# Request For Tender

## Part 5

### Statement of Requirements

<table>
<thead>
<tr>
<th>Tender Number:</th>
<th>RFTHPV2015-016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tender Name:</td>
<td>Sutures, Skin Staples &amp; Removers, and Tissue Adhesives</td>
</tr>
<tr>
<td>Tender Closing Date and time:</td>
<td>Wednesday 6 May 2015, 14:00 AEST</td>
</tr>
</tbody>
</table>

**Authorised Contact Person**

Hassan Pirov  
Category Manager

Contact through the [HPV Procurement Portal](https://www.hpv.org.au/)

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A Introduction

1 Purpose

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

(i) detail the scope and range of products sought under this Request for Tender (RFT)
(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 Sutures, Skin Staples & Removers, and Tissue Adhesives for use in Participating Health Services. The envisaged Term of the Agreement is three years plus one possible two-year extension period available to extend the contract term (3+2 years).

b The scope of this RFT includes:

(i) supply of the products listed in section Part 5.A.3 - Product Categories.

c The scope of this RFT does not include:

(i) supply of the Staple Applicators for Open and Laparoscopic Surgery
(ii) supply of the Staple Units for Open and Laparoscopic Surgery
(iii) supply of the Sutures and Suturing Devices for Laparoscopic Surgery

3 Product Categories

a The categories of Sutures, Skin Staples & Removers, and Tissue Adhesives required under this RFT include:

   Category 1 Sutures
   Category 2 Skin staples & Removers
   Category 3 Tissue adhesives

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

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

d Only products that specifically fit within the category description provided are considered.

e HPV reserves the right disregard any additional products offered.

f 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 will not consider any product that is subject to a current HPV Agreement, other than those listed below:

- HPVC2009-016 Sutures, Skin Staples and Tissue Adhesives.

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

b All product information submitted must:

(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

c To assist in managing this material, all product information submitted must be labelled with the relevant HPV category and subcategory number. HPV reserves the right to not consider any unlabelled submissions.

Any electronic information must include the HPV category and subcategory number in the filename.

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

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

f Respondents should note that product samples and research papers are not to be provided, unless specifically requested by HPV.
4.4 Third-Party Product Compatibility

a Respondents tendering third-party items must provide clinical testing and evidence of each item’s compatibility with specific models of OEM equipment.

b Successful Respondents must also make these certificates of compliance and/or evidence of testing available to Participating Health Services upon request.

c Further evidence of testing will be required for product variations requested during the contract period. Certificates of compliance and/or evidence of testing must not be more than two (2) years old at the time the variation request is made.

d HPV reserves the right to require further testing from successful Respondents if:

   (i) a product quality issue is identified during the contract
   (ii) an option period is exercised at the end of the contract principal period.

e If HPV requires further certificates of compliance and/or evidence of testing, then HPV reserves the right to remove products from contract if the successful Respondent refuses to, or cannot, produce the required evidence.

5 Definitions

a 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>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 significant negative 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>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>
B Statement of Work

1 Indicative demand

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

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

<table>
<thead>
<tr>
<th>CAT NO</th>
<th>CATEGORY NAME</th>
<th>USAGE IN EACH PER ANNUM</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Sutures</td>
<td>1,269,822</td>
</tr>
<tr>
<td>2</td>
<td>Skin Staples &amp; Removers</td>
<td>61,830</td>
</tr>
<tr>
<td>3</td>
<td>Tissue Adhesives</td>
<td>37,922</td>
</tr>
</tbody>
</table>

2 Delivery

a Sutures, Skin Staples & Removers, and Tissue Adhesives must be delivered to the location(s) specified by Participating Health Services within the shortest possible timeframe; however, this must not exceed 24 hours 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) two (2) business days from receipt of order for regional and rural Participating Health Services.

b Preference is for delivery within 24 hours to metropolitan and regional and rural participating health services.

c 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.

3 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.
Urgent deliveries must be received by Participating Health Services (at specified locations) 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

4 Training and support

a Upon request by a Participating Health Service, successful Respondents must deliver a training package and/or training materials to facilitate the introduction of their Sutures, Skin Staples & Removers, and Tissue Adhesives to clinicians in their operating environment.

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

c Successful Respondents must ensure that the following is available to Participating Health Services (in either hard-copy or electronic format):

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

d All training regimes must include appropriate levels of training to meet Workplace Health & Safety issues as required by The Victorian WorkCover Authority.

5 Warranty

a Products covered within this RFT, Sutures, Skin Staples & Removers, and Tissue Adhesives, products must be warranted for normal use.

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

5.1 Repairs and Replacements under Warranty

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

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

c Warranty repair items must be returned to Participating Health Services within two (2) business days from when the item is received by the successful Respondent.

d If requested by the Participating Health Service, successful Respondents must provide a suitable replacement item of the same make and model at no cost.
6  **Key Performance Indicators**

a  Refer to Schedule 6 of Part 7 Draft agreement - Performance Indicators.

7  **Reporting**

a  Refer to Schedule 7 of Part 7 Draft agreement - reporting requirements.

b  The successful respondent must provide to HPV other reports that may reasonably be required from time to time.
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 must 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 must 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 is MRI compatible (implantable products);
   (iii) whether the product (or packaging) contains latex or is latex-free; and
   (iv) tracking stickers.

3 Recall Process

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

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

3.2 Backorders and Discontinued Lines

a In the event that a product is unavailable for a period of two or more consecutive weeks, the successful Respondent must contact (at a minimum) the following:
   (i) Participating Health Service supply departments
   (ii) the Clinical Product Advisor (where applicable)
b In the event that a product is unavailable for a period of two or more consecutive weeks, successful Respondents must also contact:
   (i) Health Purchasing Victoria (HPV).

c Successful Respondents must 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

3.3 Superseded products

a Where a contracted item is superseded, the new product must be offered at the same price as the original item.

3.4 Infection Control

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

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

1  Substances of Concern

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

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

2  Compliance with Category specifications

   a  Products offered with optional components must also comply with the specifications for other relevant categories (where applicable).
Category 1 Sutures

a  A complete catalogue of sterile, single use sutures is required to meet clinical needs across all surgical specialties and areas of care. This includes:

(i) a full range of suture materials including:

- absorbable, braided, dyed;
- absorbable, braided, undyed;
- absorbable, monofilament, dyed;
- absorbable, monofilament, undyed;
- non-absorbable, braided, dyed;
- non-absorbable, braided, undyed;
- non-absorbable, monofilament, dyed;
- non-absorbable, monofilament, undyed;

(ii) with and without antimicrobial coatings;
(iii) with and without attached needles;
(iv) a full range of needle gauges, shapes and configurations.

Packaging

b  Sutures shall be packaged in a manner that:

(i) maintains sterility of the contents;
(ii) retains the structural integrity of the enclosed suture;
(iii) protects the suture needle (where present);
(iv) minimises the risk of tangling the enclosed suture;
(v) on opening, presents the suture needle in a manner that facilitates loading onto a suture holder or similar application device.

c  For each suture offered, Tenderers shall advise the following information in the Tender Response Worksheet:

(i) brand name of suture;
(ii) generic name of suture material;
(iii) gauge of suture;
(iv) length of suture material in centimetres;
(v) needle type;
(vi) needle shape;
(vii) needle length in millimetres;
(viii) where present, antimicrobial coating;
(ix) where more than one needle is present per thread, the number of needles;
(x) where more than one suture is present in a single foil, the number of sutures per foil.

Shelf Life

d  Sutures shall have a minimum of six months shelf life on delivery to a hospital or health service.
Where remaining product shelf life is six months or less, successful tenderers shall advise
the receiving hospital or health service to allow for effective stock management and
utilisation.

**Inventory Management and Ordering.**

Tenderers shall advise of the availability of an electronic suture inventory management and
ordering system to support effective product use. Where present, tenderers shall provide a
brief outline of the system including:

- (i) establishment and ongoing use of the system;
- (ii) allocation of support personnel;
- (iii) process to review range and volume of stock held, including frequency of review;
- (iv) management of shelf-life issues;
- (v) any limitations associated with access and use;
- (vi) any costs associated with its use.

Preference will be given to tenderers that provide an electronic suture inventory
management and ordering system.

**Service Level Agreement**

Successful tenderers shall enter into a Service Level Agreement with individual hospitals or
health services requiring use of an electronic suture inventory management and ordering
system.

The agreement shall cover all arrangements associated with the use of the system including
but not limited to those points identified in clause Category 1.f.

**Additional Information**

The following information shall be available to all contract users via hard copy or electronic
means:

- (i) research papers to support the introduction of new or modified suture materials.
Category 2 Skin staples & Removers

2.01 Skin staples

a A range of sterile, single use skin stapling devices incorporating stainless steel skin staples is required to meet clinical needs. This includes:

(i) a range of staple widths and depths;
(ii) a range of unit capacity;

b Tenderers shall advise the following information in the Tender Response Worksheet:

(i) brand name;
(ii) staple gauge;
(iii) staple depth;
(iv) staple width;
(v) number of skin staples per stapling device

c Tenderers shall advise if skin stapling devices incorporate a viewing window to visualise the staple count.

d Preference is for skin stapling devices that incorporate a viewing window.

e Skin stapling devices shall be packaged in peel-pack to facilitate ease of access.

f A full range of Skin Staple Removers is required to meet clinical needs.

g Skin Staple Removers shall be packaged individually.

2.02 Skin staple removers

a Sterile, single use skin staple removers are required to meet clinical needs.

b Skin Staple Removers shall:

(i) be of solid construction;
(ii) have no rough or sharp edges;
(iii) cleanly and smoothly remove skin strapless;
(iv) be packaged individually in peel-pack in a manner that protects the tip from accidental damage;

c For each Skin Staple Remover offered, tenderers shall provide the following information in the Tender Response Worksheet:

(i) Brand name
(ii) UNSPCS code
(iii) HPIS Classification
(iv) Latex free indication (yes/no)
Category 3 Tissue adhesives

a  Sterile, single patient use cyanoacrylate tissue adhesive (for external use only) is required for the closure of skin lacerations or incisions. This includes:

   (i) a range of volumes.
   (ii) with and without an incorporated skin closure device.

b  Tissue adhesives shall be:

   (i) supplied in a ‘ready to use’ form;
   (ii) easy to apply;
   (iii) packaged in a manner that:

       • minimises the risk of spillage, leaking or clotting of the application tip;
       • protects the integrity of the contents;
       • provides a barrier to microbial penetration.

c  Tenderers shall advise the following information in the Tender Response Worksheet:

   (i) brand name;
   (ii) volume of adhesive in each individual unit (in millilitres).

d  Tenderers shall advise the following information in the Tender Response Worksheet:

   (i) setting time, in seconds;
   (ii) sloughing time, in days;
   (iii) requirement for refrigeration storage.
   (iv) Preference will be given to tissue adhesives that do not require refrigeration.

Additional Information

e  The following information shall be available to all contract users via hard copy or electronic means:

   (i) Material Safety Data Sheet.
Appendix 1 - Product List

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>SUBCATEGORY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Sutures</td>
<td>1.01 Absorbable, braided, dyed</td>
</tr>
<tr>
<td></td>
<td>1.02 Absorbable, braided, undyed</td>
</tr>
<tr>
<td></td>
<td>1.03 Absorbable, monofilament, dyed</td>
</tr>
<tr>
<td></td>
<td>1.04 Absorbable, monofilament, undyed</td>
</tr>
<tr>
<td></td>
<td>1.05 Non-absorbable, braided, dyed</td>
</tr>
<tr>
<td></td>
<td>1.06 Non-absorbable, braided, undyed</td>
</tr>
<tr>
<td></td>
<td>1.07 Non-absorbable, monofilament, dyed</td>
</tr>
<tr>
<td></td>
<td>1.08 Non-absorbable, monofilament, undyed</td>
</tr>
<tr>
<td>2 Skin Staples &amp; Removers</td>
<td>2.01 Non-reloadable staplers</td>
</tr>
<tr>
<td></td>
<td>2.02 Skin Staple Remover, Sterile, Single Use</td>
</tr>
<tr>
<td>3 Tissue Adhesives</td>
<td>3.01 Tissue Adhesives with and without an incorporated skin closure device</td>
</tr>
</tbody>
</table>

Appendix 2 - References

A 2.a 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>
</tr>
</thead>
<tbody>
<tr>
<td>AS/NZS 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>

A 2.b Legislation

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

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