HealthShare Victoria

Statement of Requirements

ITS Number:	HPVITS2022-061
ITS Name:	Interventional Radiology
Closing Date and Time:	30 June 2022, 14:00 AEST

Contents

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.

2. Scope

a. HealthShare Victoria (HSV) is seeking responses to the Invitation to Supply (ITS) for Interventional Radiology products, for use at Participating Health Services. This is a resourcing event (brownfield) for an existing category. The envisaged Term of Agreement is a one (1) year principle/ initial term plus two (2) optional extension periods of one (1) year each (i.e.1+1+1).

b. The scope of this ITS includes:

   (i) Clinical implantables used within Interventional Radiology procedures (e.g., peripheral vascular stents, embolization coils etc.); and

   (ii) Non-implantable consumables directly associated with Interventional Radiology procedures (e.g., guidewires, catheters etc.); and

   (iii) Support for the supply of Interventional Radiology products referenced in 2.b.(i) and 2.b.(ii), including the following:

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

c. The scope of this ITS excludes:

   (i) Minimally Invasive Surgery (MIS) reusable surgical instruments; and

   (ii) Endoscopic devices which may be used in Interventional Radiology; and

   (iii) Capital equipment (e.g., angiography suite equipment); and

   (iv) Products normally associated with interventional vascular procedures conducted on coronary arteries (e.g., coronary stents), as such products are within the scope of HSV's Interventional Cardiology contract.

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

3. Product Categories

a. A complete range of Interventional Radiology Implants is required for treatment of patients across Victorian Public Health Services

b. The categories required include:

CATEGORY NUMBER	CATEGORY NAME
1	Metallic Biliary Stents
2	Vascular Stents
3	Ureteric Stents and Kits
4	Balloon Catheters
5	Drainage Catheters and Kits
6	Diagnostic Catheters
7	Guiding Catheters
8	Thrombolytic Infusion Catheters, Kits and Thrombectomy Devices
9	Guidewires
10	Introducer Sheaths and Access Kits
11	Endovascular Coils
12	IVC Filters and Retrieval Devices
13	Core Biopsy Needles and Access Needles
14	Embolization Devices
15	Microcatheters and Microcatheter Kits
16	Neurovascular Guiding Catheters
17	Neurovascular Balloon Microcatheters
18	Neurovascular Guidewires
19	Flow Diversion Devices
20	Intra Arterial Stroke Treatment Devices
21	Intracranial Stents

CATEGORY NUMBER	CATEGORY NAME
22	Carotid Stents
23	Ablation
24	Embolics
25	Intermediate/Distal Access Catheters

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

d. Only products that specifically fit within the category descriptions provided 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. Product Offering

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

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

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

   (i) HPVC2016-061

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

5. Clinical Trials

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

Product Requirements

6. Standards and Compliance

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

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

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

7. Packaging and Labelling

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

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

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

d. As per the TGA regulations stated in clause 7.b above, product packaging must indicate (where applicable):

   (i) if the product is sterile

   (ii) use-by date

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

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

   (v) tracking labels.

8. Infection Control

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

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

9. Substances of Concern

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

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

10. Product Information

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

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

c. All product information submitted should:

   (i) be in electronic format

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

(iii) be specific to the product offered

(iv) contain the Respondent's company name

(v) include the product code

(vi) Australian Government Department of Health's prostheses list billing code (where applicable)

(vii) include a detailed specification of the product

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

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

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

f. HSV may not consider unlabelled submissions.

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

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

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

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

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

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

11. Consignment Stock

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

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

c. Terms relating to Consignment Stock are set out under Part 5 Deed of Standing Offer Agreement clause 3.11.2 Consignment Stock and/or under any relevant Service Level Agreement.

12. Provision of Trolleys and Storage Systems

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

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

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

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

13. Loan Sets

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

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

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

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 occur. 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.

15. Recall Process

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

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

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

Pricing

16. Price Variation

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

17. Sole and Panel Pricing

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

c. In the Tender Response Worksheet, Respondents are to list price options for both Sole Supply (where applicable) and Panel Supply. Note, Sole Supply ensures all contracted purchases by Participating Health Services for a Category, the subject of a Sole Supply award.

d. Respondents must provide pricing for Panel Supply at a minimum, for consideration. Where applicable, Respondents to provide Sole Supply pricing as an alternative offer for consideration, where Respondents can supply all the requirements within a Category. Sole Supply pricing will not be considered based on partial supply within a Category (i.e. partial range of products or sub-categories).

e. Where HSV elects to award panel supply, Participating Health Services may choose to purchase from any or all contracted suppliers.

Delivery

18. 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.

19. Delivery

a. Products within the scope of this ITS will be delivered to the location(s) specified by Participating Health Services within the shortest possible timeframe; however, this must not exceed the following timeframes, unless otherwise agreed with the Participating Health Service:.

(i) twenty-four (24) hours from receipt of order for **metropolitan** Participating Health Services; or

(ii) forty-eight (48) hours from receipt of order for **regional** and rural Participating Health Services.; or

(iii) The timeframe agreed as per the Service Level Agreement (SLA) with the individual Participating Health Service.

b. Preference may be given to Respondent who can offer delivery within twenty-four (24) hours to metropolitan, regional and rural Participating Health Services.

c. 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.

d. All deliveries are bound as per the Deed of Standing Offer Agreement, Part 5 clause 7 .

20. 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 state-wide emergency situations.

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

c. Urgent deliveries should be received by Participating Health Services within the shortest timeframe; however, this should not exceed the following timeframes unless otherwise agreed with the Participating Health Service:

(i) twelve (12) hours from receipt of order for metropolitan Participating Health Services; or

(ii) twenty-four (24) hours from receipt of order for regional and rural Participating Health Services; or

(iii) the timeframe agreed as per the Service Level Agreement (SLA) with the individual Participating Health Service.

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

Support

21. Training

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

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

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

(ii) off-site study days for clinicians;

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

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

(v) training materials.

c. Education and training sessions provided by the successful Respondent(s), as required by the Participating Health Services is to be free of charge.

22. Customer Service and Support

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

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

(i) inherently familiar with the contracted products;

(ii) appropriately qualified;

(iii) technically/clinically knowledgeable about the contracted products; and

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

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

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

(i) liaising with clinicians to recommend products and solutions;

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

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

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

(v) providing informational materials; and

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

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

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

(i) for Interventional Radiology 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

23. Key Performance Indicators

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

24. Service Level Agreement

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

   (i) the provision of products on consignment

   (ii) requirements for stock management and rotation

   (iii) loan set requirements

   (iv) arrangements for ordering, invoicing and delivery

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

   (vi) communication arrangements for product recalls and safety alerts (refer to Part 4 clause 15).

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

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

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

25. Contract Panel of Suppliers

a. The capability of each Respondent will be assessed using the information submitted with their response to this sourcing event HPVITS2022-061 for product categories 1 to 25.

b. Only successful Respondents will be added to the Contract Panel of Suppliers for the supply of Interventional Radiology products 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.

26. Product Evaluation and Award to Contract

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

b. Only products of Respondents 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 Categories, for consideration, evaluation and addition under the contract variation request process referenced in Part 5, Draft Deed of Agreement, Clause 3.7, over the term of the new contract.

27. Patient Implant Cards and Patient Information Leaflets

a. Suppliers need to supply patient implant cards and patient information leaflets in accordance with the guidelines stipulated in Clause 13A of Schedule 1 of the Therapeutic Goods (Medical Devices) Regulations 2002 (the MD Regulations).

b. Suppliers will be required to provide confirmation that their products will be supplied with patient implant cards and patient information leaflets as part of their response to this ITS.

28. Category Specifications

a. Respondents are invited to tender products in accordance with Part 4 Statement of Requirements.

A complete range of Interventional Radiology products is required for treatment of patients across Victorian Public Health Services.

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

29. Compliance with Category Specifications

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

   (i) MRI compatibility (implantable devices)

   (ii) The field strength in Tesla Units (implantable devices)

   (iii) Whether the MRI compatibility details are included on the product labelling

   (iv) The amount of time in days after implant after which MRI is deemed safe.

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

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

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

(i) The Billing Code (where applicable) as per the Australian Government Department of Health's prostheses list

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

30. Not Used

31. Categories

Category 1 – Metallic Biliary Stents

a. A full range of Metallic Biliary Stents is required to support the complete range of Interventional Radiology procedures.

Product description

b. For all items offered, Respondent should indicate the following in the Product Description of the Tender Response Worksheet:

(i) brand name

(ii) for the stent:

- self-expanding
- re-sheathable (yes or no) (if applicable)
- fully/partially covered or uncovered, diameter of covering and length of covering
- cell design:
  - open or closed
  - woven or laser cut
- type of material (e.g. stainless steel, Nitinol)
- diameter in millimetres
- length in millimetres
- nominal size range
- retrievable or non-retrievable.

(iii) for the catheter:

- size in French gauge
- external diameter in millimetres
- length in centimetres
- sheath in French gauge and millimetres
- guidewire diameter in inches and millimetres
- tip type (straight or angled)

Category 2 – Vascular Stents

a. A full range of Peripheral Vascular Stents is required to support the complete range of Interventional Radiology procedures, excluding coronary vascular stents or stents normally associated with Interventional Cardiology procedures.

Product description

b. For each Vascular Stent offered, Respondents should indicate the following in the Product Description of the Tender Response Worksheet:

(i) brand name

(ii) application site (e.g. artery)

(iii) delivery system

- over the wire
- rapid exchange

(iv) for the stent:

- self-expanding or balloon expanding
- re-sheathable (yes or no) (if applicable)
- type of material (e.g. stainless steel, Nitinol)
- cell design
  - open or closed
  - woven or laser cut
- non-deployed and deployed diameter in millimetres
- length in millimetres
- nominal size range
- position of stent in relation to markers (e.g. in millimetres, mid marker, within marker) (where applicable)
- stent covering (where applicable) and length of covering
- impregnated/coated drug (drug eluting stents only)
- antibacterial coating (where applicable)

(v) for the Delivery System:

- size in French gauge
- external diameter in millimetres
- length in centimetres
- sheath in French gauge and millimetres
- guidewire diameter in inches and millimetres
- tip type (straight or angled)

(vi) for the balloon (where applicable):

- diameters in millimetres

- length in millimetres
- rated burst pressure in atmospheres
- nominal pressure in atmospheres
- balloon overhang in millimetres
- balloon volume in millilitres

Category 3 - Ureteric Stents and Kits

a. A full range of Ureteric Stents and Kits is required to support the complete range of Interventional Radiology procedures.

b. All Ureteric Stents shall be radiopaque or have radiopaque markers.

Product Description

c. For each Ureteric Stent or kit offered, Respondents shall indicate the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Diameter in French gauge

(iii) Length in centimetres

(iv) Range in centimetres

(v) Type of materials (e.g. polyethylene, nitinol)

(vi) Tip configuration (e.g. pigtail)

(vii) String (where applicable)

(viii) Contents of kit (where applicable)

(ix) Type of coating (where applicable)

Respondent's Note

Respondent shall only submit Ureteric Stent or Kits for use by Interventional Radiologists.

Category 4 – Balloon Catheters

a. A full range of balloon catheters is required to support the complete range of Interventional Radiology procedures, excluding products normally used in coronary procedures and/or products within the scope of HSV's Interventional Cardiology contract.

Product description

b. For each balloon catheter offered, Respondents should indicate the following information in the Product Description of the Tender Response Worksheet:

(i) brand name

(ii) compliance (where applicable, e.g. semi-compliant, non-compliant)

(iii) delivery system

- over the wire
- rapid exchange (where applicable)
- recommended sheath size in French gauge

(iv) type of coating (where applicable) e.g. hydrophilic

(v) number of radiopaque markers

(vi) for the shaft:

- diameter in French gauge
- length in centimetres
- recommended diameter of compatible guidewire in inches

(vii) For the balloon:

- material (e.g. nylon)
- diameter range in millimetres
- length in millimetres
- nominal pressure in atmospheres
- rated burst pressure in atmospheres
- drug coating name, strength and excipient (drug eluting balloons only)
- usable length in centimetres (cutting balloons only)
- sheath size in French gauge (cutting balloons only)

Category 5 – Drainage Catheters and Kits

a. A full range of Drainage Catheters and Kits is required to support the complete range of Interventional Radiology procedures.

Product description

b. For each drainage catheter offered, Respondents should advise the following information in the Product Description of the Tender Response Worksheet:

(i) brand name

(ii) eponymous name (where applicable)

(iii) universal / biliary or long term

(iv) type of material (e.g. polyurethane, nylon)

(v) type of coating (where applicable) (e.g. hydrophilic)

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

(vii) catheter:

- diameter in French gauge
- length in centimetres
- recommended diameter of compatible guidewire, in inches
- sheath size
- needle length and gauge
- wire diameter and length
- Secure placement – length of suture and type of suture (e.g., (silk)

(viii) for the tip:

- shape (e.g. pigtail)
- Echo Tip (yes or no) (if applicable)

(ix) for side holes (where applicable):

- number of side holes
- size of the holes in millimetres

(x) contents of kit (where applicable) (e.g. stiffening cannula, trocar)

(xi) where applicable, components of kits that are available individually (e.g. stiffening shaft).

Category 6 – Diagnostic Catheters

a. A full range of Diagnostic Catheters is required to support the complete range of Interventional Radiology procedures, excluding diagnostic catheters normally used in coronary procedures and/or guiding catheters within the scope of HSV's Interventional Cardiology contract.

b. Diagnostic Catheters shall be easily visible under fluoroscopy.

Product description

c. For each diagnostic catheter offered, Respondents shall indicate the following information in the product description of the Tender Response Worksheet:

(i) brand name

(ii) eponymous name (where applicable)

(iii) braided (where applicable)

(iv) type of material (e.g. polyurethane, nylon)

(v) type of coating (where applicable) (e.g. hydrophilic)

(vi) number of side holes (where applicable)

(vii) flow rate in millilitres per second

(viii) maximum pressure in pounds / square inch

(ix) catheter dimensions:

- diameter in French gauge
- internal diameter in millimetres and inches
- length in centimetres
- recommended diameter of compatible guidewire in inches.

(x) For the tip:

- shape (e.g. pigtail).
- Radiopaque tip (where applicable)

(xi) Radiopaque markers (where applicable)

Category 7 – Guiding Catheters

a. A full range of Guiding Catheters is required to support the complete range of Interventional Radiology procedures, excluding guiding catheters normally used in coronary procedures and/or guiding catheters within the scope of HSV's Interventional Cardiology contract.

Product description

b. For each Guiding Catheter offered, Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Braided (where applicable)

(iii) Catheter dimensions:

- Diameter in French gauge
- Length in centimetres
- Internal diameter in millimetres and inches
- Recommended diameter of compatible guidewire in inches

(iv) For the tip:

- Shape (e.g. hockey stick)
- Angle in degrees (where applicable)

(v) For the hub:

- Proximal type, connection (detachable or non-detachable)

(vi) Type of material (e.g. polyurethane, nylon)

(vii) Type of coating (where applicable) (e.g. hydrophilic)

(viii) Side holes and Radiopaque markers

(ix) Additional content

Category 8 – Thrombolytic Infusion Catheters, Kits and Thrombectomy Devices

a. A full range of Thrombolytic Infusion Catheters, Kits and Thrombectomy Devices is required to support the complete range of Interventional Radiology procedures, excluding products normally used in coronary procedures and/or products within the scope of HSV's Interventional Cardiology contract.

Product Description

b. For each Thrombolytic Infusion Catheter, Kit or Thrombectomy Devices offered, Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Catheter dimensions:

- Diameter in French gauge
- Length in centimetres
- Recommended diameter of compatible guidewire in inches

(iii) Infusion length in centimetres

(iv) Occlusion wire size

(v) Distal and proximal radiopaque markers (where applicable)

(vi) Type of material (e.g., polyurethane, nylon)

(vii) Contents of kit (where applicable) (e.g., occlusive wire, infusion gun)

(viii) Where applicable, components of kits that are available individually (e.g., occlusive wire)

(ix) Other components (e.g., fluid dispensing gun)

(x) For the thrombectomy devices:

- Technique / method of thrombectomy
- Is a generator required?
- Sheath size

c. Respondents will be expected to provide full details related to the provision of generators required for use of thrombectomy devices, including whether provided free on loan upon purchase of devices

Category 9 – Guidewires

a. A full range of Guidewires is required to support the complete range of Interventional Radiology procedures, excluding guidewires normally used in coronary procedures and/or guidewires within the scope of HSV's Interventional Cardiology contract.

Product Description

b. For each Guidewire offered, Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Eponymous name (where applicable) (e.g. Newton)

(iii) Guidewire dimensions:

- Outer diameter in inches
- Length in centimetres

(iv) Length of distal taper in centimetres (where applicable)

(v) For the tip:

- Configuration (e.g. straight, angled)
- Length in centimetres
- Weight in grams

(vi) Stiffness level (e.g. flexible, soft)

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

(viii) Accessories (e.g. torque device)

Category 10 - Introducer Sheaths and Access Kits

a. A full range of Introducer Sheaths and Access Kits is required to support the complete range of Interventional Radiology procedures, excluding products normally used in coronary procedures and/or products within the scope of HSV's Interventional Cardiology contract.

Product Description

b. For each Introducer Sheath or Access Kit offered, Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Radiopaque markers (where applicable)

(iii) Diameter in French gauge

(iv) Inner diameter in millimetres

(v) Length in centimetres

(vi) Removable Haemostatic Valve (where applicable)

(vii) Tip configuration:

- Tip profile in inches (where applicable)
- Shape

(viii) Contents of introducer kits (where applicable) (e.g. guidewires)

(ix) Access kit:

- Needle size
- Needle length
- Sheath size
- Wire length and diameter

Category 11 - Endovascular Coils

a. A full range of Endovascular Coils for vascular embolization is required to support the complete range of Interventional Radiology procedures, excluding endovascular coils normally used in coronary procedures and/or endovascular coils within the scope of HSV's Interventional Cardiology contract.

Product Description

b. For each Endovascular Coil offered, Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Detachable or pushable:

- Detachment mechanism (where applicable)
- Length of detachable delivery system in centimetres (where applicable)

(iii) Diameter in inches

(iv) For the coil:

- Shape (e.g. helical, complex)
- Length in centimetres
- Diameter in millimetres

(v) Fibred (where applicable)

(vi) Type of material (e.g. platinum)

(vii) Type of coating (e.g. gel)

Category 12 - IVC Filters and Retrieval Devices

a. A full range of IVC Filters and Retrieval Devices is required to support the complete range of Interventional Radiology procedures, excluding products normally used in coronary procedures and/or products within the scope of HSV's Interventional Cardiology contract.

Product Description

b. For each IVC Filter and Retrieval Device offered, Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) For the IVC Filter:

- Type of material (e.g., Nitinol)
- Surface finish (e.g., polished)
- Minimal and maximal Caval diameter in millimetres
- Access site (e.g., femoral)
- Shape (e.g., conical)
- Maximum indwell time in days
- Availability of patient alert cards

(iii) For the introducer:

- Outer diameter in French gauge

(iv) For the Retrieval Device:

- Type of Material (e.g. Cobalt Chromium)
- Type of mechanism (e.g. snare, cone)
- Sheath diameter in French gauge
- Length in centimetres

c. Respondents must note that "Not Applicable" is not an acceptable response for Maximum indwell time in days.

Category 13 - Core Biopsy Needles and Access Needles

a. A full range of Core Biopsy Needles and Access Needles is required to support the complete range of Interventional Radiology procedures, excluding products awarded within the scope of HSV's Operating Room and Wound Drainage Consumables contract.

Product Description

b. For each Core Biopsy Needle or Access Needle offered, Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Depth marker

(iii) Inner stylet throw length in millimetres

(iv) Inner stylet throw length range in millimetres (where applicable)

(v) Variable throw details

(vi) Maximum number of times it can be fired

(vii) Needle configuration:

- Single or coaxial

(viii) For the needles (where applicable):

- Size in gauge
- Length in centimetres (excluding cutting cannula needle)
- Cutting Cannula Needle length in millimetres
- Penetration depth in millimetres
- Single Needle - Tip configuration (e.g. bevelled)
- Echo tip (yes or no) (if applicable)

(ix) Contents of set (where applicable) (e.g. introducer needle, gun)

(x) Compatible biopsy gun:

- Whether the gun is single use or reprocessable

(xi) For the access needle:

- Needle length in centimetres
- Echo tip (yes or no) (if applicable)
- Recommended wire size

(xii) For the vacuum assisted biopsy devices:

- Automated or non-automated
- MRI, ultrasound visibility
- Shape
- Size

(xiii) For the markers:

- Shape
- Size in French gauge
- Flow length (variable)

Category 14 – Embolization Devices

a. A full range of embolization products is required to support the complete range of Interventional Radiology procedures.

Product Description

b. For each Coil / Device offered (as applicable), Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Type or construct of coil / device (e.g., finishing coil, framing coil)

(iii) Detachable or pushable

(iv) Fibred or non-fibred

(v) Configuration (e.g., straight, coiled)

(vi) Loop shape (e.g. helical, complex)

(vii) Diameter in millimetres

(viii) Length in centimetres; deployed and constrained

(ix) Type of materials (e.g., platinum)

(x) Type of coating (e.g., polyglycolic – polylactic acid, hydrogel polymer)

(xi) Stretch resistance (where applicable)

(xii) Level of softness (e.g., super soft)

(xiii) Diameter of delivery wire / mechanism in inches/French Gauge (where applicable)

(xiv) Detachment device / mechanism (where applicable):

- Detachment mechanism (where applicable) (e.g., locking)
- Accessory (handheld device or connecting cable). If it requires a connecting cable, please indicate whether it requires a power box and whether the power box is free-on-loan

(xv) The recommended internal diameter of the compatible Microcatheter / Delivery Catheter in inches.

c. For each alternative embolization device offered (e.g. plugs and similar), Respondents shall also advise the following information in the Tender Response Worksheet (in addition to the applicable specifications in b. above):

(i) Diameter in millimetres once deployed/unconstrained

(ii) Length/height in millimetres; deployed/unconstrained

(iii) Insertion/delivery method (e.g. catheter)

d. Respondents will be expected to provide full details related to the provision of detachment devices required for use of the embolization products, including whether provided free on loan, upon purchase of the embolization product.

Category 15 - Microcatheters and Microcatheter Kits

a. A full range of Microcatheters and Kits is required to support the neurovascular and peripheral vascular procedures.

Product Description

b. For each Microcatheter or kit offered, Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Neurovascular, Peripheral Procedure or both

(iii) Detachable or non-detachable tip

(iv) Dead space in millimetres (catheter volume)

(v) Wire included or excluded

(vi) Usable length in centimetres

(vii) Proximal diameter:

- Inner in inches
- Outer in French gauge and millimetres

(viii) Distal diameter:

- Inner lumen in inches
- Outer lumen in French gauge and millimetres

(ix) Radiopaque markers:

- The number of markers
- Distance from distal marker to end of catheter tip in millimetres

(x) Braided (where applicable)

(xi) Hydrophilic coating (where applicable)

(xii) Maximum infusion pressure in pounds per square inch

(xiii) Maximum flow rate in millilitres per second

(xiv) Tip configuration (e.g., straight, pre-shaped, steam shapable with mandrel)

- For pre-shaped tip, the measurement in degrees

(xv) Other components (e.g., shaping tool, peel away sheath)

(xvi) Content of kit (Where applicable)

(xvii) The recommended inner diameter of the compatible guiding catheter in inches and millimetres.

(xviii) Dimethyl Sulfoxide with Onyx (DMSO) compatibility

Category 16 - Neurovascular Guiding Catheters

a. A full range of Neurovascular Guiding Catheters is required to support the complete range of Interventional Radiology procedures.

Product Description

b. For each Neurovascular Guiding Catheter offered, Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Usable length in centimetres

(iii) Proximal / Distal diameters:

- Inner in millimetres
- Outer in French gauge and millimetres

(iv) Level of stiffness (e.g. highly flexible, semi-rigid)

(v) Maximum infusion pressure in pounds per square inch

(vi) Maximum flow rate in millilitres per second

(vii) For the body:

- Type of material (e.g. polyurethane / nylon)
- Braided (where applicable)
- Type of coating (where applicable) (e.g., hydrophilic)

(viii) For the balloon (where applicable):

- Balloon diameter in millimetres
- Maximum inflation volume in millilitres

(ix) For the tip:

- Straight or pre-shaped tip
- For pre-shaped tip, the measurement in degrees

(x) Additional components (e.g., introducers, haemostatic valve, inset valve)

Category 17 - Neurovascular Balloon Microcatheters

a. A full range of Neurovascular Balloon Microcatheters, Kits and Syringes are required to support neurovascular procedures within Interventional Radiology.

Product Description

b. For each Neurovascular Balloon Microcatheter, Kits or Syringes offered, Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Single or dual lumens

(iii) Compliant or semi-compliant (where applicable)

(iv) Size in French gauge

(v) Proximal outer diameter in millimetres

(vi) Distal outer diameter in millimetres

(vii) Inner diameter of lumen in inches and millimetres

(viii) Length in centimetres

(ix) Maximum flow rate in millilitres per second

(x) Hydrophilic coating (where applicable)

(xi) For the balloon:

- length in millimetres
- diameter in millimetres
- inflation priming volume in millimetres
- rated burst pressure in atmospheres
- number of balloon marker bands and distance from distal tip in millimetres

(xii) other components (where applicable)

(xiii) the recommended diameter of the compatible guidewire in inches and millimetres

(xiv) the recommended inner diameter of the guiding catheter in inches

(xv) DSMO compatibility

(xvi) Dead space in millilitres

(xvii) Kits: Including or excluding wire

Category 18 - Neurovascular Guidewires

a. A full range of Neurovascular Guidewires is required to complement the range of neurovascular catheters used within Interventional Radiology.

Product Description

b. For each Neurovascular Guidewire offered, Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Guidewire dimensions:

- Outer diameter in inches and millimetres
- Length in centimetres

(iii) Distal taper length in centimetres (where applicable)

(iv) Radiopaque length in centimetres

(v) Type of material:

- Core wire (e.g., stainless steel)
- Coil (e.g., platinum tungsten)

(vi) Type of coating (e.g., hydrophilic, PTFE)

(vii) Level of stiffness (e.g., flexible, soft)

(viii) Shapeable (where applicable)

(ix) Other components (e.g., torque device, introducer, docking extensions).

(x) Availability of a compatible docking extension (yes/no)

Category 19 - Flow Diversion Devices

a. A full range of Flow Diversion Devices is required to support the range of neurovascular procedures within Interventional Radiology.

Product Description

b. For each Flow Diversion Device offered, Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Usable length in centimetres

(iii) Type of material (e.g., cobalt chromium / platinum)

(iv) Number of braids

(v) Resheathable (where applicable)

(vi) For the stent:

- Length in millimetres
- Diameter in millimetres

(vii) Radiopaque markers:

- The number of markers
- The position (e.g., proximal, distal)

(viii) Other components (e.g. delivery system)

(ix) The recommended internal diameter of the compatible Microcatheter in inches

Category 20 - Intra – Arterial Stroke Treatment Devices

a. A full range of Intra – Arterial Stroke Treatment Devices is required to support the range of neurovascular procedures within Interventional Radiology.

Product Description

b. For each Stent Retriever offered, Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) For the device:

- Length in millimetres
- Diameter in inches and millimetres
- Material (e.g., nitinol)

(iii) For the delivery system (where applicable):

- Usable length in centimetres
- Diameter in French gauge
- Detachable (where applicable)
- Diameter of delivery wire in inches and millimetres (where applicable)

(iv) Detachable or non-detachable

(v) Additional components (where applicable)

(vi) The recommended diameter of the compatible guidewire in French gauge

(vii) The recommended internal diameter of the compatible Microcatheter in inches

c. For each Aspiration Devices offered, Respondent shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Usable length in centimetres

(iii) Proximal / Distal diameters:

- Inner in millimetres
- Outer in French gauge and millimetres

(iv) Level of stiffness (e.g., highly flexible, semi-rigid)

(v) Maximum infusion pressure in pounds / square inch

(vi) Maximum flow rate in millilitres / second

(vii) For the body:

- Type of material (e.g., polyurethane / nylon)
- Braided (where applicable)
- Type of coating (where applicable) (e.g., hydrophilic)

(viii) For the tip:

- Straight or pre-shaped tip
- For pre-shaped tip, the measurement in degrees

(ix) Other components (e.g. introducers, haemostatic valve)

d. Respondents will be expected to provide full details related to the provision of aspiration pumps and tubing required for the use of aspiration devices, including whether provided free on loan upon purchase of aspiration devices.

Category 21 - Intracranial Stents

a. A full range of Intracranial Stents is required to support the range of neurovascular procedures within Interventional Radiology.

Product Description

b. For each Intracranial Stent offered, Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Self-expanding

(iii) Retrievable or non-retrievable

(iv) Diameter in millimetres

(v) Length in millimetres

(vi) Type of cell design (e.g., closed, open, braided)

(vii) Type of material (e.g. Nitinol)

(viii) Radiopaque markers:

- The number of markers
- The position (e.g., proximal, distal)

(ix) Other components (e.g. delivery system)

(x) The recommended internal diameter of the compatible Microcatheters in inches and millimetres

Category 22 - Carotid Stents

a. A full range of Carotid Stents is required to support the neurovascular procedures in Interventional Radiology.

Product Description

b. For each Carotid Stent offered, Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Delivery system

- Over the wire
- Rapid exchange

(iii) For the stent:

- Self-expanding
- Cell design (e.g., open, closed, braided)
- Type of material (e.g., stainless steel, Nitinol)
- Strut thickness in micrometres (µm)
- Diameter in millimetres
- Length in millimetres
- Maximum expanded internal diameter in millimetres
- Position of stent in relation to markers (e.g. in millimetres, mid marker, within marker)

(iv) For the catheter:

- Diameter in French gauge
- Catheter length in centimetres
- Guidewire diameter in inches
- Where applicable, the recommended size of the compatible sheath in French gauge
- Where applicable, the recommended size of the compatible guiding catheter in French gauge and millimetres

c. For each Carotid Stent Protection Device offered, Respondent shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Guidewire dimensions:

- Outer diameter in inches and millimetres
- Length in centimetres

(iii) Radiopaque length in centimetres

(iv) Type of material:

- Core wire (e.g., stainless steel)
- Coil (e.g., platinum tungsten)

(v) Level of stiffness (e.g., flexible, soft)

(vi) Shapeable (where applicable)

(vii) Filter specifications

(viii) Other components (e.g. torque device, introducer)

Category 23 - Ablation

a. A full range of Ablation products are required to support Interventional Radiology procedures, excluding ablation products normally used in coronary procedures and/or ablation products within the scope of HSV's Interventional Cardiology contract.

Product Description

b. For each Ablation product offered, Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Needle length in centimetres

(iii) Needle size in French gauge

(iv) Ablation diameter in centimetres

(v) Needle design (e.g., straight)

(vi) Coaxial needle (where applicable)

(vii) Distance from ablation zone to needle tip

(viii) Temperature reading or probe?

(ix) Needle (single or multiple)

Category 24 - Embolics

a. A full range of Embolics is required to support neurovascular and peripheral procedures within Interventional Radiology.

Product Description

b. For each Liquid Embolic offered, Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Viscosity

(iii) Preloaded or loaded (in vial)

(iv) Agitation device

(v) Volume of the unit supplied in millilitres

c. For all Particles offered, Respondent shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Single calibrated particle or range of varying sizes offered

(iii) Product range

(iv) Material Type

(v) Minimum Delivery catheter size in millimetres

(vi) Accessories required

d. For all Drug Eluting Beads offered, Respondent shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Drug type and doses

(iii) Drug eluting time

(iv) Preparation time

(v) Preparation method

(vi) Form (e.g. powder, liquid)

(vii) Presentation (e.g. prefilled)

Category 25 - Intermediate/Distal Access Catheters

a. A full range of Intermediate/Distal Access Catheters is required to support the complete range of Interventional Radiology procedures.

Product Description

b. For each Intermediate/Distal Access Catheter offered, Respondents shall advise the following information in the Tender Response Worksheet:

(i) Brand name

(ii) Usable length in centimetres

(iii) Proximal / Distal diameters:

- Inner in millimetres
- Outer in French gauge and millimetres

(iv) Level of stiffness (e.g. highly flexible, semi-rigid)

(v) Maximum infusion pressure in pounds / square inch

(vi) Maximum flow rate in millilitres / second

(vii) For the body:

- Type of material (e.g. polyurethane / nylon)
- Braided (where applicable)
- Type of coating (where applicable) (e.g. hydrophilic)

(viii) For the tip:

- Straight or pre-shaped tip
- For pre-shaped tip, the measurement in degree

Appendix 1 – Product List

Category		Subcategory	
01	Metallic Biliary Stents	01.01	Non Retrievable Metallic Biliary Stents, Self Expanding, Covered
		01.02	Non Retrievable Metallic Biliary Stents, Self Expanding, Uncovered
		01.03	Retrievable Metallic Biliary Stents, Self Expanding, Covered
02	Vascular Stents	02.01	Bare Metal Vascular Stents, Self Expanding, Over the Wire
		02.02	Bare Metal Vascular Stents, Self Expanding, Rapid Exchange
		02.03	Bare Metal Vascular Stents, Balloon Expanding, Over The Wire
		02.04	Bare Metal Vascular Stents, Balloon Expanding, Rapid Exchange
		02.05	Bare Metal Stent, Drug Eluting
		02.06	Covered Stent, Self Expanding
		02.07	Covered Stent, Balloon Expanding
03	Ureteric Stents and Kits	03.01	Ureteric Stents
		03.02	Ureteric Stents, Kits
04	Balloon Catheters	04.01	Dilation Balloon Catheters, Compliant
		04.02	Occlusion Balloon Catheters
		04.03	Cutting Balloon Catheters
		04.04	Dilatation Balloon Catheters, Rapid Exchange
		04.05	Drug Eluting Balloon Catheters
05	Drainage Catheters and Kits	05.01	Drainage Catheters, Universal
		05.02	Drainage Catheters, Biliary
		05.03	Drainage Catheters, Kits
		05.04	Drainage Catheters, Other Components

Category		Subcategory	
06	Diagnostic Catheters	06.01	Diagnostic Catheters
07	Guiding Catheters	07.01	Guiding Catheters
08	Thrombolytic Infusion Catheters, Kits and Thrombectomy Devices	08.01	Thrombolytic Infusion Catheters
		08.02	Thrombolytic Infusion Catheters, Kits
		08.03	Thrombolytic Infusion Catheters, Other Components
		08.04	Thrombectomy Devices, Other
09	Guidewires	09.01	Guidewires
10	Introducer Sheaths and Access Kits	10.01	Introducer Sheaths
		10.02	Introducer Sheaths, Kits
		10.03	Access Kits
11	Endovascular Coils	11.01	Endovascular Coils, Detachable
		11.02	Endovascular Coils, Pushable
		11.03	Endovascular Coils, Other Components
12	IVC Filters and Retrieval Devices	12.01	IVC Filters
		12.02	Retrieval Devices
13	Core Biopsy Needles and Access Needles	13.01	Core Biopsy Needle, Single
		13.02	Core Biopsy Needles, Coaxial
		13.03	Access Needles
		13.04	Vacuum Assisted Biopsy Devices
		13.05	Markers and Other Components
14	Embolization Devices	14.01	Microcoils, Detachable
		14.02	Microcoils, Pushable
		14.03	Detachment Devices
		14.04	Alternative Embolization Devices
15		15.01	Microcatheters

Category		Subcategory	
	Microcatheters and Microcatheter Kits	15.02	Microcatheter Kits
16	Neurovascular Guiding Catheters	16.01	Neurovascular Guiding Catheters, With Balloon
		16.02	Neurovascular Guiding Catheters, Without Balloon
17	Neurovascular Balloon Microcatheters	17.01	Neurovascular Balloon Microcatheters, Single Lumen
		17.02	Neurovascular Balloon Microcatheters, Dual Lumen
		17.03	Neurovascular Balloon Microcatheters, Kits
		17.04	Neurovascular Balloon Microcatheters, Syringes
18	Neurovascular Guidewires	18.01	Neurovascular Guidewires
		18.02	Neurovascular Guidewires, Other Components
19	Flow Diversion Devices	19.01	Flow Diversion Devices
20	Intra Arterial Stroke Treatment Devices	20.01	Intra Arterial Stroke Treatment Devices, Stent Retrievers
		20.02	Intra Arterial Stroke Treatment Devices, Aspiration Devices
		20.03	Intra Arterial Stroke Treatment Devices, Pumps
21	Intracranial Stents	21.01	Intracranial Stents, Self-Expanding
22	Carotid Stents	22.01	Carotid Stents, Self-Expanding, Rapid Exchange
		22.02	Carotid Stents, Protection Devices
23	Ablation	23.01	Microwave Ablation
		23.02	Radiofrequency Ablation
		23.03	Ablation, Other Devices
24	Embolics	24.01	Liquid Embolics
		24.02	Particles
		24.03	Drug Eluting Beads
25	Intermediate/Distal Access Catheters	25.01	Intermediate Catheters
		25.02	Intermediate Catheters, Other Components

Appendix 2 - Compliance Requirements

Australian Standards, Orders, Legislation and Regulations

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

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

STANDARD NUMBER	STANDARD NUMBER
AS/NZS 4187:2014	Cleaning, disinfecting and sterilizing re-usable medical and surgical instruments and equipment and maintenance of associated environments in health care facilities
ISO 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 10555 – 6	Intravascular Catheters -Sterile and single use catheters
ISO 13485	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	Non-Active Surgical Implants – General Requirements
ISO 11070	Sterile Single Use Intravascular Introducers, Dilators and Guidewires
ISO 14708 - 1	Implants for Surgery – Active Implantable Devices – General Requirements for Safety, Marking and for Information to be provided by the Manufacturer
NA	National Safety and Quality Health Service Standards, September 2012
ISO 20697:2018	Sterile drainage catheters and accessory devices for single use
ISO 15539- 2003	Reconfirmed 2014. Cardiovascular implants – Endovascular prostheses

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

STANDARD NUMBER	STANDARD NUMBER
ASTM F2503 - 08	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
ISO 25539 - 1	Cardiovascular Implants- Endovascular Devices- Part 1: Endovascular Prostheses
ISO 9713	Neurosurgical implants - Self-closing intracranial aneurysm clip
EN 14299	Non-Active Surgical Implants- Particular requirements for cardiac and vascular implants. Specific requirements for arterial stent
ASTM F2052-06e1	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
ASTM F2213-06	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
ASTM F2182-11a	Standard Test Method for Measurement of Radio Frequency Induced Heating On and Near Passive Implants During Magnetic Resonance Imaging
ASTM F2119-07	Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
ISO/PRF TS 10974	Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device; to be published 2012

Standard requirements against interferences from external electrical and magnetic fields:

STANDARD NUMBER	STANDARD 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 legislation below include any amendments, revisions or consolidations to those references.

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

(ii) *Therapeutic Goods Act* 1989

(iii) Occupational Health and Safety Regulations 2017

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

Guidelines and Other References

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

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

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

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