Invitation to Supply

Part 5

Statement of Requirements

ITS Number:	HPVITS2019-045
ITS Name:	Interventional Cardiology
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HEALTH PURCHASING VICTORIA

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A Introduction

1 Purpose

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

(i) detail the scope and range of products sought under this Invitation to Supply (ITS)
(ii) specify the requirements that Respondents and / or their offered products must meet (these requirements also form part of any resulting Agreement between HPV and any successful Respondent)

2 Scope

a. HPV is seeking responses for Interventional Cardiology products for use in Participating Health Services. The envisaged Term of the Agreement is two (2) years plus two optional two year extension periods (2+2+2).

b. The scope of this ITS includes:

(i) Supply of Interventional cardiology products
(ii) Goods consignment service
(iii) Education and training
(iv) Company representative clinical attendance

c. Indicative volumes are listed **in part 6, TRW**

3 Product Categories

a. The categories of Interventional Cardiology products required under this ITS 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	Angioplasty Guiding Catheters
6	Angioplasty Guidewires
7	Balloon Angioplasty Dilation Catheters
8	Angioplasty Accessories and Accessory Kits

Category Number	Category Name
9	Coronary Stents
10	Temporary Pacing Equipment
11	Thrombus Aspiration Catheters
12	Occlusion Devices
13	Vessel Closure Devices, Haemostatic Devices and Kits
14	Implantable Pacemakers
15	Pacemaker Leads
16	Implantable Cardioverter Defibrillators
17	Implantable Cardioverter Defibrillator Leads
18	Pacemaker, ICD and Lead Insertion Accessories, Tools and Tool Kits
19	Remote Patient Monitoring
20	Implantable Loop Recorders
21	Electrophysiology - Standard Diagnostic Catheters
22	Electrophysiology – Guide Sheaths
23	Electrophysiology – Standard Ablation Catheters
24	Electrophysiology – Advanced Diagnostic Catheters
25	Electrophysiology – Advanced Ablation Catheters
26	Electrophysiology – Accessories
27	Transcatheter Valve Implantation

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

c. HPV reserves the right not to consider any additional products offered.

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

4 Product Conditions

4.1 Clinical Trials

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

4.2 Product Duplication

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

(i) HPVC2016-061 Interventional Radiology

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

4.3 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 HPV category and subcategory number.

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

HPV may not consider unlabelled submissions.

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

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

(i) Not labelled as per Part 5 A 4.3 d above; or
(ii) Is incomplete as to Part 5 A 4.3 c.

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

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

5 Definitions

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

TERM	DEFINITION
Agreement	A contract entered into by HPV and a Respondent for the provision of Interventional Cardiology products. Comprises the General Conditions, and all Schedules, Annexures of any kind and any attachments.
ARTG	Australian Register of Therapeutic Goods under the control of TGA
Business day	Any weekday not gazetted as a public holiday in Melbourne, Victoria.
may	Indicates an optional element; it is at the Respondent's discretion to either meet or not meet this element, and failure to meet this element will not have an impact during evaluation.
must	Indicates a mandatory requirement; failure to meet this requirement will result in the submission being eliminated from further consideration.
Participating Health Services	Public Hospitals and other Health or Related Services, as those terms are defined in Section 3 of the Health Services Act 1988 (Vic), that are described in **Appendix 4 of Part 8**.
should	Indicates a highly desirable element; unless justifiable reason exists, not meeting this element may impact evaluation.
SLA	Service Level Agreement
TGA	Therapeutic Goods Administration
will	Indicates an anticipated future condition or requirement to be met.

B Service, delivery, and support

1 Delivery

a. Interventional Cardiology products will be delivered to the location(s) specified by Participating Health Services within the shortest possible timeframe; however, this must not exceed 24 hours from receipt of order unless otherwise agreed with the Participating Health Service.

b. All deliveries are bound as per the Draft Agreement, Part 7 – 9 Acceptance and Rejection of Deliverables.

2 Urgent Deliveries

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

b. The Respondent must 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 12 hours from receipt of order.

3 Consignment Stock, Loan Kits and Instrument Sets

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

4 Consignment Stock

a. 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.

b. 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.

c. Where products are provided on consignment:

- managing stock levels must be undertaken by the successful Respondent, unless negotiated otherwise with the Participating Health Service in a Service Level Agreement
- all queries relating to consignment stock must be resolved within three months of product use
- invoices must be received within fourteen days of product use.

d. The successful Respondent's nominated Representative(s) (as per clause **Error! Reference source not found.**) will be responsible for:

- performing stocktake of consignment stock on a regular basis (as agreed with the Participating Health Service), and replacing used stock
- checking the expiry date of consigned stock, and replacing any stock that is out of date at no cost

e. 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.

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

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

5 Loan Kits and Instrument Trays

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

b. Where loan kits and instrument sets to support the implantation of offered devices are provided, loan kits must be:

(i) provided to health services in containers that are maintained in a clean and reasonable condition.
(ii) clearly named and labelled
(iii) readily available and delivered at least 24 hours prior to procedure start.
(iv) with sufficient notification, free into store
(v) supported by:

- a clear statement of all conditions associated with the provision of loan kits
- a clear process for the return of loan kits including any costs that are incurred for used or unused kits.
- detailed instructions for the reprocessing, care and maintenance of the contents at hospital or health service level
- customer service contact details
- clear ordering instructions for the acquisition of kits during and out of normal business hours.

c. Preference is for responses where loan kits and consignment stock are the same price.

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

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

6 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.

7 Training and Support

a. Successful Respondent may be required to provide training and/or training materials to facilitate the introduction of their Interventional Cardiology products to clinicians in their operating environment. Such training and/or materials must be available to Participating Health Services upon request.

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

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

d. 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.

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

8 Company Representative Attendance

a. Respondent should advise the availability of company representative to provide industry clinical support:

(i) for Interventional Cardiology procedures
(ii) out of normal business hours including weekends

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

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

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

9 Warranty

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

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

9.2 Repairs and Replacements under Warranty

a. The repair or replacement of any Interventional Cardiology products under warranty will be at no cost to Participating Health Services.

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

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

d. If requested by the Participating Health Services, successful Respondent must provide a suitable replacement item, until the repaired item is returned. This will be done at no cost to Participating Health Services.

e. Where a device or lead has to be replaced due to unexpected failure or due to a product recall that a similar device will be provided free of charge

9.3 Specific Warranty Requirements

a. In addition to section 7 and 7.2, Respondents should include specific warranties within the submission for products within the following categories:

(i) 10 - Temporary Pacing Equipment Warranty
(ii) 16 - Implantable Pacemakers Warranty
(iii) 17 - Pacemaker Leads Warranty
(iv) 18 - Implantable Cardioverter Defibrillators Warranty
(v) 19 - Implantable Cardioverter Defibrillator Leads Warranty
(vi) 21 - Remote Patient Monitoring Warranty
(vii) 22 - Implantable Loop Recorders Warranty

10 Key Performance Indicators

a. Refer to Part 7 Draft Agreement Supply Schedule, Item 17 - Key Performance Indicators.

11 Reporting

a. Refer to Draft agreement - reporting requirements.

12 Service Level Agreement

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

(i) the provision of products on consignment (refer to section B3 Consignment Stock)
(ii) requirements for stock management and rotation
(iii) arrangements for ordering, invoicing and delivery
(iv) clinical support, including clinical attendance requirements, education and training
(v) communication arrangements for product recalls and safety alerts (refer to C3 Recall Health).

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

c. HPV 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 HPV within 1 week of being finalised.

C General Requirements

1 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 0

b. Compliance Re for a list of the minimum Compliance Requirements.

c. 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. HPV recommends the use of products in accordance to TGA registered indications.

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

2 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 Order No. 37: General Requirements for Labels for Therapeutic Goods.

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

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

(i) whether the product is sterile;
(ii) whether the product is MRI compatible (implantable products);
(iii) whether the product (or packaging) contains latex or is latex-free; and
(iv) tracking labels.

3 Recall Process

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

b. Respondent should provide information in this ITS about their product recall / safety alert process. This should include:

(i) the process for identifying implanted devices within an individual Participating Health Service;
(ii) the process for notifying Participating Health Service and their clinicians;
(iii) technical support to manage reprogramming associated with explanation of affected devices and re-implantation with new devices;
(iv) responsibility for cost of devices and cardiac catheterisation laboratory or operating suite time;
(v) any supporting documentation including patient information proforma that could be used in this situation; and
(vi) how to manage removal of recalled stock, not implanted.

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

d. Class 1 recalls (as defined by the TGA's *Uniform Recall Procedure for Therapeutic Goods*) must also meet the requirements under section Part 5 - B8c

e. Warranty, where applicable.

4 Reference Sites

a. The Respondent is required to provide Australian clinical reference letters on Private or Public Hospital letter-head from hospitals that are purchasing or have trialled and evaluated each class or category of product offered in this submission unless the product offered is currently on the HPV contract HPVC2015-045 Interventional Cardiology. For the purpose of this tender, references will only be accepted from:

(i) Interventional Cardiologists for categories 1-15 and 28
(ii) Electrophysiologists and/or Device Follow-up Physicians for categories 16-27.

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

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

5 Additional information

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

(i) Details of Help Desk support, including the toll-free number, the geographical area covered by the support, and the hours available;
(ii) Copies of any proforma documentation, including order forms;
(iii) Patient Education Material including:

- Product information/booklets.
- Patient cards.

6 Infection Control

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

b. Upon request by Participating Health Services, successful Respondents must provide cleaning details for all reusable products. Recommended cleaning products must be available for purchase within Australia.

D Product Specifications

1 Substances of Concern

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

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

2 MRI Compatibility

a. Preference will be given to products that have an MRI compatibility up to 3.0 Tesla (according to TGA approval)

3 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).

Category 1 - Percutaneous Sheath Introducers and Introducer Kits

a. 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.

1.01 Product Description

a. For each Radial or Femoral Percutaneous Sheath Introducer or Introducer Kit offered, the Respondent should advise the following information in the Product Description on the Tender Response Worksheet:

1. Brand name
2. Recommended insertion site (e.g. radial, femoral)
3. Size in French Gauge
4. Length in centimetres
5. Haemostatic (where applicable)
6. Number of side arms (where applicable)
7. Tip configuration (e.g. tip profile in inches)
8. Size of maximum compatible guidewire in inches
9. Contents of Introducer Kits (where applicable)
10. Where applicable, components of Introducer Kits that are available individually (e.g. vessel dilators, obturators).
11. Capability to provide consignment

1.02 Respondent Note:

Respondent is advised that this tender excludes Sheath Introducer Kits designed for insertion of Haemodynamic Monitoring Catheters in the Critical Care area. These items are incorporated in the HPV Monitoring Products Contract **HPVC2011-021**.

Category 2 - Guidewires for Diagnostic Catheters

a. 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.

2.01 Product Description

b. For each Guidewire offered, the Respondent should advise the following information in the Product Description on the Tender Response Worksheet:

1. Brand name

2. Guidewire dimensions:

    - Diameter in inches
    - Length in centimetres

3. Tip configuration (e.g. straight, J, angled)
    - Radius of J in millimetres (where applicable)
    - Tip length in centimetres

(ii) Steerable (where applicable)

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

(iv) Type of coating (e.g. hydrophilic)

(v) Capability to provide consignment

Category 3 - Diagnostic Catheters and Diagnostic Catheter Kits

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

3.01 Product Description

a. For each Diagnostic Catheter and Diagnostic Catheter Kit offered, the Respondent should advise the following information in the Product Description on the Tender Response Worksheet:

1. Brand name
2. Recommended insertion site (e.g. radial, femoral)
3. Catheter dimensions:
    - Size in French Gauge
    - Length in centimetres
    - Internal diameter in millimetres
    - External Diameter in millimetres
4. Tip configuration (e.g. JL4)
5. Pigtail (where applicable):
    - Straight or
    - Angle in degrees (e.g. 145°)
6. Maximum PSI
7. Material (e.g. Polyurethane, Nylon)
8. Contents of kits (where applicable)(e.g. single, multiple, three pack)
9. Where applicable, components of kits that are available individually (e.g. catheters, guidewire, sheath introducer)
10. Capability to provide consignment

b. For each Diagnostic Catheter or Diagnostic Catheter Kit offered, Respondent should advise the flow rate in millilitres per second.

Category 4 - Right Heart Catheters

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

4.01 Product Description

a. For each Right Heart Catheter offered, the Respondent should advise the following information in the Product Description on the Tender Response Worksheet:

1. Brand name
2. Size in French Gauge
3. Catheter length in centimetres
4. Tip configuration (e.g. multi-purpose A catheter, balloon tip)
5. Number of lumens
6. Number of ports
7. Side holes (where applicable)
8. Capability for cardiac output measurement (where applicable)
9. Size of maximum compatible guidewire in inches
10. Injection rates in cc/s (where applicable)
11. Maximum PSI (where applicable)
12. Capability to provide consignment

4.2 Respondent' Note:

b. Respondent is advised that this tender excludes Pulmonary Artery Catheters designed for Haemodynamic Monitoring in the Critical Care area. These items are incorporated in the HPV Monitoring Products Contract **HPVC2011-021**.

Category 5 - Angioplasty Guiding Catheters

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

5.01 Product Description

a. For each Angioplasty Guiding Catheter offered, the Respondent should advise the following information in the Product Description on the Tender Response Worksheet:

1. Brand name
2. Catheter dimensions:
    - Size in French Gauge
    - Length in centimetres
    - Inner diameter in millimetres
    - Outer diameter in millimetres
3. Tip configuration (e.g. JL4, XB3.5)
4. Type of material e.g. polymer
5. Recommended access site (e.g. radial, femoral)
6. Side holes (where applicable)
7. Capability to provide consignment

Category 6 - Angioplasty Guidewires

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

6.01 Product Description:

a. For each Angioplasty Guidewire offered, the Respondent should advise the following information in the Product Description on the Tender Response Worksheet:

1. Brand name
2. Guidewire dimensions:
    - Length in centimetres
    - Diameter in inches
3. Tip:
    - Configuration (e.g. tapered, rounded)
    - Length of radiopaque segment in centimetres
    - Polymer (where applicable)
    - Stiffness (e.g. soft, intermediate)
    - Weight (where applicable)(e.g. in milligrams or grams)
    - Shaft support level (e.g. light, moderate)
    - Type of coating (where applicable)(e.g. hydrophilic)
4. Guidewire extension (where applicable)
    - Length in centimetres
5. Capability to provide consignment

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

7.01 Product Description

a. For each Balloon Angioplasty Dilation Catheter offered, the Respondent should advise the following information in the Product Description on the Tender Response Worksheet:

1. Brand name
2. Shaft:
    - Over the Wire or Rapid Exchange
    - Diameter in millimetres
    - Length in centimetres
3. Balloon:
    - Diameter in millimetres
    - Length in millimetres
    - Number of radiopaque markers
    - Compliance (where applicable) (e.g. semi-compliant, non-compliant)
4. Tip profile
5. Capability to provide consignment

Category 8 - Angioplasty Accessories and Accessory Kits

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

b. Angioplasty Accessories may be offered individually or in kit form.

8.01 Product Description

a. For each Accessory or Accessory Kit offered, the Respondent should advise the following information in the Product Description on the Tender Response Worksheet:

1. Brand name
2. Type of accessory (e.g. torque device, haemostatic valve, inflation device, introducer needle)
3. Haemostatic devices:
    - Rotating or fixed design
    - Maximum PSI
4. Contents of kit (where applicable, Respondent must provide detail content and individual pricing information of each component that comprise the kit).
5. Capability to provide consignment

Category 9 - Coronary Stents

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

9.01 Product Description

b. For each Bare-metal, Drug Eluting and Covered Coronary Stent offered, the Respondent should advise the following information in the Product Description on the Tender Response Worksheet:

1. Brand name
2. Generic name of the drug eluted (e.g. Everolimus) (where applicable)
3. Polymer type (e.g. poly n-butyl methacrylate (PBMA)) (where applicable)
4. Metal alloy (e.g. cobalt chromium)
5. Diameter in millimetres
6. Length in millimetres
7. Stent design (e.g. open, slotted)
8. Strut thickness in micrometres (µm)
9. Number of links (where applicable)
10. Maximum cell size in millimetres
11. Maximum expanded internal diameter in millimetres
12. Balloon overhang in millimetres
13. Position of stent in relation to balloon markers (e.g. in millimetres, mid marker, within marker)
14. Crossing profile
15. Duration of drug elution (where applicable)
16. Coating material (where applicable)
17. Capability to provide consignment

9.02 Additional Information

a. Successful Respondents should be able to provide research papers, data and materials safety data sheets to support the effective and efficient use of Bare-metal, Drug Eluting and Covered Coronary Stents for all upon request Participating Health Services. This information may be in hard copy or electronic form.

Category 10 - Temporary Pacing Equipment

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

b. A suitable range of Temporary Pulse Generator is required to meet clinical needs.

10.01 Product Description

a. For each Temporary Pacing Catheter offered, the Respondent should advise the following information in the Product Description on the Tender Response Worksheet:

1. Brand name
2. Atrial or ventricular pacing
3. Catheter dimensions:
    - Size in French Gauge
    - Diameter in millimetres
    - Length in centimetres
    - Curve or straight
4. Balloon (where applicable)
5. Electrode configuration (e.g. bipolar)
6. Capability to provide consignment

b. For each Temporary Pacing Pulse Generator offered, Respondent should advise the following information in the Product Description on the Tender Response Worksheet:

1. Brand name
2. Model number
3. Single or dual
4. Programmable rate, output and sensitivity
5. Battery type
6. Battery alarm
7. Protective screen or lockable cover

8. Breaching compatibility cable

9. Capability to provide consignment

c. For each Temporary Pacing Catheter Accessory offered, Respondent should advise the following information in the Product Description on the Tender Response Worksheet:

1. Contamination shields

2. Introducer sheaths

3. Adaptor pins

4. Capability to provide consignment

10.02 Warranty

a. For each Temporary Pulse Generator offered, Respondent should advise the period and extent of the warranty, including all terms and conditions. This may include details about the costs and conditions associated with the potential requirement to replace a generator.

Category 11 - Thrombus Aspiration Catheters

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

11.01 Product Description

a. For each Thrombus Aspiration Catheter offered, Respondent should advise the following information in the Product Description on the Tender Response Worksheet:

1. Brand name

2. Catheter dimensions:

   a. Size in French Gauge
   b. Catheter length in centimetres
   c. Internal diameter of Catheter with which the device can be used in inches

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

4. Capability to provide consignment

Category 12 - Occlusion Devices

a. A full range of Occlusion Devices is required to meet clinical needs.

b. Occlusion Devices are to be offered individually and in kit form.

12.02 Product Description

a. For each Occlusion Device and Occlusion Device Kit offered the Respondent should advise the following information in the Product Description on the Tender Response Worksheet:

1. Brand name
2. Indication for use
3. Material
4. Delivery system
5. Size of delivery system
6. Sizing of device
7. Balloon: (Where applicable)
    - Diameter in millimetres
    - Length in millimetres
    - Number of radiopaque markers
8. Contents of kit (where applicable, Respondent must provide detail of items that comprises the kit).
9. Capability to provide consignment or loan stock

Category 13 - Vessel Closure Devices, Haemostatic Devices and Kits

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

13.02 Product Description

a. For each Vessel Closure or Haemostatic Device or Kit offered, the Respondent should advise the following information in the Product Description on the Tender Response Worksheet:

1. Brand name

2. Vessel Closure device:

    a. Sterile (where applicable)
    b. Closure Mechanism (e.g. clip, plug)
    c. Number of lumens
    d. Number of sutures (where applicable)
    e. Suture material (where applicable)
    f. Size in French Gauge
    g. Intra or extra lumen
    h. Size of maximum compatible guidewire
    i. Minimum shelf life in months

3. Haemostatic device:

    a. Compression
    b. Sterile (where applicable)
    c. Size (e.g. small, large)
    d. Recommended site (e.g. radial, femoral)
    e. Recommended pressure range (e.g.150mmHg – 200mmHg)
    f. Pressure indicator (where applicable)
    g. Reusable accessories (where applicable) (e.g. arch, C-clamp)

4. Contents of kit (where applicable)

5. Capability to provide consignment

b. For each Vessel Closure Device offered, Respondent should advise the recommended time before re-puncture and time to ambulation.

13.03 Additional Information

a. Successful Respondent should able to provide research papers, data and materials safety data sheets upon requests from the Participating Health Services to support the effective and efficient use of Vessel Closure Devices, Haemostatic Devices and Kits for all Participating health services. This information may be in hard copy or electronic form.

Category 14 - Implantable Pacemakers

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

14.02 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):

1. All requirements for access and insertion including but not limited to lead introducer kits, stylets, locators, balloon tip catheters and guidewires
2. All components for system connectivity including but not limited to end caps, adaptors and plugs
3. All tools including but not limited to screw drivers, wrenches, rotation tools
4. Pacemaker programmers, including consumables.

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

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

1. Programmable rate, output, rate response, sensitivity and hysteresis
2. Automatic mode switching
3. Rate adaptive pacing

4. Automatic ventricular threshold testing and output setting

5. Impedance monitoring

6. Ventricular pacing minimisation

7. Electrogram storage capacity including high rate atrial and ventricular events.

g. Implantable Pacemakers should be:

1. Multi-functional and multi programmable

2. Capable of both bipolar and unipolar stimulation and sensing.

h. All Implantable Pacemaker Leads offered as part of a system offer should meet the specification for Category 15 - : Pacemaker Leads.

i. All Additional Components for Pacemakers offered as part of a system offer should meet the specification for Category 18 - : Pacemaker, ICD and Lead Insertion Accessories, Tools and Toolkits.

14.03 Pacemaker Programmers, Accessories and Consumables

a. Pacemaker Programmers, Accessories and Consumables include, but are not limited to:

1. Printer paper

2. Software and hardware upgrades

3. All support, maintenance and repairs.

b. Respondent should provide the ordering details for obtaining these items.

c. 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.

14.04 Product Description

a. For each Implantable Pacemaker offered, Respondent should advise the following information in the Product Description on the Tender Response Worksheet:

1. Brand name

2. Model number

3. Single, dual chamber or BiVentricular

4. Cardiac Resynchronisation (where applicable)

5. Connector (e.g. 3.2 mm LP BI, IS-1, IS-4 or UNI)

6. MRI compatibility (according to TGA approval)

7. Level of MRI compatibility (e.g. partial / exclusion zones). If partial or exclusion zones are stated, Respondent is required to explain the definition of partial or exclusion zones.

8. Electrogram capacity (where applicable)

9. Pulse generator:

    a. Dimensions in centimetres
    b. Volume in millilitres
    c. Weight in grams

10. Battery:

    a. Type (e.g. manganese dioxide)
    b. Stated battery capacity in ampere hours

11. Remote monitoring capability (where applicable)

12. Wireless capability (where applicable)

13. Additional features, where applicable (e.g. overdrive atrial and ventricular pacing, capability for arrhythmia termination)

14. Capability to provide consignment

b. For each Implantable Pacemaker offered, Respondent should provide the following information in the Tender Response Worksheet:

1. The availability and cost of replacement pulse generators to connect with legacy non IS1 leads (e.g. 3.2mm long pin)

2. Whether real time electrograms recorded from atrial and ventricular leads are readily displayable on the external programmer screen

3. The response of the device to:

    a. Electrical interference (e.g. surgical diathermy)
    b. Magnet application

4. Anticipated battery life with pacing at 100% on all chambers, electrograms on and at an output of 2.5V/0.5millisecs.

14.05 Respondent' Note

a. Respondent is advised preference will be given to Implantable Pacemakers that have the greatest anticipated battery life.

14.06 Warranty

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

1. Specific reference to battery life and pacemaker settings

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

3. 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.

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

5. Preference will be given to Respondent that will provide a pro rata discount on a new pacemaker where an implanted device does not achieve the stated battery life.

Category 15 - Pacemaker Leads

a. A range of Pacemaker Leads and all requirements for successful change of a Pacemaker Lead is required to meet clinical needs.

b. Requirements for the successful change of Implantable Pacemaker Leads should include at a minimum:

1. Pacemaker leads
2. All components for system connectivity, including but not limited to end caps, adaptors and plugs
3. All requirements for access and successful insertion, including but not limited to lead introducer kits, stylets and locators
4. All tools, including but not limited to, screw drivers, wrenches, rotation tools
5. Lead repair kits (if applicable)
6. Capability to provide consignment

c. Pacemaker leads must be packaged in a sterile peel pack in a manner that facilitates the removal onto the sterile field while minimising the risk of contamination.

d. All Additional Components for Pacemakers Leads offered must meet the specification for Category 18: Pacemaker, ICD and Lead Insertion Accessories, Tools and Toolkits.

15.02 Product Description

a. For each Pacemaker Lead offered, Respondent should advise the following information in the Product Description on the Tender Response Worksheet:

1. Brand name
2. Lead connector standard (e.g. IS1, IS4)
3. Placement (e.g. right atrial, left and right ventricular, epicardial)
4. MRI compatibility (according to TGA approval)
5. Level of MRI compatibility (e.g. partial / exclusion zones). If partial or exclusion zones are stated, Respondent is required to explain the definition of partial or exclusion zones.
6. Type of lead (e.g. bipolar, unipolar, quadripolar)
7. External diameter in millimetres

8. Lead length in centimetres
9. Introducer size in French Gauge
10. Tip shape (e.g. straight, J shape)
11. Type of fixation (e.g. active, passive)
12. Insulation material (e.g. silicone or polyurethane)
13. T – R spacing in millimetres
14. Steroid eluting (where applicable).
15. Capability to provide consignment

15.03 Additional Information

a. For each Pacemaker Lead offered, Respondent should advise the lead performance/survival information.

15.04 Warranty

a. For each Pacemaker Lead offered, Respondent should advise the period and extent of the warranty, including all terms and conditions. This may include details about the costs and conditions associated with the potential requirement to replace a Lead.

Category 16 - Implantable Cardioverter Defibrillators

a. 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.

16.02 System Offer

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

b. 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):

1. All requirements for access and successful insertion including but not limited to lead introducer kits, stylets, locators, balloon tip catheters and guidewires
2. All components for system connectivity including but not limited to end caps, adaptors and plugs
3. All tools including but not limited to screw drivers, wrenches, rotation tools
4. Lead repair kits (if applicable)
5. ICD programmers, including consumables.

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

1. System 1 should include the remaining requirements for successful insertion of an Implantable Cardioverter Defibrillator and lead(s).
2. System 2 should include all requirements for the successful change of an Implantable Cardioverter Defibrillator.

16.03 Component Price

a. For the purpose of this tender the component price refers to the price for a single component (e.g. ICD, ICD lead, Introducer Sheath) that is available individually.

b. ICDs should incorporate the following features:

1. Overdrive pacing for ventricular tachyarrhythmia
2. Multizone detection of ventricular tachyarrhythmia

3. High output shock ≥35 joules delivered

4. Features to minimise ventricular pacing (where applicable)

5. Electrogram storage.

c. Preference may be given to Respondent who can offer ICD automatic ventricular threshold testing and output setting.

d. All ICD Leads offered as part of System 1 should meet the specification for Category 17: Implantable Cardioverter Defibrillator Leads.

e. All Additional Components for ICD's offered as part of a system should meet the specification for Category 18: Pacemaker, ICD and Lead Insertion Accessories, Tools and Toolkits.

16.04 Warranty

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

1. Specific reference to battery life and ICD settings

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

3. 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.

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

5. Preference will be given to Respondent that will provide a pro rata discount on a new ICD where an implanted device does not achieve the stated battery life.

16.05 ICD Programmers, Accessories and Consumables

a. ICD Programmers, Accessories and Consumables include, but are not limited to:

1. printer paper

2. software and hardware upgrades

3. all support, maintenance and repairs

b. Respondent should provide the ordering details for obtaining these items.

c. 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.

16.06 Product Description

a. For each ICD offered, Respondent should advise the following information in the Product Description on the Tender Response Worksheet:

1. Brand name
2. Model number
3. MRI compatibility (according to TGA approval)
4. Level of MRI compatibility (e.g. partial / exclusion zones). If partial / exclusion zones are stated, Respondent is required to explain the definition of partial / exclusion zones.
5. Dimensions in millimetres
6. Weight in grams
7. Volume in cubic centimetres
8. Quad, Single or dual chamber
9. Cardiac Resynchronisation (where applicable)
10. Connector (e.g. 3.2 mm DF1, DF4, LP BI, IS1, IS4, UNI)
11. Electrogram capacity in minutes of ECG's
12. Remote monitoring capability (where applicable)
13. Wireless capability (where applicable)
14. Features to minimise ventricular pacing (where applicable) (e.g. MVP)
15. Battery type
16. Battery life in Amp hours based on the following measures:
    a. Single chamber at <1% pacing & 2 shocks per year
    b. Dual 50% pacing in each lead & 2 shocks per year
    c. CRT 100% pacing on 2 ventricular leads & 2 shocks per year
17. Additional features, where applicable (e.g. overdrive atrial and ventricular pacing, capability for arrhythmia termination)
18. Capability to provide consignment

Category 17 - Implantable Cardioverter Defibrillator Leads

a. A range of DF1 and DF4 ICD Leads and all requirements for successfully inserting or changing an ICD Lead is required to meet clinical needs.

b. Requirements for the successful insertion or change of ICD Leads should include at a minimum:

1. all components for system connectivity, including but not limited to end caps, adaptors and plugs
2. all requirements for access and insertion, including but not limited to lead introducer kits, stylets and locators
3. all tools, including but not limited to, screw drivers, wrenches, rotation tools
4. lead repair kits (if applicable).

c. ICD leads should be packaged in a sterile peel pack in a manner that facilitates the removal onto the sterile field while minimising the risk of contamination.

17.02 Product Description

a. For each ICD Lead offered, the Respondent should advise the following information in the Product Description on the Tender Response Worksheet:

1. Brand name
2. Type of lead (e.g. unipolar or bipolar)
3. MRI compatibility (according to TGA approval)
4. Level of MRI compatibility (e.g. partial / exclusion zones). If partial or exclusion zones are stated, Respondent is required to explain the definition of partial or exclusion zones.
5. Lead length in centimetres
6. External diameter in millimetres
7. Introducer size in French Gauge
8. Type of fixation (e.g. active or passive)
9. Terminal pin configuration (e.g. IS1/DF1, IS4/DF4)
10. Insulation material (e.g. silicone, polyurethane)
11. Number of coils

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

12. Steroid eluting (where applicable)

13. Capability to provide consignment

b. For each ICD Lead offered, Respondent should advise:

1. The anticipated life, including the conditions under which this estimation is determined

2. Lead performance/survival data.

c. All Additional Components for ICD Leads offered should meet the specification for Category 18: Pacemaker, ICD and Lead Insertion Accessories, Tools and Toolkits.

17.03 Warranty

a. For each ICD Lead offered, Respondent should advise the period and extent of the warranty, including all terms and conditions. This may include details about the costs and conditions associated with the potential requirement to replace a Lead.

Category 18 - Pacemaker, ICD and Lead Insertion Accessories, Tools and Tool Kits

a. 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.

1. The range should include, but is not limited to:
2. Lead introducer kits, stylets, locators, balloon tip catheters and guidewires
3. Lead accessories including end caps, adaptors, plugs
4. Lead insertion tools including screw drivers, wrenches and rotation tools
5. Lead repair kits (if applicable).

b. Pacemaker, ICD and Lead Insertion Accessories, Tools and Tool Kits should be packaged in a sterile peel pack in a manner that facilitates the removal onto the sterile field while minimising the risk of contamination.

18.02 Product Description

a. For each product offered, Respondent should provide the following information in the Product Description on the Tender Response Worksheet:

1. Brand name
2. Type of accessory or tool (e.g. stylet, locator, screw driver, repair kit)
3. Where applicable, size (e.g. French Gauge)
4. Length in centimetres
5. Mode of removal (where applicable) (e.g. peel away, cut away)
6. Contents of kit (where applicable)
7. Capability to provide consignment

Category 19 - Remote Patient Monitoring

a. A range of systems for the remote monitoring of Implantable Pacemakers, Cardioverter Defibrillators and Loop Recorders is required.

19.02 Product Description

a. For each Remote Patient Monitoring system offered, the Respondent should provide the following information in the Product Description on the Tender Response Worksheet:

1. Brand
2. For use with an ICD, Implantable Pacemaker or Implantable Loop Recorder
3. Method of telecommunication (e.g. cardiomessenger telemetry)
4. Wireless (where applicable)
5. Initial one-off setup cost (per patient)
6. Ongoing management cost (per annum)
7. Capability to provide consignment

b. For each Remote Patient Monitoring system offered, Respondent should advise the model/s of Implantable Pacemaker, ICD or Implantable Loop Recorder with which the system is compatible.

19.03 Warranty

a. For each Remote Patient Monitoring system offered, Respondent should advise:

1. The period and extent of the warranty, including all terms and conditions
2. Details of the ongoing support provided, including all terms and conditions
3. Details of the service plan, including all terms and conditions.

Category 20 - Implantable Loop Recorders

a. A range of Implantable Loop Recorders is required to meet clinical needs.

20.02 Product Description

a. For each Implantable Loop Recorder offered the Respondent should provide the following information in the Product Description on the Tender Response Worksheet:

1. Brand name
2. Model
3. Size in cubic centimetres
4. Dimensions in centimetres
5. Longevity (e.g. 3 years)
6. Electrogram storage capability (where applicable)
7. Atrial and ventricular monitoring (where applicable)
8. Method of activation (e.g. patient, auto)
9. Mode of implantation
10. Wireless capability (where applicable)
11. Capability for home monitoring (where applicable)
12. Accessories (where applicable) (e.g. remote device)
13. Capability to provide consignment

20.03 Warranty

a. For each Implantable Loop Recorder offered, Respondent should advise the period and extent of the warranty, including all terms and conditions.

Category 21 - Electrophysiology - Standard Diagnostic Catheters

a. A full range of Standard Diagnostic Catheters is required to meet clinical needs.

21.02 Product Description

a. For each Standard Diagnostic Catheter offered, Respondent should advise the following information in the Product Description on the Tender Response Worksheet:

1. Brand name
2. Catheter dimensions:
    a. Size in French Gauge
    b. Length in centimetres
    c. Internal diameter in millimetres
    d. External Diameter in millimetres
    e. Curve Shape
    f. Curve Radius in millimetres
    g. Tip configuration (e.g. JSN)
    h. Reach in millimetres
3. Fixed or steerable
4. Number of electrodes
5. Electrode Spacing
6. Material (e.g. Polyurethane, Nylon)
7. Capability to provide consignment

Category 22 - Electrophysiology – Guide Sheaths

a. A full range of Guide Sheaths is required to meet clinical needs.

22.02 Product Description

a. For each Sheath offered, the Respondent should advise the following information in the Product Description on the Tender Response Worksheet:

1. Brand name
2. Diameter in French Gauge
    a. Internal
    b. External
3. Length in centimetres
4. Fixed or steerable
5. Shape (e.g. SRO, SL1, SL3)
6. Capability to provide consignment

Category 23 - Electrophysiology – Standard Ablation Catheters

a. A full range of Standard Radiofrequency Ablation Catheters is required to meet clinical needs.

23.02 Product Description

a. For each Standard Ablation Catheter offered, the Respondent should advise the following information in the Product Description on the Tender Response Worksheet:

1. Brand name

2. Catheter dimensions:

   a. Size in French Gauge
   b. Length in centimetres
   c. Shaft Diameter in millimetres
   d. Deflection (e.g. unidirectional, bidirectional)
   e. Curve Shape (e.g. D, F, J, small, large)
   f. Curve Radius in millimetres
   g. Reach in millimetres
   h. Tip electrode size in millimetres
   i. Ring electrode size in millimetres

   Steering mechanism (unidirectional or bidirectional)

3. Tip electrode type (Irrigated or Non-irrigated)

4. Number of irrigated holes (where applicable)

5. Number of electrodes

6. Electrode spacing

7. Electrode material (e.g. Gold)

8. PSI range (where applicable)

9. Material (e.g. Polyurethane, Nylon)

10. Radiofrequency generator compatibilities (e.g. Stockert, Ampere)

11. Connector cables compatibility (on generator)

12. Capability to provide consignment

Category 24 - Electrophysiology – Advanced Diagnostic Catheters

a. A full range of Advanced Diagnostic Catheters is required to meet clinical needs in elctroanatomical mapping procedures.

24.02 Product Description

a. For each Advanced Diagnostic Catheter offered, the Respondent should advise the following information in the Product Description on the Tender Response Worksheet:

1. Brand name
2. Catheter dimensions:
    a. Size in French Gauge
    b. Length in centimetres
    c. Deflection (e.g. unidirectional, bidirectional)
    d. Curve shape
    e. Reach in millimetres
    f. Tip electrode size in millimetres
3. Irrigated or Non-irrigated
4. Number of irrigated holes (where applicable)
5. Number of electrodes
6. Electrode configuration (e.g. basket, grid, array)
7. Electrode material (e.g. Gold)
8. Catheter tracking (e.g. impedance, magnetic, both)
9. Mapping system compatibility (e.g. Carto, NavX, Rhythmia, multiple)
10. Material (e.g. Polyurethane, Nylon)
11. Capability to provide consignment

Category 25 - Electrophysiology – Advanced Ablation Catheters

a. A full range of Advanced Ablation Catheters is required to meet clinical needs.

25.02 Product Description

a. For each Advanced Ablation Catheter offered, the Respondent should advise the following information in the Product Description on the Tender Response Worksheet:

1. Brand name
2. Catheter dimensions:
    a. Size in French Gauge
    b. Length in centimetres
    c. Deflection (e.g. unidirectional, bidirectional)
    d. Curve shape/size (e.g. D, F, J, small, large)
    e. Reach in millimetres
    f. Tip electrode size in millimetres
    g. Ring electrode size in millimetres
3. Steering mechanism (unidirectional or bidirectional)
4. Tip electrode type (Irrigated or Non-irrigated)
5. Number of irrigated holes (where applicable)
6. Number of electrodes
7. Electrode spacing
8. Electrode material (e.g. Gold)
9. Ablation energy delivery (e.g. radiofrequency, cryoablation)
10. Energy delivery/monitoring enhancements (e.g. contact force, MiFi)
11. Mapping system compatibility (e.g. Carto, NavX, Rhythmia)
12. Material (e.g. Polyurethane, Nylon)
13. Ability to provide contact force information
14. Capability to provide consignment

Category 26 - Electrophysiology – Accessories

a. A full range of Accessories, including but not limited to, connecting cables for diagnostic and ablation catheters and surface electrodes/patches for electro anatomical mapping systems is required to meet clinical needs.

26.02 Product Description

a. For each Accessory offered, the Respondent should advise the following information in the Product Description on the Tender Response Worksheet:

1. Brand name
2. Function (e.g. access, connectivity, mapping)
3. Used with:
    a. Diagnostic electrode catheters (range)
    b. Ablation catheters (which)
    c. Mapping systems (which)
4. Compatible platform (where applicable)
5. Cables required to attach electrophysiology diagnostic catheters to the recording system
6. Cables required to attach the ablation catheters to the RF generator
7. Irrigation tubing for use with irrigated ablation catheters
8. Single-use patches which are required for 3D mapping cases

Category 27 - Transcatheter Valve Implantation

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

27.01 Product Description

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

1. Brand / Model name
2. Material (e.g. Nitinol, Cobalt Chromium)
3. Treatable native annulus size
4. Valve -Size (e.g. 23, 26 mm)
5. Type (e.g. Balloon Expanded, Self Expanding)
6. Frame height in mm
7. Cell size in mm
8. Leaflet tissue type (e.g. bovine, porcine)
9. For the Delivery system:
    a. Brand Name
    b. Sheath introducer Set in mm
    c. Minimum access vessel diameter in mm
    d. Sheath in French gauge (Fr)
10. Contents of kits (such as delivery system, inflation devices, introducer sheath etc.)

27.02 Respondent Note

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

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

E Appendices

Appendix 1 - Product List

Category	Subcategories
01 Percutaneous Sheath Introducers and Introducer Kits	01.01 Percutaneous Sheath Introducer
	01.02 Percutaneous Sheath Introducer Kit
	01.03 Percutaneous Sheath Introducer, Additional Items
02 Guidewires for Diagnostic Catheters	02.01 Guidewires for Diagnostic Catheters
03 Diagnostic Catheters and Diagnostic Catheter Kits	03.01 Diagnostic Catheter
	03.02 Diagnostic Catheter Kit
04 Right Heart Catheters	04.01 Right Heart Catheters
05 Angioplasty Guiding Catheters	05.01 Angioplasty Guiding Catheter
06 Angioplasty Guidewires	06.01 Angioplasty Guidewire
	06.02 Angioplasty Guidewire Extension
07 Balloon Angioplasty Dilation Catheters	07.01 Balloon Angioplasty Dilation Catheters, Over the Wire Type
	07.02 Balloon Angioplasty Dilation Catheters, Rapid Exchange - Compliant
	07.03 Balloon Angioplasty Dilation Catheters, Rapid Exchange - Non Compliant
08 Angioplasty Accessories and Accessory Kits	08.01 Angioplasty Accessories, Guidewire Introducer
	08.02 Angioplasty Accessories, Torque Device
	08.03 Angioplasty Accessories, Haemostatic Valve
	08.04 Angioplasty Accessories, Inflation Device
	08.05 Angioplasty Accessory Kit
	08.06 Angioplasty Accessories, Additional Items
09 Coronary Stents	09.01 Bare Metal Coronary Stent
	09.02 Drug Eluting Coronary Stent
	09.03 Covered Coronary Stent
10 Temporary Pacing Equipment	10.01 Temporary Pacing Catheter

Category	Subcategories
	10.02 Temporary Pacing Pulse Generator
	10.03 Temporary Pacing Catheter Accessories
11 Thrombus Aspiration Catheters	11.01 Thrombus Aspiration Catheters
12 Occlusion Devices	12.01 Atrial Septal Occlusion Device
	12.02 Patent Ductus Arteriosus Occlusion Device
	12.03 Left Atrial Appendage Occlusion Device
13 Vessel Closure Devices, Haemostatic Devices and Kits	13.01 Vessel Closure Device
	13.02 Haemostatic Device
	13.03 Haemostatic Device Kits
14 Implantable Pacemakers	14.01 Implantable Pacemaker, Single Chamber Pacemaker
	14.02 Implantable Pacemaker, Dual Chamber Pacemaker
	14.03 Implantable Pacemaker, BiVentricular Pacemaker
	14.04 Implantable Pacemaker, Cardiac Resynchronisation Pacemaker
	14.05 Leadless Pacemaker
	14.06 Implantable Pacemaker, Pacemaker Programmers, Accessories and Consumables
15 Pacemaker Leads	15.01 Pacemaker Leads
16 Implantable Cardioverter Defibrillators	16.01 Implantable Cardioverter Defibrillators, Single Chamber ICD
	16.02 Implantable Cardioverter Defibrillators, Dual Chamber ICD
	16.03 Implantable Cardioverter Defibrillators, Cardiac Resynchronsation ICD
	16.04 Implantable Cardioverter Defibrillators, ICD Programmers, ICD Accessories and ICD Consumables
17 Implantable Cardioverter Defibrillator Leads	17.01 Implantable Cardioverter Defibrillator Leads
18 Pacemaker, ICD and Lead Insertion Accessories, Tools and Tool Kits	18.01 Pacemaker/ICD and Lead Insertion, Accessories - Individual
	18.02 Pacemaker/ICD and Lead Insertion, Accessories - Kits
	18.03 Pacemaker/ICD and Lead Insertion, Tools - Individual
	18.04 Pacemaker/ICD and Lead Insertion, Tools - Kits
19 Remote Patient Monitoring	19.01 Remote Patient Monitoring

Category	Subcategories
20 Implantable Loop Recorders	20.01 Implantable Loop Recorders
21 Electrophysiology - Standard Diagnostic Catheters	21.01 Fixed Quadripolar Electrophysiology Catheters
	21.02 Fixed Pentapolar Electrophysiology Catheters
	21.03 Fixed Octapolar Electrophysiology Catheters
	21.04 Fixed Decapolar Electrophysiology Catheters
22 Electrophysiology – Guide Sheaths	22.01 Deflectable Quadripolar Electrophysiology Catheters
	22.02 Deflectable Decapolar Electrophysiology Catheters
	22.03 Deflectable Duodecapolar Electrophysiology Catheters
23 Electrophysiology – Standard Ablation Catheters	23.01 Irrigated Standard Ablation Catheters
	23.02 Non-Irrigated Standard Ablation Catheters
24 Electrophysiology – Advanced Diagnostic Catheters	24.01 Circular Mapping Catheters
	24.02 High Density Mapping Catheter
	24.03 Ultra High Density Mapping Catheter
25 Electrophysiology – Advanced Ablation Catheters	25.01 Irrigated Advanced Ablation Catheters
	25.02 Non-Irrigated Advanced Ablation Catheters
26 Electrophysiology – Accessories	26.01 Mapping Accessories
	26.02 Cables
	26.03 Irrigation Tubing
27 Transcatheter Valve Implantation	27.01 Transcatheter Valve Implantation

Appendix 2 - Compliance Requirements

a. Australian Standards, Orders, Legislation and Regulations

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.

The relevant legislation for Interventional Cardiology may include, but is not limited to:

i) NHMRC (2010), Australian Guidelines for the Prevention and Control of Infection in Healthcare, Commonwealth of Australia

ii) Therapeutic Goods Administration (1991), Therapeutic Goods Order no. 37: General Requirements for Labels for Therapeutic Goods

iii) Therapeutic Goods Administration (V2.0, October 2017), Uniform Recall Procedure for Therapeutic Goods, Commonwealth of Australia

iv) The relevant standards for Interventional Cardiology may include, but is not limited to:

Standard Number	Standard Name
AS/NZS 4187	Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities
ISO 10555 - 1	Sterile, single use intravascular catheters – General Requirements
ISO 10555 – 2	Part 2. Angiographic Catheters
ISO 10555 – 4	Part 4. Balloon Dilation Catheters
ISO 10555 – 5	Part 5. Over- Needle Peripheral Catheters
ISO 14972	Sterile Obturators for single use with Over Needle Peripheral Intravascular Catheters
AS ISO 15539	Cardiovascular Implants – Endovascular Prostheses
AS ISO 25539 - 1	Cardiovascular Implants – Endovascular Devices – Endovascular Prostheses
ISO 14630	Non Active Surgical Implants – General Requirements
ISO 11070	Sterile Single Use Intravascular Introducers, Dilators and Guidewires
IEC 60601 - 2	Part 2.27. Ed 2.0. Medical Electrical Equipment Part 2.7 – Safety of Electrocardiographic Monitoring Equipment
ISO 14708 - 1	Implants for Surgery – Active Implantable Devices – General Requirements for Safety, Marking and for Information to be provided by the Manufacturer