Invitation to Supply (DRAFT)

Project Number	**HPVITS2026-218**
Project Name:	**Cardiac Interventional Products, Prostheses and Heart Valves**

Part 4 - Statement of Requirements

(PRG Work-in-Progress)

Contents

PART 4: STATEMENT OF REQUIREMENTS

1. Participating Health Services

a. The Participating Health Services for this ITS are

i. All 'Public Health Services' (as legislatively defined) referred to in Schedule 1 and Schedule 5 of the *Health Services Act 1988*; and

ii. Other relevant participating health and health related organisations as follows:

- St Vincent's Hospital Melbourne.

2. Scope

a. The scope of this ITS includes:

i. Clinical implantables used within interventional cardiology procedures; and

ii. Non-implantable consumables directly associated with interventional cardiology procedures; and

iii. Heart valve replacement products used within cardiac surgery and Transcatheter valve implantation procedures

iv. Supply of products referenced in 2.a.(i) to 2.a.(iii), including the following:

- Goods consignment service
- Education and training
- Company representative clinical attendance

3. Product Categories

a. A complete range of Cardiac Interventional Products, Prostheses and Heart Valves, as required for treatment of patients across Participating Health Services

b. The categories required include:

CATEGORY NUMBER	CATEGORY NAME
1	Percutaneous Sheath Introducers and Introducer Kits
2	Guidewires for Diagnostic Catheters
3	Diagnostic Catheters and Diagnostic Catheter Kits
4	Right Heart Catheters
5	Interventional Catheters
6	Angioplasty Guidewires

CATEGORY NUMBER	CATEGORY NAME
7	Balloon Angioplasty Dilation Catheters
8	Angioplasty Accessories and Accessory Kits
9	Coronary Stents
10	Temporary Pacing Catheters
11	Thrombus Aspiration Catheters
12	Transcatheter Occlusion Devices
13	Vessel Closure Devices, Haemostatic Devices and Kits
14	Implantable Pacemakers
15	Implantable Cardioverter Defibrillators
16	Pacemaker, ICD and Lead Insertion Accessories, Tools and Tool Kits
17	Implantable Cardiac Monitors
18	Aortic Valves, Mechanical
19	Aortic Valves, Tissue/Xenograft
20	Stentless Xenograft Tissue Valves
21	Mitral Valves, Mechanical
22	Mitral Valves, Tissue / Xenograft
23	Annuloplasty Bands / Rings – Mitral
24	Annuloplasty Bands / Rings - Tricuspid
25	Surgical Septal Defect Management Devices
26	Surgical Atrial Fibrillation and Appendage Management Devices
27	Transcatheter Valve Procedures

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

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

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

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

4. Restricted and extended basket of goods

a. Not Used.

5. Product Offering

a. Respondents are to list a direct match to the part and part number listed on the 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. HPVC2019-045 Interventional Cardiology

   ii. HPVC2017-086 Heart Valve Replacement Products

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.

6. 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

7. 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. 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 ARTG certification to Participating Health Services upon request.

8. 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 clause 7.b above, individual product packaging must indicate (where applicable):

   i. whether the product is sterile or non-sterile;

   ii. the use-by date;

   iii. whether the product is MRI conditional (implantable products);

   iv. whether the product (or packaging) contains latex or is latex-free.

9. Infection Control

a. Where applicable, all items must meet the requirements of the Australian Guidelines for the Prevention and Control of Infection in Healthcare, Canberra: National Health and Medical Research Council (2019). Reusable medical devices (RMD) and agents for reprocessing RMD must meet the reprocessing standard of AS 5369:2023 Reprocessing of reusable medical devices and other devices in health and non-health related facilities.

b. Upon request by Participating Health Services, successful Respondents must provide reprocessing instructions for all reusable products within the Information for Use (IFU).

c. All reuseable items offered must be capable of being cleaned with an instrument grade disinfectant listed on the Personal Protective Equipment (PPE) contract.

d. Respondents must provide cleaning instructions based on infection control best practice for cleaning and disinfecting all reusable products.

e. Respondents must provide a full list of cleaning and disinfection products (including wipes) approved for use on the reusable item, including maximum permissible concentration level of active ingredient.

10. Substances of Concern

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

b. Suppliers must provide the Diethylhexyl phthalate (DEHP) status of the product as well as the percentage (%) of DEHP content of the product, in the Tender Response Worksheet (TRW). Preference will be given to products that meet TGA limits of 1% DEHP.

11. Product Information

a. The Respondent will 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 Response.

c. All product information submitted should:

   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 should be labelled with the relevant HSV category and subcategory number.

   i. Electronic copies should include the HSV Category and subcategory numbers in the filename or identifying metadata.

e. HSV may not consider unlabelled submissions.

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

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

   i. Not labelled as per clause d above; or

   ii. Is incomplete as to clause c.

h. Product samples are not to be provided unless specifically requested by HSV, as per Part 2, clause 19.

i. The Respondent should not submit information relating to products that are not called for in this ITS.

12. Consignment Stock

a. Respondents should indicate whether it is providing any of the Deliverables on a consignment basis.

b. Respondents should nominate a Representative to undertake consignment duties. Managing consignment stock levels must be undertaken by the successful Respondent, unless negotiated otherwise with the Participating Health Service in a Service Level Agreement

c. Terms relating to Consignment Stock are set out under PART 5: DRAFT AGREEMENT, Clause 3.2 Consignment Goods and/or under relevant Service Level Agreement

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

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. 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.

f. The successful Respondent's nominated Representative(s) (as per clause 6.b) will be responsible for:

g. performing stocktake of consignment stock on a regular basis (as agreed with the Participating Health Service), and replacing used stock

h. checking the expiry date of consigned stock, and replacing any stock that is out of date at no cost

i. Preference may be given to a Respondent that can provide, on request, a storage solution for consigned products at no cost to Participating Health Services.

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

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

l. .

13. Loan Sets and Instrument Trays

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

b. Instrument trays must be suitable for sterilisation in line with AS 5369:2023.

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

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

e. The successful Respondent should provide cleaning Instructions For Use (IFU) upon request.

f. The successful Respondent should provide to the health services a checklist of photos of instrument trays which will be able to easily indicate which instruments are to be taken apart for cleaning and sterilising.

g. The successful Respondent should clearly label part deliveries of implants (e.g. complete kit set)

h. For partial loan deliveries, the successful Respondent should clearly indicate implants or instruments that are delivered and the pending items to follow.

i. As per AS 5369: Reprocessing of reusable medical devices and other devices in health and non-health related facilities, the successful Respondent must not deliver instruments and prostheses in the same roadcase.

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

k. All instruments should be sent inside opening cases.

14. Warranty

a. Warranty for the replacement of implantable or consumable products covered within the scope of this ITS is to be extended up to the expiry date specified on the product packaging. In instances where pre-implant product failure occurs, replacement will be at the Supplier's expense. This must be stated as part of your response to this ITS.

b. Loan sets 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 during implantation, the Supplier must replace the product free-of-charge.

d. 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.

e. If the product is found to have a higher than benchmarked rate of failure, HSV will conduct an independent investigation. If such an instance arises, the supplier of the product at fault must comply with all investigation requirements. Upon request, the successful Respondent will provide information (printed or electronic) explaining product warranty process.

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

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

h. 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.

i. Respondents must include the specific warranty period for all products offered. Where products have separate warranties for battery life (where applicable), the warranties for battery life will also be provided. Preference will be given to longer term warranties.

j. Upon request, the successful Respondent will provide information (printed or electronic) explaining products' warranty.

15. Recall Process

a. All recalls must be managed in line with the *Procedure for recalls, product alerts and product corrections (PRAC).* Within three (3) months of agreement commencement, all recalls, product defects, alerts, quarantine and/or hazard alerts will be completed using GS1 Recall Health.

b. Class 1 recalls, as defined by the TGA's *Procedure for recalls, product alerts and product corrections (PRAC),* must also meet the requirements under section Part 5 on Warranty, where applicable.

Pricing

16. Price Variation

a. Price variation (if any) will be set out in and must be in accordance with PART 5: DRAFT AGREEMENT

17. Price Review

a. Price review (if any) will be set out in and must be in accordance with PART 5: DRAFT AGREEMENT, Clause 5.2.

b. HSV reserves the right to negotiate price review outcomes with the successful Respondent.

18. Market Share Pricing

a. HSV is looking to award Respondents based on Market Share Discount model for each Product Range.

b. The Market Share Discount model requires that the Respondents submit Market Share Pricing that would come into effect on a Health Service committing to purchasing a minimum Market Share Percentage from the Respondent within mutually agreed period during the Term.

c. 'Product Range' means and is limited to

   i. Drug Eluting Coronary Stent (all products under subcategory 9.01)

   ii. Dilation Balloon Catheters (all products under subcategory 7.01, 7.02, 7.03 combined)

   iii. Drug-Eluting and Cutting/Scoring Balloons (all products under subcategories 7.04, 7.05, 7.06, 7.07 combined)

   iv. All system 1 Implantable pacemakers under subcategories 14.01, 14.02, 14.03, 14.04, 14,05

   v. Transcatheter valves under subcategories 27.01, 27.02, 27.03 combined

   HSV does not require Market Share Discount under other categories of this tender.

d. 'Market Share Percentage' means the aggregated quantities (EACH) purchased by the Participating Health Service from the Respondent, over total quantities (EACH) purchased by the Participating Health Service in each Product Range.

   For this ITS, Market Share Percentage is set at 55% and/or 70%.

e. 'Market Share Pricing' means the percentage discounts from the standard Price per Unit.

f. The Respondent may submit up to two (2) Market Share Discounts for each Product Range. Market Share Discounts submitted by Respondents should specify the Market Share Percentage and the corresponding Market Share Pricing, as defined above.

c. The Respondent may enter into a Service Level Agreement with a relevant Participating Health Service to commit to a Market Share Discount. Any Service Level Agreement entered between the Participating Health Service and Supplier is established in accordance with the PART 5: DRAFT

AGREEMENT, Clause 3.2 and does not contravene or undermine the Agreement terms and conditions.

g. Market Share Discount will be established in accordance with PART 5: DRAFT AGREEMENT, Clause 5.4 Volume discount and must be detailed in the Tender Response Worksheet**.**

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. HPVITS2026-218 Cardiac Interventional Products, Prosthesis and Heart Valves will 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.

21. Urgent Deliveries

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

b. The Respondent shall 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 possible timeframe; however, this must not exceed the following timeframes, except for urgent deliveries of products used in cardiac surgeries:

   i. Twelve (12) hours from receipt of order for metropolitan Participating Health Services, unless otherwise specified in the SLA.

   ii. Twenty-four (24) hours from receipt of order for regional and rural Participating Health Services, unless otherwise specified in the SLA

d. For cardiac surgery, urgent deliveries should be received by Participating Health Services within the shortest possible timeframe; however, this must not exceed the following timeframes.

   i. Two (2) hours from receipt of order for metropolitan Participating Health Services, unless otherwise specified in the SLA.

   ii. Four (4) hours from receipt of order for regional and rural Participating Health Services, unless otherwise specified in the SLA

e. 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.

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 ITS to clinicians in their operating environment.

b. If requested by a Participating Health Service, the 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 to be free of charge.

d. 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 (demonstration or in servicing, compatibility charts, templates and user guides)

e. The successful Respondent 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.

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

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 otherwise specified in the SLA.

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. 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.

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

   vii. case support and

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

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

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

g. Respondents should advise the availability of company representatives to provide industry clinical support:

   i. for Interventional Cardiology procedures, Cardiac surgery and Transcatheter valve procedures,

   ii. outside of normal business hours, including weekends, and

   iii. at follow-up clinics for the life of the implanted device, regardless of the contract status.

Award

24. Conditional Acceptance

a. Products may be designated as 'Conditionally Accepted' where products contain incomplete information as determined by HSV.

b. Clause 6.8 of the Draft Agreement sets out terms relating to Conditionally Accepted Deliverables.

c. Products designated as 'Conditionally Accepted' may be subject to desktop and functional evaluation by health services.

d. "Acceptance for use" is confirmed by issuing a product acceptance certificate or any other form signed by an appropriate clinical representative of a Participating Health Service

e. Pricing will be as per response position and cannot be amended post Agreement acceptance.

25. Key Performance Indicators

a. Refer to Schedule 5 of PART 5. DRAFT AGREEMENT.

26. Service Level Agreement

a. Participating Health Services may enter into a Service Level Agreement (SLA) with the successful Respondent(s), on the terms set out in the Draft Agreement clause 3.2 Service Level Agreement. The SLA may cover the following arrangements:

   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. social procurement commitments or framework set out by a Participating Health Service that may be linked to the Social Procurement Framework set out in the Agreement; and / or

   vi. clinical support, including attendance requirements for Representatives in relation to education and training

   vii. communication arrangements for product recalls and safety alerts (refer PART 4 Statement of Requirements clause 15)

   viii. assist the health services in ensuring accuracy of data within Htrak or relevant ordering system

   ix. market share pricing as outlined in section 18

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. Any SLA entered into between the Supplier and a Participating Health Service must be established in accordance with the framework of the Agreement and must not contravene or undermine the 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.

27. Contract Panel of Suppliers

a. The capability of each Respondent will be assessed using the information submitted with their response to this sourcing event HPVITS2026-218 for the product categories in scope.

b. Only successful Respondents will be added to the Contract Panel of Suppliers for the supply of Cardiac Interventional Products, Prostheses and Heart Valves as described in this Statement of Requirements (SOR), 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, 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.

28. Product Evaluation and Award to Contract

a. The award of products to the Agreement will be the result of their suitability based on both their commercial and technical attributes.

b. Only products of Respondents to this ITS will be considered for evaluation and award to Contract.

c. Only the Contract Panel of Suppliers will be allowed to submit new products across Product Subcategories, for consideration, evaluation and addition under the contract variation request process, over the term of the new contract.

29. Patient Implant Cards and Patient Information Leaflets

a. Successful respondents must 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. Respondents 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 (for applicable products).

30. Compliance with Category Specifications

a. Products and composite products offered with additional/optional components must also comply with the specifications for other relevant categories (where applicable).

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

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

i. Capability to provide consignment stock

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

i. The Billing Code (where applicable) as per the Australian Government's Prostheses List

ii. If a facility for batch-tracking is incorporated on the device

Category 1 – Percutaneous Sheath Introducers and Introducer Kits

A full range of sterile, single use Radial and Femoral Percutaneous Sheath Introducers and Introducer Kits is required to support the full range of interventional procedures.

Subcategory	Subcategory Name	Description
01.01	Percutaneous Sheath Introducer – Radial Access	A vascular access device designed to facilitate the introduction of catheters and other interventional tools into the radial artery. Includes a sheath introducer, dilator, +/- guidewire +/- needle.
01.02	Percutaneous Sheath Introducer – Femoral Access	A vascular access device designed to facilitate the introduction of catheters and other interventional tools into the femoral artery. Includes a sheath introducer, dilator, +/- guidewire, +/- needle.
01.03	Percutaneous Sheath Introducer, Combination Kits	Percutaneous Sheath Introducers may be packaged with items that aid in the introduction of the sheath or closure of the access site.
01.04	Percutaneous Sheath Introducer, Accessory Items	Individual items that aid specifically in the introduction of the Percutaneous Sheath Introducer.

Mandatory Criteria

Sterile and single use

Desirable Criteria

Preference will be given to products that

a. Include haemostatic valves

b. Are supplied with comprehensive kits (eg. Dilator, guidewire, needle)

Clinical Attributes

Respondents shall provide the following information in the Tender Response Worksheet for each item offered:

a. Recommended insertion site (e.g. radial, femoral)

b. Size in French Gauge

c. Length in centimetres

d. Removable haemostatic valve (where applicable)

e. Number of side arms (where applicable)

f. Tip configuration

g. Size of maximum compatible guidewire in inches

h. Contents of Introducer Kits (where applicable)

i. Where applicable, components of Introducer Kits that are available individually (e.g. vessel dilators, obturators).

j. Material of construct

k. Material of coating (where applicable) (e.g., PVP)

Category 2 – Guidewires for Diagnostic Catheters

A full range of sterile, single use Guidewires for Diagnostic Catheters is required to facilitate the percutaneous insertion of diagnostic catheters in the Interventional Cardiology setting.

Subcategory	Subcategory Name	Description
02.01	Guidewires for Diagnostic Catheters	Flexible metal wires used to navigate through the vasculature and support the safe advancement of diagnostic catheters to target anatomy, in the Interventional Cardiology setting.

Mandatory Criteria

Sterile and single use

Desirable Criteria

Preference will be given to products that offer:

a. Radiopaque tips or markers

b. Compatibility with multiple catheter brands

Clinical Attributes

Respondents shall provide the following information in the Tender Response Worksheet for each item offered:

a. Guidewire dimensions:

  i. Diameter in inches

  ii. Length in centimetres

b. Tip configuration (e.g. straight, J, angled)

c. Radius of J in millimetres (where applicable)

d. Tip length in centimetres (where applicable)

e. Steerable (where applicable)

f. Stiffness level (e.g. flexible, standard)

g. Material of construct (e.g. nitinol, stainless steel)

h. Type of coating (e.g. hydrophilic, hybrid)

i. Presence of radiopaque markers (Yes/No)

j. Guidewire extension capability

k. Recommended compatible catheter diameter (inches)

Category 3 – Diagnostic Catheters and Diagnostic Catheter Kits

A full range of sterile, single use Diagnostic Catheters and Diagnostic Catheter Kits is required to meet clinical needs.

Subcategory	Subcategory Name	Description
03.01	Diagnostic Catheter	Individually packaged catheters used to access and visualize blood vessels during diagnostic imaging procedures, in the Interventional Cardiology setting
03.02	Diagnostic Catheter Kit	Multiple packaged catheters which serve as 'kits', in the Interventional Cardiology setting

Mandatory Criteria

Sterile and single use

Desirable Criteria

Preference may be given to devices that:

a. are pressure injector compatible; can withstand minimum pressure rating of 300 PSI and minimum flow tolerance of 4ml/sec

b. include radiopaque tips or markers

c. include reorderable kit components available individually

d. provide braided construction

Clinical Attributes

Respondents shall provide the following information in the Tender Response Worksheet for each item offered:

a. Recommended insertion site (e.g. radial, femoral)

b. Catheter dimensions:

  i. Size in French Gauge

  ii. Length in centimetres

  iii. Internal diameter in inches

  iv. External Diameter in inches

c. Tip configuration (e.g. JL4,)

d. Braided construction (Yes/No)

e. Maximum pressure tolerance (PSI)

f. Maximum flow rate (mL/s)

g. Material of construct (e.g. Polyurethane, Nylon)

h. Types of coating (e.g. hydrophilic, PTFE)

i. Radiopaque markers (if applicable)

  i. Number of radiopaque markers

  ii. Location of radiopaque markers

For each Pigtail catheter offered, respondents shall also provide the following information in the Tender Response Worksheet

a. Angle in degrees or straight

b. Number of side holes

c. Marker bands (Yes/No)

Category 4 – Right Heart Catheters

A full range of sterile, single use Right Heart Catheters is required to meet clinical needs.

Subcategory	Subcategory Name	Description
04.01	Right Heart Catheters	Right Heart Catheters are devices which enable pressure measurement across the right atrium, right ventricle, pulmonary artery and pulmonary capillary wedge. These catheters may be balloon tipped, multi-lumen, and may include thermistors for temperature-based flow measurements

Mandatory Criteria

Sterile and single use

Desirable Criteria

Preference may be given to items that:

a. Support cardiac output measurement

b. Include balloon tips for easier wedge positioning

c. Offer multi lumen options

d. Include radiopaque markers

Clinical Attributes

Respondents shall provide the following information in the Tender Response Worksheet for each item offered:

a. Size in French Gauge

b. Catheter length in centimetres

c. Tip configuration (e.g. multi-purpose A catheter, balloon tip)

d. Number of lumens

e. Number of ports

f. Side holes and location in relation to balloon (where applicable) (proximal or distal or N/A)

g. Capability for cardiac output measurement (where applicable)

h. Size of maximum compatible guidewire in inches

i. Injection rates in mL/s

j. Material of construct

k. Maximum pressure tolerance (PSI)

Category 5 – Interventional Catheters

A full range of sterile, single use Interventional Catheters is required to meet clinical needs.

Subcategory	Subcategory Name	Description
05.01	Angioplasty Guiding Catheter	Angioplasty Guiding Catheters are large-lumen catheters designed to deliver interventional devices, inject contrast media and therapeutic agents and provide coaxial alignment and trackability during coronary interventions.
05.02	PCI Microcatheters	Microcatheters are specialised, low-profile catheters designed to enhance guidewire support, facilitate device exchange, and navigate tortuous or calcified vessels, indicated for use in Complex Percutaneous Coronary Intervention (PCI).
05.03	Guide Extension Catheters	Guide extension catheters (GECs) are specialised, flexible, coaxial catheters designed to enhance support, provide coaxial alignment, and facilitate equipment delivery in complex coronary interventions.

Mandatory Criteria

Sterile and single use

Desirable Criteria

Preference shall be given to items that:

a. Are pressure injector compatible; can withstand minimum pressure rating of 300PSI and minimum flow tolerance of 4ml/sec

b. Include radiopaque tips or markers

c. Provide braided construction

Clinical Attributes

Respondents shall provide the following information in the Tender Response Worksheet for each item offered:

a. Catheter dimensions:

  i. Size in French Gauge

  ii. Length in centimetres

  iii. Inner diameter in inches

b. Material of construct e.g. polymer

c. Recommended access site (e.g. radial, femoral)

d. Side holes (where applicable)

e. Sheathless access (where applicable) (yes/no)

f. Maximum pressure rating (PSI) (where applicable)

g. Maximum flow tolerance (ml/s) (where applicable)

For each Angioplasty Guiding Catheter (05.01) offered, respondents shall also provide the following information in the Tender Response Worksheet

a. Tip configuration (e.g. JL4, XB3.5)

For each PCI Microcatheters (05.02) offered, respondents shall also provide the following information in the Tender Response Worksheet

a. Coating type (e.g. hydrophilic or hybrid)

b. Number of lumens

c. Tip shape (straight or angle in degrees)

d. Braided construction (Yes/No)

For each Guide Extension Catheters (05.03) offered, respondents shall also provide the following information in the Tender Response Worksheet

a. Distance from tip to cuff (cm)

Category 6 – Angioplasty Guidewires

A full range of sterile, single use Angioplasty Guidewires is required to meet clinical needs.

Subcategory	Subcategory Name	Description
06.01	Angioplasty Guidewire	Guidewires used during angioplasty procedures to navigate vessels and facilitate the placement of interventional devices such as balloons and stents
06.02	Angioplasty Guidewire Extension	Extension guidewires designed to connect to angioplasty guidewires, providing additional length for improved access and device delivery.

Mandatory Criteria

Sterile and single use

At least partial radiopacity in tip

Desirable Criteria

Preference shall be given to items that offer:

a. Compatibility with multiple catheter brands

Clinical Attributes

Respondents shall provide the following information in the Tender Response Worksheet for each item offered:

a. Dimensions:
   i. Length in centimetres
   ii. Diameter in inches

b. Tip:
   i. Configuration (e.g. tapered, rounded)
   ii. Length of radiopaque segment in mm
   iii. Tip load in grams
   iv. Material of construct
   v. Type of coating (e.g. nitinol)

c. Shaft
   i. Support level (e.g. light, moderate)
   ii. Coating type (Hydrophilic/hybrid, where applicable)
   iii. Presence of polymer jacketing (Yes/No)

Where guidewire extensions are available, Respondent should advise of any known compatibility issues with other brands of Angioplasty Guidewires.

Category 7 – Balloon Angioplasty Dilation Catheters

A full range of sterile, single use Balloon Angioplasty Dilation Catheters is required to meet clinical needs.

Subcategory	Subcategory Name	Description
07.01	Balloon Angioplasty Dilation Catheters, Over the Wire Type	Designed to be threaded over a full-length guidewire. Provides superior control and support for complex or long coronary interventions.
07.02	Balloon Angioplasty Dilation Catheters, Rapid Exchange - Compliant	Rapid exchange design. Compliant balloons expand gradually, suitable for delicate or tapered lesions.
07.03	Balloon Angioplasty Dilation Catheters, Rapid Exchange - Non Compliant	Rapid exchange design with rigid, fixed-diameter balloons for precise dilation, high-pressure inflation, and calcified/resistant lesions.
07.04	Drug-Eluting Balloon Angioplasty Catheters, Over the Wire Type	OTW drug-coated balloons delivering local antiproliferative therapy during inflation
07.05	Drug-Eluting Balloon Angioplasty Catheters, Rapid Exchange Type	Rapid exchange drug-eluting balloons with localized drug delivery.
07.06	Cutting Balloon Angioplasty Catheters	Balloons with micro-blades to modify plaque, facilitate vessel expansion, and treat resistant lesions.
07.07	Scoring Balloon Angioplasty Catheters	Balloons with wires to modify plaque, facilitate vessel expansion, and treat resistant lesions.

Mandatory Criteria

Sterile and single use

Desirable Criteria

Preference shall be given to items that offer:

a. Clear radiopacity for fluoroscopic visibility

b. Proven drug-elution technology with clinical evidence (for DEB's)

c. Consistent and controlled drug release profile (for DEB's)

d. Consignment stock

Clinical Attributes

Respondents shall provide the following information in the Tender Response Worksheet for each item offered:

a. Shaft:

  i. Diameter in millimetres

  ii. Length in centimetres

b. Balloon:
   i. Diameter in millimetres
   ii. Length in millimetres
   iii. Nominal inflation pressure (atm)
   iv. Burst inflation pressure (atm)
c. Number of radiopaque markers (where applicable)
d. Compliance type (e.g. semi-compliant, non-compliant)
e. Tip profile (description and dimensions)
f. Crossing profile (tip diameter, mm)
g. Compatible guidewire size (inch)
h. Material of construct
i. Coating material

For each Drug-Eluting Balloon Angioplasty Catheters (07.04 & 07.05) offered, respondents shall also provide the following information in the Tender Response Worksheet

a. Drug type and dosage
b. Duration of drug elution
c. Recommended inflation time in seconds
d. Drug disposition (eg. folds, wells)

For each Cutting Balloon (07.06) offered, respondents shall also provide the following information in the Tender Response Worksheet

a. Number and length of micro-blades
b. Blade material

For each Scoring Balloon (07.07) offered, respondents shall also provide the following information in the Tender Response Worksheet

a. Number and length of scoring wires
b. Wire material

Category 8 – Angioplasty Accessories and Accessory Kits

A full range of sterile, single use Accessories and Accessory Kits is required for use during coronary angioplasty procedures.

Subcategory	Subcategory Name	Description
08.01	Angioplasty Accessories, Guidewire Introducer	A device used to help insert and guide a guidewire into a blood vessel during angioplasty procedures
08.02	Angioplasty Accessories, Torque Device	A small handheld tool used to rotate and control the movement of the guidewire with precision, aiding in navigation through blood vessels.
08.03	Angioplasty Accessories, Haemostatic Valve	A valve used to prevent blood loss during catheter exchanges by maintaining hemostasis at the catheter insertion site while allowing passage of devices.
08.04	Angioplasty Accessories, Inflation Device	A device used to inflate and deflate balloon catheters during angioplasty, usually equipped with a pressure gauge for controlled inflation.
08.05	Angioplasty Accessory Kit	A pre-packaged set of angioplasty tools and devices (e.g., guidewires, introducers, inflation devices).

Mandatory Criteria

Sterile and single use

Clinical Attributes

Respondents shall provide the following information in the Tender Response Worksheet for each item offered:

a. Type of accessory (e.g. torque device, haemostatic valve, inflation device, introducer needle)

b. Contents of kit (where applicable, Respondent must provide detail content and individual pricing information of each component that comprise the kit).

c. Material of construct

For each Guidewire introducer (08.01) or Torque device (08.02) offered, respondents shall also provide the following information in the Tender Response Worksheet

a. Compatible guidewire diameter (inch)

For each Haemostatic device (08.03) offered, respondents shall also provide the following information in the Tender Response Worksheet

a. Rotating or push/click design

b. Maximum pressure rating (PSI)

c. Maximum inner diameter (inch)

Category 9 – Coronary Stents

A full range of sterile, single use Drug Eluting, Drug Coated and Covered Coronary Stents is required to meet clinical needs.

Subcategory	Subcategory Name	Description
09.01	Drug Eluting Coronary Stent	A stent coated with medication that is slowly released (eluted) to prevent scar tissue growth and restenosis. These stents combine mechanical support with pharmacological therapy.
09.02	Covered Coronary Stent	Also known as stent grafts, these stents are covered with a synthetic membrane. They are used in specific cases such as coronary artery perforations, aneurysms, or to seal abnormal vessel communications (e.g., fistulas).

Mandatory Criteria

a. Sterile and single use

b. Include radiopaque markers

Desirable Criteria

Preference will be given to suppliers who provide consignment stock.

Clinical Attributes

Respondents shall provide the following information in the Tender Response Worksheet for each item offered:

a. Generic name of the drug eluted (e.g. Everolimus) (where applicable)

b. Polymer type (e.g. poly n-butyl methacrylate (PBMA)) (where applicable)

c. Metal alloy (e.g. cobalt chromium)

d. Diameter in millimetres

e. Length in millimetres

f. Stent design (e.g. open, slotted)

g. Strut thickness in micrometres (µm)

h. Number of links (where applicable)

i. Maximum cell size in millimetres

j. Maximum expanded internal diameter in millimetres

k. Balloon overhang in millimetres

l. Position of stent in relation to balloon markers (e.g. in millimetres, mid marker, within marker)

m. Crossing profile (mm)

n. Duration of drug elution (where applicable)

o. Nominal and burst pressure (atm)

For each covered stents (09.02) offered, the Respondent should also advise the following information in the Tender Response Worksheet

a. Guide catheter size compatibility (internal diameter in inch)

b. Covering material (e.g. PTFE, polyurethane)

Category 10 – Temporary Pacing Catheters

A full range of sterile, single use Temporary Pacing Catheters is required to meet clinical needs.

Subcategory	Subcategory Name	Description
10.01	Temporary Pacing Catheter	A catheter inserted into the heart to deliver electrical impulses for short-term cardiac pacing. It is typically used in emergency or perioperative settings to manage bradyarrhythmia's or heart block.
10.02	Temporary Pacing Catheter Accessories	Support items used with temporary pacing systems, such as connectors, extension cables, introducers, or fixation tools. These ensure proper function and secure placement of the pacing catheter.

Mandatory Criteria

Sterile and single use (Only applicable to 10.01)

Desirable Criteria

Preference shall be given to items that:

a. Include accessories for secure catheter fixation

b. Provide contamination protection for device reuse

Clinical Attributes

For each Temporary Pacing Catheter (10.01) offered, the Respondent should advise the following information on the Tender Response Worksheet:

a. Pacing type (Atrial or ventricular)

b. Catheter dimensions:

   i. Size in French Gauge

   ii. Diameter in millimetres

   iii. Length in centimetres

   iv. Curve or straight

c. Balloon included (Yes/No) (where applicable)

d. Electrode configuration (e.g. bipolar)

For each Temporary Pacing Catheter Accessory (10.02) offered, Respondent should advise the following information on the Tender Response Worksheet:

a. Contamination shields (yes/no)

b. Introducer sheaths (yes/no)

c. Adaptor pins (yes/no)

d. Sterile (yes/no)

e. Reusable (yes/no)

Category 11 – Thrombus Aspiration Catheters

A full range of sterile, single use Thrombus Aspiration Catheters is required for use during percutaneous coronary interventions.

Subcategory	Subcategory Name	Description
11.01	Thrombus Aspiration Catheters	Thrombus aspiration catheters feature large-bore lumens and single end-holes designed to extract blood clots from coronary arteries during coronary interventional procedures.

Mandatory Criteria

Sterile and single use

Clinical Attributes

Respondents shall provide the following information in the Tender Response Worksheet for each item offered:

a. Catheter dimensions:
   i. Size in French Gauge
   ii. Catheter length in centimetres
   iii. Internal diameter of catheter with which the device can be used (inch)
   iv. Outer diameter in inch

b. Where applicable, additional components (e.g. syringes, stylet)

c. Method of aspiration (mechanical or manual)

Category 12 – Transcatheter Occlusion Devices

A full range of Transcatheter Occlusion Devices is required to meet clinical needs. Occlusion Devices are to be offered individually and in kit form.

Subcategory	Subcategory Name	Description
12.01	Septal Occlusion Device	A septal occlusion device is a minimally invasive, percutaneous, transvenous implant used to close septal defects in the heart.
12.02	Patent Ductus Arteriosus Occlusion Device	Patent Ductus Arteriosus (PDA) occlusion devices are percutaneous, self-expanding, mushroom-shaped, or coil-based devices designed for nonsurgical, catheter-based closure of the PDA.
12.03	Left Atrial Appendage Occlusion Device-Transcatheter approach	A left atrial appendage occlusion device (LAAO) is a catheter delivered implant used in patients with atrial fibrillation to block the left atrial appendage (LAA).

Mandatory Criteria

Sterile and single use

Intended for transcatheter implantation

Desirable Criteria

Preference shall be given to items that:

a. Allow for repositioning or recapture

Clinical Attributes

Respondents shall provide the following information in the Tender Response Worksheet for each item offered:

a. Intended placement area

b. Material of construct

c. Length of delivery system (cm)

d. Size of delivery system required (French Gauge)

e. Number of radiopaque markers

f. Balloon included (Yes/No), (where applicable)

g. Contents of kit (where applicable, Respondent must provide detail of items that comprises the kit).

For each Septal occlusion devices (12.01) offered, Respondent should also advise the following information on the Tender Response Worksheet:

a. Waist diameter (mm)

b. Waist length (mm)

c. Right disc diameter (mm)

- Left disc diameter (mm)

For each Patent Ductus Arteriosus Occlusion Device (12.02) offered, Respondent should also advise the following information on the Tender Response Worksheet:

a. Waist diameter (mm)

b. Distal disc diameter (mm)

c. Proximal disc diameter (mm)

d. Waist length (mm)

e. Length between discs mm (if applicable)

For each Left Atrial Appendage Occlusion Device (12.03) offered, Respondent should also advise the following information on the Tender Response Worksheet:

a. Lobe diameter (mm) (if applicable)

b. Depth (mm) (if applicable)

c. Disc diameter (mm) (if applicable)

d. Diameter in millimetres

e. Length in millimetres

Category 13 – Vessel Closure Devices, Haemostatic Devices and Kits

A full range of Vessel Closure Devices, Haemostatic Devices and Kits is required to meet clinical needs.

Subcategory	Subcategory Name	Description
13.01	Vessel Closure Device	Devices designed to achieve rapid haemostasis by closing the vascular access site (e.g., femoral or radial artery) following catheter-based procedures. Mechanisms may include clips, sutures, plugs, or sealing systems, etc..
13.02	Haemostatic Device-radial	Devices used to apply controlled external pressure to the radial artery post-procedure to achieve haemostasis.
13.03	Haemostatic Device-femoral	Devices used to apply controlled external pressure to the femoral artery post-procedure to achieve haemostasis.
13.04	Haemostatic Device Kits	Devices used to apply controlled external pressure to a vascular access site post-procedure to achieve haemostasis. Kits may be packaged with the single use haemostatic device and reusable hardware that aids the device to achieve haemostasis.

Mandatory Criteria

Sterile and single use (13.01 and 13.02 only)

Single use (13.03 only)

Desirable Criteria

Preference shall be given to items that:

a. Support early ambulation

b. Are compatible with a range of sheath sizes

Clinical Attributes

Respondents shall provide the following information in the Tender Response Worksheet for each item offered:

a. Material of construct

b. Recommended time to ambulation

c. Recommended time before re-puncture

For each Vessel Closure device (13.01) offered, Respondent should also advise the following information on the Tender Response Worksheet:

a. Closure Mechanism (e.g. clip, plug)

b. Number of lumens

c. Number of sutures (where applicable)

d. Suture material (where applicable)

e. Size in French Gauge

f. Intra or extra lumen

g. Size of maximum compatible guidewire (inch)

For each Haemostatic device -radial (13.02) offered, Respondent should also advise the following information on the Tender Response Worksheet:

a. Length (cm) (where applicable)

b. Wrist application range (cm)

c. Maximum inflation volume (mL)

For each Haemostatic device – femoral (13.03) offered, Respondent should also advise the following information on the Tender Response Worksheet

a. Sterile or non-sterile

b. Size (cm)

c. Recommended pressure range (e.g.150mmHg – 200mmHg)

d. Pressure indicator (where applicable)

e. Reusable accessories (where applicable) (e.g. arch, C-clamp)

Category 14 – Implantable Pacemakers

A full range of Implantable Pacemakers is required to meet clinical needs.

Subcategory	Subcategory Name	Description
14.01	Implantable Pacemaker, Single Chamber Pacemaker	A pacemaker with one lead placed in either the right atrium or right ventricle to regulate heart rhythm.
14.02	Implantable Pacemaker, Dual Chamber Pacemaker	This device has two leads—one in the right atrium and one in the right ventricle—to coordinate timing between the chambers.
14.03	Implantable Pacemaker, BiVentricular Pacemaker	A device implanted to pace both the right and left ventricles simultaneously to improve coordinated cardiac contraction in patients.
14.04	Implantable Pacemaker, Cardiac Resynchronisation Pacemaker	An implantable cardiac device that delivers timed electrical impulses to both ventricles to restore synchronised heart rhythm and enhance cardiac output. CRP pacemakers may include conduction system pacing functionality to pace the heart's native conduction system.
14.05	Leadless Pacemaker	A miniaturized, self-contained pacemaker implanted directly into the heart without leads.
14.06	Pacemaker Leads	Pacemaker leads are thin, insulated wires which sense electrical activity and deliver electrical impulses to maintain heart rhythm.
14.07	Implantable Pacemaker Programmers, Accessories and Consumables	Includes external programming devices used to adjust pacemaker settings, as well as accessories like leads, connectors, and sterile consumables required for implantation and follow-ups.

Mandatory Criteria

Sterile and single use (all except 14.07)

MRI conditional minimum full body 1.5T rating

14.06 Pacemaker Leads: Must include all components for system connectivity, including but not limited to end caps, adaptors and plugs

Desirable Criteria

Preference shall be given to items that offer:

a. Consignment stock
b. Longest anticipated battery life
c. Comprehensive remote and/or wireless monitoring capabilities
d. Multi-functional and fully programmable features
e. Bipolar and unipolar sensing/stimulation capability
f. Advanced diagnostics (e.g. electrogram storage, impedance monitoring)
g. Compact pulse generator size and lightweight design
h. Lead repair kits (where applicable)
i. Steroid elution technology (where applicable)
j. A pro rata discount beyond the full warranty period on a new pacemaker where an implanted device does not achieve the stated battery life

Clinical Attributes

For each Implantable Pacemaker (14.01 – 14.05) offered, Respondent should advise the following information in the Tender Response Worksheet:

a. Type of pacemaker
b. Remote monitoring capability (yes/no) (where applicable)
c. Wireless capability (yes/no) (where applicable)
d. Connector (e.g. 3.2 mm LP BI, IS-1, IS-4 or UNI)
e. MRI conditional rating (Tesla)
f. Electrogram capacity (where applicable) (e.g., capability of the device to record and analyse multiple intracardiac channels, including but not limited to HAR, HVR, Loss of capture, near filed, far field, atrium, Right / Left ventricle)
g. Electrogram storage capacity in minutes of ECG's, including high rate atrial and ventricular events
h. Weight in grams
i. Volume in cubic centimetres
j. Length and width in mm
k. Battery:
    i. Type (e.g. manganese dioxide)
    ii. Stated battery capacity Ah
    iii. Anticipated battery life with pacing at 100% on all chambers, electrograms on and at an output of 2.5V/0.5millisecs
l. Additional features, where applicable (e.g. overdrive atrial and ventricular pacing, capability for arrhythmia termination)
m. Whether real time electrograms recorded from atrial and ventricular leads are readily displayable on the external programmer screen (yes/no)
n. Programmable rate, output, rate response, sensitivity and hysteresis
o. Automatic mode switching (yes/no)
p. Rate adaptive pacing (yes/no)
q. Automatic ventricular threshold testing and output setting (yes/no)

r. Impedance monitoring (yes/no)

s. Ventricular pacing minimisation (yes/no)

t. 14.05 Leadless Pacemakers Only

   i. Fixation mechanism (e.g. nitinol tines)

   ii. Introduction catheter size (French gauge)

   iii. Communication (single or dual chamber)

For each Pacemaker lead (14.06) offered, including leads offered as part of system 1 or system 2 (as defined in section “System Offer”), Respondent should advise the following information in the Tender Response Worksheet:

a. Lead connector standard (e.g. IS1, IS4)

b. Placement (e.g. right atrial, left and right ventricular, epicardial)

c. Type of lead (e.g. bipolar, unipolar, quadripolar)

d. External diameter in millimetres

e. Lead length in centimetres

f. Introducer size in French Gauge

g. Tip shape (e.g. straight, J shape)

h. Type of fixation (e.g. active, passive)

i. Insulation material (e.g. silicone or polyurethane)

j. T – R spacing in millimetres

k. Steroid eluting (where applicable).

For each Implantable Pacemaker Programmers, Accessories and Consumables (14.07) offered, Respondent should advise the following information in the Tender Response Worksheet:

a. Sterile (yes/no)

b. Reusable (yes/no)

Please note: Implantable Pacemaker Programmers, Accessories and Consumables include, but are not limited to:

a. Software and hardware upgrades

b. All support, maintenance and repairs.

c. Printer paper

Items should be maintained ‘free on loan’ for the life of the implanted device in sufficient numbers at each site to effectively manage both implantation and follow up procedures.

System Offer

a. For the purpose of this tender a system offer refers to a single price that incorporates all requirements for the following systems relating to the insertion or change of a pacemaker and/or lead(s).

b. All system offers should include requirements for the following items that are common for the insertion or change of an Implantable Pacemaker or Implantable Pacemaker and lead(s):

   i. All requirements for access and insertion including but not limited to lead introducer kits, stylets, locators, balloon tip catheters and guidewires

ii. All components for system connectivity including but not limited to end caps, adaptors and plugs

iii. All tools including but not limited to screw drivers, wrenches, rotation tools

iv. Pacemaker programmers, including consumables.

c. The Respondent should provide the following system offers for each Implantable Pacemaker tendered in the Tender Response Worksheet:

i. System 1 should include the remaining requirements for successful insertion of an Implantable Pacemaker and lead(s)

ii. System 2 should include the remaining requirements for the successful change of an Implantable Pacemaker.

d. For the purpose of this tender, the component price refers to the price for a single component (e.g. pacemaker, pacemaker lead, pacemaker introducer sheath). Respondent should provide the price for individual components in the Tender Response Worksheet.

e. Pacemaker memory must be capable of storing patient, implant and program-related data, including details of pacemaker operation.

f. All Additional Components for Pacemakers offered as part of a system offer should meet the specification for Category 16: Pacemaker, ICD and Lead Insertion Accessories, Tools and Toolkits.

Warranty

For each Implantable Pacemaker offered, Respondent should state the period and extent of the warranty, including all terms and conditions. This should include:

a. Specific reference to battery life and pacemaker settings

b. Details around the potential requirement to replace a pacemaker and the conditions associated with this procedure

c. Respondent should advise of their ability to offer a pro rata discount beyond the full warranty period on a new pacemaker where an implanted device does not achieve the stated battery life, including circumstances where this does and does not apply.

d. Respondent should specify the duration and amount of pro-rata discount.

Category 15 – Implantable Cardioverter Defibrillators

A full range of Implantable Single and Dual Chamber, and Cardiac Resynchronisation Cardioverter Defibrillators (ICD's) compatible with DF1, DF4 & IS4 leads is required to meet clinical needs.

Subcategory	Subcategory Name	Description
15.01	Implantable Cardioverter Defibrillators, Single Chamber ICD	A type of ICD with a single lead placed in the right ventricle. It monitors heart rhythms and delivers shocks or pacing therapy when life-threatening arrhythmias (like ventricular tachycardia or fibrillation) are detected.
15.02	Implantable Cardioverter Defibrillators, Dual Chamber ICD	This ICD has two leads—typically in the right atrium and right ventricle—allowing it to differentiate between supraventricular and ventricular arrhythmias.
15.03	Implantable Cardioverter Defibrillators, Cardiac Resynchronisation ICD	Also known as CRT-D (Cardiac Resynchronization Therapy with Defibrillator), this device paces both ventricles and includes defibrillation capabilities.
15.04	Implantable Cardioverter Defibrillator Leads	ICD leads are insulated wires connecting the ICD to the heart, continuously monitoring cardiac rhythm and delivering pacing or shocks when dangerous arrhythmias are detected.
15.05	Implantable Cardioverter Defibrillator Programmers, Accessories and Consumables	Includes the external devices used by clinicians to program and monitor ICDs, as well as associated accessories (e.g., leads, adapters) and sterile consumables needed for implantation and follow-up care.

Mandatory Criteria

Sterile and single use (all except 15.05)

MRI conditional minimum full body 1.5T rating

15.05 Implantable Cardioverter Defibrillator Leads: Must include all components for system connectivity, including but not limited to end caps, adaptors and plugs

Desirable criteria

Preference shall be given to items that offer:

a. Consignment stock
b. Longest anticipated battery life
c. Comprehensive remote and/or wireless monitoring capabilities
d. Multi-functional and fully programmable features
e. Bipolar and unipolar sensing/stimulation capability
f. Advanced diagnostics (e.g. electrogram storage, impedance monitoring)
g. Compact pulse generator size and lightweight design
h. Lead repair kits (where applicable)
i. Steroid elution technology (where applicable)
j. Automatic ventricular threshold testing and output setting
k. A pro rata discount beyond the full warranty period on a new ICD where an implanted device does not achieve the stated battery life

Clinical Attributes

For each ICD (15.01 – 15.03) offered, Respondent should advise the following information in the Tender Response Worksheet:

a. Type of ICD
b. Connector (e.g. 3.2 mm DF1, DF4, LP BI, IS1, IS4, UNI)
c. MRI conditional rating (Tesla)
d. Electrogram storage capacity in minutes of ECG's
e. Weight in grams
f. Volume in cubic centimeters
g. Length and width in mm
h. Remote monitoring capability (yes/no) (where applicable)
i. Wireless capability (yes/no) (where applicable)
j. Features to minimise ventricular pacing (where applicable) (e.g. MVP)
k. Battery type
l. Battery life in Amp hours based on the following measures:
    i. Single chamber at <1% pacing & 2 shocks per year
    ii. Dual 50% pacing in each lead & 2 shocks per year
    iii. CRT 100% pacing on 2 ventricular leads & 2 shocks per year
m. Additional features, where applicable (e.g. overdrive atrial and ventricular pacing, capability for arrhythmia termination)
n. Overdrive pacing for ventricular tachyarrhythmia
o. Multizone detection of ventricular tachyarrhythmia
p. Capable of high output shock ≥35 joules (Yes/No)
q. Features to minimise ventricular pacing (where applicable)

For each ICD lead (15.04) offered, including leads offered as part of system 1 or system 2 (as defined in section “System Offer”), Respondent should advise the following information in the Tender Response Worksheet:

a. Type of lead (e.g. unipolar or bipolar)

b. Lead length in centimetres

c. External diameter in millimetres

d. Introducer size in French Gauge

e. Type of fixation (e.g. active or passive)

f. Terminal pin configuration (e.g. IS1/DF1, IS4/DF4)

g. Insulation material (e.g. silicone, polyurethane)

h. Number of coils

i. Coil coating (where applicable) (e.g. Gore-tex)

j. Steroid eluting (where applicable)

For each Implantable Cardioverter Defibrillator Programmers, Accessories and Consumables (15.05) offered, Respondent should advise the following information in the Tender Response Worksheet:

a. Sterile (yes/no)

b. Reusable (yes/no)

Please note: ICD Programmers, Accessories and Consumables include, but are not limited to:

a. Software and hardware upgrades

b. All support, maintenance and repairs

c. Printer paper

Items should be maintained ‘free on loan’ for the life of the implanted device in sufficient numbers at each site to effectively manage both implantation and follow up procedures.

System Offer

a. For the purpose of this tender a system offer refers to a single price that incorporates all requirements for the following systems relating to the insertion or change of an ICD and/or lead(s).

b. All system offers should include requirements for the following items that are common for the insertion or change of an ICD or ICD and lead(s):

   i. All requirements for access and insertion including but not limited to lead introducer kits, stylets, locators, balloon tip catheters and guidewires

   ii. All components for system connectivity including but not limited to end caps, adaptors and plugs

   iii. All tools including but not limited to screw drivers, wrenches, rotation tools

   iv. Lead repair kits (if applicable)

   v. ICD programmers, including consumables.

c. The Respondent should provide the following system offers for each Implantable ICD tendered in the Tender Response Worksheet:

   i. System 1 should include the remaining requirements for successful insertion of an Implantable Cardioverter Defibrillator and lead(s)

ii. System 2 should include the remaining requirements for the successful change of an Implantable Cardioverter Defibrillator.

d. For the purpose of this tender, the component price refers to the price for a single component (e.g. ICD, ICD lead, pacemaker introducer sheath). Respondent should provide the price for individual components in the Tender Response Worksheet.

e. All Additional Components for ICD's offered as part of a system should meet the specification for Category 16: Pacemaker, ICD and Lead Insertion Accessories, Tools and Toolkits

Warranty

For each ICD offered, Respondent should state the period and extent of the warranty, including all terms and conditions. This should include:

a. Specific reference to battery life and ICD settings

b. Details around the potential requirement to replace an ICD and the conditions associated with this procedure

c. Respondent should advise of their ability to offer a pro rata discount beyond the full warranty period on a new ICD where an implanted device does not achieve the stated battery life, including circumstances where this does and does not apply.

d. Respondent should specify the duration and amount of pro-rata discount in the Tender Response Worksheet.

Category 16 – Pacemaker, ICD and Lead Insertion Accessories, Tools and Tool Kits

A range of Pacemaker, ICD and Lead Insertion Accessories, Tools and Tool Kits is required to support the implantation of Pacemakers, ICDs and Leads, where system prices do not apply.

Subcategory	Subcategory Name	Description
16.01	Pacemaker/ICD and Lead Insertion, Accessories - Individual	Individual accessory item used during pacemaker or ICD implantation and lead placement, such as guidewires, introducers, or fixation devices
16.02	Pacemaker/ICD and Lead Insertion, Accessories - Kits	Pre-packaged kits that include multiple accessories required for pacemaker or ICD lead insertion
16.03	Pacemaker/ICD and Lead Insertion, Tools - Individual	Individual surgical or procedural tools used in device implantation and lead placement, such as stylets, sheaths, or specialized forceps
16.04	Pacemaker/ICD and Lead Insertion, Tools - Kits	Comprehensive kits containing a set of tools necessary for pacemaker or ICD implantation procedures in one package

Mandatory Criteria

Sterile and single use (all except 16.04)

Sterile (16.04)

Desirable criteria

Preference shall be given to items that:

a. Are compatible across multiple pacemaker and ICD systems

b. Have standardised connector fittings

Clinical Attributes

Respondents shall provide the following information in the Tender Response Worksheet for each item offered:

a. Material of construction

b. Type of accessory or tool (e.g. stylet, locator, screw driver, repair kit)

c. Size (where applicable) (e.g. French Gauge)

d. Length in centimetres

e. Mode of removal (where applicable) (e.g. peel away, cut away)

f. Contents of kit (where applicable)

For each Pacemaker/ICD and Lead Insertion, Tools – Kits (16.04) offered, Respondent should advise the following information in the Tender Response Worksheet:

a. Reusable (yes/no)

Category 17 – Implantable Cardiac Monitors

A range of Implantable Cardiac Monitors is required for long-term, continuous monitoring of cardiac rhythms in patients with suspected or unexplained arrhythmias, particularly for the investigation of recurrent syncope or palpitations where the diagnosis is unclear.

Subcategory	Subcategory Name	Description
17.01	Implantable Cardiac Monitors	Implantable Cardiac Monitors are small, subcutaneously implanted cardiac monitors that continuously record the heart's electrical activity.

Mandatory Criteria

Sterile and single use

Devices must support long-term cardiac rhythm monitoring with implantable functionality

Devices must support remote data transmission to clinicians

Desirable criteria

Preference shall be given to items that offer:

a. Wireless connectivity with automatic data transmission

b. Patient-activated and automatic event detection

c. Small form factor (low profile, reduced weight, ease of insertion)

d. Extended battery life

e. Compatibility with remote monitoring platforms across multiple device types

f. Support for automated alerts and clinician-configurable parameters

Clinical Attributes

Respondents shall provide the following information in the Tender Response Worksheet for each item offered:

a. Dimensions (length × width × thickness in mm)

b. Weight (in grams)

c. Battery life (in years)

d. Data storage capacity (minutes of ECGs)

e. Detection algorithms (e.g. AF detection, bradycardia, tachycardia)

f. Patient-activated event recording (Yes/No)

g. Wireless telemetry capability (Yes/No)

h. Method of telecommunication (e.g. cellular telemetry, Wi-Fi)

i. Compatible remote monitoring system(s)

j. Compatible with which Pacemaker, ICD or ICM models (where applicable)

Category 18 – Aortic Valves, Mechanical

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

Subcategory	Subcategory Name	Description
18.01	Aortic Valves, Mechanical	Mechanical aortic valves are long-lasting prosthetic valves used in surgical aortic valve replacement. Constructed from biocompatible materials.

Mandatory Criteria

a. Sterile and single use for implantable components, sizers and handles may be reusable

b. Contents of supplied kits (i.e. sizers, handles, deployment systems and associated components etc.) must be free of charge

Desirable criteria

Preference shall be given to items that:

a. Have published long-term (>15 years) clinical durability data

b. Offer design features that reduce thrombogenicity and improve flow dynamics

c. Include flexible or adaptable sewing cuff options to support varied surgical techniques.

d. Are MRI conditional at both 1.5T and 3T field

e. Have testers included free of charge

f. Offer consignment stock

Clinical Attributes

Respondents shall provide the following information in the Tender Response Worksheet for each item offered:

a. Heart position to implant the valve

b. Material of valve

c. Opening angle

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

e. For the valve:

  i. Size (e.g. 17, 25 mm)

  ii. Intra annular diameter (mm)

  iii. Sewing ring diameter (mm)

  iv. Internal orifice area (cm^2)

f. Contents of supplied kits (sizers, handles etc.)

Category 19 – Aortic Valves, Tissue/Xenograft

A full range of Tissue / Xenograft aortic valves and suture less / rapid deployment aortic valves is required to support the full range of structural heart procedures.

Subcategory	Subcategory Name	Description
19.01	Aortic Valves, Pericardial	Biological prosthetic valves constructed from bovine or equine pericardial tissue mounted on a stented frame. These valves are used in surgical aortic valve replacement.
19.02	Aortic Valves, Porcine	Stented tissue valves made from preserved porcine aortic valves. These replicate native valve anatomy, commonly used in standard surgical aortic valve replacements
19.03	Aortic Valves, Sutureless / Rapid Deployment	Tissue valves designed for surgical implantation with minimal or no sutures, facilitating faster implantation.

Mandatory Criteria

a. Sterile and single use

b. Supplied kits (i.e. sizers, handles, deployment systems and associated components etc.) must be free of charge

Desirable criteria

Preference shall be given to items that:

a. Offer proven mid-to-long-term durability (≥10 years)

b. Include anti-calcification treatment to reduce structural valve deterioration

c. Demonstrate low transvalvular gradients and large effective orifice area

d. Offer consignment stock

Clinical Attributes

Respondents shall provide the following information in the Tender Response Worksheet for each item offered:

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

b. Heart position to implant the valve

c. Material of construct

d. Valve size (mm)

e. Tissue supra annular Diameter (mm)

f. Intra Annular Diameter (mm)

g. Cuff Outer Diameter (mm, where applicable)

h. Total Height (mm)

i. Contents of kits (sizers, handles etc.)

Category 20 – Stentless Xenograft Tissue Valves

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

Subcategory	Subcategory Name	Description
20.01	Stentless Xenograft Tissue Valves	Stentless xenograft tissue valves are bioprosthetic heart valves derived from animal tissue (typically porcine or bovine) without a supporting stent frame. These valves can be implanted as full root or subcoronary replacements.

Mandatory Criteria

a. Sterile and single use

Desirable criteria

Preference shall be given to items that:

a. Demonstrate proven mid-to-long term (≥10 years) clinical durability and low rates of structural valve deterioration

b. Offer design options such as full root or subcoronary implantation techniques

c. Offer consignment stock

Clinical Attributes

Respondents shall provide the following information in the Tender Response Worksheet for each item offered:

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

b. Heart position to implant the valve

c. Material of valve

d. Valve specifications

   i. Valve size in millimetres

   ii. Outside diameter (mm)

   iii. Profile height (mm)

   iv. Effective orifice area (cm^2)

e. Contents of kits (sizers, handles etc.)

Category 21 – Mitral Valves, Mechanical

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

Subcategory	Subcategory Name	Description
21.01	Mitral Valves, Mechanical	Mechanical mitral valves are durable prosthetic heart valves designed for surgical replacement of the native mitral valve.

Mandatory Criteria

a. Sterile and single use

b. Supplied kits (i.e. sizers, handles, etc.) must be free of charge

Desirable Criteria

Preference shall be given to items that:

a. Demonstrate proven long-term clinical durability (>15 years)

b. Offer flexible or adaptable sewing cuff designs to support varied surgical approaches

c. Provide optimised haemodynamics with low transvalvular gradients

d. Offer consignment stock

Clinical Attributes

Respondents shall provide the following information in the Tender Response Worksheet for each item offered:

a. Heart position to implant the valve

b. Material of valve

c. Valve specifications:

   i. Supra Annular diameter (mm)

   ii. Intra Annular diameter (mm)

   iii. Geometric Orifice area (cm2)

   iv. Cuff Style (e.g. expanded)

   v. Material of sewing cuff

d. Contents of kits (sizers, handles etc.)

Category 22 – Mitral Valves, Tissue / Xenograft

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

Subcategory	Subcategory Name	Description
22.01	Mitral Valves, Tissue/Xenograft	Tissue or xenograft mitral valves are bioprosthetic heart valves derived from animal tissue (typically porcine or bovine) designed for surgical replacement of the native mitral valve.

Mandatory Criteria

a. Sterile and single use

b. Supplied kits (sizers, handles, etc.) must be free of charge

Desirable Criteria

Preference shall be given to items that:

a. Demonstrate proven mid-long-term (≥10 years) clinical durability and low rates of structural valve deterioration

b. Offer designs that optimize effective orifice area and minimize transvalvular gradients

c. Include flexible or adaptable sewing cuff materials to facilitate varied surgical techniques

d. Offer consignment stock

Clinical Attributes

Respondents shall provide the following information in the Tender Response Worksheet for each item offered:

a. Type of heart valve (e.g. tissue, xenograft)

b. Heart position to implant the valve

c. Material of valve

d. Valve specifications:

   i. Valve diameter (mm)

   ii. Supra annular diameter (mm)

   iii. Intra Annular diameter (mm)

   iv. Total Height (mm)

   v. Effective orifice area (cm^2)

e. Contents of kits (sizers, handles etc.)

Category 23 – Annuloplasty Bands / Rings – Mitral

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

Subcategory	Subcategory Name	Description
23.01	Rigid or Semi-rigid Rings	Annuloplasty rings made from rigid or semi-rigid materials designed to provide structural support and reshape the valve annulus during mitral valve repair, ensuring durable annular stabilization
23.02	Flexible Rings or Bands	Annuloplasty rings or bands constructed from flexible materials that allow dynamic annular motion, supporting valve repair while preserving natural annular contraction and flexibility

Mandatory Criteria

a. Sterile and single use

b. Supplied kits (i.e. sizers, handles, etc.) must be free of charge

Desirable Criteria

Preference shall be given to items that:

a. Offer proven clinical durability and positive repair outcomes

b. Include designs that optimize annular dynamics and valve function

c. Are compatible with minimally invasive and conventional surgical approaches

d. Offer consignment stock

Clinical Attributes

Respondents shall provide the following information in the Tender Response Worksheet for each item offered:

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

b. Material (e.g. Flexible polyester)

c. Ring specifications:

   i. Ring size (mm) (e.g. 24,26,28)

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

   iii. Ring profile/Height (mm)

d. Contents of kits (sizers, handles etc.)

Category 24 – Annuloplasty Bands / Rings - Tricuspid

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

Subcategory	Subcategory Name	Description
24.01	Annuloplasty Bands / Rings - Tricuspid	Tricuspid annuloplasty bands and rings are prosthetic devices used in valve repair procedures to reshape, reinforce, and stabilize the tricuspid valve annulus, available in rigid, semi-rigid, and flexible designs.

Mandatory Criteria

a. Sterile and single use

b. Supplied kits (i.e. sizers, handles, etc.) must be free of charge

Desirable Criteria

Preference shall be given to items that:

a. Demonstrate proven clinical durability and positive repair outcomes

b. Include designs that optimize annular dynamics and valve function

c. Provide accessories that improve ease and safety of implantation

d. Offer consignment stock

Clinical Attributes

Respondents shall provide the following information in the Tender Response Worksheet for each item offered:

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

b. Material (e.g. Flexible polyester)

c. Ring specifications:

   i. Ring size (mm)

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

   iii. Ring Profile/Height (mm)

d. Contents of kits (such as sizers, handles etc.)

Category 25 – Surgical Septal Defect Management Devices

A full range of Surgical Septal Defect Management Devices is required to support the full range of structural heart procedures.

Subcategory	Subcategory Name	Description
25.01	Surgical ASD & VSD Management Devices	Surgical ASD & VSD management devices are used in open heart surgery to seal a septal defect.

Mandatory Criteria

a. Sterile and single use

b. Intended for surgical implantation/use

Desirable Criteria

Preference shall be given to items that:

a. Ensure long-term durability and biocompatibility, i.e., materials chosen limit thrombosis, infection, calcification, and degeneration

b. Offer consignment stock

Clinical Attributes

Respondents shall provide the following information in the Tender Response Worksheet for each item offered:

a. Material of construct (bovine pericardium, ePTFE)

b. Type of device (e.g. patch, membrane)

c. Length (cm)

d. Width (cm)

e. Thickness (mm)

f. Coating substance (where applicable)

g. Preparation required (e.g. rinsing steps)

Category 26 – Surgical Atrial Fibrillation and Appendage Management Devices

A full range of Surgical Atrial Fibrillation and Appendage Management Devices is required to support the full range of structural heart procedures.

Subcategory	Subcategory Name	Description
26.01	Left Atrial Appendage Occlusion Device-Surgical Approach	A left atrial appendage occlusion device (LAAO) is a surgical implant designed to mechanically seal the left atrial appendage that is prone to blood clot formation in patients with atrial fibrillation.
26.02	Cryoablation Therapy Consumables	Consumable products used in cryoablation therapy in the treatment of atrial fibrillation, aims to create cryoablation lesions in tissue by delivering a cryogenic Nitrous Oxide energy source from the console to the tip of the connected probe to create an inflammatory response (cryonecrosis) that blocks the electrical conduction pathway, restoring normal sinus rhythm.
26.03	Radiofrequency Ablation Therapy Consumables	Consumable products used in radiofrequency (RF) ablation therapy. Use RF energy to ablate cardiac tissue during pulmonary vein isolation and atrial connecting lesions for the Maze procedure. Commonly used to treat cardiac arrhythmias and AF.

Mandatory Criteria

a. Sterile and single use

b. Intended for surgical implantation/use

c. The ownership and title of equipment required for 26.02 and 26.03 must remain with individual supplier at all times

d. Equipment required for 26.02 and 26.03 must be provided free of charge and ahead of procedure time to allow health services to conduct safety tests according to hospital policies

Desirable Criteria

Preference shall be given to items that:

a. Demonstrate proven mid-to long-term clinical durability and effective surgical outcomes for the definitive curable treatment of AF

b. Offer designs that optimise effective positioning in or around the atria

c. Provide enhanced visualisation during positioning (e.g. Radiopaque markers)

d. Provide accessories designed for ease and safety of implantation and use (e.g. sizers, machines)

e. Offer consignment stock

Clinical Attributes

For each Left Atrial Appendage Occlusion Device (26.01) offered, Respondents shall advise the following in the Tender Response Worksheet.

a. Type of device (e.g. Preloaded clip, probe, or clamp)

b. Material of construct

c. Contents of kits (sizers, attachments, tools, handpieces, and probes)

For each cryoablation therapy consumables (26.02) offered, Respondents shall advise the following in the Tender Response Worksheet

a. Dimensions & description of the probe (e.g., 8-10cm extendable, e.g., malleable tip & shaft)

b. Freeze (tissue) length (e.g., 10cm)

c. Freeze temperature range (e.g., -50 to -70°C)

d. Cryoablation time (60-120secs)

e. Defrosting time

f. Cycle duration

g. Freeze/Defrost Cycle max quantity (specify number of allowed cycle use per probe per manufacturer)

h. Type of Gas energy console source (e.g., Nitrous Oxide)

For each RF ablation therapy consumables (26.03) offered, Respondents shall advise the following in the Tender Response Worksheet

a. Energy type (unipolar or bipolar ablation approach)

b. Design (e.g., if Pen type- malleable shafts, if vascular clamp type)

c. Dimensions (jaw length e.g., 53mm, 63mm & curvature style and degree of jaw)

d. Generator (machine) compatibility (e.g., Multifunctional Ablation Generator (MAG), Ablation and Sensing Unit (ASU), Ablation Switch Matrix (ASB), one or multiple.

e. Lesion depth and width specification when delivered (e.g., 2mm)

f. Time required to ablate per lesion (range only, as it's tissue dependent)

g. Temperature parameters

   i. actual lesion e.g., 60-70°C

   ii. surrounding clamped region e.g., <50°C

   iii. safety threshold e.g., <38°C

Category 27 – Transcatheter Valve Procedures

A full range of Transcatheter Structural Valve Procedures is required to support the full range of structural heart procedures.

Subcategory	Subcategory Name	Description
27.01	Transcatheter Aortic Valve Implantation	Transcatheter Aortic Valve Implantation (TAVI) is a minimally invasive procedure used to replace diseased aortic valves in patients with aortic stenosis or similar conditions.
27.02	Transcatheter Mitral, Tricuspid or Pulmonary Valve Implantation	Transcatheter Mitral, Tricuspid or Pulmonary Valve Implantation (or Replacement) is a minimally invasive, catheter-based procedure designed to treat valvular regurgitation in high-risk or inoperable patients.
27.03	Transcatheter Valvular Repair Systems	Transcatheter Valvular Repair Systems are devices designed to improve blood flow by reducing valvular leakage.
27.04	Transcatheter Valve Dilatation Balloon Catheters	Transcatheter Valve Dilatation Balloon Catheters are balloons which can be used to pre and post dilate an implanted heart valve.
27.05	Transcatheter Valve Guidewires	Transcatheter guidewires are specialised wires designed to cross the diseased aortic valve and provide stability for the delivery and precise positioning of a prosthetic heart valve.

Mandatory Criteria

Sterile and single use

Desirable Criteria

Preference shall be given to items that offer:

a. Enhanced visualisation during positioning (e.g. radiopaque markers)

b. Compatibility with a range of anatomical variations (e.g. bicuspid valves, horizontal aorta)

Clinical Attributes

For each Implantable Transcatheter Valve (27.01 & 27.02) offered, Respondents shall advise the following in the Tender Response Worksheet

a. Valve:

i. Treatable native annulus size

ii. Valve diameter (mm)

iii. Deployment mechanism (e.g. Balloon Expanded, Self Expanding)

iv. Intended valve implantation site (e.g. aortic, pulmonary, tricuspid)

v. Frame height in mm

vi. Cell size in mm

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

b. Delivery system:
   i. Compatible Sheath size in French gauge
   ii. Size of delivery catheter in French gauge
   iii. Length of delivery catheter (cm)
   iv. Size of compatible guidewire (inch)
   v. Material of construct

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

For each Transcatheter Valvular Repair System (27.03) offered, Respondents shall advise the following in the Tender Response Worksheet

a. Repairable defect size (range in mm)

For each Transcatheter Valve Dilatation Balloon Catheter (27.04) offered, Respondents shall advise the following in the Tender Response Worksheet

a. Balloon length in mm

b. balloon width in mm,

c. balloon volume (mL)

d. compliant/non-compliant

For each Transcatheter Valve Guidewire (27.05) offered, Respondents shall advise the following in the Tender Response Worksheet

a. Length (cm)

b. Diameter (inch)

c. Stiffness level (flexible, standard)

d. Material of construct

e. Type of coating (hydrophilic, hybrid)

f. Presence of radiopaque markers (Yes/No)

g. Recommended compatible catheter diameter (inches)

For each Implantable Transcatheter Valve (27.01 & 27.02) 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 delivery system, please populate the corresponding ordering part number of the valve and deployment system in the “Additional Information” column

Appendix 1 - Product List

Category Number	Category Name	Subcategory Number	Subcategory Name
1	Percutaneous Sheath Introducers and Introducer Kits	01.01	Percutaneous Sheath Introducer – Radial Access
1	Percutaneous Sheath Introducers and Introducer Kits	01.02	Percutaneous Sheath Introducer – Femoral Access
1	Percutaneous Sheath Introducers and Introducer Kits	01.03	Percutaneous Sheath Introducer, Combination Kits
1	Percutaneous Sheath Introducers and Introducer Kits	01.04	Percutaneous Sheath Introducer, Accessory Items
2	Guidewires for Diagnostic Catheters	02.01	Guidewires for Diagnostic Catheters
3	Diagnostic Catheters and Diagnostic Catheter Kits	03.01	Diagnostic Catheter
3	Diagnostic Catheters and Diagnostic Catheter Kits	03.02	Diagnostic Catheter Kit
4	Right Heart Catheters	04.01	Right Heart Catheters
5	Interventional Catheters	05.01	Angioplasty Guiding Catheter
5	Interventional Catheters	05.02	PCI Microcatheters
5	Interventional Catheters	05.03	Guide Extension Catheters
6	Angioplasty Guidewires	06.01	Angioplasty Guidewire
6	Angioplasty Guidewires	06.02	Angioplasty Guidewire Extension
7	Balloon Angioplasty Dilation Catheters	07.01	Balloon Angioplasty Dilation Catheters, Over the Wire Type
7	Balloon Angioplasty Dilation Catheters	07.02	Balloon Angioplasty Dilation Catheters, Rapid Exchange - Compliant
7	Balloon Angioplasty Dilation Catheters	07.03	Balloon Angioplasty Dilation Catheters, Rapid Exchange - Non Compliant
7	Balloon Angioplasty Dilation Catheters	07.04	Drug-Eluting Balloon Angioplasty Catheters, Over the Wire Type
7	Balloon Angioplasty Dilation Catheters	07.05	Drug-Eluting Balloon Angioplasty Catheters, Rapid Exchange Type
7	Balloon Angioplasty Dilation Catheters	07.06	Cutting Balloon Angioplasty Catheters
7	Balloon Angioplasty Dilation Catheters	07.07	Scoring Balloon Angioplasty Catheters
8	Angioplasty Accessories and Accessory Kits	08.01	Angioplasty Accessories, Guidewire Introducer
8	Angioplasty Accessories and Accessory Kits	08.02	Angioplasty Accessories, Torque Device
8	Angioplasty Accessories and Accessory Kits	08.03	Angioplasty Accessories, Haemostatic Valve
8	Angioplasty Accessories and Accessory Kits	08.04	Angioplasty Accessories, Inflation Device
8	Angioplasty Accessories and Accessory Kits	08.05	Angioplasty Accessory Kit
9	Coronary Stents	09.01	Drug Eluting Coronary Stent
9	Coronary Stents	09.02	Covered Coronary Stent

Category Number	Category Name	Subcategory Number	Subcategory Name
10	Temporary Pacing Catheters	10.01	Temporary Pacing Catheter
10	Temporary Pacing Catheters	10.02	Temporary Pacing Catheter Accessories
11	Thrombus Aspiration Catheters	11.01	Thrombus Aspiration Catheters
12	Transcatheter Occlusion Devices	12.01	Septal Occlusion Device
12	Transcatheter Occlusion Devices	12.02	Patent Ductus Arteriosus Occlusion Device
12	Transcatheter Occlusion Devices	12.03	Left Atrial Appendage Occlusion Device- Transcatheter approach
13	Vessel Closure Devices, Haemostatic Devices and Kits	13.01	Vessel Closure Device
13	Vessel Closure Devices, Haemostatic Devices and Kits	13.02	Haemostatic Device- radial
13	Vessel Closure Devices, Haemostatic Devices and Kits	13.03	Haemostatic Device- femoral
13	Vessel Closure Devices, Haemostatic Devices and Kits	13.04	Haemostatic Device Kits
14	Implantable Pacemakers	14.01	Implantable Pacemaker, Single Chamber Pacemaker
14	Implantable Pacemakers	14.02	Implantable Pacemaker, Dual Chamber Pacemaker
14	Implantable Pacemakers	14.03	Implantable Pacemaker, BiVentricular Pacemaker
14	Implantable Pacemakers	14.04	Implantable Pacemaker, Cardiac Resynchronisation Pacemaker
14	Implantable Pacemakers	14.05	Leadless Pacemaker
14	Implantable Pacemakers	14.06	Pacemaker Leads
14	Implantable Pacemakers	14.07	Implantable Pacemaker Programmers, Accessories and Consumables
15	Implantable Cardioverter Defibrillators	15.01	Implantable Cardioverter Defibrillators, Single Chamber ICD
15	Implantable Cardioverter Defibrillators	15.02	Implantable Cardioverter Defibrillators, Dual Chamber ICD
15	Implantable Cardioverter Defibrillators	15.03	Implantable Cardioverter Defibrillators, Cardiac Resynchronisation ICD
15	Implantable Cardioverter Defibrillators	15.04	Implantable Cardioverter Defibrillator Leads
15	Implantable Cardioverter Defibrillators	15.05	Implantable Cardioverter Defibrillator Programmers, Accessories and Consumables
16	Pacemaker, ICD and Lead Insertion Accessories, Tools and Tool Kits	16.01	Pacemaker/ICD and Lead Insertion, Accessories - Individual
16	Pacemaker, ICD and Lead Insertion Accessories, Tools and Tool Kits	16.02	Pacemaker/ICD and Lead Insertion, Accessories - Kits
16	Pacemaker, ICD and Lead Insertion Accessories, Tools and Tool Kits	16.03	Pacemaker/ICD and Lead Insertion, Tools - Individual

Category Number	Category Name	Subcategory Number	Subcategory Name
16	Pacemaker, ICD and Lead Insertion Accessories, Tools and Tool Kits	16.04	Pacemaker/ICD and Lead Insertion, Tools - Kits
17	Implantable Cardiac Monitors	17.01	Implantable Cardiac Monitors
18	Aortic Valves, Mechanical	18.01	Aortic Valves, Mechanical
19	Aortic Valves, Tissue/Xenograft	19.01	Aortic Valves, Pericardial
19	Aortic Valves, Tissue/Xenograft	19.02	Aortic Valves, Porcine
19	Aortic Valves, Tissue/Xenograft	19.03	Aortic Valves, Sutureless / Rapid Deployment
20	Stentless Xenograft Tissue Valves	20.01	Stentless Xenograft Tissue Valves
21	Mitral Valves, Mechanical	21.01	Mitral Valves, Mechanical
22	Mitral Valves, Tissue / Xenograft	22.01	Mitral Valves, Tissue/Xenograft
23	Annuloplasty Bands / Rings – Mitral	23.01	Rigid or Semi-rigid Rings
23	Annuloplasty Bands / Rings – Mitral	23.02	Flexible Rings or Bands
24	Annuloplasty Bands / Rings - Tricuspid	24.01	Annuloplasty Bands / Rings - Tricuspid
25	Surgical Septal Defect Management Devices	25.01	Surgical ASD & VSD Management Devices
26	Surgical Atrial Fibrillation and Appendage Management Devices	26.01	Left Atrial Appendage Occlusion Device-Surgical Approach
26	Surgical Atrial Fibrillation and Appendage Management Devices	26.02	Cryoablation Therapy Consumables
26	Surgical Atrial Fibrillation and Appendage Management Devices	26.03	Radiofrequency Ablation Therapy Consumables
27	Transcatheter Valve Procedures	27.01	Transcatheter Aortic Valve Implantation
27	Transcatheter Valve Procedures	27.02	Transcatheter Mitral, Tricuspid or Pulmonary Valve Implantation
27	Transcatheter Valve Procedures	27.03	Transcatheter Valvular Repair Systems
27	Transcatheter Valve Procedures	27.04	Transcatheter Valve Dilatation Balloon Catheters
27	Transcatheter Valve Procedures	27.05	Transcatheter Valve Guidewires

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 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.

b. The relevant legislation for HPVITS2026-218 **Cardiac Interventional Products, Prostheses and Heart Valves** may include, but is not limited to:

   i. *Procedure for recalls, product alerts and product corrections (PRAC)*

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

STANDARD NUMBER	STANDARD NUMBER
AS 5369:2023	Reprocessing of reusable medical devices and other devices in health and non-health related facilities
ISO 10555 – 1:2023	Sterile, single use intravascular catheters – General Requirements
ISO 10555 – 2:2023	Sterile, single use intravascular catheters — Part 2: Angiographic catheters
ISO 10555 – 4:2023	Intravascular catheters — Sterile and single use catheters — Part 4: Balloon dilatation catheters
ISO 10555 – 5:2023	Intravascular catheters — Sterile and single use catheters — Part 5. Over- Needle Peripheral Catheters
ISO 10555 – 6:2023	Intravascular Catheters -Sterile and single use catheters — Part 6: Subcutaneous implanted ports
ISO 11070:2018	Sterile Single Use Intravascular Introducers, Dilators and Guidewires
ISO 13485: 2016	A quality management system for the provision of medical devices
ISO 14972	Sterile Obturators for single use with Over Needle Peripheral Intravascular Catheters
ISO 14630:2025	Non-Active Surgical Implants – General Requirements
ISO 14708-1:2014	Implants for Surgery – Active Implantable Devices – General Requirements for Safety, Marking and for Information to be provided by the Manufacturer
ISO 15539- 2003	Cardiovascular implants – Endovascular prostheses
ISO 20697:2018	Sterile drainage catheters and accessory devices for single use
ISO 5840-1:2021 (EN)	Cardiovascular implants — Cardiac valve prostheses — Part 1: General requirements
ISO 5840-2:2021 (EN)	Cardiovascular implants — Cardiac valve prostheses — Part 2: Surgically implanted heart valve substitutes

STANDARD NUMBER	STANDARD NUMBER
ISO 5840-3:2021 (EN)	Cardiovascular implants — Cardiac valve prostheses — Part 3: Heart valve substitutes implanted by transcatheter techniques
ISO/DIS 5910 (EN)	Cardiovascular implants and extracorporeal systems — Cardiac valve repair devices
NSQHS Standards	National Safety and Quality Health Service Standards (second addition), 2021

Current standards and guidelines considering MR safety and MR compatibility for medical implants:

STANDARD NUMBER	STANDARD NUMBER
ASTM F2052-06e1	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
ASTM F2119-07	Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
ASTM F2182-11a	Standard Test Method for Measurement of Radio Frequency Induced Heating On and Near Passive Implants During Magnetic Resonance Imaging
ASTM F2213-06	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
ASTM F2503 - 08	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
EN 14299	Non-Active Surgical Implants- Particular requirements for cardiac and vascular implants. Specific requirements for arterial stent
ISO 25539 - 1	Cardiovascular Implants- Endovascular Devices- Part 1: Endovascular Prostheses
ISO/TS 10974:2018	Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device

Standard requirements against interferences from external electrical and magnetic fields:

STANDARD NUMBER	STANDARD NUMBER
EN 45502-1	Active implantable medical devices. General requirements

Standards for safety and pulse sequences of (MRE) magnetic resonance equipment:

STANDARD NUMBER	STANDARD NUMBER
IEC 60601-2-33 ed3.0	Medical electrical equipment - Part 2-33: 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

Test methods for radiopacity:

STANDARD NUMBER	STANDARD NUMBER
ASTM F640-07	Standard Test Methods for Determining Radiopacity for Medical Use
DIN 13273-7 Catheters for medical use. Part 7	Determination of the x-ray attenuation of catheters. Requirements and testing.

Legislation

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

i. NHMRC (2019), *Australian Guidelines for the Prevention and Control of Infection in Healthcare, Commonwealth of Australia*

ii. *Procedure for Recalls, Product Alerts and Product Corrections (PRAC).* Therapeutic Goods Administration (2011), *Australian Regulatory Guidelines for Medical Devices*