PART 4: STATEMENT OF REQUIREMENTS

1. Participating Health Services

a. The Participating Health Services for this ITS are

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

(ii) Other relevant participating health and health related organisations.

2. Scope

a. HSV is seeking responses for Surgical Instruments - Open and Laparoscopic for use in Participating Health Services. The envisaged Term of the Agreement is three (3) years plus one optional two-year extension period (3+2).

b. The scope of this ITS includes:

(i) Single-use and limited reuse surgical instruments used in the following specialist laparoscopic surgeries including bariatric surgery:

- upper gastro-intestinal
- cardio-thoracic
- urology
- gynaecology
- hepato-biliary
- colo-rectal

(ii) instruments used for open surgery (where indicated in this Part 5 – Statement of Requirements). preference will be given for single-use instruments

c. The scope of this ITS does not include:

(i) surgical instruments used in the following specialist laparoscopic surgeries:

- spinal
- ENT
- neurosurgery
- orthopaedic
- plastic

(ii) skin staples and removers or tissue adhesives.

3. Product Categories

a. A complete range of Surgical Instruments Open and Laparoscopic is required for treatment of patients across Victorian Public Health Services

b. The categories of products required under this ITS include:

CATEGORY NUMBER	CATEGORY NAME
1	Clip Applicators for Open and Laparoscopic Surgery
2	Clips for Open and Laparoscopic Surgery
3	Staple Applicators for Open and Laparoscopic Surgery
4	Staple Reload Cartridge for Open and Laparoscopic Surgery
5	Surgical Mesh for Open and Laparoscopic Surgery
6	Surgical Mesh Fixation Devices and Applicators for Open and Laparoscopic Surgery
7	Insufflation Consumables for Laparoscopic Surgery
8	Suction Irrigation Consumables for Laparoscopic Surgery
9	Access Devices for Laparoscopic Surgery
10	Access Devices for Open Surgery
11	Balloon Dilation and Dissection Device for Laparoscopic Surgery
12	Single-use Instruments for Laparoscopic Surgery
13	Diathermy Electrodes for Laparoscopic Surgery
14	Cutting and Coagulation Instruments for Laparoscopic Surgery
15	Specimen Retrieval Device/Bag for Laparoscopic Surgery
16	Sutures and Suturing Devices for Laparoscopic Surgery
17	Gynaecology/Uterine Ablation Surgical Instruments
18	Gynaecology/Uterine Manipulation and Vacuum Curette Surgical Instruments
19	Gynaecology/Pelvic Floor Reconstruction Surgical Instruments
20	Gynaecology/Morcellation Surgical Instruments
21	Gynaecology/Vaginal Speculums
22	Gynaecology/Tubal Ligation Applicators and Clips

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

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

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

4. Restricted and extended basket of goods (Not Used)

5. Product Offering

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

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

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

   (i) HPVC2018-036 Surgical Instruments Open and Laparoscopic

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

6. Clinical Trials

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

Product Requirements

7. Standards and Compliance

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

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

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

8. Packaging and Labelling

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

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

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

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

   (i) whether the product is sterile;

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

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

   (iv) manufacturing date

   (v) tracking labels.

   (vi) expiry date

9. Infection Control

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

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

c. All reuseable items offered must be capable of being cleaned with a hospital or instrument grade disinfectant. Preference will be given if the disinfectant is listed on the Hand Hygiene, Disinfectants and Chemical Products contract.

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

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

f. Sterilisation compatible with cleaning agents on HPVC2016-124 Hand Hygiene, Disinfectants and Chemical Products Contract – this will change to PPE contract.

10. Substances of Concern

a. Suppliers must provide the latex status and latex status labelling for every product tendered, in the Tender Response Worksheet (TRW).

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

c. Suppliers must provide the Diethylhexyl phthalate (DEHP) status of the product as well the percentage (%) of DEHP content of the product, in the Tender Response Worksheet (TRW).

d. Preference will be given to products that meet TGA limits of 1% DEHP.

11. Product Information

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

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

c. All product information submitted should:

(i) be in electronic format

(ii) be in English

(iii) be specific to the product offered

(iv) contain the Respondent's company name

(v) include the product code

(vi) include a detailed specification of the product

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

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

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 in accurately identifying 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 d above; or

(ii) Is incomplete as to clause c.

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

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

12. Consignment Stock (Not Used)

13. Loan Sets and Instrument Trays (Not Used)

14. Warranty

a. All products covered in this ITS are to be issued with a warranty for 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.

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

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

e. It is 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.

15. Recall Process

a. All recalls must be managed in line with the *Uniform Recall Procedure for Therapeutic Goods* (URPTG) (V2.4, March 2024).

b. All recalls and/or hazard alerts are to be completed using GS1 Recall OR Recall Health.

c. Class 1 recalls (as defined by the TGA's *Uniform Recall Procedure for Therapeutic Goods* (URPTG) (V2.4, March 2024) must also meet the requirements under section Part 5 on Warranty, where applicable.

d. Delivery cost of replaced items and recalled items should be free of charge. Refer to Part 5 – Module A, 11.1 Defective Goods and Defective Delivery.

Pricing

16. Price Variation

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

17. Sole and Panel Pricing

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

b. In the Tender Response Worksheet, Respondents are to list price options for both Sole Supply and Panel Supply. Note sole supply ensures all contracted purchases by health services for a subcategory the subject of a sole supply award.

c. Where HSV elects to award panel supply, health services may choose to purchase from any or all contracted suppliers.

d. If HSV elects to award sole supply, HSV reserves the right to negotiate outcomes with successful Respondent.

18. Price review

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

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

Delivery

19. Electronic Data Interchange

a. The Participating Health Services prefer to exchange orders, payments, acknowledgements, invoices, remittance notices and other records (Data) electronically, in place of tangible documents. Successful Respondents are required to work with the Participating Health Services to achieve this outcome.

20. Delivery

a. Surgical Instruments Open and Laparoscopic will be delivered to the location(s) specified by Participating Health Services within the shortest possible timeframe; however, this shall not exceed two (2) Business Days from receipt of order unless otherwise agreed with the Participating Health Service.

21. Urgent Deliveries

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

b. The Respondent shall be able to receive and action urgent delivery requests 24 hours a day, 7 days a week.

c. Urgent deliveries should be received by Participating Health Services within 24 hours from receipt of order.

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.

Support

22. Training

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

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

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

   (ii) off-site study days for clinicians

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

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

   (v) training materials.

23. Customer Service and Support

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

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

   (i) inherently familiar with the contracted products

   (ii) appropriately qualified

   (iii) technically/clinically knowledgeable about the contracted products

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

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

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

   (i) liaising with clinicians to recommend products and solutions

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

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

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

   (v) providing informational materials

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

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

Award

24. Conditional Acceptance

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

b. Clause 7.11 of the Draft Agreement sets out terms relating to Conditionally Accepted Deliverables.

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

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

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

25. Key Performance Indicators

a. Refer to PART 5: DRAFT AGREEMENT.

26. Service Level Agreement

a. Participating Health Services may enter into a Service Level Agreement (SLA) with the successful Respondent(s), on the terms set out in the Draft Agreement clause 4.3 Service Level Agreement. The SLA may cover the following arrangements:

   (i) the provision of products on consignment

   (ii) requirements for stock management and rotation

   (iii) arrangements for ordering, invoicing and delivery

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

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

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

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

CATEGORY 1 – CLIP APPLICATORS FOR OPEN AND LAPAROSCOPIC SURGERY

A range of clip applicators is required for use in open and laparoscopic surgery.

Mandatory Criteria
All clip applicators offered shall be

a. sterile

Clinical Attributes
For each clip applicator offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. single-use/reusable
b. for single and multiple clip application
c. a range of lengths, shapes and sizes
   (i) micro, small, medium, medium large, large, extra Large
d. a range of handle lengths
e. a range of grip formats (e.g. pistol, lever)
f. With or without single-use clips
g. to suit the range of clip sizes and reload unit sizes
h. with and without colour-code identification
i. with and without a clip counter

Additional Information
Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. Where clips are included with the applicator, these items shall also comply with the specifications in Category 2.
b. Free on loan Re-usable Clip applicators are required when purchasing clips under category 2.

CATEGORY 2 – CLIPS FOR OPEN AND LAPAROSCOPIC SURGERY

A range of sterile, single-use clips is required for use in open and laparoscopic surgery.

Mandatory Criteria
All single-use clips are required for use in open and laparoscopic surgery shall be

a. sterile
b. single-use

Clinical Attributes
For each clip offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. non-absorbable and absorbable
b. a range of shapes and sizes
c. a range of load unit sizes (i.e. various numbers of clips)
d. clip load units for single-use and reusable clip applicators
e. with and without a ‘last clip’ indicator on clip cartridge
f. with and without colour-code identification
g. material of construction

CATEGORY 3 – STAPLE APPLICATORS FOR OPEN AND LAPAROSCOPIC SURGERY

A range of staple applicators to suit a range of staple sizes is required for use in open and laparoscopic surgery.

Mandatory Criteria
All staple applicators shall be

a. sterile

Clinical Attributes
For each clip applicator offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. reloadable and non-reloadable
b. single-use and limited reuse
c. single-use, reusable limited reuse
d. with and without a single-use staple unit
e. with a range of grip formats (e.g. pistol, lever)
f. size
g. dimensions (L x H mm)
h. for straight and curved stapling units
i. for straight and roticulating units
j. for cutting and non-cutting staple units
k. for articulating and non-articulating staple units
l. for rotating and non-rotating staple units
m. with and without colour-code identification
n. with and without a graduated staple closure and integrated reload
o. powered and non-powered
p. material of construction

Additional Information
Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. Where a single-use staple unit is incorporated with the staple applicator, it shall comply with the specifications set out in Category 4.

CATEGORY 4 – STAPLE RELOAD CARTRIDGE FOR OPEN AND LAPAROSCOPIC SURGERY

A range of sterile, single-use staple units is required for use in open and laparoscopic surgery.

Mandatory Criteria
All staple units offered shall be

a. sterile
b. single-use
c. staple units must be clearly labelled to differentiate size.

Clinical Attributes
For each staple unit offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. a full range of sizes of staple size (i.e. height, length)
b. a full range of sizes of reload size (i.e. length)
c. with and without colour-code identification
d. reloadable and non-reloadable
e. cutting and non-cutting
f. angled and curved tip
g. reinforced and non-reinforced
h. articulating and non-articulating
i. with and without a graduated staple closure
j. with and without an integrated reload
k. material of construction
l. bioabsorbable staple line reinforcement
    (i) a range of sizes (in mm)
    (ii) a range of colours
    (iii) number of units

CATEGORY 5 – SURGICAL MESH FOR OPEN AND LAPAROSCOPIC SURGERY

A range of sterile surgical mesh is required for use in open and laparoscopic surgery.

Mandatory Criteria
All surgical mesh shall be

a. sterile
b. single-use

Clinical Attributes

For each Surgical Mesh offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. absorbable and non-absorbable
b. single and multiple layer (specify number of layers)
c. non-impregnated or impregnated (specify substance)
d. a range of materials, including (but not limited to):
    (i) polypropylene
    (ii) polyglycolic acid
    (iii) silicone
    (iv) biological
    (v) PTFE
e. a range of forms, including:
    (i) monofilament and multifilament
    (ii) open and close weave mesh
    (iii) self-fixating and non self-fixating
f. a full range of shapes
g. a full range of sizes
h. with and without:
    (i) an application device
    (ii) a fixation device
    (iii) sleeves
    (iv) straps
    (v) a memory
i. dyed and undyed

CATEGORY 6 – SURGICAL MESH FIXATION DEVICES AND APPLICATORS FOR OPEN AND LAPAROSCOPIC SURGERY

A range of sterile, single-use surgical mesh fixation devices is required for use in open and laparoscopic surgery.

Mandatory Criteria
All mesh fixation devises shall be

a. sterile
b. single-use

Clinical Attributes
For each mesh fixation device offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. type
b. a range of sizes
c. reloadable and non-reloadable applicators devices
d. absorbable and non-absorbable
e. material of construction
f. with or without cartridge

Additional Information

Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

Note – Fixation glue currently in Category 16 of HPVC2024-057 Operating Room and Wound Drainage Consumables is out of scope in this contract.

CATEGORY 7 – INSUFFLATION CONSUMABLES FOR LAPAROSCOPIC SURGERY

A range of sterile insufflation devices(consumables) is required for use in laparoscopic surgery.

Mandatory Criteria

a. sterile
b. single-use
c. pneumo-peritoneum needles must incorporate a stopcock
d. all filters must be hydrophobic and filter 0.1 microns
e. all connections for insufflation devices must be luer-lock

Clinical Attributes

For each insufflation consumable offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. single-use pneumo-peritoneum needles
   (i) a range of needle sizes and lengths
   (ii) blunt and sharp
b. single-use insufflation tubing with a filter is required, including
   (i) a range of tubing lengths and diameters
   (ii) with and without
      - heating
      - humidification
      - powered
c. insufflation tubing shall be:
   (i) kink resistant
   (ii) compatible with a wide range of insufflation equipment

CATEGORY 8 – SUCTION IRRIGATION CONSUMABLES FOR LAPAROSCOPIC SURGERY

A range of sterile laparoscopic suction irrigation consumable units are required.

Mandatory Criteria

a. sterile

Clinical Attributes

For each suction irrigation unit offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. single-use or reusable
b. suction / irrigation consumables
c. irrigation tubing:
   (i) single or double spiked
   (ii) in a range of lengths (cm)
d. with and without a probe
e. probe (where applicable):
   (i) diameter (mm)
   (ii) with and without irrigation holes
f. thumb-operated or finger-operated valve activation mechanism
   (i) interchangeable to probe diameter
g. battery operated or non-battery (pressurised) operated

Additional Information

Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. The activation mechanism/trumpet valve assembly shall incorporate colour-coded suction and irrigation valve buttons
b. If presented in a fused manner, suction and irrigation tubing shall be readily separated at the distal end
c. The suction limb must incorporate a compatible to connection to fit standard wall suction systems

CATEGORY 9 – ACCESS DEVICES FOR LAPAROSCOPIC SURGERY

A range of sterile ports, trocars, sleeves, seals and cannulae used to gain and provide access for laparoscopic surgery is required.

Mandatory Criteria
All Access devices for laparoscopic surgery shall be

a. sterile
b. single-use

Clinical Attributes
For each access devices offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. material of construction
b. ports and trocars
   (i) a full range of sizes (diameter in mm) and lengths (cm's)
   (ii) threaded and non-threaded
   (iii) with and without trocars
   (iv) shielded and non-shielded
   (v) blunt and sharp
   (vi) bladed and bladeless (non-bladed)
   (vii) with and without an insufflation port
   (viii) with and without a fixation device
   (ix) for a range of approaches, including stepped, dilating, hand access and visual access
c. laparoscopic access device
   (i) full range of sizes flexible or non-flexible
   (ii) type of port – single/multiple
   (iii) insufflation with or without
   (iv) colour coded
d. laparoscope warming device
   (i) with or without reusable battery pack
   (ii) disposable or partially reusable device
   (iii) device length
   (iv) heating duration (hours)
e. laparoscope defogging/cleaning agent
   (i) solution or wipe – dimension or volume
   (ii) active ingredient

CATEGORY 10 – ACCESS DEVICES FOR OPEN SURGERY

A full range of open surgical retractors and elastic stays required.

Mandatory Criteria
All open surgical retractors and elastic stays shall be

a. Sterile

Clinical Attributes
For each open surgical retractor and elastic stays offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. open retractors
   (i) brand name
   (ii) single-use/reusable
   (iii) a range of lengths, shapes and sizes
   (iv) with and without colour-code identification
   (v) self-Retaining: Have mechanisms to hold themselves in place.
b. elastic stays
   (i) a range of sizes, colours and lengths
   (ii) with sharp or blunt hooks (single or double)

CATEGORY 11 – BALLOON DILATION AND DISSECTION DEVICES FOR LAPAROSCOPIC SURGERY

A range of sterile, single-use balloon dilation and dissection devices is required to create an operative space for laparoscopic surgery.

Mandatory Criteria
All balloon dilation and dissection devices shall be

a. sterile
b. single-use

Clinical Attributes
For each balloon dilation and dissection devices offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. a range of shapes, lengths and diameters
b. with or without insufflation
c. with or without fixation
d. material: Biocompatible materials
e. insufflation type – saline/Co2
f. laparoscopic Systems: Must be compatible with standard laparoscopic equipment and port sizes.

CATEGORY 12 – SINGLE-USE INSTRUMENTS FOR LAPAROSCOPIC SURGERY

A range of sterile hand-held laparoscopic surgical instruments is required.

Mandatory Criteria

Laparoscopic surgical instruments shall be

a. sterile
b. all bipolar connection points must have fixed pins.
c. single-use

Clinical Attributes

For each instrument offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. a range of laparoscopic scissors is required, including
   (i) a full range of sizes (mm) and lengths (mm/cm)
   (ii) a range of tip length (cm) and design (curved, straight, parrot/hook)
   (iii) with monopolar and bipolar electrosurgery potential
b. a range of laparoscopic dissectors is required, including
   (i) a full range of sizes (mm) and lengths (mm/cm)
   (ii) a range of tip configurations
   (iii) with monopolar and bipolar electrosurgery potential
   (iv) ratcheted and non-ratcheted
c. laparoscopic graspers including
   (i) a full range of sizes and lengths
   (ii) a range of tip configurations
   (iii) with monopolar and bipolar electrosurgery potential
   (iv) ratcheted and non-ratcheted
d. laparoscopic retractors, including
   (i) a full range of sizes and lengths
   (ii) a range of tip configurations
   (iii) locking mechanism
   (iv) number of prongs
   (v) articulating or non-articulating
e. a range of laparoscopic cholangiogram forceps
   (i) full range of lengths and diameters
   (ii) ratcheted or non-ratcheted handle
f. laparoscopic Needle holders including
   (i) full range of lengths and diameters
   (ii) ratcheted or non-ratcheted handle
   (iii) tip configurations (i.e. right, left, straight)
   (iv) bariatric drop down for lengths (mm)
   (v) diameter (mm)

Additional Information

Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. Out of Scope for the purpose of this ITS

   (i) Reposable
   (ii) Robotics instruments

CATEGORY 13 – DIATHERMY ELECTRODES FOR LAPAROSCOPIC SURGERY

A range of sterile, insulated laparoscopic diathermy electrodes is required.

Mandatory Criteria
All diathermy electrodes will be

a. sterile
b. single-Use

Clinical Attributes
For diathermy electrodes offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. monopolar and bipolar
b. foot or hand controlled
c. a range of lengths and sizes
d. a range of tip configurations
e. with and without reusable cables

Additional Information
Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. Diathermy electrodes with a suction/irrigation lumen are considered out of scope for the purposes of this ITS.
b. Diathermy consumables used for open surgery – refer to HPVC2024-057 Operating Room and Wound Drainage Consumables contract considered out of scope.

CATEGORY 14 – CUTTING AND COAGULATION INSTRUMENTS FOR LAPAROSCOPIC SURGERY

A range of sterile instruments is required for use with cutting and coagulation equipment in and laparoscopic surgery.

Mandatory Criteria
All cutting and coagulation instruments shall be

a. sterile

Clinical Attributes
For cutting/coagulation instruments offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. limited reuse instruments (i.e. cable)
b. mechanics of instrument (i.e. ultrasonic, electrosurgical)
c. a range of lengths and diameters
d. a range of shapes (e.g. curved/straight)
e. a range of tip configurations
f. foot and hand controls
g. with and without reusable connecting cables

Additional Information
Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. Note - This category excludes other standard diathermy items listed in Diathermy consumables used for open surgery – refer to HPVC2024-057 Operating Room and Wound Drainage Consumables contract considered out of scope.

CATEGORY 15 – SPECIMEN RETRIEVAL BAG FOR LAPAROSCOPIC SURGERY

A range of sterile, single-use specimen retrieval device for use in laparoscopic surgery is required.

Mandatory Criteria
Specimen retrieval devices for laparoscopic surgery shall be:

a. sterile
b. single-use

Clinical Attributes
For each specimen retrieval devices offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. range of bag sizes (length x diameter) volumes
b. material of construction
c. bag closure mechanism closure with drawstring or other closing mechanism

CATEGORY 16 – SUTURES AND SUTURING DEVICE FOR LAPAROSCOPIC SURGERY

A range of sterile, single-use laparoscopic sutures and single-use suturing device is required.

Mandatory Criteria
Sutures and suturing devices for laparoscopy will be

a. sterile
b. single-use

Clinical Attributes
For each laparoscopic sutures and single-use suturing device offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. sutures
   (i) a range of absorbable and non-absorbable suture materials
   (ii) a range of suture/needle sizes and lengths
   (iii) ligating loops
   (iv) single-use loading units for single or multiple stitches
   (v) colour-code identification
   (vi) tip type
   (vii) dyed & undyed
b. suturing device
   (i) for internal suturing and tying/ligation
   (ii) a range of size: diameter and length

Additional Information
Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. Non-laparoscopic sutures are out of scope of this category and are offered on the HPVC2020-016 Sutures, Skin Staples and Removers, and Tissue Adhesives contract

CATEGORY 17 – GYNAECOLOGY/UTERINE ABLATION SURGICAL INSTRUMENTS

A range of sterile single-use instruments and accessories used in gynaecology ablation surgery is required.

Mandatory Criteria
Gynaecology/Uterine Ablation will be

a. sterile
b. single-use

Clinical Attributes
For each instrument used in gynaecology ablation offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. uterine ablation devices
   (i) one handpiece
   (ii) provide a range of sizes options
b. uterine tissue removal accessories such as fluent, specimen bags, small plastic caps, arthroscopic tubing scope seals, flow-pack procedure kit, tissue socks
   (i) range of sizes options

CATEGORY 18 – GYNAECOLOGY/ UTERINE MANIPULATION AND VACUUM CURETTE SURGICAL INSTRUMENTS

A range of reusable and single-use instruments used in gynaecology manipulation surgery is required.

Mandatory Criteria
Gynaecology/Uterine Manipulation will be

a. sterile

Clinical Attributes
For each instrument used in gynaecology Manipulation offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. uterine manipulator handpiece
   (i) reusable
   (ii) sterilisation compatible with cleaning agents on HPVC2016-124 Hand Hygiene, Disinfectants and Chemical Products Contract – this will change to PPE contract
b. uterine manipulator accessories
   (i) single-use
   (ii) cup in different diameters, lengths and colours
   (iii) range of tip lengths
   (iv) tips in a range of colours and being colour coded
c. vacuum curette
   (i) single-use
   (ii) rigid or flexible
   (iii) straight or curved
   (iv) a range of tips
   (v) a range of sizes
   (vi) with or without suction tubing
   (vii) with or without orientation markings
   (viii) number of openings

CATEGORY 19 – GYNAECOLOGY/PELVIC FLOOR RECONSTRUCTION SURGICAL INSTRUMENTS

A range of sterile single-use instruments used in gynaecology reconstructive surgery is required.

Mandatory Criteria
Gynaecology/Uterine reconstruction will be

a. sterile

Clinical Attributes
For each instrument used in gynaecology reconstructive surgery offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. single-use
b. suture capturing device
   (i) shaft diameter
   (ii) head width
c. sutures
   (i) two sutures per packet
   (ii) absorbable and non-absorbable
   (iii) a range of sizes
   (iv) a range of colours
d. mayo suture needle (without suture material attached)
   (i) needle size
   (ii) needle shape
   (iii) tip type (e.g. taper/cutter)

CATEGORY 20 – GYNAECOLOGY/MORCELLATION SURGICAL INSTRUMENTS

A range of sterile single-use instruments used in gynaecology Morcellation surgery is required.

Mandatory Criteria
Gynaecology/Uterine reconstruction must

a. sterile
b. X-ray detectable indicator
c. single-use

Clinical Attributes
For each instrument used in gynaecology Morcellation surgery offered, Tenderers shall provide the following information in the Tender Response Worksheet

a. disposable morcellator instrument
   (i) blade material of construction
   (ii) battery powered and non-battery powered
   (iii) rotating or non-rotating blade
b. morcellator tissue retrieval accessories (i.e. bag)
   (i) colour coded tabs
   (ii) range of sizes and dimension
   (iii) closure with drawstring or other closing mechanism

CATEGORY 21 – GYNAECOLOGY/VAGINAL SPECULUMS

A range of sterile single-use and reusable instruments used in gynaecology surgery is required.

Mandatory Criteria
N/A in this category

Clinical Attributes
For each, instruments used in gynaecology surgery offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. sterile and non-sterile
b. smoke extraction tube
c. insulated and non-insulated
d. a range of sizes
e. material of construction
f. adjustable opening
g. reusable speculums
    (i) autoclavable
h. single-use speculums
    (i) sterile
    (ii) with or without battery/external light source

Additional Information
Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. For reusable instruments, the disinfectant used must be compatible with cleaning agents on HPVC2016-124 Hand Hygiene, Disinfectants and Chemical Products Contract – this will transition to PPE contract

CATEGORY 22 – GYNAECOLOGY/TUBAL LIGATION APPLICATORS AND CLIPS

A range of sterile single-use instruments used in gynaecology/ Tubal Ligation surgery is required.

Mandatory Criteria
Gynaecology/ Tubal Ligation instruments will be

a. sterile
b. single- use

Clinical Attributes
For each instrument used in Gynaecology/ Tubal Ligation surgery offered, tenderers shall provide the following information in the Tender Response Worksheet:

a. tubal ligation applicator
   (i) a range of lengths
   (ii) adjustable/Non-adjustable handpiece
   (iii) components in the kit (ie. Number of clips, trocar…)
b. tubal ligation clips and accessories
   (i) a range of sizes
   (ii) clip material of construction

Appendix 1 - Product List

Category No.	Category Description	Sub Category No.	Subcategory Description	Comments
01	Clip Applicators for Open and Laparoscopic Surgery	01.01	Single Clip Applicator, Reusable, without Clips	
01	Clip Applicators for Open and Laparoscopic Surgery	01.02	Multiple Clip Applicator, Single-use, with Clips	
01	Clip Applicators for Open and Laparoscopic Surgery	01.03	Multiple Clip Applicator, Reusable, without Clips	
02	Clips for Open and Laparoscopic Surgery	02.01	Absorbable	
02	Clips for Open and Laparoscopic Surgery	02.02	Non-absorbable	
03	Staple Applicators for Open and Laparoscopic Surgery	03.01	Curved, Reloadable, with Staple Unit	
03	Staple Applicators for Open and Laparoscopic Surgery	03.02	Curved, Reloadable, without Staple Unit	
03	Staple Applicators for Open and Laparoscopic Surgery	03.03	Curved, Non-Reloadable, with Staple Unit	
03	Staple Applicators for Open and Laparoscopic Surgery	03.04	Straight, Reloadable, with Staple Unit	
03	Staple Applicators for Open and Laparoscopic Surgery	03.05	Straight, Reloadable, without Staple Unit	
03	Staple Applicators for Open and Laparoscopic Surgery	03.06	Straight, Non-Reloadable, with Staple Unit	
04	Staple Reload Cartridge for Open and Laparoscopic Surgery	04.01	Straight, Cutting	
04	Staple Reload Cartridge for Open and Laparoscopic Surgery	04.02	Straight, Non-cutting	
04	Staple Reload Cartridge for Open and Laparoscopic Surgery	04.03	Articulating, Cutting	

Category No.	Category Description	Sub Category No.	Subcategory Description	Comments
04	Staple Reload Cartridge for Open and Laparoscopic Surgery	04.04	Articulating, Non-cutting	
04	Staple Reload Cartridge for Open and Laparoscopic Surgery	04.05	Curved, Cutting	
04	Staple Reload Cartridge for Open and Laparoscopic Surgery	04.06	Curved, Non-cutting	
04	Staple Reload Cartridge for Open and Laparoscopic Surgery	04.07	Bioabsorbable Staple Line Reinforcement	New Subcategory added
05	Surgical Mesh for Open and Laparoscopic Surgery	05.01	Surgical Mesh, Absorbable, Single layer, Impregnated	Subcategory change
05	Surgical Mesh for Open and Laparoscopic Surgery	05.02	Surgical Mesh, Absorbable, Single layer, Non-Impregnated	Subcategory change
05	Surgical Mesh for Open and Laparoscopic Surgery	05.03	Surgical Mesh, Absorbable, Multi-layer, Impregnated	Subcategory change
05	Surgical Mesh for Open and Laparoscopic Surgery	05.04	Surgical Mesh, Absorbable, Multi-layer, Non-Impregnated	Subcategory change
05	Surgical Mesh for Open and Laparoscopic Surgery	05.05	Surgical Mesh, Non-Absorbable, Single layer, Impregnated	Subcategory change
05	Surgical Mesh for Open and Laparoscopic Surgery	05.06	Surgical Mesh, Non-Absorbable, Single layer, Non-Impregnated	Subcategory change
05	Surgical Mesh for Open and Laparoscopic Surgery	05.07	Surgical Mesh, Non-Absorbable, Multi-layer, Impregnated	Subcategory change
05	Surgical Mesh for Open and Laparoscopic Surgery	05.08	Surgical Mesh, Non-Absorbable, Multi-layer, Non-Impregnated	Subcategory change
05	Surgical Mesh for Open and Laparoscopic Surgery	05.09	Biological Mesh	Subcategory change
06	Surgical Mesh Fixation Devices and Applicators for Open and Laparoscopic Surgery	06.01	Absorbable, Reloadable	

Category No.	Category Description	Sub Category No.	Subcategory Description	Comments
06	Surgical Mesh Fixation Devices and Applicators for Open and Laparoscopic Surgery	06.02	Absorbable, Non-reloadable	
06	Surgical Mesh Fixation Devices and Applicators for Open and Laparoscopic Surgery	06.03	Non-absorbable, Reloadable, with cartridges	
07	Insufflation Consumables for Laparoscopic Surgery	07.01	Pneumo-peritoneum Needles, Sharp	
07	Insufflation Consumables for Laparoscopic Surgery	07.02	Pneumo-peritoneum Needles, Blunt	
07	Insufflation Consumables for Laparoscopic Surgery	07.03	Insufflation Tubing with Filter, Plain	
08	Suction Irrigation Consumables for Laparoscopic Surgery	08.01	Single Spike, with Probes	
08	Suction Irrigation Consumables for Laparoscopic Surgery	08.02	Single Spike, without Probes	
08	Suction Irrigation Consumables for Laparoscopic Surgery	08.03	Double Spike, with Probes	
08	Suction Irrigation Consumables for Laparoscopic Surgery	08.04	Double Spike, without Probes	
08	Suction Irrigation Consumables for Laparoscopic Surgery	08.05	Probe, Reusable	
08	Suction Irrigation Consumables for Laparoscopic Surgery	08.06	Probe, Single-use	
09	Access Devices for Laparoscopic Surgery	09.01	Port with Trocar, Sharp	Subcategory change
09	Access Devices for Laparoscopic Surgery	09.02	Port with Trocar, blunt	Subcategory change

Category No.	Category Description	Sub Category No.	Subcategory Description	Comments
09	Access Devices for Laparoscopic Surgery	09.03	Port without Trocar, blunt	Subcategory change
09	Access Devices for Laparoscopic Surgery	09.04	Wound Retractors - Laparoscopic	Subcategory change
09	Access Devices for Laparoscopic Surgery	09.05	Laparoscope Warming Devices	New Subcategory added
09	Access Devices for Laparoscopic Surgery	09.06	Laparoscope Defogging/Cleaning Agents	New Subcategory added
10	Access Devices for Open Surgery	10.01	Open Wound Retractor	New Subcategory added
10	Access Devices for Open Surgery	10.02	Elastic Stays	New Subcategory added
11	Balloon Dilation and Dissection Devices for Laparoscopic Surgery	11.01	Balloon Dilation and Dissection Devices for Laparoscopic Surgery with Trocar	
12	Single-use Instruments for Laparoscopic Surgery	12.01	Scissors, without inserts	
12	Single-use Instruments for Laparoscopic Surgery	12.02	Scissors, with inserts	
12	Single-use Instruments for Laparoscopic Surgery	12.03	Dissectors, without inserts	
12	Single-use Instruments for Laparoscopic Surgery	12.04	Dissectors, with inserts	
12	Single-use Instruments for Laparoscopic Surgery	12.05	Graspers, without inserts	
12	Single-use Instruments for Laparoscopic Surgery	12.06	Graspers, with inserts	
12	Single-use Instruments for Laparoscopic Surgery	12.07	Retractors	

Category No.	Category Description	Sub Category No.	Subcategory Description	Comments
12	Single-use Instruments for Laparoscopic Surgery	12.08	Cholangiogram Forceps	
12	Single-use Instruments for Laparoscopic Surgery	12.09	Needle Holders	New Subcategory added
13	Diathermy Electrodes for Laparoscopic Surgery	13.01	Single-use, Monopolar, Foot controlled	
13	Diathermy Electrodes for Laparoscopic Surgery	13.02	Single-use, Monopolar, Hand controlled	
13	Diathermy Electrodes for Laparoscopic Surgery	13.03	Single-use, Bipolar, Hand controlled	
14	Cutting and Coagulation Instruments for Laparoscopic Surgery	14.01	Cutting and Coagulation Instruments, Straight, Foot controlled	
14	Cutting and Coagulation Instruments for Laparoscopic Surgery	14.02	Cutting and Coagulation Instruments, Straight, Hand controlled	
14	Cutting and Coagulation Instruments for Laparoscopic Surgery	14.03	Cutting and Coagulation Instruments, Curved, Foot controlled	
14	Cutting and Coagulation Instruments for Laparoscopic Surgery	14.04	Cutting and Coagulation Instruments, Curved, Hand controlled	
15	Specimen Retrieval Device/Bag for Laparoscopic Surgery	15.01	Specimen Retrieval Bag	
16	Sutures and Suturing Device for Laparoscopic Surgery	16.01	Absorbable	
16	Sutures and Suturing Device for Laparoscopic Surgery	16.02	Non-absorbable	
16	Sutures and Suturing Device for Laparoscopic Surgery	16.03	Suturing Devices	
17	Gynaecology/Uterine Ablation Surgical Instruments	17.01	Uterine Ablation Devices	New Subcategory added

Category No.	Category Description	Sub Category No.	Subcategory Description	Comments
17	Gynaecology/Uterine Ablation Surgical Instruments	17.02	Uterine Tissue Removal Accessories	New Subcategory added
18	Gynaecology/ Uterine Manipulation and Vacuum Curette Surgical Instruments	18.01	Uterine Manipulator Handpiece, Single-use	New Subcategory added
18	Gynaecology/ Uterine Manipulation and Vacuum Curette Surgical Instruments	18.02	Uterine Manipulator Handpiece, Reusable	New Subcategory added
18	Gynaecology/ Uterine Manipulation and Vacuum Curette Surgical Instruments	18.03	Uterine Manipulator Accessories	New Subcategory added
18	Gynaecology/ Uterine Manipulation and Vacuum Curette Surgical Instruments	18.04	Vacuum Curettes	New Subcategory added
19	Gynaecology/Pelvic Floor Reconstruction Surgical Instruments	19.01	Suture Capturing Devices	New Subcategory added
19	Gynaecology/Pelvic Floor Reconstruction Surgical Instruments	19.02	Sutures for Vaginal Repair	New Subcategory added
19	Gynaecology/Pelvic Floor Reconstruction Surgical Instruments	19.03	Mayo needles	New Subcategory added
20	Gynaecology/Morcellation Surgical Instruments	20.01	Single-use fully disposable morcellator instrument	New Subcategory added
20	Gynaecology/Morcellation Surgical Instruments	20.02	Morcellator tissue retrieval accessories (i.e. bag)	New Subcategory added
21	Gynaecology/Vaginal Speculums	21.01	Single-use, Insulated Speculum	New Subcategory added
21	Gynaecology/Vaginal Speculums	21.02	Single-use, Non-Insulated Speculums	New Subcategory added

Category No.	Category Description	Sub Category No.	Subcategory Description	Comments
21	Gynaecology/Vaginal Speculums	21.03	Reusable, Insulated Speculum	New Subcategory added
21	Gynaecology/Vaginal Speculums	21.04	Reusable, Non-Insulated Speculums	New Subcategory added
22	Gynaecology/Tubal Ligation Applicators and Clips	22.01	Tubal Ligation Applicator	New Subcategory added
22	Gynaecology/Tubal Ligation Applicators and Clips	22.02	Tubal Ligation Clips and Accessories	New Subcategory added

Appendix 2 – References

Standards

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

STANDARD NUMBER	STANDARD NUMBER
AS/NZS 5369	AS 5369:2023 specifies the requirements and practices necessary for the effective and safe reprocessing, storage, handling and transportation of reusable medical devices and other devices used in human health care and other treatments.
ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 19351:2019	Fallopian rings - Requirements and test methods
ISO 18340:2020	Endoscopes — Trocar pins, trocar sleeves and endotherapy devices for use with trocar sleeves
ISO 16571:2024	Systems for evacuation of plume generated by medical devices
ISO 7151:2024	Surgical instruments - non-cutting, articulated instruments - General requirements and test methods
ISO 16054:2019	Implants for surgery - Minimum data sets for surgical implants
ISO 14577-5:2022	Metallic materials — Instrumented indentation test for hardness and materials parameters — Part 5: Linear elastic dynamic instrumented indentation testing (DIIT)

Appendix 3 – Compliance Requirements

Australian Standards, Orders, Legislation and Regulations

It is the responsibility of the Respondent to ensure that all products offered comply with the Compliance Requirements listed below. This is not an exhaustive list; Respondents must ensure 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.

The relevant legislation for HPVITS2025-036 may include, but is not limited to:

- *Uniform Recall Procedure for Therapeutic Goods* (URPTG) (V2.1, February 2019)

Legislation

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

a. *Therapeutic Goods (Medical Devices) Regulations* 2002

b. *Therapeutic Goods Act* 1989

c. Occupational Health and Safety Regulations 2017

d. Occupational Health and Safety (Manual Handling) Regulations 1999

Guidelines and Other References

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

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

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

V11 Acorn Standards 2023 -Standards for Safe and Quality Care in the Perioperative Environment (SSQCPE) for Individuals

V111Acorn Standards 2023 -Standards for Safe and Quality Care in the Perioperative Environment (SSQCPE) for Organisations

Australian Guidelines for the Prevention and Control of Infection in Healthcare, Canberra: National Health and Medical Research Council (2019)

Uniform Recall Procedure for Therapeutic Goods (URPTG) (V2.3, June 2022). Therapeutic Goods Administration (2011), Australian Regulatory Guidelines for Medical Devices.

Therapeutic Goods Administration (2011), Australian Regulatory Guidelines for Medical Device

WHO Guidelines for Safe Surgery (2009) World Health Organisation

Implementation Manual WHO Surgical Safety Checklist (2009) World Health Organisation

Australian Commission on Safety and Quality in Health Care (ACSQHC). Preventing and controlling healthcare associated infections [Internet]. Sydney: ACSQHC; 2017 [cited 2020 March 4]. Available from: www.safetyandquality.gov.au/ publications/national-safety-and-quality-health-servicestandards. [S]