HEALTH PURCHASING VICTORIA

Invitation to Supply

Part 5 - Statement of Requirements

Invitation to Supply Number:	**HPVITS2017-086**
Invitation to Supply Name:	**Heart Valve Replacement Products**
Closing Date and time:	**Wednesday, 10 May 2017, 14:00 AEST**

Authorised Contact Person

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Contact through the
HPV Procurement Portal
https://www.hpv.org.au/

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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 Heart Valve Replacement Products for use in Participating Health Services. The envisaged Term of the Agreement is two (2) years plus optional two times two-year period available to extend the contract term (2+2+2).

b. The scope of this ITS includes:

(i) the supply of Heart Valve Replacement products

(ii) goods consignment service

(iii) service requirements

(iv) education and training

(v) company representative clinical attendance

c. The scope of this ITS does not include:

(i) Valved grafts
(ii) Pericardial patches
(iii) Tissue-bank valves

d. Indicative volumes are listed in Part 6 – Tender 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 Heart Valve Replacement Products required under this ITS include:

Category Number	Category Name
1	Aortic Valves, Mechanical - General
2	Aortic Valves, Tissue/Xenograft - General
3	Stentless Xenograft Tissue Valves
4	Mitral Valves, Mechanical - General
5	Mitral Valves, Tissue/Xenograft - General
6	Annuloplasty Bands/Rings - Mitral
7	Annuloplasty Bands/Rings - Tricuspid
8	Transcatheter Aortic Valve Implantable

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 right 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 will not consider any product that is subject to a current HPV Agreement, other than those listed below:

- HPVC2014-086 Heart Valve Replacement Products

b. The Respondent must 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. Respondent 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 is available, this should be submitted with the Respondent's tender.

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
(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.

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 D above; or
(ii) Is incomplete as to C.

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

h. Respondent should not submit information relating to products that are not called for in this Invitation to Supply.

4.4 Third-Party Product Compatibility

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

b. Successful Respondent 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 5 - Section A, 4.4c and Part 5 – Section A, 4.4d, 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 Heart Valve Replacement Products. 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.
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 8b**.
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

TERM	DEFINITION
should	Indicates a highly desirable element; unless justifiable reason exists, not meeting this element may have a medium 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. Heart Valve Replacement 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

(ii) Twenty-four (24) hours from receipt of order for **regional and rural** Participating Health Services

Please refer to https://www2.health.vic.gov.au/hospitals-and-health-services/public-hospitals-victoria for the definition of metropolitan, regional and rural health services.

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 the Draft Agreement, Part 7 – 11 Acceptance and Rejection of Deliverables.

2 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. Respondents should be 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 the shortest timeframe; however, this should not exceed the following timeframes:

(i) Two (2) hours from receipt of order for **metropolitan** Participating Health Services

(ii) Four (4) hours from receipt of order for **regional and rural** Participating Health Services

3 Consignment Stock

a. Respondents must advise on the ability to provide goods on consignment and the responsibility for insurance of consigned goods once “on shelf” in the Participating Health Services.

b. Preference will be given to Respondents that are able to provide goods on consignment and replacement stock within twenty-four (24) hours of order placement.

c. Where products are provided on consignment, managing stock levels and reporting should be undertaken by the successful Respondent, unless negotiated otherwise with the Participating Health Services in a Service Level Agreement.

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

e. 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) performing stocktake of consignment stock on a regular basis, and replacing used stock

(iv) 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

(v) The turnaround time for replacement of used consignment stock following order replacement.

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

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

g. 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.

h. Damaged or broken consignment stock must be replaced free of charge.

i. For all consignment orders, invoice must be received within thirty (30) days of product use.

j. Preference will be given to the use of Radio-frequency identification (RFID) technology for stock management purposes.

4 Training and Support

a. Successful Respondent(s) may be required to provide training and/or training materials to facilitate the introduction of their Heart Valve Replacement 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 Respondent 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 sessions and training provided by the successful Respondent, as required by the Participating Health Services is free of charge.

d. Successful Respondent(s) 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)

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

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

f. 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)

(v) training materials

5 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.

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

c. The successful Respondent(s) 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

(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 must 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. Respondent should advise in the ITS Response the availability of company representative to provide industry clinical support:

(i) for Heart Valve Replacement Products 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

f. 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.

g. Preference will be given to Respondent(s) who are able to provide company representative attendance upon request from the Participating Health Services.

h. 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 Insurnace Prostheses List for products purchased by the Participating Health Services.

i. The clinical support provided by the Respondent must be provided free of charge to the Participating Health Services.

6 Replacement

a. Replacement of any Heart Valve Replacement Products due to faulty manufacture or design will be at no cost to the Participating Health Services.

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

7 Key Performance Indicators

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

8 Reporting

a. Refer to Item 12 of Supply Schedule - Reporting Requirements.

b. Successful Respondent must provide to HPV other reports that may reasonably be required from time to time.

9 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 – Section B, 3)

(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 – Section C, 3)

(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(s).

c. The SLA will be in addition to the Agreement between the successful Respondent(s) 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.

e. Successful Respondent(s) must provide a copy of all Service Level Agreements to HPV within one week of being finalised.

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. All Heart Valve Replacement Products must be sterile and packaged in a manner that protects the contents from contamination and damage during transportation, storage and handling.

b. Tissue valves must be delivered in a temperature-controlled container that is maintained between 5^0C to 25^0C and which has a heat-sensor fitted on the outside of the container to monitor the temperature during transit and / or storage.

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

d. Items must be delivered in accordance with the manufacturer's instructions.

e. It is desirable for individual product packaging to include (where applicable):

(i) whether the product is MRI compatible (implantable products);

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

(iii) a minimum of four tracking labels (peelable or reusable); and

(iv) 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 Recallnet.

c. Class 1 recalls (as defined by the TGA's *Uniform Recall Procedure for Therapeutic Goods*) must also meet the requirements under section Part 5 – B6 Replacement, where applicable.

4 Backorders and Discontinued Lines

a. In the event that a product is unavailable for a period of more than one week, the successful Respondent must notify in writing (at a minimum) the following:

(i) Supply department of the Participating Health Services

(ii) Participating Health Services' Cardiac Surgery department;

(iii) Nurse Unit Manager of Operating Suite;

(iv) 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 must notify Participating Health Service staff and HPV (as per clause a) as soon as possible, but no less than six (6) months before the last date of manufacture.

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

(i) the anticipated timeframe for resolving the issue

(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).

6 Reference Sites

a. Respondents are 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 unless the product offered is currently on the HPV contract HPVC2014-086 Heart Valve Replacement Products. For the purpose of this tender, references will only be accepted from:

(i) Categories 1 – 7: Cardiac Surgeon

(ii) Category 8: Interventional Cardiologist and at least one Cardiac Surgeon

b. Where a product category contains a variety of specific subcategories, Respondents are 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. Respondent should not nominate a referee without their express permission.

7 MRI Compatibility

For each product tendered, Respondent should advise in the relevant columns of the Tender Response Worksheet:

Whether it is MRI compatible (implantable devices). If it is MRI conditional, the Respondent need to provide details of conditional level in Part 6 – Tender Response Worksheet

- Whether the MRI compatibility details are included on the product labelling
- The amount of time in days after implant after which MRI is deemed safe
- Radio opaque

8 Tracking of Product

Respondent should advise in the ITS Response the tracking process of each product after implantation that is used to enable the Respondent to locate the implantable product and facilitate notification where necessary.

9 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).

c. Sizers and accessories must be provided free of charge upon purchase of any Heart Valve Replacement Products.

1.2 Category Specifications

a. Respondents are invited to tender products in accordance with Part 5 – Statement of Requirements. A complete size and range of Heart Valve Replacement Products is required for treatment of patients across Victorian Public Health Services.

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

1.3 Compliance with Category Specifications

a. All products shall be sterile, single use, and presented in product appropriate packaging unless otherwise indicated.

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

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

- The Billing Code as per the Health Insurance Prosthesis List
- If a facility for batch-tracking is incorporated on the device.

Category 1 - Aortic Valves, Mechanical - General

a A full range of Mechanical Aortic Valves is required to support the full range of structural heart procedures.

1.02 Product Description

b For each Mechanical Aortic Valve offered, Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Heart position to implant the valve

(iii) Material of valve

(iv) Opening angle

(iv) Cuff style (e.g. standard, flexible)

(v) For the valve:

- Size (e.g. 17, 25 mm)
- Intra annular diameter (mm)
- Sewing ring diameter (mm)
- Internal orifice area (cm^2)
- Contents of kits (i.e. such as sizers, handles etc.)

Category 2 - Aortic Valves, Tissue/Xenograft – General

a A full range of Tissue / Xenograft Aortic Valves, Pericardial Internal stents and suture less/rapid deployment aortic valves is required to support the full range of structural heart procedures.

2.02 Product Description

b For each Tissue / Xenograft Aortic Valve offered, Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Type of aortic valve (e.g. Pericardial Tissue, Tissue)

(iii) Heart position to implant the valve

(iv) Material of valve

(v) Valve size (mm)

(vi) Tissue supra annular Diameter (mm)

(vii) Intra Annular Diameter (mm)

(viii) Cuff Outer Diameter (mm) , if applicable

(ix) Total Height (mm)

(x) Contents of kits (i.e. such as sizers, handles etc.)

2.03 Respondent Note

For each Aortic Valve offered, the tendered price offered shall include all the associated sizers, deployment system and associated components for the implantation.

Category 3 - Stentless Xenograft Tissue Valves

a A full range of Stentless Xenograft Tissue Valves is required to support the full range of structural heart procedures.

3.02 Product Description

c For each Stentless Xenograft Tissue Valve offered, Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Type of heart valve (e.g. full root, subcoronary)

(iii) Heart position to implant the valve

(iv) Material of valve

(v) Valve size in millimetres

(vi) Outside diameter (mm)

(vii) Profile height (mm)

(viii) Contents of kits (i.e. such as sizers, handles etc.)

Category 4 - Mitral Valves, Mechanical – General

a A full range of General Mechanical Mitral Valves is required to support the full range of structural heart procedures.

4.02 Product Description

b For each General Mechanical Mitral Valve offered, Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Type of heart valve (e.g. mechanical)

(iii) Heart position to implant the valve

(iv) Material of valve

(v) For Valve:

- Supra Annular diameter (mm)
- Intra Annular diameter (mm)
- Geometric Orifice area (cm2)
- Cuff Style (e.g. expanded)
- Material of sewing cuff
- Contents of kits (i.e. such as sizers, handles etc.)

Category 5 - Mitral Valves, Tissue / Xenograft – General

a A full range of Xenograft / Tissue Mitral Valve is required to support the full range of structural heart procedures.

5.02 Product Description

For each Xenograft / Tissue Mitral Valve offered, Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Type of heart valve (e.g. tissue)

(iii) Heart position to implant the valve

(iv) Material of valve

(v) Valve diameter (mm)

(vi) Supra annular diameter (mm)

(vii) Intra Annular diameter (mm)

(viii) Total Height (mm)

(ix) Contents of kits (i.e. such as sizers, handles etc.)

Category 6 - Annuloplasty Bands / Rings – Mitral

A full range of Mitral Annuloplasty Bands / Rings is required to support the full range of structural heart procedures.

6.02 Product Description

For each Mitral Annuloplasty Bands / Rings offered, Respondents shall advise the following information in the Response Worksheet:

(i) Brand Name

(ii) Type of ring (e.g. rigid / semi rigid, flexible)

(iii) Material (e.g. Flexible polyester)

(iv) Ring size (e.g. 24,26,28)

(v) Internal 2-D Orifice Area (cm^2), if applicable

(vi) Contents of kits (i.e. such as sizers, handles etc.)

Category 7 - Annuloplasty Bands / Rings - Tricuspid

A full range of Tricuspid Annuloplasty Bands / Rings is required to support the full range of structural heart procedures.

7.02 Product Description

For each Tricuspid Annuloplasty Bands / Rings offered, Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand Name

(ii) Type of ring (e.g. rigid / semi rigid, flexible)

(iii) Material (e.g. Flexible polyester)

(iv) Ring size (e.g. 24,26)

(v) Contents of kits (i.e. such as sizers, handles etc.)

Category 8 - Transcatheter Aortic Valves Implantable

A full range of Implantable Transcatheter Aortic Valves is required to support the full range of structural heart procedures.

8.02 Product Description

For each Implantable Transcatheter Aortic Valves offered, Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand / Model name

(ii) Heart position to implant the valve

(iii) Material (e.g. Nitinol, Cobalt Chromium)

(iv) Annulus area (e.g. 338-430 mm^2)

(v) Annulus diameter by TEE (e.g. 18-22mm)

(vi) Valve -Size (e.g. 23, 26 mm)

(vii) Type (e.g. Balloon Expanded, Self Expanding)

(viii) Frame height in mm

(ix) Leaflet tissue type (e.g. bovine, porcine)

(x) For the Delivery system:

- Brand Name
- Sheath introducer Set in mm
- Minimum access vessel diameter in mm
- Certitude Sheath in French gauge (Fr)

(xi) Contents of kits (such as delivery system, inflation devices, introducer sheath etc.)

8.03 Respondent Note

For each Transcatheter Aortic Valve Implantable offered, the tendered price offered shall include the associated delivery system and components for the implantation. If there is separate ordering part number for the valve and deployment system, please populate the corresponding ordering part number of the valve and deployment system in the “Additional Information” column.

In a rare situation several Transcatheter Aortic Valve Implantable may be used in a single procedure. The Participating Health Service will only be charged the Transcatheter Aortic Valve Implantable that has been successfully implanted to the patient.

E Appendices

Appendix 1 - Product List

a. Preference will be given to Respondent(s) offering the best value for money across 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
01	Aortic Valves, Mechanical - General	01.01	Aortic Valves, Mechanical - General
02	Aortic Valves, Tissue/Xenograft - General	02.01	Aortic Valves, Pericardial
		02.02	Aortic Valves, Porcine
		02.03	Pericardial Internal Stent
		02.04	Aortic Valves, Sutureless / Rapid Deployment
03	Stentless Xenograft Tissue Valves	03.01	Stentless Xenograft Root
04	Mitral Valves, Mechanical - General	04.01	Mitral Valves, Mechanical - General
05	Mitral Valves, Tissue/Xenograft - General	05.01	Mitral Valves, Tissue/Xenograft - General
06	Annuloplasty Bands/Rings - Mitral	06.01	Rigid or Semi-rigid Rings
		06.02	Flexible Rings or Bands
07	Annuloplasty Bands/Rings - Tricuspid	07.01	Annuloplasty Bands/Rings - Tricuspid
08	Transcatheter Aortic Valves Implantable	08.01	Transcatheter Aortic Valve Implantable

Appendix 2 - References

A 2.a Standards

The references to the below standards include any amendments, revisions or consolidations to those standards. Where applicable, Interventional Radiology 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
ISO 13485	A quality management system where for provision of medical devices
ISO 14630	Non Active Surgical Implants – General Requirements
ISO 14708 - 1	Implants for Surgery – Active Implantable Devices – General Requirements for Safety, Marking and for Information to be provided by the Manufacturer
NSQHS standards	National Safety and Quality Health Service Standards, September 2012
Current standards and guidelines considering MR safety and MR compatibility for medical implants:	
ASTM F2503 - 08	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
ISO 25539 - 1	Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses
Test methods for MR safety and MR compatibility:	
ASTM F2052-06e1	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
ISO/PRF TS 10974	Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device; to be published 2012
Standard requirements against interferences from external electrical and magnetic fields:	

STANDARD NUMBER	STANDARD NAME
EN 45502-1	Active implantable medical devices. General requirements
Standards for safety and pulse sequences of (MRE) magnetic resonance equipment:	
IEC 60601-2-33 ed3.0	Medical electrical equipment - Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis
IEC 62464-2 (2010-11) Ed. 1.0	Magnetic resonance equipment for medical imaging - Part 2: Classification criteria for pulse sequences

A 2.b Legislation

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

- Therapeutic Goods (Medical Devices) Regulations 2002
- Therapeutic Goods Act 1989
- and any other relevant legislation that is both mandatory and fundamental to the operation of the eventual contract of Interventional Radiology

A 2.c 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