Invitation to Supply

Part 5

Statement of Requirements

Invitation to Supply Number:	HPVITS2018-036
Invitation to Supply Name:	Surgical Instruments – Open and Laparoscopic
Closing Date and time:	11 July 2018 14:00 AEST

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Position	Category Manager
Contact through the HPV Procurement Portal	https://www.hpv.org.au

HEALTH PURCHASING VICTORIA

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A Introduction

1 Purpose

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

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

2 Scope

a. HPV is seeking responses for Surgical Instruments- Open and Laparoscopic for use in Participating Health Services. The envisaged Term of the Agreement is four (4) years plus one optional two year extension period (4+2).

b. The scope of this ITS includes:

- Single Use and limited reuse surgical instruments used in the following specialist laparoscopic surgeries including bariatric surgery:
    a. upper gastro-intestinal
    b. cardio-thoracic
    c. urology
    d. gynaecology
    e. hepato-biliary
    f. colo-rectal
- 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:

- surgical instruments used in the following specialist laparoscopic surgeries:
    a. spinal
    b. ENT
    c. neurosurgery
    d. orthopaedic
    e. plastic
- skin staples, skin staplers, skin staple removers or tissue adhesives.

3 Product Categories

a. The categories of product 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 Units 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 Devices for Laparoscopic Surgery
8	Suction Irrigation Units for Laparoscopic Surgery
9	Access Devices for Laparoscopic Surgery
10	Balloon Dilation and Dissection Device for Laparoscopic Surgery
11	Surgical Instruments for Laparoscopic Surgery
12	Diathermy Electrodes for Laparoscopic Surgery
13	Cutting and Coagulation Instruments for Open and Laparoscopic Surgery
14	Specimen Retrieval Devices for Laparoscopic Surgery
15	Sutures and Suturing Devices for Laparoscopic Surgery

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. Products offered in 'additional component' subcategories under Category 11 Surgical Instruments for Laparoscopic Surgery will only be considered where the product meets the specification and the Respondent is successful in at least one of the specific subcategories of that category.

e. 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:

(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 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:

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

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

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

5 Definitions

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

TERM	DEFINITION

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

B Service, delivery, and support

1 Delivery

a. Surgical instruments must be delivered to the location(s) specified by Participating Health Services within the shortest possible timeframe; however, this must not exceed the following timeframes from receipt of order unless otherwise agreed with the Participating Health Service.

(i) two (2) business days from receipt of order for **metropolitan** Participating Health Services
(ii) three (3) business days from receipt of order for **regional** and **rural** Participating Health Services.

b. Preference may be given to Respondents who can offer delivery within 24 hours.

c. All deliveries are bound as per the Draft Agreement, Part 7 – 7.2Acceptance and Rejection of Goods

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 must be received by Participating Health Services within the shortest possible timeframe; however, this should not exceed the following timeframes:

(i) 12 hours from receipt of order for metropolitan Participating Health Services
(ii) 24 hours from receipt of order for regional and rural Participating Health Services.

3 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.

4 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 surgical instruments to clinicians in their operating environment. Such training and/or materials must be available to Participating Health Services at the time of purchase.

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.

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

d. Successful Respondents must ensure that details of any available support are available to Participating Health Services (in either hard-copy or electronic format), including:

(i) any costs associated with such support
(ii) the credentials of any staff who would be providing support
(iii) the hours of availability for support
(iv) the geographical area covered by the support (if support is available on-site)
(v) details of educational and/or support materials available to clinicians.

5 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.

6 Warranty

a. Where applicable, surgical instruments, devices and cables must be warranted 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.

Repairs and Replacements under 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 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.

7 Key Performance Indicators

a. Refer to Part 7 Draft agreement -Key Performance Indicators.

8 Reporting

a. Refer to Part 7 Draft agreement - Reporting.

9 Service Level Agreement

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

(i) arrangements for ordering, invoicing and delivery

(ii) clinical support, including attendance requirements for Representatives in relation to education and training
(iii) communication arrangements for product recalls and safety alerts (refer to C3 Recallnet).

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

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

3 Recall Process

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

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

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 - B7 Warranty, where applicable.

3.2 Backorders and Discontinued Lines

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

(i) Perioperative Services Managers
(ii) Supply Departments
(iii) Clinical Product Advisors
(iv) HPV.

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

(i) the anticipated timeframe for resolving the issue
(ii) the availability of an agreed substitute product

c. 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.

3.3 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) or latest version.

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

D Product Specifications

1 Substances of Concern

a. Preference may 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 REUSABLE AND LIMITED REUSE DEVICES

a. For reusable and limited reuse devices, the following information must be readily available to all Participating Health Services in either hardcopy and/or electronic format:

(i) instructions for cleaning, sterilisation and reuse
(ii) warranty information.

b. For limited reuse devices only, the following information must also be readily available to all Participating Health Services in either hardcopy and/or electronic format:

(i) the recommended number of uses and conditions for reuse of each specific item
(ii) the recommended process for tracking the use of each item.

3 CABLES

(i) For cables offered (for Categories 11, 12, 13 and 14), successful Respondents must provide the following information (in either hard copy or electronic format) to Participating Health Services:

- the brands and models of equipment with which the cable is compatible
- warranty details, including any conditions
- the replacement policy for faulty cables, particularly where user damage is not evident
- the anticipated life when used and maintained in accordance with the manufacturer's instructions
- a description of the cable construction, including measures to minimise wire fractures
- cleaning and disinfection requirements.

4 Category Specifications

a. A complete range of surgical instruments is required for treatment of patients across Victorian Public Health Services.

CATEGORY 1 – CLIP APPLICATORS FOR OPEN AND LAPAROSCOPIC SURGERY

(i) A range of sterile clip applicators is required for use in open and laparoscopic surgery, including:

- single use and reusable
- a range of lengths, shapes and sizes
- a range of handle lengths
- a range of grip formats (e.g. pistol, lever)
- for single and multiple clip application
- without single-use clips
- to suit the range of clip sizes and reload unit sizes
- with and without colour-code identification
- with and without a clip counter.

(ii) Note: Where clips are included with the applicator, these items must also comply with the specifications in Category 2.

CATEGORY 2 – CLIPS FOR OPEN AND LAPAROSCOPIC SURGERY

(i) A range of sterile, single use clips is required for use in open and laparoscopic surgery, including:

- a range of shapes and sizes
- straight
- a range of load unit sizes (i.e. various numbers of clips)
- clip load units for single-use and reusable clip applicators
- with and without a 'last clip' indicator
- with and without colour-code identification.

(ii) Metallic clips must be made of titanium.

CATEGORY 3 – STAPLE APPLICATORS FOR OPEN AND LAPAROSCOPIC SURGERY

(i) A range of staple applicators to suit a range of staple sizes is required for use in open and laparoscopic surgery, including:

- single use and limited reuse
- sterile and non-sterile
- with and without a single use staple unit
- straight and curved
- reloadable and non-reloadable
- with a range of grip formats (e.g. pistol, lever)
- for straight and circular stapling units
- for straight and roticulating units

- for cutting and non-cutting staple units
- for articulating and non-articulating staple units
- with and without colour-code identification
- with and without a graduated staple closure and integrated reload
- powered and non-powered.

(iii) Where a single use staple unit is incorporated with the staple applicator, it must comply with the specifications set out in Category 4.

CATEGORY 4 – STAPLE UNITS FOR OPEN AND LAPAROSCOPIC SURGERY

(i) A range of sterile, single use staple units is required for use in open and laparoscopic surgery. This includes:

- a full range of shapes and sizes
- with and without colour-code identification reloadable
- cutting and non-cutting
- roticulating and non roticulating
- articulating and non-articulating
- rotating and non-rotating
- a full range of sizes of staple units (i.e. numbers of staples)
- with and without a graduated staple closure and integrated reload.

(iv) Staple units must be clearly labelled to differentiate size.

(v) Staples must be made of titanium.

CATEGORY 5 – SURGICAL MESH FOR OPEN AND LAPAROSCOPIC SURGERY

(i) A range of sterile surgical mesh is required for use in open and laparoscopic surgery. This includes:

- a full range of shapes and sizes
- a range of forms, including:
  - absorbable and non-absorbable
  - monofilament and multifilament
  - single and multiple layer
  - open and close weave mesh
- a range of materials, including (but not limited to):
  - polypropylene
  - polyglycolic acid
  - porcine
  - silicone
  - Gore-Tex
- plain and impregnated
- with and without:

- an application device
- a fixation device
- sleeves
- straps
- a memory

- coloured and undyed.

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

(i) A range of sterile, single use surgical mesh fixation devices is required for use in open and laparoscopic surgery. This includes:

- a range of sizes
- device applicators
- reloadable and non-reloadable applicators
- devices
- absorbable and non-absorbable.

(ii) All metallic devices must be made of titanium

CATEGORY 7 – INSUFFLATION DEVICES FOR LAPAROSCOPIC SURGERY

(i) A range of sterile, insufflation devices is required for use in laparoscopic surgery, including:

- single-use pneumo-peritoneum needles
- single-use insufflation tubing with a filter.

Pneumo-Peritoneum Needles

(vi) A range of sterile, single-use safety pneumo-peritoneum needles is required, including:

- a range of needle sizes and lengths
- blunt and sharp.

(vii) Pneumo-peritoneum needles must incorporate a stopcock.

Insufflation Tubing with a Filter

(viii) A range of single-use insufflation tubing with a filter is required, including:

- a range of tubing lengths and diameters
- with and without:
  - heating
  - humidification.

Insufflation tubing must be:

- kink resistant
- compatible with a wide range of insufflation equipment.

(ix) All connections for insufflation devices must be luer lock.

(x) All filters must be hydrophobic and filter to 0.1 microns.

CATEGORY 8 – SUCTION IRRIGATION UNITS FOR LAPAROSCOPIC SURGERY

(i) A range of sterile laparoscopic suction irrigation units is required, including:

- irrigation tubing:
  - △ single or double spiked
  - △ in a range of lengths and diameters
- with and without a cannula
- cannulae (where applicable):
  - △ single-use and reusable
  - △ 5mm and 10mm diameter
  - △ with and without irrigation holes
  - △ interchangeable
- thumb-operated or finger-operated valve activation mechanism
- individual system components or complete systems.

(ii) The activation mechanism/trumpet valve assembly must incorporate colour-coded suction and irrigation valve buttons.

(iii) Laparoscopic suction irrigation systems must be leak-proof.

(iv) The internal diameter of laparoscopic suction irrigation units must be sufficient to allow the passage of clots and debris.

(v) If presented in a fused manner, suction and irrigation tubing must be readily separated at the distal end.

(vi) The suction limb must incorporate a connection to fit standard wall suction systems.

CATEGORY 9 – ACCESS DEVICES FOR LAPAROSCOPIC SURGERY

(i) A range of sterile ports, trocars, accessories, wound retractors used to gain and provide access for laparoscopic surgery is required, including:

- twin packs and individual components
- single-use components for reusable devices
- radiolucent and non-radiolucent.

Ports

(ii) A range of ports for a range of approaches, including stepped, dilating, hand access and visual access including:

- a full range of sizes and lengths
- threaded and non-threaded
- with and without trocars
- trocars (where applicable):
  - shielded and non-shielded
  - blunt and sharp
- bladed and non-bladed
- with and without an insufflation port
- with and without a fixation device
- .

Trocars

(iii) A range of trocars is required, including:

- a full range of sizes and lengths
- shielded and non-shielded
- blunt and sharp
- bladed and non-bladed
- optical

Wound Retractors

(iv) A range of wound retractors is required, including:

- a full range of sizes and lengths

Accessories

(v) A range of sleeves and seals is required, including:

- reducing and expandable sleeves
- seals, with and without a stopcock

(vi) All stopcocks must have luer lock fittings.

CATEGORY 10 – BALLOON DILATION AND DISSECTION DEVICES FOR LAPAROSCOPIC SURGERY

(i) A range of sterile, single-use balloon dilation and dissection devices is required to create an operative space for laparoscopic surgery, including:

- balloons in a range of sizes, shapes and lengths
- with and without trocars.

CATEGORY 11 – SINGLE USE OR LIMITED REUSE SURGICAL INSTRUMENTS FOR LAPAROSCOPIC SURGERY

(i) A range of sterile hand-held laparoscopic surgical instruments is required, including:

- scissors
- dissectors
- graspers
- handles
- sheaths
- retractors
- cholangiogram forceps
- single-use components for reusable instruments
- with and without monopolar or bipolar electrosurgery potential
- with and without electrosurgery connecting cables.

(ii) Note: Robotics instruments are out of scope for the purposes of this ITS.

(iii) Laparoscopic surgical instruments must have no rough or sharp edges other than those required by the pattern of the instruments.

(iv) All surfaces must be free from pores, crevices and grinding marks.

(v) The action of laparoscopic surgical instruments must be smooth.

(vi) Where a box or screw joint is included in the design of the instrument, it must not allow for movement at the joint in opposition to the action of the instrument.

(vii) Where an instrument includes jaws, the jaws must close in apposition.

(viii) Where the instrument includes toothed jaws, there must be no gaps in the teeth section when the jaws are closed, other than those required by the pattern of the instrument.

(ix) Where the design of an instrument includes teeth or blades, they must not grate or catch during use or when closing the instrument.

(x) Where a ratchet is included in the design of an instrument, the ratchet must be able to be clamped and unclamped with one hand.

(xi) All bipolar cables must have fixed pins.

Scissors

(xii) A range of scissors is required, including:

- fixed, articulating and rotating
- a full range of sizes and lengths
- a range of tip configurations
- with monopolar and bipolar electrosurgery potential.

Dissectors

(xiii) A range of dissectors is required, including:

- a full range of sizes and lengths
- a range of tip configurations
- with monopolar and bipolar electrosurgery potential.

Graspers

(xiv) A range of graspers is required, including:

- a full range of sizes and lengths
- a range of tip configurations
- grasper inserts
- with monopolar and bipolar electrosurgery potential.

Handles

(xv) A range of handles is required, including:

- ratcheted and non-ratcheted
- rotating and fixed
- with monopolar and bipolar electrosurgery potential.

Sheaths

(xvi) A range of insulated sheaths is required, including a range of sizes.

Retractors

(xvii) A range of retractors is required, including:

- a full range of sizes and lengths
- a range of tip configurations.

Cholangiogram Forceps

(xviii) A range of cholangiogram forceps is required, including a full range of lengths

CATEGORY 12 – DIATHERMY ELECTRODES FOR LAPAROSCOPIC SURGERY

(i) A range of sterile, insulated laparoscopic diathermy electrodes is required, including:

- single use, limited reuse and reusable
- monopolar and bipolar
- foot and hand controlled
- a range of lengths and sizes
- a range of tip configurations

- with and without cables.

(ii) Note: Diathermy electrodes with a suction/irrigation lumen are considered out of scope for the purposes of this ITS.

CATEGORY 13 – CUTTING AND COAGULATION INSTRUMENTS FOR OPEN AND LAPAROSCOPIC SURGERY

(i) A range of sterile instruments is required for use with cutting and coagulation equipment in open and laparoscopic surgery, including:

- single-use instruments
- limited reuse instruments (including single-use components)
- ultrasonic and other
- a range of shears:
  - curved and straight
  - in a range of sizes, lengths and diameters
  - a range of tip configurations
- foot and hand controls
- with and without reusable connecting cables.

(ii) Note: This category excludes other standard diathermy items listed in Category 11.

CATEGORY 14 – SPECIMEN RETRIEVAL DEVICES FOR LAPAROSCOPIC SURGERY

(i) A range of sterile, single-use specimen retrieval devices for use in laparoscopic surgery is required, including:

- a range of sizes and volumes
- pouches and bags.

(ii) Specimen retrieval pouches and bags must be made of tear-resistant material.

(iii) Pouches and bags must not separate from the retrieval mechanism when used in accordance with the manufacturer's instructions.

CATEGORY 15 – SUTURES AND SUTURING DEVICES FOR LAPAROSCOPIC SURGERY

(i) A range of sterile, single use laparoscopic sutures and single-use suturing devices is required.

Sutures

(ii) A range of sutures is required, including:

- a range of absorbable and non-absorbable suture materials

- a range of suture sizes and lengths
- ligating loops
- single-use loading units for single or multiple stitches
- colour-code identification.

Suturing Devices

(iii) A range of suturing devices is required, including:

- for closure of trocar sites
- for internal suturing and tying/ligation.

E Appendices

Appendix 1 - Product List

Category No.	Category Description	Sub Category No.	Sub Category Description	Comments
001	Clip applicator Devices for Open and Laparoscopic Surgery	01.01	Single Clip Applicator, Reusable, Without Clips	
001	Clip applicator Devices for Open and Laparoscopic Surgery	01.02	Multiple Clip applicator, Single use, With Clips	
001	Clip applicator Devices for Open and Laparoscopic Surgery	01.03	Multiple Clip applicator, Reusable, Without Clips	
002	Clips for Open and laparoscopic Surgery	02.01	Absorbable	
002	Clips for Open and laparoscopic Surgery	02.02	Non-Absorbable	
003	Staple applicators for Open and Laparoscopic Surgery	03.01	Curved, Reloadable, With Staple Unit	
003	Staple applicators for Open and Laparoscopic Surgery	03.02	Curved, Reloadable, Without Staple Unit	
003	Staple applicators for Open and Laparoscopic Surgery	03.03	Curved, Non-Reloadable, With Staple Unit	
003	Staple applicators for Open and Laparoscopic Surgery	03.04	Straight, Reloadable, With Staple Unit	
003	Staple applicators for Open and Laparoscopic Surgery	03.05	Straight, Reloadable, Without Staple Unit	
003	Staple applicators for Open and Laparoscopic Surgery	03.06	Straight, Non-Reloadable, With Staple Unit	

004	Staple Units for Open and Laparoscopic Surgery	04.01	Straight, Cutting	
004	Staple Units for Open and Laparoscopic Surgery	04.02	Straight, Non-cutting	
004	Staple Units for Open and Laparoscopic Surgery	04.03	Articulating, Cutting	
004	Staple Units for Open and Laparoscopic Surgery	04.04	Articulating, Non-cutting	
004	Staple Units for Open and Laparoscopic Surgery	04.05	Curved, Cutting	
004	Staple Units for Open and Laparoscopic Surgery	04.06	Curved, Non-cutting	
005	Surgical Mesh for Open and laparosopic Surgery	05.01	Absorbable, Monofilament, Single layer, Open Weave, Impregnated	
005	Surgical Mesh for Open and laparosopic Surgery	05.02	Absorbable, Monofilament, Single layer, Open Weave, Non-Impregnated	
005	Surgical Mesh for Open and laparosopic Surgery	05.03	Absorbable, Monofilament, Multi-layer, Open Weave, Impregnated	
005	Surgical Mesh for Open and laparoscopic Surgery	05.04	Absorbable, Monofilament, Multi-layer, Open Weave, Non-Impregnated	
005	Surgical Mesh for Open and laparoscopic Surgery	05.05	Absorbable, Monofilament, Multi-layer, Closed Weave, Impregnated	
005	Surgical Mesh for Open and laparoscopic Surgery	05.06	Absorbable, Monofilament, Multi-layer, Closed Weave, Non-Impregnated	
005	Surgical Mesh for Open and laparoscopic Surgery	05.07	Absorbable, Multifilament, Single layer, Open Weave,	

			Impregnated	
005	Surgical Mesh for Open and laparoscopic Surgery	05.08	Absorbable, Multifilament, Single layer, Open Weave, Non-Impregnated	
005	Surgical Mesh for Open and laparoscopic Surgery	05.09	Absorbable, Multifilament, Single layer, Closed Weave, Impregnated	
005	Surgical Mesh for Open and laparoscopic Surgery	05.10	Absorbable, Multifilament, Single layer, Closed Weave, Non-Impregnated	
005	Surgical Mesh for Open and laparoscopic Surgery	05.11	Absorbable, Multifilament, Multi-layer, Open Weave, Impregnated	
005	Surgical Mesh for Open and laparoscopic Surgery	05.12	Absorbable, Multifilament, Multi-layer, Open Weave, Non-Impregnated	
005	Surgical Mesh for Open and laparoscopic Surgery	05.13	Non-Absorbable, Monofilament, Single layer, Open Weave, Impregnated	
005	Surgical Mesh for Open and laparoscopic Surgery	05.14	Non-Absorbable, Monofilament, Single layer, Open Weave, Non-Impregnated	
005	Surgical Mesh for Open and laparoscopic Surgery	05.15	Non-Absorbable, Monofilament, Single layer, Closed Weave, Impregnated	
005	Surgical Mesh for Open and laparoscopic Surgery	05.1	Non-	

		6	Absorbable, Monofilament, Single layer, Closed Weave, Non-Impregnated	
005	Surgical Mesh for Open and laparoscopic Surgery	05.17	Non-Absorbable, Monofilament, Multi-layer, Open Weave, Impregnated	
005	Surgical Mesh for Open and laparoscopic Surgery	05.18	Non-Absorbable, Monofilament, Multi-layer, Open Weave, Non-Impregnated	
005	Surgical Mesh for Open and laparoscopic Surgery	05.19	Non-Absorbable, Monofilament, Multi-layer, Closed Weave, Impregnated	
005	Surgical Mesh for Open and laparoscopic Surgery	05.20	Non-Absorbable, Monofilament, Multi-layer, Closed Weave, Non-Impregnated	
005	Surgical Mesh for Open and laparoscopic Surgery	05.21	Non-Absorbable, Multifilament, Single layer, Open Weave, Impregnated	
005	Surgical Mesh for Open and laparoscopic Surgery	05.22	Non-Absorbable, Multifilament, Single layer, Open Weave, Non-Impregnated	
005	Surgical Mesh for Open and laparoscopic Surgery	05.23	Non-Absorbable, Multifilament, Single layer,	

			Closed Weave, Non-Impregnated	
005	Surgical Mesh for Open and laparoscopic Surgery	05.24	Biological Mesh	
006	Surgical Mesh Fixation Devices and Applicators for Open and laparoscopic Surgery	06.01	Absorbable, Reloadable	
006	Surgical Mesh Fixation Devices and Applicators for Open and laparoscopic Surgery	06.02	Absorbable, Non-reloadable	
006	Surgical Mesh Fixation Devices and Applicators for Open and laparoscopic Surgery	06.03	Non absorbable, Reloadable, with cartridges	
007	Insufflation Devices for laparoscopic surgery	07.01	Pneumo-peritoneum needles, Sharp	
007	Insufflation Devices for laparoscopic surgery	07.02	Pneumo-peritoneum needles, Blunt	
007	Insufflation Devices for laparoscopic surgery	07.03	Insufflation tubing with filter, Plain	
008	Suction Irrigation Units for laparoscopic surgery	08.01	Single Spike, With probes	
008	Suction Irrigation Units for laparoscopic surgery	08.02	Single Spike, Without probes	
008	Suction Irrigation Units for laparoscopic surgery	08.03	Double spike, With probes	
008	Suction Irrigation Units for laparoscopic surgery	08.04	Double spike, Without probes	
008	Suction Irrigation Units for laparoscopic surgery	08.05	Probe, Reusable	
008	Suction Irrigation Units for laparoscopic surgery	08.06	Probe, Single use	
009	Access Devices for laparoscopic surgery	09.01	Port with trocar, blunt, threaded, without insufflation port, without fixation device	
009	Access Devices for laparoscopic surgery	09.02	Port with trocar, blunt, threaded, with insufflation port, without	

			fixation device	
009	Access Devices for laparoscopic surgery	09.03	Port with trocar, blunt, threaded, with insufflation port, with fixation device	
009	Access Devices for laparoscopic surgery	09.04	Port with trocar, blunt, non-threaded, without insufflation port, without fixation device	
009	Access Devices for laparoscopic surgery	09.05	Port with trocar, blunt, non-threaded, with insufflation port, without fixation device	
009	Access Devices for laparoscopic surgery	09.06	Port with trocar, blunt, non-threaded, with insufflation port, with fixation device	
009	Access Devices for laparoscopic surgery	09.07	Port with trocar, sharp, threaded, without insufflation port, without fixation device	
009	Access Devices for laparoscopic surgery	09.08	Port with trocar, sharp, threaded, with insufflation port, without fixation device	
009	Access Devices for laparoscopic surgery	09.09	Port with trocar, sharp, threaded, with insufflation port, with fixation device	
009	Access Devices for laparoscopic surgery	09.10	Port with trocar, sharp,	

			non-threaded, without insufflation port, without fixation device	
009	Access Devices for laparoscopic surgery	09.11	Port with trocar, sharp, non-threaded, with insufflation port, without fixation device	
009	Access Devices for laparoscopic surgery	09.12	Port with trocar, sharp, non-threaded, with insufflation port, with fixation device	
009	Access Devices for laparoscopic surgery	09.13	Trocar, sharp, non-threaded, without insufflation port, without fixation device	
009	Access Devices for laparoscopic surgery	09.14	Trocar, sharp, non-threaded, with insufflation port, without fixation device	
009	Access Devices for laparoscopic surgery	09.15	Trocar, sharp, non-threaded, with insufflation port, with fixation device	
009	Access Devices for laparoscopic surgery	09.16	Trocar, blunt	
009	Access Devices for laparoscopic surgery	09.17	Sleeves	
009	Access Devices for laparoscopic surgery	09.18	Seals	
009	Access Devices for laparoscopic surgery	09.19	Wound Retractors	New Subcategory added
009	Access Devices for laparoscopic surgery	09.20	Other	
010	Balloon dilation and dissection devices for	10.0	With Trocar	

	laparoscopic surgery	1		
010	Balloon dilation and dissection devices for laparoscopic surgery	10.02	Without Trocar	
011	Surgical instruments for laparoscopic surgery	11.01	Scissors, without inserts	
011	Surgical instruments for laparoscopic surgery	11.02	scissors, with inserts	
011	Surgical instruments for laparoscopic surgery	11.03	Dissectors, without inserts	
011	Surgical instruments for laparoscopic surgery	11.04	Dissectors, with inserts	
011	Surgical instruments for laparoscopic surgery	11.05	Graspers, without inserts	
011	Surgical instruments for laparoscopic surgery	11.06	Graspers, with inserts	
011	Surgical instruments for laparoscopic surgery	11.07	Retractors	
011	Surgical instruments for laparoscopic surgery	11.08	Cholangiogram Forceps	New Subcategory added
011	Surgical instruments for laparoscopic surgery	11.09	Additional components including handles and sheaths	
012	Diathermy electrodes for laparoscopic surgery	12.01	Single use, Monopolar, Foot controlled	
012	Diathermy electrodes for laparoscopic surgery	12.02	Single use, Monopolar, Hand controlled	
012	Diathermy electrodes for laparoscopic surgery	12.03	Reusable, Monopolar, Hand controlled	
012	Diathermy electrodes for laparoscopic surgery	12.04	Single use, Bipolar, Hand controlled	
013	Cutting and coagulation instruments for open and laparoscopic	13.01	Shears, Straight, Foot controlled	
013	Cutting and coagulation instruments for open and laparoscopic	13.02	Shears, Straight, Hand controlled	
013	Cutting and coagulation instruments for open and laparoscopic	13.03	Shears, Curved, Foot controlled	

013	Cutting and coagulation instruments for open and laparoscopic	13.04	Shears, Curved, Hand controlled	
014	Specimen retrieval device for laparoscopic surgery	14.01	Bag	
014	Specimen retrieval device for laparoscopic surgery	14.02	Pouches	
015	Sutures and suturing device for laparoscopic surgery	15.01	Absorbable	
015	Sutures and suturing device for laparoscopic surgery	15.02	Non absorbable	
015	Sutures and suturing device for laparoscopic surgery	15.03	Suturing devices	

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 4187:2014	Reprocessing of Reusable medical devices in health service organisations

A 2.b Legislation

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

i. Therapeutic Goods (Medical Devices) Regulations 2002

ii. Therapeutic Goods Act 1989

A 2.c Guidelines and Other References

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

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

ii. Therapeutic Goods Administration (2004), Uniform Recall Procedure for Therapeutic Goods, Commonwealth of Australia

iii. Therapeutic Goods Administration (2011), Australian Regulatory Guidelines for Medical Devices