HEALTH PURCHASING VICTORIA

# Invitation to Supply

## Part 5 - Statement of Requirements

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|---|---|
| **Invitation to Supply Number:** | **HPVITS2019-047** |
| **Invitation to Supply Name:** | **Orthopaedic Prostheses – Hips and Knees** |
| **HPVITS2018-047Closing Date and time:** | **Wednesday, 19 September 2018, 14:00 AEST** |


**Authorised Contact Person**

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**Contact through**
**HPV Procurement Portal**



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# A Introduction

## 1 Purpose

a. The purpose of this Part 5 - Statement of Requirements is to:

(i) detail the scope and range of products sought under this Invitation to Supply (ITS)

(ii) specify the requirements that Respondent and/or their offered products must meet

These requirements also form part of any resulting Agreement between HPV and any successful Respondent(s).

## 2 Scope

a. HPV is seeking responses for Hip and Knee Prostheses products for use in Participating Health Services. The envisaged Term of the Agreement is three (3) years plus one optional two year extension period available to extend the contract term (3+2).

b. The scope of this ITS includes:

(i) the supply of Orthopaedic Prostheses – Hip and Knee products goods consignment service

(ii) service requirements

(iii) education and training

(iv) company representative clinical attendance

c. The scope of this ITS does not include:

(i) Products within the scope of HPVC2012-046 Trauma Implants

(ii) Products not related to arthroplasty of hip and knee

d. Indicative volumes are listed in Part 6 – Response Worksheet. Respondents are to note that any usage figures provided are indicative only, and are provided to assist Respondent in the preparation of their submission.

# 3 Product Categories

a. The categories of Orthopaedic Prostheses – Hip and Knee products required under this ITS includes:

| Category Number | Category Name |
|---|---|
| 1 | Primary Hips Prostheses |
| 2 | Hip Resurfacing |
| 3 | Complex/Revision Hip Prostheses |
| 4 | Primary Knee Prostheses |
| 5 | Partial Primary Knee Prostheses |
| 6 | Patello – Femoral Replacements |
| 7 | Complex/Revision Knee Prostheses |
| 8 | Cement and Cement Accessories |
| 9 | Navigation Systems |
| 10 | Miscellaneous |

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

c. Only products that specifically fit within the category descriptions provided will be considered.

d. HPV reserves the rights not to consider any additional products offered.

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

# 4 Product Conditions

## 4.1 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.

## 4.2 Product Duplication

a. HPV may not consider any product that is subject to a current HPV Agreement.

b. The Respondent will ensure that each product is offered in only one subcategory. It is at the Respondent's discretion to ensure that each product is submitted in the most appropriate subcategory.

## 4.3 Product Information

a. Respondents are required to submit a copy of relevant product diagrams, specifications or brochures to assist in accurately identifying products offered.

b. Where research papers or relevant scientific information are available, this should be submitted with the Respondent's ITS response.

c. All product information submitted must:

(i) be in electronic format;

(ii) be in English;

(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; and

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

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

Electronic copies must include the HPV category and subcategory numbers in the filename or identifying metadata.

HPV may not consider unlabelled submissions.

e. Product information will not be evaluated, but is necessary to assist in accurately identifying products offered.

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

(i) Not labelled as per Part 5 A 4.3d above; or

(ii) Is incomplete as to Part 5 A 4.3c.

g. Product samples are not to be provided unless specifically requested by HPV, as per Part 3 – 8 Samples.

h. Respondents should not submit information relating to products that are not called for in this ITS.

## 4.4 Third-Party Product Compatibility

a. Respondents tendering third-party items must provide clinical testing and evidence of each item's compatibility with specific models of OEM equipment.

b. Successful Respondents must also make these certificates of compliance and/or evidence of testing available to Participating Health Services upon request.

c. Further evidence of testing will be required for product variations requested during the contract period. Certificates of compliance and/or evidence of testing must not be more than two (2) years old at the time of the variation request.

d. HPV reserves the right to require further testing from successful Respondent if:

(i) a product quality issue is identified during the contract; or

(ii) an option period is exercised at the end of the contract principal period.

e. Ensuing clauses Part 5A4.4c and Part 5A4.4d, in the event that HPV requires further certificates of compliance and/or evidence of testing to be provided, HPV reserves the right to remove products from contract if the successful Respondent refuses to or cannot produce the required evidence.

# 5 Definitions

a. The following definitions apply to this Part 5 – Statement of Requirements, unless otherwise stated.

| TERM | DEFINITION |
|---|---|
| Agreement | A contract entered into by HPV and a Respondent for the provision of Orthopaedic Prostheses – Hip and Knee product. Comprises the General Conditions, and all Schedules, Annexures of any kind and any attachments. |
| ARTG | Australian Register of Therapeutic Goods under the control of TGA |
| Business day | Any weekday not gazetted as a public holiday in Melbourne, Victoria. |

| TERM | DEFINITION |
|---|---|
| DMSO | Dimethyl Sulfoxide |
| HPV | Health Purchasing Victoria |
| may | Indicates an optional element; it is at the Respondent's discretion to either meet or not meet this element, and failure to meet this element will not have an impact during evaluation. |
| MRI | Magnetic Resonance Imaging |
| must | Indicates a mandatory requirement; failure to meet this requirement result in the submission being eliminated from further consideration |
| normal use | Means the item has undergone use for which it was manufactured and intended, and shows no signs of physical damage other than regular wear and tear |
| OEM | Original Equipment Manufacturer |
| Participating Health Services | Public Hospitals and other Health or Related Services, as those terms are defined in Section 3 of the Health Services Act 1988 (Vic), that are described in **Appendix 4 of Part 8**. |
| Respondent | Any person, company or organization representing to this ITS and, unless the context otherwise requires, includes those who may access the ITS for the purpose of submitting a ITS |
| should | Indicates a highly desirable element; unless justifiable reason exists, not meeting this element may impact evaluation. |
| SLA | Service Level Agreement |
| TGA | Therapeutic Goods Administration |
| will | Indicates an anticipated future condition or requirement to be met |

# B Service, delivery, and support

## 1 Delivery

a. Orthopaedic Prostheses – Hip and Knee products must be delivered to the location(s) specified by Participating Health Services within the shortest possible timeframe; however, this must not exceed the following timeframes:

(i) Twenty-four (24) hours from receipt of order for **metropolitan** Participating Health Services, unless otherwise specified in the SLA.

(ii) Forty-eight (48) hours from receipt of order for **regional and rural** Participating Health Services, unless otherwise specified in the SLA.

b. Except where there is evidence of inappropriate handling by the receiving Participating Health Services, all damaged or broken products and equipment must be replaced free of charge.

c. All deliveries are bound as per Part 7 Draft Agreement and Part 8 Return of Appendices.

## 2 Consignment Stock, Equipment and Instruments

a. Respondents should advise in the Response Worksheet on the ability to provide goods on consignment in Participating Health Services.

b. Respondents are responsible for the insurance of consigned goods once “on shelf” in Participating Health Services.

c. HPV views favourably the use of Radio-frequency identification (RFID) technology for stock management purpose.

d. Where products are provided on consignment, managing stock levels and reporting must be undertaken by the successful Respondent, unless negotiated otherwise with the Participating Health Services in a Service Level Agreement. The maximum turnaround time for replacement of used consignment stock following placement of an order should be up to a maximum of twenty four (24) hours.

e. The successful Respondent must remove, and replace any consignment goods on the Participating Health Service’ shelf before the expiry date of the consignment items.

(i) The successful Respondent’s nominated Representative(s) will be responsible for performing stocktake of consignment stock on a regular basis (as agreed with the Participating Health Service), and replacing used stock;

(ii) checking the expiry date of consigned stock, and replacing any stock that is out of date at no cost; and

f. The successful Respondent’s nominated Representative(s) will be responsible for the maintenance of consignment instruments and equipments, and the preference will be given to a Respondent who can provide the maintenance on a regular basis (as agreed with the Participating Health Services).

g. HPV views favourably a Respondent that can provide, on request, a storage solution for consigned products at no cost to Participating Health Services.

h. Except where there is evidence of inappropriate handling by the receiving hospital or health service, all damaged or broken goods and equipment shall be replaced free of charge.

i. Consignment arrangements shall be reviewed by the successful Respondent and the Participating Health Services on a monthly basis at a minimum or as negotiated. The review should include but not limited to reporting of backorder, any stock that has been removed and reallocated and queries relating to consignment stock consumption.

j. For all consignment orders received prior to 3pm on business days, stock is to be delivered on the next business day.

k. For all consignment orders, invoice must be received within fourteen (14) days of product use.

l. All queries relating to consignment stock will be resolved within three (3) months of item use.

m. The successful Respondent should reach an agreement with each Participating Health Service concerning:

(i) identification of products that require consignment;

(ii) appropriate stock levels;

(iii) a stock management system to ensure effective and efficient use of goods including identification of slow moving items and the management of short dated stock. The turnaround time for replacement of used consignment stock following order replacement; and

(iv) reporting of any stock that has been removed and reallocated by the successful Respondent.

# 3 Training and Support

a. Successful Respondents must provide training and/or training materials to facilitate the introduction of their Hip and Knee Prostheses products to clinicians in their operating environment. Such training and/or materials must be available to Participating Health Services upon request.

b. If requested by a Participating Health Service, successful Respondents should provide a plan detailing how they will provide training to nominated staff. The number of staff involved in training may vary greatly between Participating Health Services.

c. Education session and training provided by the successful Respondent as required by the Participating Health Services should be free of charge.

d. Respondents should advise in the ITS response the representative's ability to provide pricing information for each component at the time of the procedure.

e. Successful Respondents must ensure that the following is available to Participating Health Services (in either hard-copy or electronic format):

(i) the credentials of any staff who would be providing training and industry clinical support;

(ii) the hours of availability of support;

(iii) the geographical area covered by the support (if support is available on-site); and

(iv) details of educational and/or support materials available to clinicians.

f. All training regimes should include appropriate levels of training to meet Workplace Health & Safety issues as required by The Victorian WorkCover Authority.

g. 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 procedure techniques;

(iv) training on cleaning and sterilisation to nominated personnel and the Participating Health Services' Central Sterile Supply Department (CSSD) or Sterile Supply Unit SSU (for reusable instruments); and

(v) training materials. (demonstration or in servicing, compatibility charts, templates and user guides).

# 4 Customer Service and Company Representative Attendance

a. The successful Respondent must be able to deliver 24-hour, 7-day customer service and support to Participating Health Services unless otherwise specified in the SLA.

b. The successful Respondent should nominate at least one representative to provide support and undertake consignment duties.

c. The successful Respondent should 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; and

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

d. It is desirable that nominated representatives have a clinical background or experience. The successful Respondent should notify the Participating Health Services in writing, in a timely manner if there is any change of company's representative during the Term of the contract.

e. 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;

(vii) case support; and

(viii) proactively update and provide accurate billing code as per the Health Insurance Prostheses List for products purchased by the Participating Health Services.

f. The clinical support provided by nominated representatives must be provided free of charge to the Participating Health Services.

g. Respondents should advise in the ITS Response the availability of company representative to provide industry clinical support:

(i) for Hip and Knee Prostheses procedures;

(ii) out of normal business hours including weekends;

(iii) at follow-up clinics for the life of the implanted device, regardless of the contract status; and

(iv) for after-hours at the high volume trauma centres.

h. Participating Health Services' requirements of company representative attendance should be incorporated into the Service Level Agreement between the successful Respondent and individual Participating Health Service.

i. The successful Respondents should ensure that their sales representatives do not change the contents of the loan kits ordered by health services without prior approval of the health services.

# 5 Warranty

a. A minimum 12-monthy warranty for normal use of devices will be provided from the date of commissioning where applicable.

b. Upon request, the successful Respondent must provide information (printed or electronic) explaining product warranty.

## 5.2 Repairs and Replacements under Warranty

a. The repair or replacement of any Orthopaedic Prostheses – Hip and Knee product under warranty will be provided free of charge for the Participating Health Services.

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

c. Items repaired under warranty should be returned to Participating Health Services within twenty-eight (28) business days from when the item is received by the successful Respondent.

d. It is highly desirable that the successful Respondent provides Participating Health Services with a replacement or suitable loan item free of charge until the repaired item is returned.

# 6 Key Performance Indicators

a. Refer to item 17 of Supply Schedule – Key Performance Indicators.

# 7 Reporting

a. Refer to item 12 of Supply Schedule – Reporting Requirements.

b. Successful Respondents will provide to HPV other reports that may reasonably be required from time to time.

# 8 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 including arrangements and communication requirements for establishment, ongoing management, review and cessation of consignment stock requirements (refer to Part 5 B2 – Consignment Stock);

(ii) requirements for stock management and rotation;

(iii) arrangements for ordering, invoicing and delivery;

(iv) clinical support, including clinical attendance requirements, education and training;

(v) communication arrangements for product recalls and safety alerts (refer to Part 5 C3 – Recallnet Process); and

(vi) assist the health services in ensuring accuracy of data within Htrack or relevant ordering system.

b. The terms of the SLA are to be agreed between the Participating Health Service and the successful Respondent.

c. The SLA will be in addition to the Agreement between the successful Respondent and HPV, and will not alter any terms of the Agreement.

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

# C General Requirements

## 1 Standards and Compliance

a. All items offered must comply with relevant Australian Standards (or their equivalent International Standards). Refer to Appendix 2 - References for a list of the minimum relevant standards.

b. All items offered must be approved by the Australian Therapeutic Goods Administration (TGA), unless exempt. The Respondent must provide evidence of this (i.e. ARTG certificates) in its response.

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

## 2 Packaging and Labelling

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

b. All labels should comply with the Therapeutic Goods Order No. 37: General Requirements for Labels for Therapeutic Goods.

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

d. Successful Respondents should ensure individual product packaging to include (where applicable):

(i) whether the product is sterile or non-sterile;

(ii) whether the product (or packaging) contains latex or is latex-free;

(iii) Whether the product has PVC content or no PVC content;

(iv) Whether the product is single use or reusable; and

(v) Barcodes.

## 3 Recall Process

a. All recalls must be managed in line with the *Uniform Recall Procedure for Therapeutic Goods* (2004).

b. Within six (6) months of contract commencement, all recalls and/or hazard alerts must be completed using GS1 Recall.

c. Class 1 recalls (as defined by the TGA's *Uniform Recall Procedure for Therapeutic Goods*) should also meet the requirements under Part 5 B5 – Warranty, where applicable.

## 4 Backorders and Discontinued Lines

a. In the event that a product is unavailable for a period of two or more consecutive weeks, the successful Respondent will notify in writing (at a minimum) to the following:

(i) Supply department of the Participating Health Services;

(ii) Participating Health Services' Orthopaedic / Neurosugery Department

(iii) HPV ; and

provide a backorder report and a list of recommended substituted items (where applicable) to the Participating Health Services and HPV for reference.

b. In the event that an item is discontinued, successful Respondents will notify Participating Health Service staff and HPV as soon as possible, but no less than six (6) months before the last date of manufacture.

c. Successful Respondents will inform the affected Participating Health Services and HPV of:

(i) the anticipated timeframe for resolving the issue; and

(ii) the availability of an agreed substitute product

## 5 Infection Control

a. Where applicable, all items must meet the requirements of the Australian Guidelines for the Prevention and Control of Infection in Healthcare (2010).

b. Upon request by Participating Health Services, successful Respondents should provide details of their cleaning processes for all reusable products.

c. Successful Prespondent should follow the instructions of the Central Sterilisation Service Department (CSSD) Reference Sites.

## 6 Reference Sites

**a.** Respondent is required to provide a minimum of three (3) Australian clinical references that are purchasing or have trialled and evaluated each class or category of product offered in this submission. For the purpose of this tender, references will only be accepted from **at least three Orthopaedic Surgeons**

b. Where a product category contains a variety of specific subcategories, Respondent is to ensure that the reference sites provided are representative of the full range of products tendered.

c. HPV reserves the right to verify this information with hospital personnel and seek user feedback as to the acceptability of these products.

d. Respondents should not nominate a referee without their express permission.

# 7 Construct Prices

a. Respondents should provide in Part 6 – Response Worksheet the construct components for Hip and Knee implant scenarios found in Appendix 3 – Construct List.

b. Each construct price should include all requirements to undertake the listed procedure including all relevant components and consumable items.

c. Respondents should list all components that are included in the construct price including the relevant product code and product description in the Response Worksheet.

# 8 Additional information

a. The following information will be available to all Participating Health Services as hard and/or electronic information:

(i) Details of Help Desk support, including the toll-free number, the geographical area covered by the support, and the hours available;

(ii) Copies of any proforma documentation, including order forms;

(iii) Patient Education Material including:

- Product information/booklets.
- Patient cards.

# D Product Specifications

## 1 General Specifications

### 1.1 Substances of Concern

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

b. Preference may be given to products that are free of phthalate content, particularly diethylhexyl phthalate (DEHP).

## 2 Provision of Trolleys and Storage Systems

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

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 – References.

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

### 2.2 Instrument Trays

a. All instrument trays should be provided with tray lists.

b. Instrument trays should be suitable for sterilisation in line with AS/NZS 4187.

c. Instrument trays (including all contents) should weigh less than five (5) kilograms.

d. Respondents should advise in the ITS response if they have the ability to provide checklist photos of instrument trays which will be able to easily indicate which instruments are to be taken apart for cleaning and sterilising.

e. The successful Respondent should ensure that the trays provided should not have any sharp edges and contain a smooth bottom.

f. All instruments should be sent in side opening cases.

g. Successful Respondents will be responsible for the maintenance and repair of instrumentation provided in instrument trays except where there is evidence of inappropriate handling by the receiving hospital or health service.

h. Removal instruments must be retainded for a period of no less than 20 years from the end of the contract. Where the situation arises that a product becomes obsolete, the componentry that may be required for revision must remain available for a period of no less than 20 years.

## 2.3 Loan Kits

a. Respondents are to advise the availability of loan kits and instrument trays to support the implanation of tendered products in their ITS response.

b. Preference will be given to Respondents who provide unused loan kits free of charge. Also loan kits that have been used by the health services should be provided free of charge.

c. Respondents should advise the following in the ITS Response:

(i) the minimum required notification time to ensure availability of loan kits and instrument sets;

(ii) availability to provide unused kits at no cost;

(iii) any variation to these costs for metropolitan, regional and rural hospitals and health services;

(iv) all conditions associated with the provision of loan kits; and

(v) the process for return of loan kits.

d. Where loan kits to support the implantation of tendered devices are provided, loan kits should be:

(i) provided to health services in containers that are maintained in a clean and reasonable condition;

(ii) road / transport case or tub should meet OH & S manual handling requirements and if applicable be clearly labelled as to why it does not comply. i.e. heavy, top loading;

(iii) provided in a container without sharp edges and a smooth bottom;

(iv) clearly named and labelled;

(v) readily available and delivered at least 24 hours prior to procedure start;

(vi) with sufficient notification, free into store unless they are subsequently not used;

(vii) supported by:

- a clear statement of all conditions associated with the provision of loan kits;
- a clear process for the return of loan kits including any costs that are incurred for unused kits;
- details instruction for the reprocessing, care and maintenance of the contents at hospitals or health services level;

- customer service contact details; and
- clear ordering instructions for the acquisition of kits during and out of normal business hours.

e. Product supplied in loan kits or as consignments stock should be provided at the same price of the tendered products.

f. If consignment stock please document in tender response worksheet (TRW) the price.

## 2.4 Screw Banks

a. Respondents should advise the availability of Screw Banks to facilitate the management of screw inventory. Where Screw Banks are available, Respondent 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 HPV or health services; and

(v) the availability 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.

# 3 Category Specifications

a. Respondents are invited to tender products in accordance with Part 5 Statement of Requirements.

A complete range of Hip and Knee Prostheses products is required for treatment of patients across Victorian Public Health Services.

b. Preference will be given to the Respondent offering both the greatest range and best value for money across and/or within product categories called for in this ITS. Exceptions to this will be for niche product ranges only.

# 4 Compliance with Category Specifications

a. Preference will be given to products that are sterile, single use and presented in peel pack packaging unless otherwise indicated.

b. All products that are offered as part of a kit should meet the speciafications for their relevant originating category.

c. For each item offered, where applicable, Respondent should advise the following information on the Response Worksheet:

(i) the Billing Code as per the Health Insurance Prostheses List; and

(ii) if a facility for batch-tracking is incorporated on the device.

# 5 Additional Information

a. Items offered in the 'Miscellaneous' category will only be considered for contract award where the tendered product meets the specification AND the Respondent is successful in at least one of the category. HPV reserves the right to not consider any additional items offered.

**b. Respondents note: Consumable items procured through the Trauma Implants Contract are excluded from this tender.**

## Category 1 - **Primary Hip Prostheses**

**Femoral Components**

**Combined Femoral Stem and Head (Monoblock)**

**A range of combined femoral head and stem products is required, including:**

- cemented or cementless
- for femoral stem, a range of:
  - profiles e.g. curved
  - dimensions in millimetres
- for femoral head, a range of:
  - diameters in millimetres
- materials e.g. metal

***Femoral Stems- Modular***

**A range of Modular femoral stems is required, including:**

- cemented and cementless
- ceramic or metal
- right and left side orientation
- with a range of:
  - sizes
  - dimensions
  - coating e.g.internal and external coating and type e.g. HA
  - trunnion types e.g.12/14
  - neck shaft angles e.g. 135 degrees
  - offsets e.g. standard
  - collared and non collared
  - profiles e.g. tapered
  - material e.g. titanium

- surface finishes including:
    - porous or non porous
    - polished or matte

***Centralisers***

**A range of centralisers/bone plugs is required, including**

- proximal and distal
- with a range of:
    - materials *e.g. PMMA*
    - sizes

For each product offered, Respondents should idenitify:

- additional modality

***Femoral heads – modular***

**A range of femoral heads is required, including:**

- A range of
    - diameters, in millimetres
    - neck lengths, in millimetres
    - trunnion sizes on standard stem *e.g.12/14*
    - materials e.g. chromium cobalt, ceramic

***Acetabular Components***

***Acetabular Monoblock Components***

**A range of acetabular monoblock components is required, including:**

- cemented or cementless
- with a range of:
    - materials e.g. polyethylene

- of dimensions including:
    - inner diameters, in millimetres
    - outer diameters, in millimetres.

***Acetabular Shells***

**A range of Acetabular Shells is required, including:**

- cementless
- with a range of:
    - materials e.g. titanium
- a range of surface finishes including:
    - porous or non porous
    - a range of coating types e.g. HA
    - finish to internal and external surface
- outer diameters, in millimetres
- profiles including:
    - hemispherical or non hemispherical
- solid or with screw holes
    - when with screw holes, the distribution of holes
- liner locking mechanisms
- apex hole eliminators and/or dome plugs.

***Acetabular Liners***

**A range of acetabular liners is required, with a range of :**

- materials types e.g. polyethylene
    - if polyethylene, a range of types *e.g. highly cross-linked*
- configurations *e.g. flat, hood*
- inner diameters, in millimetres
- outer diameter, in millimetres
- thicknesses, in millimetres.

- Degree of the lip *e.g. 10°, 20°*

**Additional Components**

**A range of additional components is required, including:**

- screws:
  - in a range of metal types, *e.g. titanium*
  - with a range of lengths and diameters, in millimetres
- single use drill bits:
  - with a range of lengths and diameters in millimetres.

**Single Use Instruments**

**A range of single use instruments is required, including:**

- single use instruments required for implantation of primary hip prostheses.

## Category 2 - **Hip Resurfacing**

### Femoral Components

**A range of femoral components is required, including:**

- cemented or cementless
- with a range of:
    - dimensions, in millimetres for inner and outer diameter
- surface finishes:
    - porous or non porous
    - types of coating *e.g. HA*
- types of material e.g. cobalt chromium

### Single Use Instruments

**A range of single use instruments is required, including:**

- single use instruments required for implantation of hip resurfacing prostheses.

## Category 3 - **Complex/Revision Hip Prostheses**

**Femoral Components**

***Femoral Stems - Modular***

**A range of femoral components is required, including:**

- cemented or cementless
- with a range of:
  - sizes
  - dimensions
  - right and left side orientation
  - coating e.g. internal and external coating and type e.g. HA
  - trunnion types e.g.12/14
  - neck shaft angle e.g. 135 degrees
  - offsets e.g. standard
  - collared and non collared
  - profiles e.g. tapered
  - material e.g. titanium
- surface finishes including:
  - porous or non porous
  - polished or matte

**Centralisers/bone plugs**

**A range of centralisers/ bone plugs is required , including:**

- Proximal or distal
- With a range of :
  - Material e.g PMMA
  - Sizes

***Femoral Modular Body***

**A range of femoral modular body components is required, including:**

- cemented or cementless
- with a range of:
  - shapes
  - neck lengths in millimetres
  - neck angles e.g.125 degrees
  - offsets *e.g. high*
- surface finishes:
  - porous or non porous
  - a range of types of coating e.g. HA
- Calcar replacing options (where applicable)

***Femoral Heads***

**A range of femoral heads is required, including:**

- A range of:
  - diameters in millimetres
  - trunnion sizes eg. 12/14
  - materials eg. Cr Co
  - neck length in millimetres
  - types of bearing surface e.g. metal on metal

**Acetabular Components**

***Monoblock Acetabular***

**A range of acetabular monoblock components is required, including:**

- cemented or cementless
- with a range of:
  - materials e.g. polyethylene
  - if polyethylene, a range of the type e.g. highly crosslinked

- dimensions including:
    - inner diameters, in millimetres

***Acetabular Shells***

**A range of acetabular shells is required including:**

- cemented or cementless
- with a range of:
    - materials e.g. titanium
- a range of surface finishes including:
    - porous or non porous
    - a range of coating types e.g. HA
    - finish to internal and external surface
- outer diameters, in millimetres
- profiles including:
    - hemispherical or non hemispherical
- solid or with screw holes
    - when with screw holes, the distribution of holes
- liner locking mechanisms
- apex hole eliminators and/or dome plugs.

***Acetabular Augments/Restrictors/Cages***

**A range of acetabular augments/restrictors/cages is required including:**

- cemented or cementless
- with a range of:
    - lengths, widths and diameters in millimetres
    - shapes *e.g. hole*
    - screw hole geometry *e.g. solid, cluster, multi-hole*
    - surface finishes:
        - porous or non porous

- types of coating *e.g. HA, grit blasted*.
- types of construction materials *e.g. titanium*
- cages:
- right or left configuration
- long or short flange.

***Acetabular Liners***

**A range of acetabular liners is required including a range of:**

- materials types e.g. polyethylene
  - if polyethylene, a range of types *e.g. highly cross-linked*
- configurations *e.g. flat, hood*
- inner diameters, in millimetres
- outer diameter, in millimetres
- thicknesses, in millimetres.
- Degree of the lip *e.g. 10°, 20°*

***Additional Components***

**A range of additional components is required, including:**

- screws:
  - in a range of metal types, e.g. titianium
  - a range of lengths and diameters, in millimetres
- single use drill bits:
  - with a range of lengths and diameters in millimetres.

***Single Use Instruments***

**A range of single use instruments is required, including:**

- single use instruments required for implantation of revision hip prostheses.

## Category 4 - **Primary Knee Prostheses**

### Femoral Component

**A range of femoral components is required, including:**

- cemented or cementless
- cruciate retaining
- posterior stabilised / constrained.
- side specific e.g. right or left
- with a range of:
  - sizes *e.g. 1 or A*
  - types of construction material *e.g. cobalt chromium*
  - bearing surfaces e.g. metal

### Tibial Component

**A range of tibial components is required, including:**

- cemented or cementless
- side specific e.g.right, left or neutral (symmetrical)
- bearing base plate e.g. fixed,mobile, rotating platform
- with a range of:
  - degrees
  - sizes *e.g. 3 or C*
  - dimensions: width and depth in millimetres
  - lengths and diameters of stem in millimetres
  - types of material e.*g. cobalt chromium*
  - type of bearing surface e.g.polyethylene and type
  - fixed or unfixed stems and keel
  - surface finish

### Tibial Insert

**A range of tibial inserts is required, including:**

- fixed or mobile bearing
- if fixed bearing , either cruciate retaining, posterior stabilised , medial pivot
- with a range of:
  - width and depth in millimetres
  - thickness in millimetres
  - bearing surfaces
  - types of polyethylene
  - types of locking mechanism
  - options e.g. deep dish

### Patella Component

**A range of patella components is required, including:**

- cemented or cementless
- with a range of:
  - diameters and heights in millimetres
  - thicknesses in millimetres
  - numbers of pegs
  - types of material *e.g.polyethylene*
  - surface finishes
  - porous or non porous
  - porous with coating *e.g. HA*.

### Additional Components

**A range of additional components is required, including:**

- screws:
    - in a range of metal types e.g. stainless steel
    - with a range of lengths and diameters in millimetres.
- single use drill bits:
    - with a range of lengths and diameters in millimetres

**Single Use Instruments**

**A range of single use instruments is required, including:**

- single use instruments required for implantation of primary knee prostheses.

## Category 5 - **Partial Primary Knee Prostheses**

**Unicompartmental**

**Femoral Component**

**A range of femoral components is required including:**

- cemented, cementless or hybrid
- fixed or mobile bearing
- side specific: e.g. left, right
- aspect e.g. medial, lateral, distal, posterior or combination
- with a range of:
    - sizes e.g. 1 or A
    - types of construction material e.g. titanium
    - Bearing surface e.g. metal
    - Porous or nonporous

**Tibial Components**

**A range of tibial components is required,including:**

- cemented, cementless or hybrid
- Side specific e.g. right, left or neutral (symmetrical)
- Bearing base plate e.g. fixed, mobile, rotating platform
- with a range of:
    - sizes e.g.3 or C
    - ranges in degrees
    - dimensions:width and depth in millimetres
    - length and diameter of stem in millimetres
    - types of material e.*g. cobalt chromium*
    - type of bearing surface e.g.polyethylene and type
    - fixed or unfixed stems and keel

- surface finish

**Tibial Insert**

**A range of tibial inserts is required, including:**

- fixed bearing e.g. cruciate retaining, posterior stabilised and medial pivot
- mobile
- with a range of:
  - width and depth in millimetres
  - thickness in millimetres
  - bearing surfaces
  - types of polyethylene
  - types of locking mechanism
  - options e.g deep dish

**Additional Components**

**A range of additional components is required, including:**

- screws:
  - In a range of metal types e.g. stainless steel
  - With a range of lengths and diameters, in millimetres
- Single use drill bits:
  - With a range of lengths and diameters in millimetres

**Single Use Instruments**

**A range of single use instruments is required, including:**

**A single use instruments required for implantation of partial primary knee prostheses.**

## Category 6 - **Patello- Femoral Replacements**

**A range of patella-femoral replacements is required including:**

- cemented, cementless or hybrid
- with a range of:
    - types of material e.g. titanium
    - surface finishes:
        - Polished or unpolishes
        - Porous or nonporous
    - Type of coating e.g HA
- Dimensions,length , height and thickness in millimetres

**Additional Components**

**A range of additional components is required, including:**

- screws:
    - in a range of metal types, e.g. Cobalt Chromium
    - with a range of lengths and diameters, in millimetres

**Single Use Instruments**

**A range of single use instruments is required, including:**

- single use instruments required for implantation of patello-femoral prostheses.

## Category 7 - **Complex /Revision Knee Prostheses**

**A range of femoral components is required including:**

- cemented or cementless
- cruciate retaining
- posterior stabilised / constrained.
- side specific e.g. right or left
- with a range of:
    - sizes e.g. 1 or A
    - types of construction material e.g. cobalt chromium
    - bearing surfaces e.g. metal

**A range of tibial components is required,including:**

- cemented, cementless or hybrid
- Side specific e.g. right or left, symmetrical ( neutral)
- Bearing base plate e.g. fixed, mobile, rotating platform
- with a range of:
    - sizes e.g.3 or C
    - ranges in degrees
    - dimensions:width and depth in millimetres
    - length and diameter of stem in millimetres
    - type of stem e.g fixed or keel
    - type of material e.g cobalt chromium
    - bearing surface -type of polyethylene
    - surface finishes

**Tibial Insert**

**A range of tibial inserts is required, including:**

- fixed or mobile bearing
    - for fixed e.g. cruciate retaining, posterior stabilised and medial pivot.
- with a range of:
    - width and depth in millimetres
    - thickness in millimetres
    - bearing surfaces
    - types of polyethylene
    - types of locking mechanism
    - options e.g deep dish

**Patella Component**

**A range of patella components is required,including:**

- cemented or cementless
- with a range of:
    - diameters and heights in millimetres
    - thickness in millimetres
- number of pegs
- types of polyethylene
- Surface finishes
    - Porous or nonporous
    - Porous with coating e.g. HA

**Stabilisation Devices**

**A range of stabilisation devices is required including:**

- cemented or cementless
- PCL retaining

- posterior stabilised
- constrained
- hinged:
    - rotating, including self centering or
    - non rotating
- with a range of:
    - types of material e.g. titanium
    - surface finishes:
- porous or non-porous
- a range of types of coating e.g. HA
    - dimensions,lengths, height and thickness in millimetres

**Component Extensions**

**A range of stems, blocks, wedges, augments and cones is required including:**

- cement or cementless
- adaptors (if applicable) with a range of degrees of offset
- with a range of:
    - types of material e.g. titanium
    - surface finishes:
    - polished or unpolished
    - porous or non-porous
    - a range of types of coating e.g. HA.
    - dimensions: length, height and thickness, in millimetres
    - configurations e.g. slots, fluted.
    - offsets

### Additional Components

**A range of additional components is required, including:**

- screws:
    - in a range of metal types, e.g. Cobalt Chromium
    - with a range of lengths and diameters, in millimetres

### Single Use Instruments

**A range of single use instruments is required, including:**

- single use instruments required for implantation of complex/revision knee prostheses.

## Category 8 - **Cement and Cement Accessories**

**A range of sterile cement and accessories is required for implantation of orthopaedic prostheses. This includes:**

- cement:
  - with and without antibiotics
  - with a range of pack sizes
  - type of material e.g. PMMA
  - weight in grams e.g. PMMA
  - viscosity: low, medium, high
  - name of antibiotic where applicable

**All cement products must be radiopaque**

- mixing systems
- vacuum mixing systems
- accessories are to include a range of:
  - plugs, with or without inserter rods
  - pressuriers, small, medium or large
  - Injector gun cartridges, nozzles, nozzle seal

**Respondents Note: Injector guns are to be supplied free of charge as part of a loan or consignment kit**

## Category 9 - **Navigation Systems**

**A range of navigation systems is required to support the effective and efficient implantation of any orthopaedic prostheses offered in this tender.**

- Consumables associated with passive and active systems include but are not limited to:
    - drills
    - pins
    - batteries
    - navigation spheres.

**For each system offered, the range of options includes:**

- the type of system *e.g. infrared, line of sight or EM*
- all components of the system

## Category 10 - **Miscellaneous**

**A range of Miscellaneous is required, including any single use and reusable components and specialised instruments required for implantation or removal.** This includes but is not restricted to**:**

- Pins
- Drill bit (single use)
- MIS guide / K-wires

Variations may include:

- Full range in size and length
- Material
- Sterile, individually wrapped or non-sterile
- Single use and Reusable Components
- Length

### Product Description

For each Miscellaneous product offered, Respondents shall advise the following Product Description apsects in the Tender Response Worksheet:

- Brand name
- Item description
- Shape (where applicable) (e.g. wedge, strip)
- Size (e.g. dimensions in millimetres)
- Length (e.g. dimensions in millimetres)
- Angle (where applicable)
- Ready to use (where applicable)
- Other equipment and consumables (where applicable).

# E Appendices

## Appendix 1 - Product List

a. Preference will be given to Respondent(s) offering the best value for money across and/or with product categories called for in this Statement of Requirements. Exceptions to this will be for niche product ranges only.

| PRODUCT CATEGORY NUMBER | PRODUCT CATEGORY NAME | PRODUCT SUB-CATEGORY NUMBER | PRODUCT SUB-CATEGORY NAME |
|---|---|---|---|
| 1 | Primary Hip Prostheses | 1.01 | Hip Prostheses,Combined Femoral Stem and Head (Monoblock),Cemented |
| | | 1.02 | Hip Prostheses,Combined Femoral Stem and Head(Monoblock), Cementless |
| | | 1.03 | Hip Prostheses, Femoral Stem Modular,Cemented |
| | | 1.04 | Hip Prostheses, Femoral Stem Modular,Cementless |
| | | 1.05 | Hip Prostheses, Centralisers/bone plugs |
| | | 1.06 | Hip Prostheses, Femoral head,Metal |
| | | 1.07 | Hip Prostheses, Femoral head,Ceramic |
| | | 1.08 | Hip Prostheses, Femoral head, Unipolar |
| | | 1.09 | Hip Prostheses, Acetabular Monoblock Components |
| | | 1.10 | Hip Prostheses, Acetabular Shells, Cemented |
| | | 1.11 | Hip Prostheses, Acetabular shells,Cementless |
| | | 1.12 | Hip Prostheses, Acetabular liners, Poly |
| | | 1.13 | Hip Prostheses, Acetabular liners, Ceramic |
| | | 1.14 | Hip Prostheses, Acetabular liners, Metal |
| | | 1.15 | Hip Prostheses, Additional components |
| | | 1.16 | Hips Prostheses, Single use instruments |
| 2 | Hip Resurfacing | 2.01 | Hip Resurfacing, Femoral components |
| | | 2.02 | Hip Resurfacing, Single use instruments |
| 3 | Complex/ Revision Hip Prostheses | 3.01 | Complex/Revision Hip Prostheses, Femoral Stem Modular |
| | | 3.02 | Complex/ Revision Hip Prostheses, Centralisers/bone components |
| | | 3.03 | Complex/Revision Hip Prostheses, Femoral modular body |
| | | 3.04 | Complex/Revision Hip Prostheses, Femoral head metal |
| | | 3.05 | Complex/Revision Hip Prostheses, Femoral head ceramic |
| | | 3.06 | Complex/Revision Hip Prostheses, Acetabular Monoblock |

| | | | |
|---|---|---|---|
| | | 3.07 | Complex/Revision Hip Prostheses, Acetabular shell |
| | | 3.08 | Complex/Revision Hip Prostheses, Acetabular augments/restrictors/cages |
| | | 3.09 | Complex/Revision Hip Prostheses, Acetabular liner, poly |
| | | 3.10 | Complex/Revision Hip Prostheses, Acetabular liner, ceramic |
| | | 3.11 | Complex/Revision Hip Prostheses, Acetabular liner, dual mobility |
| | | 3.12 | Complex/Revision Hip Prostheses, Additional components |
| | | 3.13 | Complex/Revision Hip Prostheses, Single use instruments |
| **4** | **Primary Knee Prostheses** | 4.01 | Knee Prostheses, Femoral Component, Cemented,Cruciate Retaining |
| | | 4.02 | Knee Prostheses, Femoral Component, Cemented, Posterior Stabilised |
| | | 4.03 | Knee Prostheses, Femoral Component, Cementless,Cruciate Retaining |
| | | 4.04 | Knee Prostheses, Femoral Component, Cementless, Posterior Stabilised |
| | | 4.05 | Knee Prostheses, Tibial Component, Cemented |
| | | 4.06 | Knee Prostheses, Tibial Component, Cementless |
| | | 4.07 | Knee Prostheses, Tibial Insert, Cruciate Retaining |
| | | 4.08 | Knee Prostheses,Tibial Insert, Posterior Stabilised |
| | | 4.09 | Knee Prostheses,Tibial Insert, Mobile Bearing |
| | | 4.10 | Knee Prostheses, Patella component, Cemented |
| | | 4.11 | Knee Prostheses, Patella component, Cementless |
| | | 4.12 | Knee Prostheses, Additional components |
| | | 4.13 | Knee Prostheses, Single use instruments |
| **5** | **Partial Primary Knee Prostheses** | 5.01 | Partial Knee Prostheses, Femoral Component, Unicompartmental, Cemented |
| | | 5.02 | Partial Knee Prostheses, Femoral Component, Unicompartmental, Cementless |
| | | 5.03 | Partial Knee Prostheses, Tibial Component,Unicompartmental,Cemented |
| | | 5.04 | Partial Knee Prostheses, Tibial Component,Unicompartmental,Cementless |
| | | 5.05 | Partial Knee Prostheses, Tibial Insert, Unicompartmental, Hybrid |
| | | 5.06 | Partial Knee Prostheses, Additional components |
| | | 5.07 | Partial Knee Prostheses, Single use instruments |
| **6** | | 6.01 | Patello-femoral Replacements, Cemented |
| | | 6.02 | Patello-femoral Replacements, Cementless |
| | | 6.03 | Patello-femoral Replacements, Hybrid |

| | | | |
|---|---|---|---|
| | **Patello – Femoral Replacements** | 6.04 | Patello-femoral Replacements, Additional components |
| | | 6.05 | Patello-femoral Replacements, Single use instruments |
| **7** | **Complex/ Revision Knee Prostheses** | 7.01 | Complex/Revision Knee Prostheses, Femoral Component, Cemented,Cruciate Retaining |
| | | 7.02 | Complex/Revision Knee Prostheses, Femoral Component, Cemented, Posterior Stabilised |
| | | 7.03 | Complex/Revision Knee Prostheses, Femoral Component, Cementless,Cruciate Retaining |
| | | 7.04 | Complex/Revision Knee Prostheses, Femoral Component, Cementless, Posterior Stabilised |
| | | 7.05 | Complex/Revision Knee Prostheses, Tibial Components, Cemented |
| | | 7.06 | Complex/Revision Knee Prostheses, Tibial Components, Cementless |
| | | 7.07 | Complex/Revision Knee Prostheses, Tibial Insert, Cruciate Retaining |
| | | 7.08 | Complex/Revision Knee Prostheses, Tibial Insert, Posterior Stabilised |
| | | 7.09 | Complex/Revision Knee Prostheses, Tibial Insert, Mobile bearing |
| | | 7.10 | Complex/Revision Knee Prostheses, Patella Component, Cemented |
| | | 7.11 | Complex/Revision Knee Prostheses, Patella Component, Cementless |
| | | 7.12 | Complex/Revision Knee Prostheses, Stabilisation Device, Cemented |
| | | 7.13 | Complex/Revision Knee Prostheses, Stabilisation Device, Cementless |
| | | 7.14 | Complex/Revision Knee Prostheses, Component extensions , Cemented |
| | | 7.15 | Complex/Revision Knee Prostheses, Component extensions , Cementless |
| | | 7.16 | Complex/Revision Knee Prostheses, Additional Components |
| | | 7.17 | Complex/Revision Knee Prostheses, Single Use Instruments |
| **8** | **Cement and Cement Accessories** | 8.01 | Cement |
| | | 8.02 | Mixing Systems and accessories |
| **9** | **Navigation Systems & consumables** | 9.01 | Navigation systems, procedure cost |
| | | 9.02 | Navigation systems, Consumables |
| | | 9.03 | Navigation systems, device cost (including free-on-loan) |
| **10** | **Miscellaneous** | 10.01 | Miscellaneous, Miscellaneous items including any single use and reusable components and specialised instruments |

# Appendix 2 - References

## Standards

The references to the below standards include any amendments, revisions or consolidations to those standards. Where applicable, Hip and Knee Prostheses products should comply with the requirements of the following standards:

| Standard Number | Standard Name |
|---|---|
| **AS/NZS 4187** | Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities |
| **AS /NSZ 3872** | Orthopaedic Implants – General Requirements for Marking, Packaging and Labelling |
| **AS/NZS 2817** | Implants for Surgery – Care and handling of Orthopaedic Implants |
| **OHS 2014** | Occupational Health and Safety Act 2014 |
| **OHS 1999** | Occupational Health and Safety (Manual Handling) Regulations 1999 |
| **Worksafe Victoria** | Orthopaedic Surgical Instrument Sets - Reducing Risks of Musculoskeletal Disorders as at 6 June 2005 |

## Guidelines and Other References

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

- NHMRC (2010), Australian Guidelines for the Prevention and Control of Infection in Healthcare, Commonwealth of Australia
- Therapeutic Goods Administration (1991), Therapeutic Goods Order No. 37: General Requirements for Labels for Therapeutic Goods
- Therapeutic Goods Administration (2004), Uniform Recall Procedure for Therapeutic Goods, Commonwealth of Australia

## Appendix 3 - Construct List

*Please refer to Part 6 - Tender response worksheet.*