HEALTH PURCHASING VICTORIA

Invitation to Supply

Part 5 - Statement of Requirements

Invitation to Supply Number:	HPVITS2017-057
Invitation to Supply Name:	Operating Room and Wound Drainage Consumables
HPVITS2017-057 Closing Date and time:	01 March 2017 14:00 AEST / AEDT

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https://www.hpv.org.au/

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A Introduction

1 Purpose

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

   a. detail the scope and range of products sought under this Invitation to Supply (ITS)
   b. 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 Operating Room & Wound Drainage Consumables for use in Participating Health Services. The envisaged Term of the Agreement is two (2) years plus two optional two year extension periods (eg 2+2+2).

b. The scope of this ITS includes:

   a. the supply of Operating Room and Wound Drainage Consumables (standard purchases and on consignment)
   b. the supply of devices for the Operating Room and Wound Drainage Consumables (standard purchases and on consignment)
   c. service requirements

c. Indicative volumes are listed **in Part 6, Tender Response Worksheet.**

3 Product Categories

a. The categories of Operating Room and Wound Drainage Consumables required under this ITS include:

- Category 1 - Electrosurgical Return Electrodes
- Category 2 - Diathermy Consumables
- Category 3 - Smoke Evacuation Devices and Consumables
- Category 4 - Vessel Identification Loops
- Category 5 - Suture Boot Jaw Covers
- Category 6 - Surgical Clamp Inserts
- Category 7 - Scalpels, Scalpel Handles and Scalpel Blades
- Category 8 - Stitch Cutter Blades
- Category 9 - Scrub Brushes
- Category 10 - Patient Warming/Cooling Units and Consumables
- Category 11 - Sharps Containment Devices
- Category 12 - Surgical Marking Pens
- Category 13 - Surgical Clippers
- Category 14 - Irrigation Sets

- Category 15- Light Handle Covers
- Category 16 - Haemostatic Agents and Sealants
- Category 17 - Suction Tubing - ENT and Neurosurgery only
- Category 18 - Embolectomy Catheters
- Category 19 - Chest Drainage Systems and Consumables
- Category 20 - Wound Drainage Systems and Consumables

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.

b. The Respondent will ensure that each product is offered in only **one** subcategory.

It is at the Respondent's discretion to ensure that each product is submitted in the most appropriate subcategory.

4.3 Product Information

a. 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:

a. be in electronic format
b. be in English
c. be specific to the product offered
d. contain the Respondent's company name
e. include the product code
f. include a detailed specification of the product
g. include clear diagrams/pictures of the product.

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

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

HPV may not consider unlabelled submissions.

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

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

a. Not labelled as per Part 5 A 4.3 d above; or
b. 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 **Error! Reference source not found.**. 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.
Device	Electronic, mechanical or other equipment used with consumables in scope. May include, but is not limited to, units or systems.
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.

TERM	DEFINITION
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
SSU	Sterilisation Service Unit
TGA	Therapeutic Goods Administration
TUR	Trans Urethral Resection
will	Indicates an anticipated future condition or requirement to be met.

B Service, delivery, and support

1 Delivery

a. Operating Room and Wound Drainage Consumables must be delivered to the location(s) specified by Participating Health Services within the shortest possible timeframe; however, this must not exceed two (2) business days 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 24 hours from receipt of order.

3 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 Operating Room and Wound Drainage Consumables to clinicians in their operating environment.

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

   a. face-to-face training at Participating Health Service sites (i.e. in-service training)
   b. off-site study days for clinicians
   c. updates and refresher training on new products and/or equipment and surgical techniques
   d. training on cleaning and sterilisation to nominated personnel and the Participating Health Services' CSSD and SSU (for reusable instruments)
   e. training materials.

4 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 nominate at least one Representative to provide support and undertake consignment duties (see section **Error! Reference source not found. Error! Reference source not found.**).

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

   a. inherently familiar with the contracted products
   b. appropriately qualified
   c. technically/clinically knowledgeable about the contracted products
   d. available to respond to Participating Health Services' queries 24 hours a day.

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

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

   a. liaising with clinicians to recommend products and solutions
   b. promptly answering clinicians' queries (including after hours)
   c. liaising with various hospital departments (for example: operating theatre, Nurse Unit Managers)
   d. providing on-site clinical support during cases (if requested)
   e. providing informational materials
   f. providing education and in-service training upon request.

5 Warranty

a. All products covered in this ITS (including devices) are to be issued a warranty for a minimum or twelve (12) months from the delivery date for normal use.

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

5.2 Repairs and Replacements under Warranty

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

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

c. It highly desirable that the successful Respondent provides Participating Health Services with a replacement or suitable loan item at no cost until the repaired item is returned.

6 Key Performance Indicators

a. Refer to Part 7, Schedule 6 - Draft agreement – Key Performance Indicators.

7 Reporting

a. Refer Part 7, Schedule 7 - Draft agreement - Reporting requirements.

8 Service Level Agreement

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

   a. requirements for stock management and rotation
   b. arrangements for ordering, invoicing and delivery
   c. clinical support, including attendance requirements for Representatives in relation to education and training
   d. 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 (or their equivalent International Standards). Refer to Appendix 2 - References for a list of the minimum relevant standards.

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

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

2 Packaging and Labelling

a. Sterile products 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. Individual product packaging should include (where applicable):

   a. whether the product is sterile;
   b. whether the product is MRI compatible (implantable products);
   c. whether the product (or packaging) contains latex or is latex-free; and
   d. tracking labels.

3 Recall Process

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

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

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

4 Backorders and Discontinued Lines

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

   a. Procurement Officers of all Participating Health Services
   b. Supply Manager / Business Managers of all Participating Health Services
   c. HPV

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

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

   a. the anticipated timeframe for resolving the issue
   b. the availability of an agreed substitute product

5 Infection Control

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

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

6 Superseded Products

a. Where a contracted item is superseded, the new product must be offered at the same price as the original item. This change request must be submitted to HPV for approval through HPV's Contract Variation process.

7 Shelf Life

a. Products that have an Expiry Date (where applicable) are to have a minimum of six (6) months shelf life upon delivery to all Participating Health Services. If a product is to expire within 6 months delivery, the supplier must advise the Participating Health Service prior to delivery.

8 Reference Sites

a. Respondents are required to provide a minimum of three (3) Australian clinical references that are purchasing or have trialled and evaluated the product offered in this submission.

b. Where a product category contains a variety of specific sub-categories, Respondent are to ensure that the clinical references provided are representative of the full range of products tendered.

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

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

9 Provision of Devices

a Devices for consumables shall be offered under the following arrangements:

(i) outright purchase of devices: for use where the customer owns the device with which the consumables are to be used; and

(ii) devices provided 'free-on-loan': for use where the smoke evacuation devices are being provided without charge for use with the associated consumables.

b Where devices are provided 'free on loan':

(i) they shall remain the property and responsibility of the Respondent;

(ii) the responsibility for service and maintenance shall be retained by the Respondent

(iii) Respondents shall fully detail the arrangement by which devices are received and maintained. This includes:

- arrangements for device delivery and acceptance testing;
- arrangements for preventative inspection/maintenance service and repair including timing for replacement of defective or ageing equipment and to indicate if these services are done on-site or off-site;
- management and reporting of device inventory provided to the hospitals or health services;
- the responsibility and any costs where devices are inadvertently damaged or lost. This should take into account the age of the device and depreciation in value across the life of the contact; and
- provision of essential accessories (e.g. external power supplies, pole-mount, etc.)

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

2 General Specifications

a. A complete range of **Error! Use the Home tab to apply HPV ITS Title to the text that you want to appear here.** is required for treatment of patients across Victorian Public Health Services.

b. All items shall include the following minimum requirements, plus additional requirements as advised.

c. For each product offered, the following shall be advised as applicable:

- Brand name
- Size (e.g neonate)
- Dimensions in millimetres or French gauge for catheter size
- Colour
- Construction material (e.g silicone, tungsten, surgical steel)
- Sterile or non-sterile
- Single use, limited reusable or reusable
- Safety features, where applicable

Items shall be:

- Radio opaque

Packaging shall:

- Be a peel-pack that peels cleanly
- Be in a manner that protects the user and item from accidental damage
- Be clearly labelled with size and shape of the product
- Facilitate ease of access, separation, counting and storage

2.2 Additional Information:

a. Information relating to the reprocessing of limited reuse items that will assist hospitals in complying with the requirements of AS/NZS4187 Cleaning, disinfecting and sterilising reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities shall be readily available for all contract users as hard and/or electronic copy. This includes:

- Instructions for cleaning, disinfection and sterilisation
- Information advising the maximum number of reuses or the recommended period of reuse for a single item or the means by which it can be determined if a reusable diathermy pencil is no longer fit for use
- A description of the process for tracking the use of each item
- Information relating to the conditions of warranty.

3 Device Specifications

3.1 Ease of Use

a. Smoke evacuation devices should be easy to set up and use;

b. Controls shall be easy to set and logically arranged;

c. Labels and displays shall clearly and concisely identify the functions of all switches, controls, monitors and displays;

d. The control setting values shall be easy to read and determine;

e. The external housing of the device shall be easy to clean; and

f. A brief set of instructions and important precautions shall be permanently and prominently displayed on the device.

3.2 Mains Power

a. Mains Power shall:

- Unless otherwise specified, all devices must work from standard 240V AC power points (if electrically driven), as supplied in Australia;
- include a power supply system immune to the effects of common power surges and power fluctuations;
- include external power supplies that fit squarely and firmly in a typical power outlet and mid-length style power supplies. External power supplies must isolate extra low voltage and incorporate over temperature and short circuit protection.

b. External power supplies and power supply cables that are faulty or damaged will be replaced at no cost to health services. Faulty cables includes those cables which have intermittent loss of power.

3.3 Battery Power

a. Battery Power shall incorporate:

- a battery system that will maintain power to fully operate the device in the event of the removal of the mains supply; and
- an indicator that clearly identifies that the device is running on battery power.

b. The battery shall be continuously charged from a mains power supply, even if the power control switch of the device is turned off.

c. A clear visual indication and audible alarm must be given to warn that the battery power is nearly exhausted.

d. Devices shall start up and continue to operate accurately on mains power despite a fully discharged battery being connected.

e. Tenders shall provide the following information on the Tender Response Worksheet:

- the life expectancy of the battery;
- the time required (in minutes) to fully charge a fully discharged battery;
- the period of time (in hours) for which a fully charged battery can operate
- the time duration that the device will continue to run after battery low alarm first sounds.

3.4 Marking Information

a. Each device offered shall be marked legibly and permanently with:

- manufacturer's name or registered trade mark;
- model number or name specific to the particular design;
- equipment serial number;
- supply voltage, frequency and the current or power rating;
- fuse type and ratings;
- control function labels, connector function labels;
- hazard warnings (if applicable); and
- electrical safety classifications.

3.5 Displays

a. Displays shall be easily read at one (1) metre from the device.

b. LCD displays shall have a backlight facility.

c. An indicator on the display shall be present that indicates:

- device is in progress;
- the device is running on battery or mains power; and
- amount of battery life remaining (if applicable).

d. Preference may be given if additional parameters are displayed by the device for example on the following:

- Filter life indicator
- System malfunction.

3.6 Devices training requirements

a. Operator Training

a. Respondents shall provide the following information in their response.

- full details of the operator training program including the duration and content

b. Training shall:

- be provided by personnel experienced in training;
- include all aspects required for safe and effective device operation including set-up and operation, trouble-shooting, any safety and emergency procedures, and equipment cleaning;
- occur on-site at the relevant hospital or health service;
- accommodate all relevant staff over a number of shifts.

c. Successful Respondents shall ensure that service and/or educational personnel do not discuss or suggest other products or devices, other than those products or devices that they have been requested to support.

b. Training of Hospital Biomedical Engineers

a. Respondents shall provide in their response:

- full details, including curriculum and costs, of a recognised and approved manufacturer's technical training course on the device/s offered.

b. The training courses shall be of a recognised and approved manufacturer's technical training course (both state and national) on the device/s offered and shall be equal to the course/s that the manufacturer's biomedical engineering staff is required to undertake.

c. This training shall include, but not be limited to:

- equipment operation;
- inspection;
- preventative maintenance and calibration;
- trouble-shooting; and
- repair.

d. Respondents shall provide the following information in their response:

- the availability of loan devices to cover extended repairs; and
- all costs and responsibilities associated with the provision of devices including spare parts, and specialist tools/equipment.

3.7 Software Updates

a. In the event of a software update, the Respondent shall:

- provide such updates at no cost;
- perform supplementary in-service training at no cost in the event that the software updates changes the operation or servicing of any equipment;

3.8 Service and Parts

a. Respondents shall provide the following information in their response:

- the full details of service & maintenance programs including all costs;

- the recommended frequency of preventive inspection/maintenance required to ensure quality control.

b. A written report shall be provided to the relevant hospital representative for all services undertaken; details of test results must be available to PHS on request.

c. Respondents shall guarantee the supply of all necessary spare parts, special tools and instruments, revised and tested software and all other technical data:

- for the duration of any resulting contract; and
- for a minimum of five (5) years from the date that any model of device offered is no longer manufactured.

d. Successful Respondents must notify HPV and Participating Health Services of 'end of support' for all devices and associated consumables and semi-consumables by the last date of manufacture. If an upgrade is required to ensure continuing support, the cost of this upgrade should not be more than 50% of the cost of a new replacement device (if the upgrade cost exceeds this amount, the device will be considered to be no longer supported).

e. Where provided, diagnostic software shall:

- be supplied in the appropriate form e.g. compact discs, flash drives, together with one (1) copy of a user manual for such software;
- not be copy-protected and shall be identical in all aspects with the software used by the manufacturer's field service personnel; and
- be the latest updated and tested version available at the time of delivery.

f. Any sets required for calibration or performance testing of Smoke Evacuation Devices and accessories shall be supplied to Health Services at no cost regardless if the devices are purchase outright or free-on-loan.

3.9 Warranty

a. Devices shall have a minimum warranty period of twelve (12) months.

b. The Respondent shall provide the following information in their response:

- the period and extent of the warranty period, including all terms and conditions; and
- details of any preventative maintenance to be undertaken at the Respondent's expense during the warranty period, including frequency of service and nature of work.

3.10 Operating Manuals

a. Operator User Manuals

a. For each type of device offered, successful Respondents shall provide one complete copy of all operator user manuals for retention by hospital or health service based Biomedical Engineering services.

b. Operating user manuals shall be in English and shall include but not be limited to:

- the comprehensive operating instructions;
- all information necessary to operate the equipment in accordance with specifications and without exceeding safety limits;

- recommended procedures for cleaning, battery charging, etc;
- all error messages and troubleshooting procedures; and
- safety requirements and precautions.

b. Technical Maintenance Manual

a. For each type of device offered, successful Respondents shall provide one complete copy of all technical maintenance information necessary to carry out preventive inspection/maintenance and repair. The technical documentation shall contain all details available to the manufacturer's service staff including tools required, available spare parts and costs for retention by hospital or health service based Biomedical Engineering services.

c. Additional Information

a. The following information shall be readily available for all contract users as hard and electronic copy:

- service and maintenance information including:

a. location and capability of the repair/service facility;

b. location and availability of spare parts and consumable items and their pricing;

c. the work address, telephone/fax numbers including mobile and e-mail contact, for service or maintenance; and

d. the process for handling repairs/equipment breakdown including the guaranteed response time to a call-out following notification of the problem.

3.11 Acceptance Testing

a. Successful Respondents shall provide the following information in their response:

- an overview of equipment acceptance/performance testing procedures carried out on devices prior to delivery to the customer; and
- any requirements and the availability of specialised, device specific equipment required for testing the system, for the period of installation and acceptance testing.

Category 1 - Electrosurgical Return Electrodes

a A full range of Electrosurgical Return Electrodes is required to meet clinical needs.

b Electrosurgical Return Electrodes shall include a conductive layer that ensures effective contact with the patient for the purpose of current dispersion.

c When applied in accordance with the manufacturer's instructions, Electrosurgical Return Electrodes shall:

(i) Maintain their adhesive and conductive qualities throughout the surgical procedure

(ii) Remove cleanly and without damage to human tissue

(iii) Not have any hot spots created by uneven distribution of high frequency current.

d For each Electrosurgical Return Electrode offered, Respondents shall advise the following information in the Product Description on the Tender Response Worksheet:

(i) Recommended weight range in kilograms

(ii) Recommended surgical positions (e.g. supine)

(iii) Split or solid

(iv) Minimum and maximum power setting in Watts for:

- Coagulation
- Cutting

(v) Type of adhesive (where applicable)

(vi) With lead (where applicable)

- Length of lead in centimetres

e For each product offered in this category, Respondents shall provide the additional information on the Tender Response Worksheet:

(i) Bendable or flexible over positioning devices

(ii) For use with electrosurgical generators with or without a contact quality monitoring system.

Additional Information

f A copy of the "Instructions for Use" which should include all requirements for application, removal and safe use of electrosurgical electrodes

g Information relating to cleaning and safe management of leads and any checking or testing procedures that will assist in ongoing safe use for the expected life of the lead

h The expected useful life of any lead when used and cleaned in accordance with the manufacturer's instructions.

i Where electrodes are packaged in a multi-pack, the effective shelf life of pads once the multi-pack has been opened and when stored in accordance with the manufacturer's instructions.

Category 2 - Diathermy Consumables

Diathermy Pencils

a A full range of Diathermy Pencils is required to meet clinical needs.

b Diathermy pencils shall be widely and safely compatible with a range of brands of both diathermy tips and electrosurgical generators, including those with integrated smoke evacuation.

c Single use diathermy pencils shall be sterile and wrapped in a peel-pack for ease of access.

d Limited reuse diathermy pencils shall be:

(i) Clinically clean

(ii) Packaged individually.

e Leads shall:

(i) Be flexible and memory-free

(ii) Drape readily across the operative field

(iii) Not spring back when tension is released from the unit.

f For each product offered in this category, Respondents shall provide the additional information in the Product Description on the Tender Response Worksheet:

(i) Switching mechanism (e.g. rocker hand switch)

(ii) Holster (where applicable)

(iii) Smoke evacuation tubing (where applicable)

(iv) Length in centimetres (with extension increments if applicable)

(v) Integrated suction (where applicable)

(vi) Length of lead in centimetres

(vii) Spatula tip included (where applicable).

Diathermy Pencil Tips

a A full range of Diathermy Pencil Tips is required to meet clinical needs.

b Diathermy tips shall incorporate a universal shank to safely and securely fit a range of diathermy pencils.

c Sterile diathermy tips shall be presented in a peel-pack.

d Pencil tips shall be protected to avoid damage to packaging or sharps injury.

e For each Diathermy Pencil Tip offered, Respondents shall advise the additional information in the Product Description on the Tender Response Worksheet:

(i) Shape (e.g. spatula, needle point)

(ii) Length in millimetres

(iii) Tip size in millimetres

(iv) Insulated or non-insulated

(v) Coated or non-coated

(vi) Coating material (where applicable).

Diathermy Scratch pads

a A full range of Diathermy Scratch Pads is required to meet clinical needs.

b Diathermy Scratch Pads shall:

(i) Incorporate a sponge layer to provide support during use

(ii) Incorporate a method of attachment (e.g. adhesive strip).

c For each Diathermy Scratch Pad offered, Respondents shall advise the additional information in the Product Description on the Tender Response Worksheet:

(i) Size in centimetres.

Category 3 - Smoke Evacuation Devices and Consumables

Smoke Evacuation Devices

A full range of Smoke Evacuation Devices and consumables are required to meet clinical needs.

Provision of Devices

For all smoke evacuation devices offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

a

(i) brand name;

(ii) the overall physical dimensions in centimetres;

(iii) configuration (e.g. mobile, pole-mount, etc.)

(iv) range of use (e.g. ESU, laser, laparoscopic, etc.)

(v) gross mass including battery in kg;

(vi) net mass excluding charger (where present) in kg;

(vii) Global Medical Device Nomenclature System (GMDNS) preferred term;

(viii) Filtration system

(ix) Maximum flow setting (cubic feet/minute)

I. Variable flow

(x) Maximum flow setting, cfm (cubic feet/min)

I. Variable flow control

(xi) Maximum vacuum pressure, mmHg

(xii) Footswitch (type)

(xiii) Remote activation feature

(xiv) Safety features

(xv) Mains Power, Vac

(xvi) Cleaning and Infection Control

I. Cleaning details/instructions

II. List of suitable cleaning products

III. List of non-suitable cleaning products

(xvii) Year product entered the market
(xviii) Other Specifications

Power Supply

All Smoke Evacuation Devices shall be both battery and mains powered.

Minimum battery life.

a

Performance

b

During the delivery cycle, the suction rate shall remain as continuous as possible.

Smoke Evacuation Devices should have:

a

(i) A maximum flow rate (e.g. 65 cfm) for smokier conditions;

b

(ii) A maximum flow rate (e.g. 20 cfm) for standard conditions;

(iii) Suction that effectively clears the field of view.

Displays

In addition to above display requirements, Smoke Evacuation Devices should display:

(i) Filter-life indicator

a

Alarms

Smoke evacuation devices shall have the following clearly audible and visual alarms as a minimum:

(i) set dislodgement/free-flow detection;

(ii) empty bag/container/infusion complete detection (filter change);

b

(iii) occlusion alarm; and

c

(iv) battery depleted/low alarm.

The cause of each alarm condition shall be readily identifiable by the user.

Respondents shall advise on the Tender Response Worksheet if:

(i) the volume of the device alarm is adjustable (must remain sufficient to hear in presence of moderate ambient noise)

(ii) Alarm noise level, dB

(iii) the alarm can be switched off; and

(iv) the alarm can be disabled.

Smoke Evacuation Consumables

a A full range of Smoke Evacuation Consumables is required to meet clinical needs.

b Single use smoke evacuation pen with integrated cannula and tubing shall be sterile and supplied in a peel pack.

c For each Smoke Evacuation set offered, respondents shall advise the following information in the Product Description on the Tender Response Worksheet:

(i) Smoke evacuation filters:

- Odour absorption (where applicable)
- Filter level in microns (≥ ULPA filter)
- Filter-life in hours

(ii) Smoke evacuation tubing:

- Diameter in millimetres
- Length in centimetres (with extension increments where applicable)
- Smooth or corrugated

(iii) Sponge guard (where applicable)

(iv) Valve (where applicable)

(v) Smoke evacuation wand:

- Length in centimetres
- Diameter in millimetres

(vi) Laser resistant (where applicable)

(vii) Contents of kit (where applicable).

d For each product offered in this category, Respondents shall provide the additional information on the Tender Response Worksheet:

(i) Compatibility with various devices.

Category 4 - Vessel Identification Loops

a A full range of Vessel Identification Loops is required to meet clinical needs.

b Vessel Identification loops shall be packaged in peel-pack in a manner that:

(i) Prevents identification loops from separating during movement from packaging onto the sterile field

c Vessel Identification Loops shall be:

(i) 100% silicone

(ii) Soft, elastic and pliable

(iii) Smooth and uniform in presentation with no joins or sharp edges.

d For each Vessel Identification Loop offered, Respondents shall provide the additional information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Colour (e.g. red)

(iii) Size (e.g. mini, maxi).

(iv) Length in centimetres

Category 5 - Suture Boot Jaw Covers

a A full range of Suture Boots Jaw Covers is required to meet clinical needs.

b Suture Boot Instrument Jaw Covers shall:

(i) Incorporate a method of adhesion to secure them within the operative field.

(ii) Include number of Jaw Covers per tray (e.g: 2,4 or 6)

Category 6 - Surgical Clamp Inserts

a A full range of Surgical Clamp Inserts is required to meet clinical needs.

b Surgical Clamp Insert shall :

(i) Include number of inserts per pack.

c For each Surgical Clamp insert offered, Respondents shall provide the additional information in the Product Description on the Tender Response Worksheet:

(i) Ridged, soft, hydra, safe, fibra, latis, traction, ever grip, etc.

(ii) Length in Millimetres

Category 7 - Scalpels, Scalpel Handles and Scalpel Blades

a A full range of single use Scalpels, Scalpel Handles and Scalpel Blades is required to meet clinical needs.

b Disposable scalpel blades shall meet the requirements of:

(i) AS ISO 7740–2004 Instruments for surgery Scalpels with detachable blades – Fitting dimensions.

c Disposable scalpel blades and scalpels shall be packaged in:

(i) A peel-pack that peels cleanly to expose the blade connection or handle

(ii) A manner that protects the user and the blade from accidental damage.

d For each product offered in this category, Respondents shall provide the additional information in the Product Description on the Tender Response Worksheet:

(i) Shape (e.g. sabre)

(ii) Size (e.g. No.3)

(iii) Blade material (e.g. Carbon steel or stainless steel)

(iv) Handle material (where applicable) (e.g. plastic)

(v) Measurement markings in millimetres (where applicable)

(vi) Safety features (where applicable) (e.g. retractable blade).

Category 8 - Stitch Cutter Blades

a A full range of Stitch Cutter Blades is required to meet clinical needs.

b Stitch Cutter Blades shall be packaged in:

(i) A peel-pack that peels cleanly to expose the blade connection.

(ii) A manner that protects the user and the blade from accidental damage.

c For each Stitch Cutter Blade offered, Respondents shall provide the additional information in the Product Description on the Tender Response Worksheet:

(i) Blade size (e.g. long, midi)

(ii) Blade material (e.g. carbon steel or stainless steel)

(iii) Inbuilt safety features (where applicable).

Category 9 - Scrub Sponge

a A full range of Scrub Sponges is required to meet clinical needs.

b Sterile Scrub Sponges shall be individually packaged in a peel pack that peels cleanly to facilitate ease of access to the contents.

c For each Scrub Sponge offered, Respondents shall provide the additional information in the Product Description on the Tender Response Worksheet:

(i) Impregnating solution (where applicable) (e.g. povidone iodine)

(ii) Nail pick (where applicable)

Category 10 - Warming and Cooling Units and Consumables

a A full range of warming and cooling units (air, convection and liquid) are required to suit a range of clinical procedures and clinical needs

(i) TGA's ARTG No.

(ii) Standard Compliance to which Standards

(iii) Configuration (e.g. mobile, pole-mount, etc.)

(iv) Controller/Main unit

(v) Indicators/parameters displayed

(vi) Temperature range/settings, °C

(vii) Maximum Temperature , °C

(viii) Safety Thermostats

- High limit, °C
- Low limit, °C

(ix) Alarms

- Alarm conditions
- Alarm indicators, audible/visual

(x) Automatic shutoff, hrs

(xi) Dimensions, H x W x D, cm

(xii) Weight, kg

(xiii) Battery

- Rechargeable
- Operating time, hrs
- Recharge time, hrs

(xiv) Accessories

- Hose
- Hose length, m
- List spare parts for hose

(xv) Noise Level, dB

(xvi) Connectors

- Number
- Integral connector

(xvii) Warm-up time, min

(xviii) Fan speed, cfm (e.g. air flow, cubic feet/min)

(xix) Filter, type (main unit inlet filter)

(xx) Cleaning and Infection Control

(xxi) Cleaning details/instructions

(xxii) List of suitable cleaning products

(xxiii) List of non-suitable cleaning products

(xxiv) Mains Power, Vac

(xxv) Heater Power, W

(xxvi) Sensor(s)

Warming/Cooling Units (Air)

Over Temperature Cut-out, °C

(i) Indicators

- Hour Meter
- Others

Warming Units (Conductive)

(i) Blanket, over-body

- Reusable/Disposable
- Blanket material, describe
- Life expectancy
- Heating element material
- Latex-free

(ii) Mattress, under-body

- Reusable/Disposable
- Mattress material, describe
- Life expectancy
- Heating element material

- Dimensions, W x L, cm
- Weight, kg

(iii) Simultaneous operation of blanket/mattress

(iv) Radiolucent

(v) Other Specifications

(vi) Accessories

Warming/Cooling Units (Liquid)

(i) Modes of operation

- Cooling
- Warming
- Cooling and Warming
- Patient temperature monitoring

(ii) Refrigerant system

(iii) Control panel function indicators

(iv) Fluid temperature range, °C

(v) Patient temperature range, °C

(vi) Patient temperature probe

(vii) Automatic shutoff, hrs

(viii) Reservoirs

- Number
- Capacity, L
- Type of fluid
- Flow, L/hr
- Flow indicator

(ix) Other Specifications

(x) Accessories

Consumables

a For each Warming/Cooling consumable (e.g. blanket, underlays, pad) offered, Respondents shall provide the additional information in the Product Description on the Tender Response Worksheet:

(i) TGA's ARTG No.

(ii) Standard Compliance to which Standards

(iii) Applications (e.g. full body or localised, warming/cooling, etc.)

(iv) Recommended use (pre-operative, intra-operative etc.)

(v) Recommended patient age range (e.g. paediatric, neonate, etc.)

(vi) Single patient use or Reusable

(vii) Method of warming (e.g. fluid, air,convection, conduction)

(viii) Method of use (e.g. under or over patient, wrap around)

(ix) Shape (e.g. rectangular, torso wrap, leg wrap)

(x) Size in centimetres

(xi) Method of securing (e.g. ties, adhesive tabs).

(xii) Material (Construction shall be from low linting, tear resistant and non-flammable material)

(xiii) Compatibility with various devices.

b For each fluid filled product offered in this category, Respondents shall provide the additional information on the Tender Response Worksheet:

(i) Unfilled or initial weight in grams

(ii) Filled weight in grams

(iii) Fluid flow rate, litres/ min

(iv) Patient weight limit.

c Where Warming/Cooling products are designed to be reusable, the additional information shall be readily available to all contract users as hard and/or electronic copy:

(i) Advice as to any testing required ensuring product integrity and safety.

(ii) Cleaning and infection control

- Cleaning details/instructions
- List of suitable cleaning products
- List of non-suitable cleaning products

(iii) Number of uses (if applicable)

d For each blanket offered in this category, Respondents shall provide the additional information on the Tender Response Worksheet:

(i) Reusable/Disposable

(ii) Sizes, cm

(iii) Hose length, m

(iv) Noise Level, dB

(v) Warm-up time, min

(vi) Fan speed, cfm (e.g. air flow, cubic feet/min)

e For each pad offered in this category, Respondents shall provide the additional information on the Tender Response Worksheet:

(i) Single patient use/ reusable

(ii) Size (e.g. XXS, L)

(iii) Hose length, metres

(iv) Warm up time , minutes

Category 11 - Sharps Containment Devices

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

b Sharps Containment devices shall:

(i) Be constructed from rigid plastic that allows safe enclosure of sharps

(ii) Incorporate foam of suitable density to safely house a variety of sizes of sharps, and/or

(iii) Incorporate magnets of suitable strength to retain sharps

(iv) Be of a distinctive colour to distinguish them from operating room drapes and sterilisation material

(v) Incorporate a durable catch mechanism to allow closure and re-access of the containment device

c For each Sharps Containment Device offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Size in centimetres

(iii) Clear lid (where applicable)

(iv) Needle counter range (where applicable)

(v) Method for attaching needles and blades (e.g. foam, magnet)

(vi) Where applicable method of attachment to the sterile field (e.g. adhesive strip on base)

(vii) Blade removing facility (where applicable).

d For each product offered in this category, Respondents shall provide the additional information on the Tender Response Worksheet:

(i) Non slip base (where applicable).

Category 12 - Surgical Marking Pens

a A full range of Surgical Marking Pens is required to meet clinical needs.

b Surgical Marking Pens shall:

(i) Contain gentian violet-coloured ink

(ii) Be non-toxic, non-irritating and non-smearing

(iii) Be indelible on all surfaces including skin, mucous membrane, blood vessels and scalp

(iv) Be resistant to the effects of skin preparation solutions so that marking remains visible after skin preparation.

(v) Sterile skin marking pens shall be packaged in peel-pack for ease of access.

c For each Surgical Marking Pen offered, Respondents shall provide the additional information in the Product Description on the Tender Response Worksheet:

(i) Type of tip (e.g. fine, dual)

(ii) Ruler (where applicable)

(iii) Labels (where applicable).

Category 13 - Surgical Clippers

a A full range of battery powered Surgical Clippers and single use blades are required to meet clinical needs.

b The Surgical Clipper shall:

(i) Be powered by a rechargeable battery

(ii) Be robust, water resistant, and be easy to clean

(iii) Readily and securely fit into the battery charger unit.

(iv) Clipper blades shall:

- Be clinically clean
- Readily attach to and detach from the blade connection
- Be packaged in a manner that allows ready access while providing protection to the blade.

(v) Battery charger units shall:

- Be capable of being wall mountable
- Incorporate an indicator that shows the battery is charging.

c For each product offered in this category, Respondents shall provide the additional information in the Product Description on the Tender Response Worksheet:

(i) Blades

(ii) Application (e.g. Neurosurgery, abdomen)

(iii) Blade width in millimetres

(iv) Proximity of shave in millimetres.

d For each product offered in this category, Respondents shall provide the following information on the Tender Response Worksheet:

(i) The run time of the Surgical Clippers when the battery is fully charged

(ii) The time required to charge a fully discharged battery.

(iii) The terms and conditions under which Surgical Clippers and Units will be supplied.

Additional Information

e The following information shall be readily available for all contract users as hard and/or electronic copy:

(i) Instructions for use

(ii) Instructions for cleaning

(iii) Information relating to the conditions of warranty.

Category 14 - Irrigation Sets

a A range of sterile, single use Irrigation Sets is required to suit a number of surgical procedures including arthroscopy, hysteroscopy, laparoscopic and urology.

b Irrigation Sets shall incorporate:

(i) A clamping mechanism that will completely stop the flow of fluid when in it is in the closed position

(ii) Plastic spikes

(iii) A connector or series of connectors that permits connection to the relevant endoscope and where appropriate, subsequent connection to a Foley catheter.

(iv) Irrigation sets that incorporate a hand pump shall also include a one-way valve mechanism to prevent backflow of fluid

(v) Hand pumps shall be flexible and permit rapid and consistent delivery of fluid to the operative site

(vi) On Y sets, each limb shall incorporate a clamp that will completely stop the flow of fluid when it is in the closed position.

(vii) Preference will be given to Irrigation Sets intended for T.U.R. and urological procedures that incorporate a roller clamp to regulate the flow of fluid delivery.

c For each Irrigation Set offered, Respondents shall provide the additional information in the Product Description on the Tender Response Worksheet:

(i) Single or double spike

(ii) Length in centimetres

(iii) Integral hand pump (where applicable)

(iv) Type of clamp for management of fluid flow (e.g. G clamp)

(v) Drip chamber (where applicable).

Category 15 - Light Handle Covers

a A range of sterile, single use Light Handle Covers is required to meet operative needs.

b Light Handle Covers shall:

(i) Fix securely to light handles

(ii) Be packaged in a peel pack.

c For each product offered in this category, Respondents shall provide the additional information in the Product Description on the Tender Response Worksheet:

(i) Rigid or semi rigid

(ii) For use with camera light (where applicable).

d Respondents shall advise on the Tender Response worksheet the availability of adaptors to facilitate use of handles with the range of operating room lights.

Category 16 - Haemostatic Agents and Sealants

a A range of sterile, topical, absorbable, Haemostatic Agents and Sealants for internal use is required to meet clinical needs.

b For each product offered in this category, Respondents shall provide the additional information in the Product Description on the Tender Response Worksheet:

(i) Haemostatic agent or sealant

(ii) Material (e.g. cellulose-based, gelatine-based, Wax-based, Fibrin-based)

(iii) Size (e.g. dimensions in centimetres, weight in grams, volume in millilitres)

(iv) Presentation (e.g. sheet, film, syringe, powder)

(v) Diluent (where applicable)

(vi) Active ingredient (where applicable)(e.g. thrombin)

(vii) Tracking labels (where applicable).

c For each product offered in this category, Respondents shall provide the following information on the Tender Response Worksheet:

(i) Storage (e.g. freezer, refrigerator)

(ii) Storage Temperatures (e.g. 25 °C).

(iii) Cannula; length in mm, diameter in mm, attachment system (e.g. luer lock)

(iv) Catheter; length in cm, French size, minimum accessory channel in mm

(v) Application Devices

(vi) Surgical air or CO2 Sealants requirements (if applicable)

(vii) Other

Respondents' Note

d Only surgeons will be considered as clinical references for Haemostatic Agents and Application systems (Laparoscopic or Open).

Category 17 - Suction Tubing (ENT and Neurosurgery)

a A full range of fine bore, sterile, single use Suction Tubing is required for use in ENT and Neurosurgery.

b Suction Tubing shall be transparent to allow for visualisation of fluids.

c For each product offered in this category, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) Inner diameter (I.D.) in millimetres

(ii) Outer diameter (O.D) in millimetres

(iii) Length in centimetres

(iv) Double or single wrapped

(v) Connectors (where applicable) (e.g. Linket)

(vi) Attached suction device (where applicable).

Category 18 - Embolectomy Catheters

a A range of sterile, single use Embolectomy Catheters is required to meet clinical needs, including but not restricted to use in arterial, venous and peripheral vasculature and in synthetic grafts.

b Embolectomy Catheters shall:

(i) Be radio-opaque to aid in visualisation and catheter placement.

(ii) Be clearly marked with the balloon volume.

c For each product offered in this category, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) Vessel or area of use (e.g. arterial, venous)

(ii) Length in centimetres

(iii) Inflated balloon volume in millilitres

(iv) Recommended PSI range

(v) Stylet (where applicable)

(vi) Colour coding (e.g. purple)

(vii) Latex content (%).

d For each product offered in this category, Respondents shall provide the additional information on the Tender Response Worksheet:

(i) Low profile balloon (where applicable).

Category 19 - Chest Drainage Systems and Consumables

Chest Drainage Tubes, Valves and Kits

a A range of sterile, single use Chest/Mediastinal Drainage Tubes, Valves and Kits is required to meet clinical needs.

b Chest Drainage Valves shall be one way.

c Chest Drainage Tubes shall:

(i) Incorporate a radio-opaque line to assist in the determination of correct tube positioning

(ii) Incorporate graduated markings in centimetres to assist in determination of depth of placement

(iii) Incorporate a flexible connection area that permits secure connection of a Chest Drainage Valve or System

(iv) Include the expiry date and lot number on the packaging of individual items

(v) Be smooth and kink resistant.

(vi) Respondents shall advise the product tracking process for recall purposes.

d For each Drainage Tubes, Valves and Kits product offered, Respondents shall provide the additional information in the Product Description on the Tender Response Worksheet:

(i) Straight or angled

(ii) Trocar (where applicable)

(iii) Blunt or sharp

(iv) Position of drainage holes (e.g. central)

(v) Connector type (e.g. Luer Lock)

(vi) Trimmable (where applicable)

(vii) Compatibility options (e.g. Linket, Y – Connector)

(viii) Contents of kit (where applicable)

(ix) Individual components of kits (e.g. valve)

e Respondents shall advise on the Tender Response Worksheet the availability of tracking stickers.

Chest Drainage Systems

a A range of sterile, single patient use Chest Drainage Systems is required to meet clinical needs.

b The drainage chamber shall incorporate a graduated scale to allow for estimation of drainage volume.

c Drainage tubing shall incorporate a means of minimising the risk of kinking.

d Chest Drainage Systems shall incorporate a valve system to prevent mixing of underwater seal fluid and drainage fluid in the event that the unit is tipped over.

e Where present, the water seal chamber shall be transparent or translucent to allow clear visualisation of the presence of a water seal.

f Preference will be given to systems incorporating stabilisers that enable them to stand freely and safely on the floor.

g For each product offered in this category, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) Patient age range (e.g. paediatric, adult)

(ii) Capacity in millilitres

(iii) Graduation scale (e.g. 5 millilitres or 25 millilitres)

(iv) Number of chambers (e.g. single or triple)

(v) Dry or wet suction

- Suction regulator (where applicable)
- Indicator of suction in centimetres of H2O

(vi) Filter (where applicable)

- Level of filtration in microns
- Pressure relief valve (where applicable)

(vii) Tubing

- Length of tubing in centimetres
- Inner diameter in millimetres
- Outer diameter in millimetres

(viii) Anti-coagulation properties (where applicable)

(ix) Manometer or negative pressure gauge (where applicable)

(x) Needle free ports (where applicable)

(xi) Number of ports

(xii) Auto-transfusion blood bags (where applicable)

(xiii) Capacity in millilitres

(xiv) Additional components (e.g. connectors, connection tubing).

h For each product offered in this category, Respondents shall provide the following information in the Tender Response Worksheet:

(i) Carrying device or handle on unit

(ii) Method of attachment (where applicable).

Additional Information

i The following information shall be readily available for all contract users in hard and/or electronic copy:

(i) Instructions for use

(ii) Information relating to the conditions of warranty.

Ambulatory Chest Drainage Systems

a A range of sterile, single patient use Ambulatory Chest Drainage systems is required for the management of patients in the non-hospital setting or where connection of a more complex chest drainage system is impractical or not warranted for managing a patient's clinical condition.

b Ambulatory Chest Drainage Systems shall incorporate a one way valve to prevent backflow into the pleural cavity.

c Catheters offered as part of an Ambulatory Chest Drainage System shall also comply with the specifications of Category 19.01 and 19.02??

d For each product offered in this category, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) Dimensions in centimetres

(ii) Capacity in millilitres

(iii) Graduations in millilitres

(iv) Filter (where applicable)

(v) Integral vent disc (where applicable)

(vi) Empty valve (where applicable)

(vii) With requisites for insertion (where applicable)

(viii) Attachment device (where applicable)

(ix) Catheter (where applicable)

(x) Additional components (where applicable)

(xi) Contents of kit (where applicable).

Chest Drainage Systems Powered

a A range of powered devices with sterile, single patient use Powered Chest Drainage Systems is required to meet clinical needs.

b The drainage chamber shall incorporate a graduated scale to allow for estimation of drainage volume.

c Drainage tubing shall incorporate a means of minimising the risk of kinking.

d Powered Chest Drainage Systems shall incorporate both filter and valve systems, with preference given to antimicrobial valves.

e Powered Chest Drainage Systems will continue to provide consistent suction irrespective of patient position or height of device

f Preference will be given to systems incorporating stabilisers that enable them to stand freely and safely on the floor.

g Preference will be given to compact, portable, light-weight systems

h Preference will be given to systems incorporating patient lock-out safety measures

i Safety mechanism and alarm system (e.g. detection of rapid changes to output volume, changes to pressure readings, blockages, air leaks)

j Data recorded from device shall be able to be uploaded onto external devices (e.g. PC, tablets)

k For each product offered in this category, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) Safety mechanism and alarm specifications (e.g. parameters for alarms)

(ii) Patient age range (e.g. paediatric, adult)

(iii) Device/Powered system specifications

- Functional test capacity and requirements/recommendations

(iv) Digital display on Powered Chest Drainage System

- What device records and measures
- Measurement scale (e.g. Mls/min)
- Access to device history

- Capacity to store patient history on device (e.g. days stored)
- Accuracy of data recorded (e.g. accuracy associated with air leak)

(v) Battery operation and power supply specifications

- Power source (e.g. cables or batteries or combined)
- Length of battery life (where applicable, whilst machine not in power source)
- Recharge capability of battery

(vi) Software specifications

- Upgrade requirements and availabilities

(vii) Canister specifications

- Capacity in millilitres
- Graduation scale (e.g. 5 millilitres or 25 millilitres)
- Sterile
- Material of canister
- Presence of safety chamber
- Presence of solidifiers
- Number of chambers (e.g. single or triple)
- Open or closed system

(viii) Suction regulator (where applicable)

(ix) Indicator of suction in centimetres of H_2O

(x) Filter (where applicable)

- Level of filtration in microns
- Pressure relief valve (where applicable)

(xi) Tubing

- Length of tubing in centimetres
- Inner diameter in millimetres
- Outer diameter in millimetres
- Flush ability (e.g. automated/manual)

(xii) Anti-coagulation properties (where applicable)

(xiii) Safety seals (e.g. anti-splash)

(xiv) Manometer or negative pressure gauge (where applicable)

(xv) Needle free ports (where applicable)

(xvi) Number of ports

(xvii) Capacity in millilitres

(xviii) Weight of system (e.g. before application of canister)

(xix) Additional components (e.g. connectors, connection tubing).

l For each product offered in this category, Respondents shall provide the following information in the Tender Response Worksheet:

(i) Accessories for unit (e.g. bed/rail brackets, straps, support brackets)

(ii) Method of attachment (where applicable)

Additional Information

m The following information shall be readily available for all contract users as hard and/or electronic copy:

(i) Instructions for use

(ii) Information relating to the conditions of warranty.

Category 20 - Wound Drainage Systems and Consumables

Wound Drainage Tubes and Sets

a A range of sterile, single patient use Wound Drainage Tubes and Sets is required to drain a wide range of operative sites.

b Wound Drainage Tubes shall be kink resistant.

c Use by dates and lot numbers shall be clearly marked on the packaging of individual items.

d Trocar tips shall be protected to avoid damage to packaging or sharps injury prior to insertion.

e Respondents shall advise in the HPV Procurement Portal the product tracking process for recall purposes.

f For each product offered in this category, Respondents shall provide the additional information in the Product Description on the Tender Response Worksheet:

(i) Trocar (where applicable)

(ii) Free-draining or for connection to a wound drainage system

(iii) Material (e.g. PVC)

(iv) Shape (e.g. flat)

(v) Corrugated or smooth

(vi) Soft or firm

(vii) Number of channels

(viii) Central or lateral drainage perforations (where applicable)

(ix) Drainage bag (where applicable)

(x) Connectors (where applicable)

(xi) Sets and individual components (drain tubes and trocars only).

g Respondents shall advise on the Tender Response Worksheet the availability of tracking stickers.

Wound Drainage Systems and Components

a A range of sterile, single patient use, closed Wound Drainage Systems and Components is required to meet clinical needs.

b For each product offered in this category, Respondents shall provide the additional information in the Product Description on the Tender Response Worksheet:

(i) Capacity in millilitres

(ii) The level or range of suction in millimetres of mercury (mmHg)

(iii) Tubing length in centimetres

(iv) Type of connection (e.g. single, double)

(v) Reinfusion capacity in millilitres (where applicable)

(vi) Additional components (e.g. cardio connector).

E Appendices

Appendix 1 - Product List

Category		Subcategories	
1	Electrosurgical Return Electrodes	1.01	Electrosurgical Return Electrode, Split, For Use With Contact Quality Monitoring Systems, Single Use, Lead
		1.02	Electrosurgical Return Electrode, Split, For Use With Contact Quality Monitoring Systems, Single Use, No Lead
		1.03	Electrosurgical Return Electrode, Solid, For Use With Contact Quality Monitoring Systems, Single Use, Lead
		1.04	Electrosurgical Return Electrode, Solid, For Use With Contact Quality Monitoring Systems, Single Use, No Lead
		1.05	Electrosurgical Return Electrode, Solid, For Use Without Contact Quality Monitoring Systems, Reusable, Lead
		1.06	Electrosurgical Return Electrode Lead, Full Range Of Lengths To Fit A Range Of Electrosurgical Units
		1.07	Electrosurgical Return Electrode, Other
2	Diathermy Consumables	2.01	Diathermy Pencil, With Universal Connector, Sterile, Single Use, Peel Pack
		2.02	Diathermy Pencil, With Universal Connector, Clinically Clean, Limited Re-use, Peel Pack
		2.03	Diathermy Pencil, Sterile, Other
		2.04	Diathermy Pencil Tips, Loop, Sterile, Single Use, Single Wrapped, Peel Pack
		2.05	Diathermy Pencil Tips, Needle, Sterile, Single Use, Single Wrapped, Peel Pack
		2.06	Diathermy Pencil Tips, Ball, Sterile, Single Use, Single Wrapped, Peel Pack
		2.07	Diathermy Pencil Tips, Blade, Sterile, Single Use, Single Wrapped, Peel Pack
		2.08	Diathermy Pencil Tips, Snare, Sterile, Single Use, Single Wrapped, Peel Pack
		2.09	Diathermy Pencil Tips, Spatula, Sterile, Single Use, Single Wrapped, Peel Pack
		2.10	Diathermy Pencil Tips, Other, Sterile, Single Use, Single Wrapped, Peel Pack
		2.11	Diathermy Pencil Tips, Loop, Reusable, Non Sterile
		2.12	Diathermy Pencil Tips, Needle, Reusable, Non Sterile
		2.13	Diathermy Pencil Tips, Ball, Reusable, Non Sterile
		2.14	Diathermy Pencil Tips, Blade, Reusable, Non Sterile
		2.15	Diathermy Pencil Tips, Other, Reusable, Non Sterile

Category		Subcategories	
		2.16	Diathermy Scratch Pad, Sterile, Single Use, Single Wrapped, Peel Pack
3	Smoke Evacuation Devices and Consumables	3.01	Smoke Evacuation Filters, Sterile, Single Use, Single Wrapped, Peel Pack
		3.02	Smoke Evacuation Tubing, Sterile, Single Use, Single Wrapped, Peel Pack
		3.03	Smoke Evacuation Wands, Sterile, Single Use, Single Wrapped, Peel Pack
		3.04	Smoke Evacuation Kits
		3.05	Smoke Evacuation Diathermy, Sterile, Single Use, Peel pack
		3.06	Smoke Evacuation Consumables, Other
		3.07	Smoke Evacuation Devices
4	Vessel Identification Loops	4.01	Vessel Identification Loops, Sterile, Single Use, X-Ray Detectable
5	Suture Boot Jaw Covers	5.01	Suture Boot Instrument Jaw Covers, Sterile, Single Use, X-Ray Detectable
6	Surgical Clamp Inserts	6.01	Clamp inserts, Sterile, Single Use
7	Scalpels, Scalpel Handles and Scalpel Blades	7.01	Scalpel Handle, Single use
		7.02	Scalpel Blade, Sterile, Single Use Carbon Steel, Sterile, Peel Pack
		7.03	Scalpel Blade, Sterile, Single Use, Stainless Steel, Sterile, Peel Pack
		7.04	Scalpel And Scalpel Blade, Sterile, Single Use, Carbon Steel, Sterile, Peel Pack
		7.05	Scalpel And Scalpel Blade, Sterile, Single Use, Stainless Steel, Sterile, Peel Pack
8	Stitch Cutter Blades	8.01	Stitch Cutter Blades, Sterile, Single Use
9	Scrub Sponges	9.01	Scrub Sponge, Single Use, Impregnated
		9.02	Scrub Sponge, Single Use, Non Impregnated
10	Warming/Cooling Units and Consumables	10.01	Warming/Cooling Units (Air, Liquid, convection)
		10.02	Warming/Cooling Units Accessories (e.g. tubing)
		10.03	Warming/Cooling Blankets, Single Use, Sterile, Peel Pack
		10.04	Warming/Cooling Blankets, Single Use, Non Sterile, Peel Pack
		10.05	Warming/Cooling Blankets, Reusable
		10.06	Warming/Cooling mattress overlays, Single use
		10.07	Warming/Cooling Consumables, mattress overlays, reusable
		10.08	Warming/Cooling Consumables, Pads, Single use
		10.09	Warming/Cooling Consumables, other (e.g. underlays, etc.)
11	Sharps Containment Devices	11.01	Sharps Containment Device, Sterile, Rigid Plastic
12	Surgical Marking Pens	12.01	Surgical Marking Pen, Sterile, Single use, Peel Pack

Category		Subcategories	
		12.02	Surgical Marking Pen, Non-Sterile, Single use
13	Surgical Clippers	13.01	Surgical Clippers, Battery Powered
		13.02	Surgical Clipper Blades, Single Use, Clinically Clean
		13.03	Battery Charger, with Charging Indicator Light
14	Irrigation Sets	14.01	Irrigation Set, Arthroscopy, Sterile, Single Use, Single Spike, With Drip Chamber, Peel Pack
		14.02	Irrigation Set, Arthroscopy, Sterile, Single Use, Single Spike, Without Drip Chamber, Peel Pack
		14.03	Irrigation Set, Arthroscopy, Sterile, Single Use, Double Spike, With Drip Chamber, Peel Pack
		14.04	Irrigation Set, Arthroscopy, Sterile, Single Use, Double Spike, Without Drip Chamber, Peel Pack
		14.05	Irrigation Set, Hysteroscopy, Sterile, Single Use, Single Spike, With Drip Chamber, Peel Pack
		14.06	Irrigation Set, Hysteroscopy, Sterile, Single Use, Single Spike, Without Drip Chamber, Peel Pack
		14.07	Irrigation Set, Hysteroscopy, Sterile, Single Use, Double Spike, With Drip Chamber, Peel Pack
		14.08	Irrigation Set, Hysteroscopy, Sterile, Single Use, Double Spike, Without Drip Chamber, Peel Pack
		14.09	Irrigation Set, Urological, Sterile, Single Use, Single Spike, With Drip Chamber, Peel Pack
		14.10	Irrigation Set, Urological Sterile, Single Use, Single Spike, Without Drip Chamber, Peel Pack
		14.11	Irrigation Set, Urological, Sterile, Single Use, Double Spike, With Drip Chamber, Peel Pack
		14.12	Irrigation Set, Urological, Sterile, Single Use, Double Spike, Without Drip Chamber, Peel Pack
15	Light Handle Covers	15.01	Light Handle Cover, Rigid, Reusable
		15.02	Light Handle Cover, Sterile, Single Use, Peel Pack
16	Haemostatic Agents and Sealants	16.01	Haemostatic Agent, Sterile Pack, Topical and Absorbable, Cellulose Based
		16.02	Haemostatic Agent, Sterile Pack, Topical and Absorbable, Gelatin Based
		16.03	Haemostatic Agent, Sterile Pack, Topical, Wax Based
		16.04	Haemostatic Agent, Sterile Pack, Topical and Absorbable, Fibrin Based
		16.05	Haemostatic Agent, Sterile Pack, Topical and Absorbable, Other Based

Category		Subcategories	
		16.06	Haemostatic Sealant, Sterile Pack, Topical
		16.07	Haemostatic Agents and Sealants Accessories
		16.08	Haemostatic Agents and Sealants Application Devices
17	Suction Tubing (ENT and Neurosurgery)	17.01	Suction Tubing, With Connectors, Sterile, Single Use, Double Wrapped, Peel Pack
		17.02	Suction Tubing, Without Connectors, Sterile, Single Use, Double Wrapped, Peel Pack
18	Embolectomy Catheters	18.01	Embolectomy Catheter, Sterile, Single Use, With Stylet, Peel Pack
		18.02	Embolectomy Catheter, Sterile, Single Use, Without Stylet, Peel Pack
19	Chest Drainage Systems and Consumables	19.01	Chest Drainage Tube, PVC, Sterile, Single Use, Straight, with Trocar, Peel Pack
		19.02	Chest Drainage Tube, PVC, Sterile, Single Use, Straight, without Trocar, Peel Pack
		19.03	Chest Drainage Tube, PVC, Sterile, Single Use, Angled, without Trocar, Peel Pack
		19.04	Chest Drainage Tube, Silicone, Sterile, Single Use, Straight, without Trocar, Peel Pack
		19.05	Chest Drainage Tube, Silicone, Sterile, Single Use, Straight, with Trocar, Peel Pack
		19.06	Chest Drainage Tube, Silicone, Sterile, Single Use, Angled, without Trocar, Peel Pack
		19.07	Heimlich Valves, Sterile, Single Use, Peel Pack
		19.08	Chest Drainage Insertion Kits, Sterile, Single Use, Peel Pack
		19.09	Chest Drainage Individual Components, Sterile, Single Use, Peel Pack
		19.1	Chest Drainage System, Sterile, Single Use, Single Chamber, Dry Suction With Auto-transfusion, With Integral Tubing
		19.11	Chest Drainage System, Sterile, Single Use, Single Chamber, Dry Suction Without Auto-transfusion, With Integral Tubing
		19.12	Chest Drainage System, Sterile, Single Use, Single Chamber, Wet Suction With Auto-transfusion, With Integral Tubing
		19.13	Chest Drainage System, Sterile, Single Use, Single Chamber, Wet Suction Without Auto-transfusion, With Integral Tubing
		19.14	Chest Drainage System, Sterile, Single Use, Single Chamber Without Integral Tubing
		19.15	Chest Drainage System, Sterile, Single Use, Multiple Chamber Dry Suction With Blood Recovery/Auto-transfusion
		19.16	Chest Drainage System, Sterile, Single Use, Multiple Chamber Dry Suction Without Blood Recovery/Auto-transfusion

Category		Subcategories	
		19.17	Chest Drainage System, Sterile, Single Use, Multiple Chamber Wet Suction With Blood Recovery/Auto-transfusion
		19.18	Chest Drainage System, Sterile, Single Use, Multiple Chamber Wet Suction Without Blood Recovery/Auto-transfusion
		19.19	Tubing (For Chest Drainage Systems Without Integral Tubing) Sterile, Single Use
		19.2	Chest Drainage System, Auto-transfusion Blood Bags, Sterile, Single Use
		19.21	Chest Drainage System, Individual Components, Sterile, Single Use
		19.22	Chest Drainage System, Floor Stand/Bed Hanger
		19.23	Chest Drainage System, Other
		19.24	Chest Drainage System Powered
		19.25	Chest Drainage System Powered, Consumables
		19.26	Ambulatory Chest Drainage Systems, Sterile, Single Use
		19.27	Ambulatory Chest Drainage Systems, Individual Components, Sterile, Single Use
20	Wound Drainage Systems and Consumables	20.01	Wound Drainage Tube, PVC Single Channel, Sterile, Single Use, Without Trocar, Peel Pack
		20.02	Wound Drainage Tube, PVC Multiple Channel, Sterile, Single Use, Without Trocar, Peel Pack
		20.03	Wound Drainage Tube, Silicone Single Channel, Sterile, Single Use, Without Trocar, Peel Pack
		20.04	Wound Drainage Tube, Silicone Multiple Channel, Sterile, Single Use, Without Trocar, Peel Pack
		20.05	Wound Drainage Tube, PVC Corrugated, Sterile, Single Use, Without Trocar, Peel Pack
		20.06	Wound Drainage Sets, Silicone Corrugated, Sterile, Single Use, Without Trocar, Peel Pack
		20.07	Wound Drainage Sets, PVC Single Channel, Sterile, Single Use, With Trocar, Peel Pack
		20.08	Wound Drainage Sets, PVC Multiple Channel, Sterile, Single Use, With Trocar, Peel Pack
		20.09	Wound Drainage Sets, Silicone Single Channel, Sterile, Single Use, With Trocar, Peel Pack
		20.10	Wound Drainage Sets, Silicone Multiple Channel, Sterile, Single Use, With Trocar, Peel Pack
		20.11	Wound Drainage Sets, PVC Corrugated, Sterile, Single Use, With Trocar, Peel Pack
		20.12	Wound Drainage Sets, Silicone Corrugated, Sterile, Single Use, With Trocar, Peel Pack

Category		Subcategories	
		20.13	Wound Drainage, Trocars only, Sterile, Single Use, Peel Pack
		20.14	Kits (Trocars and Drain Tubes only), Sterile, Single Use, Peel Pack
		20.15	Other, Sterile, Single Use, Peel Pack
		20.16	Wound Drainage System, Low Suction, With blood recovery/auto-transfusion capacity, Sterile, Single Use
		20.17	Wound Drainage System, Low Suction, Without blood recovery/auto-transfusion capacity, Sterile, Single Use
		20.18	Wound Drainage System, Medium Suction, With blood recovery/auto-transfusion capacity, Sterile, Single Use
		20.19	Wound Drainage System, Medium Suction, Without blood recovery/autotransfusion capacity, Sterile, Single Use
		20.20	Wound Drainage System, High Suction, With blood recovery/auto-transfusion capacity, Sterile, Single Use
		20.21	Wound Drainage System, High Suction, Without blood recovery/auto--transfusion capacity, Sterile, Single Use
		20.22	Wound Drainage System, Auto-transfusion Blood Bags, Sterile, Single Use
		20.23	Wound Drainage Individual Components, Sterile, Single Use

Appendix 2 - References

A 2.a Standards

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

Standard Number	Standard Name
AS/NZS 3200.1.0:1998	Medical electrical equipment Part 1.0: General requirements for safety – Parent Standard
AS/NZS 3200.2.2:1999	Medical electrical equipment Part 2.2: Particular requirements for safety – High frequency surgical equipment (modified and including the full text of IEC 60601-2-2:1998) or,

Standard Number	Standard Name
ANSI/AAMI HF18: 2001	Electrosurgical devices
AS/NZS 3200.1.0:1998	Medical electrical equipment Part 1.0: General requirements for safety – Parent Standard
AS/NZS 3200.2.2:1999	Medical electrical equipment Part 2.2: Particular requirements for safety – High frequency surgical equipment (modified and including the full text of IEC 60601-2-2:1998) or,
AS/NZS 3200.1.1:1995	Approval and test specification – Medical electrical equipment Part 1.1: General requirements for safety – Collateral Standard: Safety requirements for medical electrical use.
AS/NZS 3200.1.2:2005	Approval and test specification – Medical electrical equipment Part 1.2: General requirements for safety – Collateral Standard: Electromagnetic compatibility requirements and tests.
AS/NZS 3200.2.35 1999	Medical electrical equipment – Particular requirements for safety - Blankets, pads and mattresses intended for heating in medical use
AS/NZS 4173:2004	Guide to the Safe Use of Lasers in Healthcare
AS/NZS 2211.10:2004	Safety Laser Products – Application Guide and Explanatory Notes
AUSTRALIAN STANDARD – AS16571:2015	Systems for evacuation of plume generated by medical devices (ISO 1651:2014,MOD)

A 2.b Guidelines and Other References

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

- NHMRC (2010), *Australian Guidelines for the Prevention and Control of Infection in Healthcare, Commonwealth of Australia*
- Therapeutic Goods Administration (1991), *Therapeutic Goods Order No. 37: General Requirements for Labels for Therapeutic Goods*
- Therapeutic Goods Administration (2004*), Uniform Recall Procedure for Therapeutic Goods, Commonwealth of Australia*
- ACORN Standards: Laser Safety and Surgical Plume and Surgical hand antiseptics, gowning and gloving