PART 5

STATEMENT OF REQUIREMENTS

Surgical Instruments –
Open & Laparoscopic

RFTHPV2014–036
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INTRODUCTION

5.1 PURPOSE

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

- detail the scope and range of products sought under this Request for Tender (RFT)
- 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(s)).

5.2 SCOPE

5.2.1 HPV is seeking responses for surgical instruments (open and laparoscopic) for use in Participating Health Services for a duration of two (2) years plus two possible one (1) year extension (2+1+1).

5.2.2 The scope of this RFT includes:

- surgical instruments used in the following specialist laparoscopic surgeries:
  - upper gastro-intestinal
  - cardio-thoracic
  - urology
  - gynaecology
  - hepatobiliary
  - colo-rectal
- instruments used for open surgery (where indicated in this Part 5 – Statement of Requirements).

5.2.3 The scope of this RFT does not include:

- surgical instruments used in the following specialist laparoscopic surgeries:
  - spinal
  - ENT
  - neurosurgery
  - orthopaedic
  - plastic
- skin staples, skin staplers or skin staple removers.
5.3 PRODUCT CATEGORIES

5.3.1 The categories of product required under this RFT include:

<table>
<thead>
<tr>
<th>CATEGORY NUMBER</th>
<th>CATEGORY NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Clip Applicators for Open and Laparoscopic Surgery</td>
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<td>2</td>
<td>Clips for Open and Laparoscopic Surgery</td>
</tr>
<tr>
<td>3</td>
<td>Staple Applicators for Open and Laparoscopic Surgery</td>
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<td>4</td>
<td>Staple Units for Open and Laparoscopic Surgery</td>
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<td>5</td>
<td>Surgical Mesh for Open and Laparoscopic Surgery</td>
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<td>6</td>
<td>Surgical Mesh Fixation Tacks and Applicators for Open and Laparoscopic Surgery</td>
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<td>7</td>
<td>Insufflation Devices for Laparoscopic Surgery</td>
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<tr>
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<td>9</td>
<td>Access Devices for Laparoscopic Surgery</td>
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<td>10</td>
<td>Balloon Dilation and Dissection Device for Laparoscopic Surgery</td>
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<tr>
<td>11</td>
<td>Surgical Instruments for Laparoscopic Surgery</td>
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<tr>
<td>12</td>
<td>Diathermy Electrodes for Laparoscopic Surgery</td>
</tr>
<tr>
<td>13</td>
<td>Cutting and Coagulation Instruments for Open and Laparoscopic Surgery</td>
</tr>
<tr>
<td>14</td>
<td>Specimen Retrieval Devices for Laparoscopic Surgery</td>
</tr>
<tr>
<td>15</td>
<td>Sutures and Suturing Devices for Laparoscopic Surgery</td>
</tr>
</tbody>
</table>

5.3.2 Respondents may offer products in one, some or all categories.

5.3.3 Preference may be given to Respondents who offer the greatest range and best value for money across and/or within product categories (with the exception of niche product ranges).

5.3.4 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.

5.3.5 HPV reserves the right to not consider any additional products offered.
5.3.6 For a full list of product categories and subcategories, see Appendix 1 – Product List.

5.4 PRODUCT CONDITIONS

Clinical Trials

5.4.1 Participating Health Services may, at their discretion, research or trial new technology or use non-contracted products to perform clinical trials at any time throughout any resulting Agreement.

Product Duplication

5.4.2 HPV will not consider any product that is subject to a current HPV Agreement other than HPVC2011-036A Surgical Instruments – Open & Laparoscopic.

5.4.3 Respondents must 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.

Product Information

5.4.4 For each product tendered, Respondents must submit a copy of relevant product diagrams, specifications and/or brochures.

5.4.5 All product information submitted must:
- be in electronic format
- be in English
- be specific to the product offered
- contain the Respondent’s company name
- include the product code.

5.4.6 To assist in managing this material, all product information submitted must be labelled with the relevant HPV category and subcategory number (this should also be included in the file name). HPV reserves the right to not consider any unlabelled submissions.

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

5.4.8 Where offered products are unidentifiable and the product information provided is not clearly labelled, HPV reserves the right to remove these products from evaluation.

5.4.9 Respondents should note that product samples and research papers are not to be provided, unless specifically requested by HPV.

5.4.10 Respondents should not submit information relating to products that are not called for in this RFT.
5.5 DEFINITIONS

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

<table>
<thead>
<tr>
<th>TERM</th>
<th>DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>business day</td>
<td>Any weekday that is not gazetted as a public holiday in Melbourne, Victoria.</td>
</tr>
<tr>
<td>limited reuse</td>
<td>A device that can be reprocessed (cleaned and sterilised) for a given number of reuses prior to disposal.</td>
</tr>
<tr>
<td>may</td>
<td>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.</td>
</tr>
<tr>
<td>must</td>
<td>Indicates a mandatory requirement; failure to meet this requirement will have a significant negative impact during evaluation.</td>
</tr>
<tr>
<td>Participating Health Services</td>
<td>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.</td>
</tr>
<tr>
<td>reusable</td>
<td>A device designed or intended by the manufacturer as suitable for reprocessing and reuse.</td>
</tr>
<tr>
<td>should</td>
<td>Indicates a highly desirable element; unless justifiable reason exists, not meeting this element may have a medium impact during evaluation.</td>
</tr>
<tr>
<td>single use</td>
<td>A device that is intended to be used on an individual patient, during a single procedure, and then discarded.</td>
</tr>
<tr>
<td>SLA</td>
<td>Service Level Agreement</td>
</tr>
<tr>
<td>will</td>
<td>Indicates an anticipated future condition or requirement.</td>
</tr>
</tbody>
</table>
STATEMENT OF WORK

5.6 INDICATIVE DEMAND

5.6.1 Please refer to Appendix 1 – Product List for details of indicative demand.

5.6.2 Respondents are to note that any usage figures provided are indicative only, and are provided to assist Respondents in the preparation of their submission.

5.7 DELIVERY

5.7.1 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:

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

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

5.7.3 Except where there is evidence of inappropriate handling by the receiving Participating Health Service, all damaged or broken products and equipment must be replaced free of charge.

Urgent Deliveries

5.7.4 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.

5.7.5 Respondents should be able to receive and action urgent delivery requests 24 hours a day.

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

- 12 hours from receipt of order for metropolitan Participating Health Services
- 24 hours from receipt of order for regional and rural Participating Health Services.
5.8 TRAINING AND SUPPORT

5.8.1 Successful Respondents may be required to provide training 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.

5.8.2 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.

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

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

5.9 WARRANTY

5.9.1 Where applicable, surgical instruments, devices and cables must be warranted for normal use.

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

Repairs and Replacements under Warranty

5.9.3 The repair of any item under warranty will be at no cost to Participating Health Services.

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

5.9.5 Wherever possible, successful Respondents should provide Participating Health Services with a suitable replacement item of the same make and model until the repaired item is returned. This will be done at no cost to Participating Health Services.

5.10 KEY PERFORMANCE INDICATORS

5.10.1 Refer to Schedule 6 of Part 7 – Draft Agreement for Key Performance Indicators.
5.11 REPORTING

5.11.1 Refer to Schedule 7 of Part 7 – Draft Agreement for reporting requirements.
GENERAL REQUIREMENTS

5.12 STANDARDS AND COMPLIANCE

5.12.1 All items offered must comply with relevant standards, guidelines and legislation. Refer to Appendix 2 – References for a list of the minimum relevant standards.

5.12.2 All items offered must be approved by the Australian Therapeutic Goods Administration (TGA). Respondents must provide evidence of this (i.e. ARTG certificates) in their response.

5.12.3 Successful Respondents must provide evidence of ARTG certification to Participating Health Services upon request.

5.13 RECALL PROCESS

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

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

5.14 BACKORDERS AND DISCONTINUED LINES

5.14.1 In the event that a product is unavailable for a period of one or more consecutive weeks, successful Respondents must contact (at a minimum):

- Perioperative Services Managers
- Supply Departments
- Clinical Product Advisors
- HPV.

5.14.2 Successful Respondents must inform the affected Participating Health Services and HPV of:

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

5.15 INFECTION CONTROL

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

5.15.2 Upon request by Participating Health Services, successful Respondents must provide cleaning and/or re-sterilisation details for all reusable and limited reuse products.
PRODUCT SPECIFICATIONS

GENERAL SPECIFICATIONS

5.16 SUBSTANCES OF CONCERN

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

5.16.2 Preference may be given to products that are DEHP-free.

5.17 REUSABLE AND LIMITED REUSE DEVICES

5.17.1 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:

- instructions for cleaning, sterilisation and reuse
- warranty information.

5.17.2 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:

- the recommended number of uses and conditions for reuse of each specific item
- the recommended process for tracking the use of each item.

5.18 IMPLANTABLE DEVICES

5.18.1 For all implantable devices offered, multiple labels should be provided for recording product numbers and lot numbers in patient history (in order to track implantable devices).

5.19 CABLES

5.19.1 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.

## CATEGORY SPECIFICATIONS

### 5.20 CATEGORY 1 – CLIP APPLICATORS FOR OPEN AND LAPAROSCOPIC SURGERY

5.20.1 A range of clip applicators is required for use in open and laparoscopic surgery, including:
- single use and reusable
- sterile and unsterile
- 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.

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

### 5.21 CATEGORY 2 – CLIPS FOR OPEN AND LAPAROSCOPIC SURGERY

5.21.1 A range of sterile, single use clips is required for use in open and laparoscopic surgery, including:
- a range of shapes and sizes
- non-absorbable and absorbable
- 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
- colour-code identification.

5.21.2 Metallic clips must be made of titanium.
5.22 **CATEGORY 3 – STAPLE APPLICATORS FOR OPEN AND LAPAROSCOPIC SURGERY**

5.22.1 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.

5.22.2 **Note:** Where a single use staple unit is incorporated with the staple applicator, it must comply with the specifications set out in Category 4.

5.23 **CATEGORY 4 – STAPLE UNITS FOR OPEN AND LAPAROSCOPIC SURGERY**

5.23.1 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
- colour-code identification (where applicable)
- 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.

5.23.2 Staple units must be clearly labelled to differentiate size.

5.23.3 Staples must be made of titanium.
5.24 CATEGORY 5 – SURGICAL MESH FOR OPEN AND LAPAROSCOPIC SURGERY

5.24.1 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.

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

5.25.1 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
- tack applicators
- reloadable and non-reloadable applicators
- tacks
- absorbable and non-absorbable.

5.25.2 All metallic tacks must be made of titanium.
5.26 CATEGORY 7 – INSUFFLATION DEVICES FOR LAPAROSCOPIC SURGERY

5.26.1 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**

5.26.2 A range of single-use safety pneumo-peritoneum needles is required, including:
- a range of needle sizes and lengths
- blunt and sharp.

5.26.3 Pneumo-peritoneum needles must incorporate a stopcock.

**Insufflation Tubing with a Filter**

5.26.4 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.

5.26.5 Insufflation tubing must be:
- kink resistant
- compatible with a wide range of insufflation equipment.

5.26.6 All connections for insufflation devices must be luer lock.

5.26.7 All filters must be hydrophobic and filter to 0.1 microns.

5.27 CATEGORY 8 – SUCTION IRRIGATION UNITS FOR LAPAROSCOPIC SURGERY

5.27.1 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 probe
- probes (where applicable):
  - single-use and reusable
  - 5mm and 10mm diameter
5.27.2 The activation mechanism/trumpet valve assembly must incorporate colour-coded suction and irrigation valve buttons.

5.27.3 Laparoscopic suction irrigation systems must be leak-proof.

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

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

5.27.6 The suction limb must incorporate a connection to fit standard wall suction systems.

5.28 CATEGORY 9 – ACCESS DEVICES FOR LAPAROSCOPIC SURGERY

5.28.1 A range of sterile ports, trocars and accessories used to gain and provide access for laparoscopic surgery is required, including:

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

Ports

5.28.2 A range of ports is required, 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
• for a range of approaches, including stepped, dilating, hand access and visual access.

**Trocars**

5.28.3 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
• visual.

**Accessories**

5.28.4 A range of accessories is required, including:
• reducing and expandable sleeves
• seals, with and without a stopcock
• wound retractors.

5.28.5 All stopcocks must have luer lock fittings.

**5.29 CATEGORY 10 – BALLOON DILATION AND DISSECTION DEVICES FOR LAPAROSCOPIC SURGERY**

5.29.1 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.

**5.30 CATEGORY 11 – SURGICAL INSTRUMENTS FOR LAPAROSCOPIC SURGERY**

5.30.1 A range of hand-held laparoscopic surgical instruments is required, including:
• sterile and non-sterile
• scissors
• dissectors
• graspers
• handles
• sheaths
• retractors
• single-use instruments
• limited reuse instruments
• single-use components for reusable instruments
• with and without monopolar or bipolar electrosurgery potential
• with and without electrosurgery connecting cables.

5.30.2 **Note:** Robotics instruments are out of scope for the purposes of this RFT.

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

5.30.4 All surfaces must be free from pores, crevices and grinding marks.

5.30.5 The action of laparoscopic surgical instruments must be smooth.

5.30.6 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.

5.30.7 Where an instrument includes jaws, the jaws must close in apposition.

5.30.8 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.

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

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

5.30.11 All bipolar cables must have fixed pins.

**Scissors**

5.30.12 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**

5.30.13 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

5.30.14 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

5.30.15 A range of handles is required, including:
- ratcheted and non-ratcheted
- rotating and fixed
- with monopolar and bipolar electrosurgery potential.

Sheaths

5.30.16 A range of insulated sheaths is required, including a range of sizes.

Retractors

5.30.17 A range of retractors is required, including:
- a full range of sizes and lengths
- a range of tip configurations.

5.31 CATEGORY 12 – DIATHERMY ELECTRODES FOR LAPAROSCOPIC SURGERY

5.31.1 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.

5.31.2 Note: Diathermy electrodes with a suction/irrigation lumen are considered out of scope for the purposes of this RFT.
5.32 CATEGORY 13 – CUTTING AND COAGULATION INSTRUMENTS FOR OPEN AND LAPAROSCOPIC SURGERY

5.32.1 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.

5.32.2 Note: This category excludes other standard diathermy items listed in Category 11.

5.33 CATEGORY 14 – SPECIMEN RETRIEVAL DEVICES FOR LAPAROSCOPIC SURGERY

5.33.1 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.

5.33.2 Specimen retrieval pouches and bags must be made of tear-resistant material.

5.33.3 Pouches and bags must not separate from the retrieval mechanism when used in accordance with the manufacturer’s instructions.

5.34 CATEGORY 15 – SUTURES AND SUTURING DEVICES FOR LAPAROSCOPIC SURGERY

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

Sutures

5.34.2 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**

5.34.3 A range of suturing devices is required, including:
• for closure of trocar sites
• for internal suturing and tying/ligation.
## APPENDIX 1 – PRODUCT LIST

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>SUBCATEGORY</th>
<th>EST. USAGE IN EACH P.A.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Clip Applicators for Open and Laparoscopic Surgery</td>
<td>Single Clip Applicator Reusable Without Clips</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>Multiple Clip applicator Single use With Clips</td>
<td>11,925</td>
</tr>
<tr>
<td></td>
<td>Multiple Clip applicator Reusable Without Clips</td>
<td>N/A</td>
</tr>
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<td>2. Clips for Open and Laparoscopic Surgery</td>
<td>Absorbable</td>
<td>N/A</td>
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<tr>
<td></td>
<td>Non-Absorbable</td>
<td>700,112</td>
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<td>3. Staple Applicators for Open and Laparoscopic Surgery</td>
<td>Curved Reloadable With Staple Unit</td>
<td>607</td>
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<td>Curved Reloadable Without Staple Unit</td>
<td>594</td>
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<td>Curved Non-Reloadable With Staple Unit</td>
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<td>Straight Reloadable With Staple Unit</td>
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<td>Straight Non-Reloadable With Staple Unit</td>
<td>236</td>
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<td>4. Staple Units for Open and Laparoscopic Surgery</td>
<td>Straight Cutting</td>
<td>4,503</td>
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<td>Straight Non-cutting</td>
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<td></td>
<td>Articulating Cutting</td>
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<tr>
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<td>Articulating Non-cutting</td>
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<td>Curved Cutting</td>
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<tr>
<td></td>
<td>Curved Non-cutting</td>
<td>N/A</td>
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<tr>
<td>5. Surgical Mesh for Open and Laparoscopic Surgery</td>
<td>Absorbable Monofilament Single layer Open Weave Impregnated</td>
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<td></td>
<td>Absorbable Monofilament Single layer Open Weave Non-Impregnated</td>
<td>1,539</td>
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<td>Absorbable Monofilament Multi-layer Open Weave Impregnated</td>
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<td>Absorbable Monofilament Multi-layer Open Weave Non-Impregnated</td>
<td>693</td>
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<tr>
<td></td>
<td>Absorbable Monofilament Multi-layer Closed Weave Impregnated</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Absorbable Monofilament Multi-layer Closed Weave Non-Impregnated</td>
<td>N/A</td>
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<td>CATEGORY</td>
<td>SUBCATEGORY</td>
<td>USAGE IN EACH P.A.</td>
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<tr>
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<td>Single layer</td>
</tr>
<tr>
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<td>Multifilament</td>
<td>Multi-layer</td>
</tr>
<tr>
<td>Non-Absorbable</td>
<td>Monofilament</td>
<td>Single layer</td>
</tr>
<tr>
<td>Non-Absorbable</td>
<td>Monofilament</td>
<td>Single layer</td>
</tr>
<tr>
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<td>Monofilament</td>
<td>Single layer</td>
</tr>
<tr>
<td>Non-Absorbable</td>
<td>Monofilament</td>
<td>Multi-layer</td>
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<tr>
<td>Non-Absorbable</td>
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<td>Multifilament</td>
<td>Single layer</td>
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<tr>
<td>Non-Absorbable</td>
<td>Multifilament</td>
<td>Single layer</td>
</tr>
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</tr>
<tr>
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<td>6. Surgical Mesh Fixation Tacks and Applicators for Open and Laparoscopic Surgery</td>
<td>Absorbable Reloadable</td>
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<td></td>
<td>Absorbable Non-reloadable</td>
<td>2,854</td>
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<td>Non absorbable Reloadable with cartridges</td>
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<td>7. Insufflation Devices for Laparoscopic Surgery</td>
<td>Pneumo-peritoneum needles Sharp</td>
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<td></td>
<td>Pneumo-peritoneum needles Blunt</td>
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<td>Insufflation tubing with filter Plain</td>
<td>12,200</td>
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<td>8. Suction Irrigation Units for Laparoscopic Surgery</td>
<td>Single Spike With probes</td>
<td>9,350</td>
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<tr>
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<td>Single Spike Without probes</td>
<td>2,420</td>
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<tr>
<td></td>
<td>Double spike With probes</td>
<td>1,410</td>
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<td></td>
<td>Double spike Without probes</td>
<td>6,080</td>
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<tr>
<td></td>
<td>Probe Reusable</td>
<td>27</td>
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<td></td>
<td>Probe Single use</td>
<td>420</td>
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<td>9. Access Devices for Laparoscopic Surgery</td>
<td>Port with trocar blunt threaded without insufflation port without fixation device</td>
<td>659</td>
</tr>
<tr>
<td></td>
<td>Port with trocar blunt threaded with insufflation port without fixation device</td>
<td>15,123</td>
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<td></td>
<td>Port with trocar blunt threaded with insufflation port with fixation device</td>
<td>42</td>
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<td></td>
<td>Port with trocar blunt non threaded without insufflation port without fixation device</td>
<td>1,350</td>
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<td>Port with trocar blunt non threaded with insufflation port with fixation device</td>
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<td>Port with trocar sharp threaded without insufflation port without fixation device</td>
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<td></td>
<td>Port with trocar sharp threaded with insufflation port without fixation device</td>
<td>6,832</td>
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<td>Port with trocar sharp non threaded with insufflation port without fixation device</td>
<td>1,292</td>
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<td></td>
<td>Port with trocar sharp threaded with insufflation port without fixation device</td>
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<td></td>
<td>Port with trocar sharp threaded with insufflation port with fixation device</td>
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<tr>
<td>----------</td>
<td>-------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>Port with trocar</td>
<td>sharp</td>
<td>non threaded</td>
</tr>
<tr>
<td>Port with trocar</td>
<td>sharp</td>
<td>non threaded</td>
</tr>
<tr>
<td>Trocar</td>
<td>sharp</td>
<td>non threaded</td>
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<td>Trocar</td>
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<td>non threaded</td>
</tr>
<tr>
<td>Trocar</td>
<td>sharp</td>
<td>non threaded</td>
</tr>
<tr>
<td>Trocar</td>
<td>blunt</td>
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<tr>
<td>Accessory</td>
<td></td>
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</tr>
<tr>
<td>Other</td>
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</table>

10. Balloon Dilation and Dissection Device for Laparoscopic Surgery

<table>
<thead>
<tr>
<th>Category</th>
<th>Subcategory</th>
<th>Est. Usage in Each P.A.</th>
</tr>
</thead>
<tbody>
<tr>
<td>with Trocar</td>
<td></td>
<td></td>
</tr>
<tr>
<td>without Trocar</td>
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11. Surgical Instruments for Laparoscopic Surgery

<table>
<thead>
<tr>
<th>Category</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Scissors</td>
<td>without inserts</td>
<td></td>
</tr>
<tr>
<td>scissors</td>
<td>with inserts</td>
<td></td>
</tr>
<tr>
<td>Dissectors</td>
<td>without inserts</td>
<td></td>
</tr>
<tr>
<td>Dissectors</td>
<td>with inserts</td>
<td></td>
</tr>
<tr>
<td>Graspers</td>
<td>without inserts</td>
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<td>Graspers</td>
<td>with inserts</td>
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<tr>
<td>Retractors</td>
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<td></td>
</tr>
<tr>
<td>Additional components including handles and sheaths</td>
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<td></td>
</tr>
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</table>

12. Diathermy Electrodes for Laparoscopic Surgery

<table>
<thead>
<tr>
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<th>Subcategory</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Single use</td>
<td>Monopolar</td>
<td>Foot controlled</td>
</tr>
<tr>
<td>Single use</td>
<td>Monopolar</td>
<td>Hand controlled</td>
</tr>
<tr>
<td>Reusable</td>
<td>Monopolar</td>
<td>Hand controlled</td>
</tr>
<tr>
<td>Single use</td>
<td>Bipolar</td>
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13. Cutting and Coagulation Instruments for Open and Laparoscopic Surgery

<table>
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<th>Subcategory</th>
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</tr>
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<tbody>
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<td>Shears</td>
<td>Straight</td>
<td>Foot controlled</td>
</tr>
<tr>
<td>Shears</td>
<td>Straight</td>
<td>Hand controlled</td>
</tr>
<tr>
<td>Shears</td>
<td>Curved</td>
<td>Foot controlled</td>
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<td>Hand controlled</td>
</tr>
<tr>
<td>CATEGORY</td>
<td>SUBCATEGORY</td>
<td>EST. USAGE IN EACH P.A.</td>
</tr>
<tr>
<td>----------</td>
<td>-------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>14. Specimen Retrieval Devices for Laparoscopic Surgery</td>
<td>Bag</td>
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</tr>
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<td></td>
</tr>
<tr>
<td></td>
<td>Pouches</td>
<td>400</td>
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<td></td>
<td></td>
<td>14,371</td>
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<tr>
<td>15. Sutures and Suturing Devices for Laparoscopic Surgery</td>
<td>Absorbable</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>non absorbable</td>
<td>17,881</td>
</tr>
<tr>
<td></td>
<td>suturing devices</td>
<td>968</td>
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</table>
APPENDIX 2 – REFERENCES

Standards

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

<table>
<thead>
<tr>
<th>STANDARD NUMBER</th>
<th>STANDARD NAME</th>
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</thead>
<tbody>
<tr>
<td>AS 4187</td>
<td>Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities</td>
</tr>
</tbody>
</table>

Legislation

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

- Therapeutic Goods (Medical Devices) Regulations 2002
- Therapeutic Goods Act 1989

Guidelines and Other References

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

- NHMRC (2010), Australian Guidelines for the Prevention and Control of Infection in Healthcare, Commonwealth of Australia
- Therapeutic Goods Administration (2011), Australian Regulatory Guidelines for Medical Devices