).

Category 2 – Cages and Spacers

a. A range of cages and spacers is required in all patient age ranges and sizes. This includes, but is not restricted to:

(i) cervical ACDF cages

(ii) cervical corpectomy cages with end caps

(iii) thoracolumbar anterior cages

(iv) thoracolumbar posterior cages

(v) thoracolumbar lateral cages

(vi) thoracolumbar corpectomy cages with end caps

(vii) artificial cervical discs

(viii) artificial lumbar discs

(ix) ACDF cage inserts

(x) lateral interbody cage inserts

(xi) articulating expandable interbody cages.

b. Variations may include:

- full range in size, diameter, height and angle
- material
- sterile, individually wrapped or non-sterile
- flat or lordotic (where applicable)
- any additional single-use or re-usable components and specialised instruments required to facilitate insertion or removal
- for open and minimally invasive procedures
- all associated additional components for corpectomy cages.

c. Product description:

For each cage and spacer offered, Respondents are to include the following attributes in the product description section of the Response Worksheet:

(i) brand name

(ii) item description (e.g. removal instrumentation set etc)

(iii) sterile, individually wrapped or non-sterile

(iv) type of material (e.g. titanium, stainless steel, carbon etc)

(v) dimensions in millimetres

(vi) for cages and spacers:

- site (where applicable) e.g. cervical, thoracic, lumbar
- sided (where applicable) e.g. left or right side-specific
- fixed: flat or lordotic
- expandable: articulating, expandable (where applicable)

(vii) for instrumentation:

- single use or re-useable
- contents of loan sets and trays (where applicable)
- any additional components (where applicable)

(viii) additional Information.

Respondents shall indicate in the relevant column of the Tender Response Worksheet whether any general sets which might be necessary for insertion or removal are included.

Category 3 – Rods, Crosslinks and Connectors

a. A range of rods and connectors is required. This includes any additional single-use or re-usable components and specialised instruments required to facilitate insertion or removal. This includes, but is not restricted to:

(i) straight rods

(ii) pre-bent rods

(iii) transitional rods

(iv) hinged rods (occipital)

(v) crosslinks

(vi) connectors (rod-to-rod)

(vii) connectors/clamps (rod-to-screw).

Variations may include:

- complete range in size, diameter and length
- material of manufacture
- shape
- length
- orientation
- sterile, individually wrapped or non-sterile
- associated / all additional components for crosslinks and connectors.

b. Product description:

For each implantable rod, crosslink and connector offered, Respondents are to include the following attributes in the product description of the Response Worksheet:

(i) brand name

(ii) item description e.g. straight, contoured, transition etc.

(iii) sterile or non-sterile

(iv) type of material e.g. titanium, stainless steel etc.

(v) size/diameter in millimetres

(vi) length in millimetres

(vii) any additional components (where applicable)

(viii) for instrumentation:

- single-use or re-useable
- contents of loan sets and trays (where applicable).

Category 4 – Plate and Screw Sets, Endplates and Staples

a. A range of plates, endplates and staples is required in all patient age ranges and sizes. This includes, but is not restricted to:

(i) cervical plates

(ii) cervical plate screws

(iii) thoracolumbar plates

(iv) thoracolumbar plate screws

(v) occipital plates

(vi) occipital plate screws

(vii) staples (anterior screw rod constructs)

(viii) laminoplasty kit.

b. Variations may include:

- full range in size, thickness and height
- material
- high/low contact plate
- locking and non-locking plate and screw
- self-drilling
- self-tapping
- sterile, individually wrapped or non-sterile
- any additional single-use or re-usable components and specialised instruments required to facilitate insertion or removal
- low contact plate for open and minimally invasive procedures.

c. Product description:

For each plate, endplate and staple offered, Respondents shall include the following attributes in the product description section of the Response Worksheet:

(i) brand name

(ii) item description e.g. removal instrumentation set etc.

(iii) sterile and individually wrapped or non-sterile

(iv) type of material e.g. titanium, stainless steel etc.

(v) dimensions in millimetres

(vi) locking or non-locking (where applicable)

(vii) fixed or variable angled (where applicable)

(viii) for plates:

- number of holes
- compatible screw and their sizes
- site (where applicable) e.g. cervical, thoracic, lumbar etc.

- sided (where applicable) e.g. left or right side specific

(ix) for endplates:

- number of holes
- compatible screw/cage and their sizes
- site (where applicable) e.g. cervical, thoracic, lumbar etc.
- sided (where applicable) e.g. left or right side-specific

(x) for instrumentation:

- single use or re-useable
- contents of loan sets and trays (where applicable)

(xi) any additional components (where applicable).

d. Additional information:

Respondents are to indicate in the relevant column of the Tender Response Worksheet whether any general sets that are necessary for insertion or removal are included.

Category 5 – Hooks

a. A range of hooks is required, including any single use and re-usable components and specialised instruments required for implantation or removal. This includes, but is not restricted to:

(i) pedicle hooks

(ii) transverse process hooks

(iii) sub-lamina hooks

(iv) supra-lamina hooks

(v) any single-use or re-usable components and specialised instruments required for implantation or removal.

Variations may include:

- full range of sizes
- materials
- orientation (where applicable) e.g. up, down, offset, up-angled, down-angled etc.
- sided (where applicable) e.g. left or right side-specific.

b. Product description:

For each hook offered, respondents are to include the following attributes in the product description of the Response Worksheet:

(i) brand name

(ii) item description e.g. condylar screw, washer, end cap

(iii) sterile or non-sterile

(iv) type of material e.g. titanium, stainless steel

(v) length in millimetres

(vi) diameter in millimetres

(vii) any additional components (where applicable)

(viii) for instrumentation:

- size of compatible guidewires and drill bits in millimetres
- single use or re-usable
- contents of loan sets and trays (where applicable).

c. Additional information:

Respondents shall indicate, in the relevant column of the Tender Response Worksheet, whether any general sets necessary for insertion or removal are included.

Category 6 – Wires, Cables and Tapes

a. A range of wires, cables and tapes is required, including any single-use and re-usable components and specialised instruments required for implantation or removal. This includes, but is not restricted to:

(i) wires

(ii) cables

(iii) tapes

(iv) variations may include:

- complete range in size and length
- materials
- sterile, individually wrapped or non-sterile
- length
- all additional single-use or re-usable components and instruments required to facilitate insertion, construction or removal.

b. Product description:

For each wire, cable and tape offered, Respondents shall advise the following in the product description of the Response Worksheet:

(i) brand name

(ii) item description e.g. guidewires

(iii) sterile or non-sterile

(iv) type of material (e.g. titanium, stainless steel)

(v) diameter (in millimetres)

(vi) length (in millimetres)

(vii) any additional components (where applicable)

(viii) for instrumentation:

- size of compatible guidewires and drill bits (in millimetres)
- single-use or re-useable
- contents of sets (where applicable).

Category 7 – Miscellaneous

a. A range of miscellaneous products is required, including any single-use components (where applicable) and specialised instruments required for implantation or removal. This includes, but is not restricted to:

(i) pins (distractor or retractor)

(ii) pins (temporary fixation)

(iii) drill bits (single-use)

(iv) MIS guidewires or k-wires

(v) tethering staples

(vi) vertebroplasty / kyphoplasty kits

(vii) variations may include:

- full range of sizes and lengths
- materials
- sterile, individually wrapped or non-sterile
- length (in millimetres).

b. Product description:

For each miscellaneous product offered, Respondents are to include the following attributes in the product description of the Response Worksheet:

(i) brand name

(ii) item description

(iii) shape (where applicable) e.g. wedge, strip etc.

(iv) size (dimensions in millimetres)

(v) length (dimensions in millimetres)

(vi) angle (where applicable)

(vii) ready-to-use (where applicable)

(viii) other equipment and consumables (where applicable).

Category 8 – Spine-specific Bone Substitutes

a. A full range of spine-specific bone substitutes is required. This includes, but is not restricted to, the following range of presentations:

   (i) cage inserts or bone substitutes

   (ii) allogeneic bone – spine

   (iii) other bone substitutes.

b. Variations may include:

   - contains or is compatible with antibiotics
   - biological or non-biological
   - pack sizes
   - equipment and consumables required for preparation and use
   - materials
   - shape
   - size and angle.

c. Product description:

For each spine-specific bone substitute offered, Respondents are to indicate the following attributes in the product description of the Response Worksheet:

   (i) brand name

   (ii) item description e.g. granules, pre-formed etc.

   (iii) shape (where applicable) e.g. wedge, strip etc.

   (iv) size e.g. volume in millilitres, dimensions in millimetres etc. as applicable.

   (v) angle (where applicable)

   (vi) compatible with antibiotics (where applicable)

   (vii) with premixed antibiotics (where applicable)

d. Type of antibiotic (e.g. Gentamicin):

   (i) ready-to-use (where applicable)

   (ii) other equipment and consumables (where applicable).

e. Additional information:

Respondents shall advise the following in the relevant column of the Response Worksheet:

   (i) the materials used in the bone substitute

   (ii) if the bone substitute is drillable

   (iii) setting time in minutes

   (iv) absorption time in weeks.

Appendix 1 - Product List

Category		Subcategory	
1	Screws and Caps	1.01	Fixed / Monoaxial Pedicle Screws
		1.02	Polyaxial / Multiaxial Pedicle Screws
		1.03	MIS Pedicle Screws
		1.04	Single Inner Set Screws / End Caps / Blockers
		1.05	Reduction / Dual Inner Set Screws
		1.06	Monoaxial Lateral Mass Screws (Posterior C-Spine)
		1.07	Polyaxial Lateral Mass Screws (Posterior C-Spine)
		1.08	Uniplanar Screws
2	Cages and Spacers	2.01	Cervical ACDF Cages
		2.02	Cervical Corpectomy Cages with End Caps
		2.03	Thoracolumbar Anterior Cages
		2.04	Thoracolumbar Posterior Cages
		2.05	Thoracolumbar Lateral Cages
		2.06	Thoracolumbar Corpectomy Cages with End Caps
		2.07	Artificial Cervical Discs
		2.08	Artificial Lumbar Discs
		2.09	ACDF Cage Inserts
		2.10	Lateral Interbody Cage Inserts
		2.11	Articulating Expandable Interbody Cages
3	Rods, Crosslinks and Connectors	3.01	Straight Rods
		3.02	Pre-bent Rods
		3.03	Transitional Rods
		3.04	Hinged Rods (Occipital)
		3.05	Crosslinks

Category		Subcategory	
		3.06	Connectors (Rod-to-Rod)
		3.07	Connectors / Clamps (rod-to-screw)
4	Plate and Screw Sets, Endplates and Staples	4.01	Cervical Plates
		4.02	Cervical Plate Screws
		4.03	Thoracolumbar Plates
		4.04	Thoracolumbar Plate Screws
		4.05	Occipital Plates
		4.06	Occipital Plate Screws
		4.07	Staples (Anterior Screw Rod Construct)
		4.08	Laminoplasty Kits
5	Hooks	5.01	Pedicle Hooks
		5.02	Transverse Process Hooks
		5.03	Sub-Lamina Hooks
		5.04	Supra-Lamina Hooks
		5.05	Specialised Implantation / Removal Instruments
6	Wires, Cables and Tapes	6.01	Wires
		6.02	Cables
		6.03	Tapes (Including Screw)
7	Miscellaneous	7.01	Pins (Distractor / Retractor)
		7.02	Pins (Temporary Fixation)
		7.03	Drill Bits (Single-use)
		7.04	MIS Guidewires / K-wires
		7.05	Tethering Staples
		7.06	Vertebroplasty / Kyphoplasty Kits
8	Spine Specific Bone Substitutes	8.01	Cage Inserts or Bone Substitutes

Category		Subcategory	
		8.02	Allogeneic Bone Substitutes - Spine
		8.03	Other

Appendix 2 - Compliance Requirements

Australian Standards, Orders, Legislation and Regulations

a. It is the responsibility of the Respondent to ensure that all products offered comply with the Compliance Requirements listed below. This is not an exhaustive list; Respondents must ensure that they comply with any other Compliance Requirements that are not listed below. This includes primary and subordinate instruments of the State and Commonwealth and any relevant amendments, revisions or consolidations.

   The relevant legislation for HPVITS2021-126 may include, but is not limited to:

   (i) *Uniform Recall Procedure for Therapeutic Goods* (URPTG) (V2.1, February 2019)

STANDARD NUMBER	STANDARD NUMBER
AS/NZS 4187:2014	Cleaning, disinfecting and sterilizing re-usable medical and surgical instruments and equipment and maintenance of associated environments in health care facilities
ISO 19227:2018	Implants for Surgery – Cleanliness of orthopaedic implants – General requirements
AS ISO 8828:2015	Implants for Surgery – Care and handling of orthopaedic implants
ISO 18192-3:2017	Implants for surgery – Wear of total intervertebral and spinal disc prostheses
ISO 12189:2008	Implants for surgery – Mechanical testing of implantable spinal devices – Fatigue test method for spinal implant assemblies using an anterior support

Legislation

a. The references to the legislation below include any amendments, revisions or consolidations to those references.

   (i) *Therapeutic Goods (Medical Devices) Regulations* 2002

   (ii) *Therapeutic Goods Act* 1989

   (iii) Occupational Health and Safety Regulations 2017

   (iv) Occupational Health and Safety (Manual Handling) Regulations 1999

Guidelines and Other References

a. The references to the guidelines below include any amendments, revisions or consolidations to those guidelines.

   (i) Australian Guidelines for the Prevention and Control of Infection in Healthcare, Canberra: National Health and Medical Research Council (2021)

   (ii) *Uniform Recall Procedure for Therapeutic Goods* (URPTG) (V2.1, February 2019). Therapeutic Goods Administration (2011), *Australian Regulatory Guidelines for Medical Devices.*

Appendix 3 – Abbreviations

ABBREVIATION	DEFINITION
ALIF	Anterior Lateral Interbody Fusion
TLIF	Transformal Lateral Interbody Fusion
PLIF	Posterior Lateral Interbody Fusion
XLIF	Extreme Lateral Interbody Fusion
OLIF	Oblique Lateral Interbody Fusion
DLIF	Direct Lateral Interbody Fusion
ACDF	Anterior Cervical Discectomy and Fusion
ACF	Anterior Cervical Fusion
PLF	Posterior Lumbar Fusion
MIS	Minimally Invasive Surgery
PEEK	Polyetheretherketone
IBF	Interbody Fusion
CSSD	Central Sterilising Services Department