HealthShare Victoria

Invitation to Supply (Draft)

Invitation to Supply Number:	**HPVITS2025-079**
Invitation to Supply Name:	**Intravenous Access Devices, Administration and Neural Connector Consumables (IVADANCC)**
HPVITS2025-079 Closing Date and time:	**15 November 2024 14:00 AEDT**

Part 4 - Statement of Requirements (SOR)

Table of Contents

1 Participating Health Services

a. The Participating Health Services (PHS) for this Invitation to Supply (ITS) are

(i) All 'Public Health Services' (as legislatively defined) referred to in Schedule 1 and Schedule 5 of the *Health Services Act 1988*; and
(ii) Other relevant participating health and health related organisations as follows:

- Eligible non-mandated health services

2 Scope

a. HSV is seeking responses for Intravenous Access Devices, Administration and Neural Connector Consumables (IVADANCC) products for use in Participating Health Services (PHS). The envisaged term of the agreement is four (4) years plus one option to extend for two (2) year period.(i.e. 4+2).

b. The scope of this ITS includes:

(i) The supply of Intravenous Access Devices, Administration and Neural Connector Consumables (IVADANCC) products covered in section Part 5 – Module A Specification (standard purchases service requirements).
(ii) Education and training
(iii) company representative clinical attendance

c. The scope of this ITS does not include the following:

(i) Supply of Long-term Haemodialysis Catheters.
(ii) Supply of Pharmaceutical products used in conjunction with Closed System Transfer Devices (CSTD)
(iii) Supply of CSTDs and associated consumables for pharmaceutical compounding by a third-party on behalf of a Participating Health Service; and
(iv) Supply of products that are currently in other active HSV Contracts.

3 Product Categories

a. A complete range of Intravenous Access Devices, Administration and Neural Connector Consumables (IVADANCC) is required for treatment of patients across Victorian Public Health Services.

b. The categories of Intravenous Access Devices, Administration and Neural Connector Consumables (IVADANCC) required under this Invitation to Supply (ITS) include:

- Category 1 - Peripheral Intravenous Cannulae
- Category 2 - Winged Intravenous and Sub-Cutaneous Devices
- Category 3 - Peripherally Inserted Central Catheters
- Category 4 - Central Venous Catheters and Guidewires
- Category 5 - Gravity Intravenous Administration Sets
- Category 6 - Burettes
- Category 7 - Intravenous Extension Tubing

- Category 8 - Single Lumen IV Extension Sets and Filters
- Category 9 - Multi Lumen IV Adaptors
- Category 10 - Needleless Connectors
- Category 11 - Intravenous Access Port Caps
- Category 12 - Stopcocks
- Category 13 - Port Access Needles
- Category 14 - Antiseptic Skin Preparation Swab Sticks, Wipes & Applicators
- Category 15 - IV Start Kits
- Category 16 - Non-Powered Ambulatory Infusion Devices
- Category 17 - Closed System Transfer Devices
- Category 18 - Acute Haemofiltration Catheters
- Category 19 - Midline Catheters
- Category 20 - Intraosseous Needles & Drivers
- Category 21 - Neural Connector Devices
- Category 22 - Totally Implantable Venous Access Devices (TIVADs)
- Category 23 - Pre-Filled Saline Syringe for IV Catheter Flush
- Category 24 - IV (Intravenous) Arm Boards

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

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

e. For a full list of product categories and subcategories, see Appendix 1 - Category and Subcategory .

4 Product Offering

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

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

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

   (i) HPVITS2025-079 Intravenous Access Devices, Administration and Neural Connector Consumables (IVADANCC)

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

e. Successful responses must ensure inventory holding of at least 6 months' supply.

5 Clinical Trials

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

Product Requirements

6 Standards and Compliance

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

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

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

7 Packaging and Labelling

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

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

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

d. Include batch numbers on packaging – on the outer carton and individual packaging

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

Mandatory

(i) whether the product is sterile.

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

(iii) manufacturing date

Desirable

(i) whether the product is MRI conditional (implantable products).

(ii) tracking labels.

(iii) expiry date

(iv) Preference for recyclable and sustainable material used in packaging

8 Infection Control

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

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

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

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

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

9 Substances of Concern

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

b. Preference will be given to products that are free of diethylhexyl phthalate (DEHP).

10 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. OR Research papers should not be provided unless specifically requested by HSV.

c. All product information submitted should:

(i) be in electronic format

(ii) be in English

(iii) be specific to the product offered

(iv) contain the Respondent's company name

(v) include the product code

(vi) include a detailed specification of the product

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

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

e. Electronic copies should include the HSV Category and subcategory numbers in the filename or identifying metadata.

f. HSV may not consider unlabelled submissions.

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

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

(i) Not labelled as per clause d above; or

(ii) Is incomplete as to clause c.

i. Product samples are to be provided unless specifically requested by HSV.

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

11 Warranty

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

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

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

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

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

f. All sterile and non-sterile goods must have at least 6-months' expiry at delivery, unless otherwise agreed upon in writing between parties.

g. Subject to clause 11f, in the event a product is supplied to any Participating Health Service with a 'less than 6 months' expiry date, that product must be replaced free of charge or replaced with a credit.

12 Recall Process

a. All recalls must be managed in line with the Uniform Recall Procedure for Therapeutic Goods (URPTG) (V2.3 February 2022).

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

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

d. Delivery cost of replaced items and recalled items should be free of charge. Refer to Part 5.

Pricing

13 Sole and Panel Pricing

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

b. In the Tender Response Worksheet, Respondents are to list price options for Panel Supply.

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

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

14 Price review

a. Price review (if any) will be set out in and must be in accordance with Part 5: Module A Clinical Goods.

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

Delivery

15 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.

16 Delivery

a. Intravenous Access Devices, Administration and Neural Connector Consumables will be delivered to the location(s) specified by Participating Health Services within the shortest possible timeframe; however, this must not exceed three (3) Business Days from receipt of order unless otherwise agreed with the Participating Health Service.

b. All deliveries are bound as per the Deed of Standing Offer Agreement.

17 Urgent Deliveries

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

b. The Respondent must be able to receive and action urgent delivery requests at a minimum of 8am to 5pm on business days. Preference will be given for better availability.

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

d. Any additional costs associated with Urgent Deliveries shall be clearly outlined in the User Guide tab of the Tender Response Worksheet and shall be discussed and agreed with the ordering health service prior to acceptance of any urgent order.

Support

18 Training

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

b. Suppliers will comply with all sign-in and vaccination requirements (i.e. health care management representative management systems)

c. 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.

19 Customer Service and Support

Customer Support

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

b. Refer to Part 5 – Module A: 7.3 Good Shortages (a) to (g).

Representative Support

c. 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 during business hours.

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

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

(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.

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

Award

20 Conditional Acceptance

a. Products may be designated as 'Conditionally Accepted' for the following reasons:

(i) Where products offered are not 'known and accepted' but represent value for money; or

(ii) Where products are inactive and have not been in use for at least 12 months.

(iii) Where minimum data information is not provided e.g. UNSPSC code.

b. Draft Deed of Standing Offer Agreement sets out terms relating to Conditionally Accepted Deliverables.

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

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

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

f. Refer more at Part 5 – Module A: 7.11 Conditional Acceptance (a) to (f).

21 Key Performance Indicators

a. Refer to Part 5 – Module A Clinical Goods, Schedule 6.

22 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) requirements for stock management and rotation

   (ii) arrangements for ordering, invoicing and delivery

   (iii) provision of a non-binding estimated forecast at periodic intervals

   (iv) clinical support, including attendance requirements for Representatives in relation to education and training

   (v) communication arrangements for product recalls and safety alerts

b. The SLA will be in addition to the Agreement between the successful Respondent(s) and HSV and will not alter any terms of the Agreement.

c. HSV 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 HSV within 1 week of being executed.

Category 1 - Peripheral Intravenous Cannulae

A range of sterile, peripheral intravenous cannulae is required for the administration of intravenous therapy.

Mandatory Criteria

All peripheral intravenous cannulae offered shall be

a. radiopaque

b. sterile.

Clinical Attributes

For each peripheral intravenous cannula offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. brand name
b. sterile
c. contains latex or latex free
d. DEHP %
e. safety or non-safety
f. passive or active (where applicable); and
g. cannula:
    i. gauge
    ii. length, in millimetres
    iii. material of construction (e.g. polyurethane)
        - securement features (where applicable) (e.g. winged
        - whether wings are removable or not (if applicable)
    iv. with or without extension tubing; and
    v. any additional features, such as an integral access port.

h. extension tubing (where applicable):
    i. diameter, in millimetres
    ii. length, in millimetres
    iii. straight or Y-ports
    iv. type of clamps (e.g. slide or pinch)
    v. integral access ports:
        - brand name
        - number of ports; and
    vi. number of port caps (where applicable).

Additional Information

For each peripheral intravenous cannula offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. whether the product is marked as single use on the external packaging
b. maximum flow rate, in millilitres per minute
c. priming volume of extension tubing, in millilitres (where applicable)
d. whether the peripheral intravenous cannula contains a blood control mechanism/technology
e. whether the peripheral intravenous cannula is recommended for use with a power injector, and if so:

i. the recommended pressure rating, in PSI
ii. the recommended injection rate, in millilitres per second; and
iii. the recommended number of power injections or dwell time.

f. whether the peripheral intravenous cannula is:
i. MRI compatible.
ii. lipid compatible.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Category 2 - Winged Intravenous and Sub-cutaneous Devices

A range of sterile, winged devices is required for the administration of intravenous and subcutaneous therapy.

Tenderers note

This category does not include winged infusion devices with integral adaptors for evacuated blood collection. These devices are situated in the **Pathology Consumables Contract: HPVC2017-042.** Also please note that items with a primary purpose of being an intravenous cannula will be part of Category 1 and not a part of this category (whether wings are present or not).

Mandatory Criteria

All winged intravenous devices offered shall be radiopaque.

Clinical Attributes

For each winged intravenous device offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. brand name
b. sterile
c. contains latex or latex free
d. DEHP %
e. safety or non-safety
f. cannula:
g. gauge
h. length, in millimetres
i. material of construction
j. with or without extension tubing.
k. extension tubing:
    i. diameter, in millimetres
    ii. length, in millimetres
    iii. straight or Y-ports
    iv. type of clamps (e.g. slide or pinch)
    v. integral access ports (where applicable):
        - brand name
        - number of ports
    vi. number of port caps (where applicable)

Additional Information

For each winged intravenous and subcutaneous device offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. whether the product is marked as single use on the external packaging
b. maximum flow rate, in millilitres per minute
c. manufacturer recommended dwell time
d. priming volume of extension tubing, in millilitres; and
e. whether the winged intravenous device is:
    i. MRI compatible; and
    ii. lipid compatible.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Category 3 - Peripherally Inserted Central Catheters

A range of sterile peripherally inserted central catheters (PICCs) is required to meet clinical needs for adult, paediatric and neonatal patients.

Mandatory Criteria

PICCs shall:

a. be flexible and radiopaque; and
b. incorporate graduated markings in centimetres to assist with catheter positioning by indicating the position in the body**.**

Desirable Criteria

Preference will be given to multi-lumen PICCs that have the size of each individual lumen clearly printed on the external connector of each lumen.

Clinical Attributes

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

a. brand name
b. sterile
c. contains latex or latex free
d. DEHP%
e. PICC:
    i. open or closed-ended (valve/non-valve);
    ii. material of construction (e.g. silicone, polyurethane);
    iii. diameter, in French gauge
    iv. length, in centimetres
    v. length of taper, in centimetres
    vi. reverse taper or standard
    vii. number of lumens
    viii. trimmable or non-trimmable
    ix. integral access ports (where applicable)
    x. type of coating:
        - plain
        - antimicrobial
        - antibiotic.
        - heparin
        - silver
        - location of coating-internal, external or impregnated
    xi. type of securement (e.g. adhesive, suture); and
    xii. type of clamps (where applicable)
f. guidewire (where applicable):
    i. diameter, in
        - millimetres
        - French gauge
    ii. length, in centimetres.
g. a list of kit contents and component dimensions.

Additional Information

For each PICC offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. whether the product is marked as single use on the external packaging
b. maximum flow rate, in millilitres per minute
c. whether the size and position of individual lumens is clearly labelled on the external connector of each lumen
d. insertion technique required (e.g. modified Seldinger or peel-away cannula);
e. whether the PICC is recommended for use under hyperbaric pressure, and if so:
    i. the recommended pressure rating in atmospheres (atms).
f. whether the PICC is recommended for use with a power injector, and if so:
    i. the recommended pressure rating, in PSI
    ii. the recommended injection rate, in millilitres per second
    iii. the recommended number of power injections or dwell time; and
    recommended minimum syringe size. (e.g. 5ml, 10ml)
g. whether the PICC is:
    i. MRI compatible; and
    ii. lipid compatible.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Category 4 - Central Venous Catheters and Guidewires

A range of sterile central venous catheters and guidewires is required to meet clinical needs for adult, paediatric and neonatal patients.

Mandatory Criteria

Central venous catheters shall:

a. be radiopaque; and
b. have centimetre markings along the distal portion of the catheter to facilitate accurate measurement of the depth of insertion.

Desirable Criteria

Preference will be given to multi-lumen central venous catheters that have the size of each individual lumen clearly printed on the external connector of each lumen.

Clinical Attributes

For each central venous catheter offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. brand name
b. sterile
c. contains latex or latex free
d. DEHP%
e. catheter:
    i. size, in French gauge
    ii. length, in centimetres
    iii. number of lumens (e.g. single, triple)
    iv. with cuff or without cuff
    v. type of coating:
        - plain
        - antimicrobial
        - antibiotic.
        - heparin
        - silver
        - location of coating-internal, external or impregnated
f. guidewire (where applicable):
    i. diameter, in
        - millimetres
        - French gauge
    ii. length, in centimetres.
g. a list of kit contents and component dimensions.

Additional Information

For each central venous catheter, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. whether the product is marked as single use on the external packaging
b. maximum flow rate for rapid infusion catheters, in millilitres per minute
c. whether the central venous catheter is recommended for use with a power injector, and if so:
    i. the recommended pressure rating, in PSI
    ii. the recommended injection rate, in millilitres per second; and
    iii. the recommended number of power injections or dwell time.

d. whether the size and position of individual lumens is clearly labelled on the external connector of each lumen
e. whether the central venous catheter is:
   i. MRI compatible.
   ii. lipid compatible.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Category 5 - Gravity Intravenous Administration Sets

A wide range of sterile, needleless luer access, luer lock, kink-resistant administration sets is required for gravity infusion of intravenous fluids, blood and blood products including lines used primarily in the anaesthetic environment.

Clinical Attributes

For each gravity intravenous administration set offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. brand name
b. sterile
c. contains latex or latex free
d. DEHP%
e. type of set:
    i. blood, solution, universal (defined as used for solutions or blood);
    ii. primary or secondary
    iii. Whether secondary set has a filter or not (if applicable);
    iv. single- or double-spiked; and
    v. vented or non-vented.
f. tubing:
    i. microbore or macrobore
    ii. diameter, in millimetres
    iii. length, in centimetres
    iv. flow rate, in millilitres per minute
    v. tint colour (where applicable) (e.g. amber); and
    vi. type of luer lock connectors:
        - fixed or rotating
        - male or female.
g. integral set components (where applicable):
    i. integral hand pump
    ii. integral burette
    iii. integral access ports:
        - open or closed luer access
        - for closed luer access, brand name
        - number of ports
        - distance from the patient connection, in centimetres; and
        - position (i.e. proximal or distal).
h. where applicable, other set components:
    i. blood filters
    ii. anti reflux valves
    iii. roller clamps for flow control; and
    iv. side-arm.

Additional Information

For each gravity intravenous administration set offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. whether the product is marked as single use on the external packaging
b. filter pore size in microns (where applicable)
c. drops per millilitre
d. priming volume in millilitres; and
e. whether the gravity intravenous administration set is:
    i. MRI compatible; and
    ii. lipid compatible.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.
Tenderers are to state the required frequency for Intravenous line changes due to drug leaching/absorption into the plastic giving set. E.g. Administration of GTN/ Insulin/Amiodarone

Category 6 - Burettes

A wide range of sterile, needleless luer access burettes is required for the administration of intravenous therapy.

Mandatory Criteria

All burettes offered shall include graduation measurements.

Clinical Attributes

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

a. brand name
b. sterile
c. contains latex or latex free
d. DEHP%
e. burette:
    i. volume, in millilitres
    ii. extension tubing:
        - diameter, in millimetres
        - length, in centimetres
        - position (i.e. proximal or distal); and
        - type of clamps (e.g. slide, pinch, roller).
    iii. type of shut-off valves (where applicable)
    iv. manufacturer recommended dwell time
    v. residual burette volume
    vi. cap or clamp on air inlet filter; and
    vii. vented or non-vented.

Preference for

- Burettes with no residual volume

Additional Information

For each burette offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. whether the product is marked as single use on the external packaging
b. whether a hanger is present
c. the scale of graduations (e.g. 0.1 millilitres); and
d. whether the burettes administration set is:
    i. MRI compatible; and
    ii. lipid compatible.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.
Tenderers are to state the required frequency for Intravenous line changes due to drug leaching/absorption into the plastic giving set. E.g. Administration of GTN/ Insulin/Amiodarone

Category 7 - Intravenous Extension Tubing

A wide range of completely sterile, luer fitting, kink-resistant intravenous extension tubing is required for the administration of intravenous therapy.

Tenderers note

This category includes extension tubing only. All other extension set configurations are presented in **Error! Reference source not found. and Filters.**

Clinical Attributes

For each intravenous extension tube offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. brand name
b. sterile
c. contains latex or latex free
d. DEHP%
e. tubing:
   i. microbore or macrobore
   ii. internal diameter, in millimetres
   iii. outer diameter, in millimetres
   iv. length, in centimetres
   v. type of clamps (where applicable) (e.g. slide or pinch)
   vi. tint colour (where applicable) (e.g. amber); and
   vii. type of luer connectors (where applicable):
      - fixed or rotating
      - male or female.
      - Luer lock or luer slip

Additional Information

For each intravenous extension tube offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. whether the product is marked as single use on the external packaging
b. priming volume, in millilitres
c. whether the intravenous extension tube is recommended for use with a power injector, and if so:
   i. the recommended pressure rating, in PSI
   ii. the recommended injection rate, in millilitres per second; and
   iii. the recommended number of power injections or dwell time.
d. whether the intravenous extension tube is:
   i. MRI compatible; and
   ii. lipid compatible.
e. Whether known incompatibility with Needleless connector.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Tenderers are to state the required frequency for Intravenous line changes due to drug leaching/absorption into the plastic giving set. E.g. Administration of GTN/ Insulin/Amiodarone

Category 8 - Single Lumen IV Extension Sets and Filters

A wide range of sterile, needleless luer access, luer lock, kink-resistant extension sets, and intravenous filters are required for the administration of intravenous therapy.
Primary focus will be single lumen extension tubing with or without in-line access/one or more ports and with or without filters.

Tenderers, please note that the closed system transfer devices should be tendered under **Category 18 - Closed System Transfer Devices**.

Clinical Attributes

For each intravenous extension set offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. brand name
b. sterile
c. contains latex or latex free
d. DEHP%
e. tubing:
   i. microbore or macrobore
   ii. inner diameter, in millimetres
   iii. Outer diameter, in millimetres
   iv. length, in centimetres
   v. type of clamps (where applicable) (e.g. slide or pinch); and
   vi. type of luer lock connectors:
      - fixed or rotating
      - male or female.
f. set components, for example:
   i. type of valve (where applicable) (e.g. anti-reflux valve, anti-syphon valve, back check valve)
   ii. side-arms (where applicable)
      - integral filters in microns.
   iii. access ports:
      - open or closed luer access
      - for closed luer access, brand name
      - number of access ports
      - distance from the patient connection, in centimetres
      - position (i.e. proximal or distal); and

Additional Information

For each intravenous extension set offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. whether the product is marked as single use on the external packaging
b. priming volume, in millilitres
c. whether the intravenous extension set is recommended for use with a power injector, and if so:
   i. the recommended pressure rating, in PSI
   ii. the recommended injection rate, in millilitres per second; and
   iii. the recommended number of power injections or dwell time.
d. whether the intravenous extension set is:
   i. MRI compatible; and
   ii. lipid compatible.

e. whether known incompatibility with needleless connector.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet

Tenderers are to state the required frequency for Intravenous line changes due to drug leaching/absorption into the plastic giving set. E.g. Administration of GTN/ Insulin/ Amiodarone

Category 9 - Multi Lumen IV Adaptors

A wide range of completely sterile, needleless luer access, luer lock multi-flow / multi lumen adaptors (with or without integral filter) required for the administration of intravenous therapy.

Desirable Criteria

Preference will be given to multi-lumen adaptors where each limb of the multi-lumen adaptor incorporates a clamp that totally occludes fluid flow within the limb without damaging the tubing.

Clinical Attributes

For each multi-lumen adaptor offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. brand name
b. sterile
c. contains latex or latex free
d. DEHP%
e. tubing (where applicable):
    i. number of limbs (e.g. two-way, three-way)
    ii. microbore or macrobore or both
    iii. inner diameter, in millimetres
    iv. length, in centimetres
    v. type of clamps (e.g. slide or pinch); and
    vi. type of luer lock connectors:
        - fixed or rotating; and
        - male or female.
f. other components (where applicable)
    i. access ports:
        - open or closed luer access
        - for closed luer access, brand name; and
        - number of access ports.
    ii. type of valve (e.g. anti-reflux valve, anti-syphon valve, back check valve)
    iii. integral filters in microns.

Additional Information

For each multi-lumen adaptor offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. whether the product is marked as single use on the external packaging
b. maximum flow rate, in millilitres per minute
c. priming volume, in millilitres
d. whether the multi-flow adaptor is recommended for use with a power injector, and if so:
    i. the recommended pressure rating, in PSI
    ii. the recommended injection rate, in millilitres per second; and
    iii. the recommended number of power injections or dwell time.
e. whether the multi-flow adaptor is:
    i. MRI compatible; and
    ii. lipid compatible.
f. whether known incompatibility with needleless connector.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet

Tenderers are to state the required frequency for Intravenous line changes due to drug leaching/absorption into the plastic giving set. E.g. Administration of GTN/ Insulin/Amiodarone

Category 10 - Needleless Connectors

A wide range of sterile, closed luer access, luer lock needleless connectors is required for the administration of intravenous therapy.

Tenderers note

Intravenous access ports with extension tubing are to be tendered in **Error! Reference source not found.**
Connectors for CSTD are to be tendered in **Category 18 – Closed System Transfer Devices**

Anti-reflux and anti-siphon valves are included in this category.

Clinical Attributes

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

a. brand name
b. sterile
c. contains latex or latex free
d. DEHP%
    i. type of mechanism (e.g. split septum, mechanical or other); and
    ii. type of displacement (e.g. negative, neutral, positive, anti-reflux, anti-siphon)
    iii. type of luer lock connectors:
        - fixed or rotating; and
        - male or female.
e. additional components (where applicable) (e.g. caps).
f. manufacturer recommended dwell time

Additional Information

For each needleless connector offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. whether the product is marked as single use on the external packaging
b. maximum flow rate, in millilitres per minute
c. priming volume, in millilitres
d. compatibility with glass syringes
e. whether the needleless connector is recommended for use with a power injector, and if so:
    i. the recommended pressure rating, in PSI
    ii. the recommended injection rate, in millilitres per second; and
    iii. The recommended number of power injections or dwell time.
f. whether the needleless connector is:
    i. MRI compatible; and
    ii. lipid compatible.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Category 11 - Intravenous Access Port Caps

A wide range of sterile, single & double-ended, luer lock intravenous access port caps is required for the administration of intravenous therapy.

Clinical Attributes

For each access port cap offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. brand name
b. sterile
c. contains latex or latex free
d. DEHP%
e. colour
f. type of antimicrobial (if any)
g. manufacturer recommended dwell time
h. percentage of antimicrobial
i. single or double-ended; and
j. male or female.

Additional Information

For each access port cap offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. whether the product is marked as single use on the external packaging
b. whether the access port cap is:
    i. MRI compatible; and
    ii. lipid compatible.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Category 12 - Stopcocks

A wide range of sterile, needleless luer access, multi-directional, luer lock stopcocks are required for the administration of intravenous therapy.

Clinical Attributes

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

a. brand name.
b. sterile
c. contains latex or latex free
d. DEHP%
e. stopcock:
   i. with or without extension tubing
   ii. number of flow directions (e.g. two-way, three-way or four-way);
   iii. colour
   iv. directional arrows or markers (where applicable); and
   v. type of luer lock connectors:
      - fixed or rotating
      - male or female.
f. extension tubing (where applicable):
   i. microbore or macrobore
   ii. diameter, in millimetres
   iii. length, in centimetres
   iv. anti-reflux valves (where applicable);
   v. type of clamps (where applicable) (e.g. slide or pinch); and
   vi. access ports (where applicable):
      - with or without caps
      - open or closed luer access
      - for closed luer access, brand name
      - number of access ports.

Additional Information

For each stopcock offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. whether the product is marked as single use on the external packaging
b. maximum flow rate, in millilitres per minute
c. priming volume, in millilitres
d. whether the stopcock is recommended for use with a power injector, and if so:
   i. the recommended pressure rating, in PSI
   ii. the recommended injection rate, in millilitres per second; and
   iii. the recommended number of power injections or dwell time.
e. whether the stopcock is:
   i. MRI compatible
   ii. manufacturers Chemotherapy rating; and
   iii. lipid compatible

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Category 13 - Port Access Needles

A wide range of sterile, non-coring port access needles is required for the administration of intravenous therapy.

Clinical Attributes

For each port access needle offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. brand name
b. sterile
c. contains latex or latex free
d. DEHP%
e. safety or non-safety
f. with or without extension tubing
g. colour (to indicate size)
h. needle:
    i. gauge
    ii. length, in millimetres
    iii. profile (e.g. straight, right-angled).
i. extension tubing (where applicable):
    i. length, in centimetres
    ii. diameter, in millimetres
    iii. straight or Y-port
    iv. access ports (where applicable):
        - brand name
        - number of access ports.
j. type of clamps (e.g. slide or pinch).

Additional Information

For each port access needle offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. whether the product is marked as single use on the external packaging
b. maximum flow rate, in millilitres per minute
c. whether the needle is high-profile or low-profile
d. whether the port access needle is recommended for use with a power injector, and if so:
    i. the recommended pressure rating, in PSI
    ii. the recommended injection rate, in millilitres per second; and
    iii. the recommended number of power injections or dwell time
e. whether the port access needle is:
    i. MRI compatible; and
    ii. lipid compatible.
    iii. compatible with CT contrast injection

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Category 14 - Antiseptic Skin Preparation Swab Stick, Wipes and Applicators

A range of skin preparation swab sticks, wipes and applicators is required for skin preparation for clinical procedures.
The Therapeutic Good Administration now considers antiseptic swabs with antiseptic claims to be medicines (Guidance on boundary and combination products, 2023)

Mandatory Criteria

a. All isopropyl alcohol items shall have a minimum strength of 70%
b. All chlorhexidine gluconate *without* alcohol items shall have a minimum strength of 2%
c. All chlorhexidine gluconate *with* alcohol items shall have a minimum strength of 0.5% chlorhexidine gluconate and a minimum strength of 70% alcohol
d. All povidone-iodine items shall have a minimum strength of 10%; and
e. Antiseptic skin preparation swab sticks, wipes and applicators shall be package in a manner that maintains the integrity of the contents.

Desirable Criteria
All antiseptic skin preparation swab sticks, wipes and applicators offered shall preferably come in a peel pack or steri peel.
Preference for packaging which reduces cross contamination or is compliant with Aseptic Non-Touch Technique (ANTT).

Clinical Attributes

For each swab stick, wipe or applicator offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. brand name
b. sterile or non-sterile
c. contains latex or latex free
d. antiseptic concentration as a percentage (e.g. chlorhexidine gluconate 2%, isopropyl alcohol 70%, povidone-iodine 10%)
e. swab stick, wipe or applicator dimensions (i.e. width and length), in millimetres
f. for swab sticks and applicators, stick length in millimetres
g. for wipes, one or two ply
h. where swab stick multi-packs are offered, number of swab sticks per pack
i. tint colour (where applicable); and
j. maximum surface area for preparation.

Additional Information

For each swab stick, wipe or applicator offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. whether the product is marked as single use on the external packaging.

Category 15 - IV Start Kits

A range of sterile IV start kits is required for inserting intravenous access devices.

Mandatory Criteria

a. All IV start kits shall be packaged in a peel pack that peels cleanly to expose the contents of the kit.
b. Each IV start kit shall contain the following components as a minimum:
   i. 1 x sterile plastic wrap
   ii. 1 x transparent IV film dressing
   iii. 1 x cotton woven (minimum two-ply) gauze wipe; and
   iv. 1 x drape, at least 30 x 30 centimetres.
c. Additional kit components may include **but not limited to**:
   i. 1 x disposable latex-free tourniquet (with or without clasp);
   ii. 1 x antimicrobial agent wipe, swab stick or applicator
   iii. 1 x pre-filled syringes; and
   iv. 1 x pre-printed self-adhesive label to accommodate the date of insertion.

Desirable Criteria

All IV start kits shall preferably have sustainable packaging and avoid plastic in the packaging where possible.

Clinical Attributes

For each IV start kit offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. brand name
b. sterile
c. contains latex or latex free
d. DEHP%
e. list of kit contents, including:
   i. concentration (as percentage) of chlorhexidine gluconate and alcohol (if applicable) contained in wipes, swab sticks or applicators,
   ii. widths and lengths in centimetres for:
      - plastic wrap
      - wipes, swab sticks and applicators
      - transparent film dressings
      - cotton woven gauze wipes
      - drape
      - self-adhesive labels
      - latex-free tourniquets; and
      - any other additional kit components not listed in the minimum requirements.

Additional Information

For each IV start kit offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. whether the product is marked as single use on the external packaging; and
b. whether the swab sticks and applicators are inside or outside the inner pack.

Category 16 - Non-Powered Ambulatory Infusion Devices

A range of non-powered ambulatory infusion devices is required to administer various medications in the hospital and home setting.

Desirable Criteria

Preference will be given to suppliers who provide carry bags free of charge.

Clinical Attributes

For each non-powered ambulatory infusion device offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. brand name
b. sterile or non-sterile
c. contains latex or latex free
d. DEHP%
e. device:
    i. elastomeric or spring loaded
    ii. device capacity, in millilitres
    iii. tubing length, in centimetres
    iv. whether tubing has a clamp
    v. where filters are present, their position and function
    vi. infusion duration in hours, days or minutes
    vii. flow rate, in millilitres per hour
    viii. a list of additional consumables required for the infusion device to function accurately (e.g. syringes, extension tubing, filters, catheterisation kit) including the dimensions of these consumables; and if they are sterile or non-sterile
    ix. a list of kit components (where applicable), including dimensions of each component.

Additional Information

For each non-powered ambulatory infusion device offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. whether the product is marked as single use on the external packaging
b. manufacturer recommended dwell time
c. dose accuracy, in percentage/+- (e.g. +7%)
d. filter size, in microns (where applicable)
e. whether the device is:
    i. capable of administering boluses
    ii. refillable; (specify maximum number of uses)
    iii. suitable for intravenous infusion, subcutaneous infusion or both
    iv. MRI compatible; and
    v. lipid compatible.
f. available accessories (e.g. carry bags and thermal pouches).

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Category 17 - Closed System Transfer Devices

A range of completely sealed devices that mechanically prohibit the escape of hazardous drug, environmental (chemical and microbiological) or vapour concentrations outside the system throughout the entire process of dose preparation, administration and the handling of waste from hazardous drug therapy. Devices may include:

a. devices to protect the handler from the vial/ampoule
b. devices to protect the operator during preparation; and
c. devices to protect the administrator during administration of the hazardous drug to the patient.

Criteria

a. devices remain airtight (dry) and leak proof throughout all manipulations involved in the preparation, administration and disposing of hazardous drug doses
b. allow a closed system for intravenous, intramuscular and subcutaneous infusions and injections; and intravesicular administration.
c. closed pressure equalisation to ensure there is no overpressure or vacuum when air or fluid is injected into or aspirated from the vial.

Clinical Attributes

Tenderers shall provide the following information in the Tender Response Worksheet:

a. brand name
b. sterile
c. contains latex or latex free
d. DEHP%
e. a list of additional consumables required for the closed system to function accurately (e.g. syringes, vial/bag spikes, extension tubing, access devices, filters, adaptors, ports/caps, etc.).

Additional information

For each device offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Sheet:

a. compatibility with specific types of needleless access systems
b. compatibility with other chemotherapy compounding equipment and infusion devices such as ambulatory pump cassettes and non-powered ambulatory infusion devices
c. compatibility with specific infusion devices
d. compatibility with certain types of syringes
e. where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet
f. the maximum recommended pressure rating (in PSI) of the connectors used for hazardous drug administration; and
g. the maximum recommended flow rate of the connectors used in hazardous drug administration.
h. the availability of dead space/priming volume details.

Out of Scope

a. pharmaceutical products used in conjunction with CSTDs
b. any use of CSTDs and associated consumables for pharmaceutical compounding by a third-party on behalf of a Participating Health Service; and
c. any products consumables currently in an active HPV Contract.
d. intravenous infusion pump lines compatible to CSTD components.

Category 18 - Acute Haemofiltration Catheters

A range of sterile haemofiltration catheters for short-term use i.e. less than 4 weeks, to meet clinical needs of adult, **paediatric and neonatal patients.**

Criteria

Haemofiltration catheters shall:

a. be radiopaque
b. have a clamp on each separate lumen; and
c. priming volume (millilitres) indicated on each lumen.

Desirable criteria

a. Multi-lumen haemofiltration catheters, with legible print on catheter extension detailing size (French gauge) and catheter volume (millilitres); and
b. Centimetre markings along the catheter to facilitate accurate measurement of the depth of insertion.

Clinical Attributes

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

a. brand name
b. sterile
c. contains latex or latex free
d. DEHP%
e. catheter:
    i. size, in French gauge (including paediatric and neonatal)
    ii. length, in centimetres
    iii. number of lumens (e.g. single, double, triple)
    iv. lumen configuration (e.g. coaxial)
    v. priming volume of each lumen
    vi. maximum flow rate and pressure reading at this flow rate
    vii. extension type (e.g. straight extension, curved extension and pre-curved catheter legs)
    viii. material of construction (e.g. silicone, polyurethane)
    ix. type of coating, if any:
        - plain
        - antimicrobial-coated
        - antibiotic coated.
f. guidewire (where applicable):
    i. diameter, in:
        - millimetres
        - French gauge
    ii. length, in centimetres.
g. where haemofiltration catheters are offered in kit form, a list of kit contents and component dimensions.

Additional Information

For each haemofiltration catheter offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. whether the product is marked as single use on the external packaging
b. maximum flow rate, in millilitres per minute and pressure at this flow rate

c. manufacturer recommended dwell time
d. whether the size and position of individual lumens is clearly labelled on the external connector of each lumen and if individual lumens are colour coded; and
e. insertion technique required for haemofiltration catheter (e.g. Seldinger)
f. whether the haemofiltration catheter is:
   i. MRI compatible
   ii. lipid compatible

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Out of scope

Long-term haemodialysis catheters will not be considered.

Category 19 - Midline Catheters

A range of sterile peripherally inserted midline catheters is required to meet clinical needs for adult, paediatric or neonatal patients.

Mandatory Criteria

Midline catheters shall:

a. be flexible and radiopaque
b. incorporate graduated markings in centimetres to assist with catheter positioning by indicating the position in the body**.**

Desirable Criteria

Preference will be given to midline catheters that have the size of each individual lumen clearly printed on the external connector of each lumen.

Clinical Attributes

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

a. brand name.
b. sterile
c. contains latex or latex free
d. DEHP%
e. material of construction (e.g. silicone, polyurethane)
f. diameter, in French gauge
g. length, in centimetres
h. depth markers on catheter in centimetres
i. trimmable or non-trimmable
j. type of securement (e.g. adhesive, suture)
k. number of lumens
l. type of clamps (where applicable); and
m. a list of kit contents and component dimensions.

Additional Information

For each Midline Catheter offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. whether the product is marked as single use on the external packaging
b. maximum flow rate, in millilitres per minute
c. insertion technique required (e.g. modified Seldinger or peel-away cannula);
d. whether the midline catheter is recommended for use under hyperbaric pressure, and if so:
    i. the recommended pressure rating in atmospheres (atms).
e. whether the midline catheter is recommended for use with a power injector, and if so:
    i. the recommended pressure rating, in PSI
    ii. the recommended injection rate, in millilitres per second; and
    iii. The maximum number of power injections or dwell time.
f. whether the midline catheter is:
    i. MRI compatible
    ii. lipid compatible.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Category 20 - Intraosseous Needles & Drivers

A wide range of sterile, Intraosseous needles is required for the administration of intravenous therapy.

Mandatory Criteria

Intraosseous driver:

a. Powered driver must have a battery level indicator.

Clinical Attributes

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

a. brand name
b. sterile or non-sterile
c. contains latex or latex free
d. DEHP%
e. manual or powered
f. with or without extension tubing
g. colour (to indicate size)
h. needle:
    i. gauge
    ii. length, in millimetres
i. extension tubing (where applicable):
    i. length, in centimetres
    ii. diameter, in millimetres
j. type of clamps (e.g. slide or pinch).

Additional Information

For each intraosseous needle offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. whether the product is marked as single use on the external packaging
b. maximum flow rate, in millilitres per minute
c. whether the needle is high-profile or low-profile
d. whether the intraosseous needle is recommended for use with a power injector, and if so:
    i. the recommended pressure rating, in PSI
    ii. the recommended injection rate, in millilitres per second
    iii. the recommended maximum number of power injections or dwell time.
e. Intended patient weight (kg)

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

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

a. brand name
b. model
c. ARTG Number
d. powered or non-powered driver
e. battery Type, e.g. NiCad, Li-Ion
f. battery capacity; x Volts y AmpHour
g. battery capacity; no. of insertions
h. battery shelf-life
i. battery replaceable; and
j. a training unit should be available for powered drivers.

Category 21 - Neural Connector Devices

A range of sterile neural connector devices is required to meet clinical needs for adult, paediatric and neonatal patients.

This category includes the neural connector devices only. All neural connector infusion lines/sets for infusion pumps are situated in the **Infusion Pumps Contract: HPVC2021-055**

Mandatory Criteria

All neural connector devices offered must comply with ISO 80369-6

Desirable Criteria

All neural connector devices offered shall preferably be identifiable as neural connectors by the presence of yellow colouring present on device.

Clinical Attributes

For each neural connector device offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. brand name
b. Sterile or non-sterile
c. contains latex or latex free
d. size
e. colour
f. material
g. DEHP %
h. any safety features
i. neural connector spinal/epidural needles:
    i. profile/bevel type (e.g. whitacre, quincke, tuohy, sprotte, pencil point)
    ii. type/usage of needle:
        - drawing up needle
        - spinal needle
        - filter needle
        - peripheral nerve block needle
        - epidural needle
        - introducer needle
        - needle hub colour (where applicable)
    iii. gauge
    iv. length, in millimetres
    v. diameter, in millimetres
j. neural connector epidural catheters:
    i. outer diameter of epidural catheter, in millimetres
    ii. inner diameter of epidural catheter, in millimetres
    iii. length of epidural catheter, in millimetres
    iv. number of lateral eyes
    v. type of tip (e.g. soft tip, open tip, closed tip)
    vi. material (e.g. nylon, polyurethane)
    vii. whether epidural catheter is radiopaque
k. neural connector epidural/spinal kits:
    i. outer diameter of epidural catheter, in millimetres
    ii. inner diameter of epidural catheter, in millimetres
    iii. length of epidural catheter, in millimetres
    iv. spinal/epidural needle type/usage, profile, gauge and length.
    v. whether it is a combined epidural and spinal kit

l. neural connector syringes:
   i. a full range of syringes and volumes
   ii. capacity of syringe (e.g. 5ml, 7ml, 10ml)
   iii. type of syringe (e.g. slip lock, luer lock, loss of resistance/LOR)
m. neural connector filters:
   i. membrane pore size, in microns
   ii. filter type (e.g. flat)
n. neural connector catheter connectors:
   i. mechanism of connection (e.g. twist, click, push, clamp)
o. neural connector catheter fixation devices:
   i. dimensions of device, in millimetres
   ii. method of fixation/securement (e.g. adhesive pad, glue, clip, fastener)
   iii. material of construction (e.g. fabric, plastic, foam)
p. neural connector extension tubing:
   i. internal diameter, in millimetres.
   ii. outer diameter, in millimetres.
   iii. length, in centimetres
   iv. type of clamps (where applicable) (e.g. slide or pinch)
   v. priming volume, in millilitres
q. neural connector spinal manometers:
   i. analogue, single use manometer
   ii. graduated measurements in cmH20 on tubing
   iii. maximum pressure device can measure, in cmH20 (e.g. 30cmH20)
   iv. whether manometer comes with 3-way stopcock
   v. whether manometer tubing is flexible or rigid
   vi. additional components available for manometer (e.g. manometer extension tubing)

Additional Information

For each neural connector device offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. whether the product is marked as single use on the external packaging
b. priming volume of extension tubing, in millilitres (where applicable)
c. dwell time of device (e.g. dwell time of epidural catheters, lines, filters, extension sets and manometers)
d. where a filter is present:
   i. size of filter, in microns
   ii. priming volume, in millilitres
e. for any kits tendered, a list of kit contents and component dimensions
f. whether the neural connector device is:
   i. MRI compatible

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Out of Scope

Pharmaceutical products used in conjunction with Neural connector devices and in kits.

Category 22 - Totally Implantable Venous Access Devices (TIVADs)

A range of sterile TIVADs is required to meet clinical needs for adult, paediatric and neonatal patients.

Mandatory Criteria

TIVADs shall:

a. have radiopaque catheters; and
b. comply with the Therapeutic Goods Administration guidelines on Medical Device Patient Information Leaflets and Implant cards, 2022

Desirable Criteria

Preference will be given to TIVADs that have a radiopaque “CT” on the TIVAD body to identify it as power injectable (on x-ray view).

Clinical Attributes

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

a. brand name
b. sterile
c. contains latex or latex free
d. size (e.g. standard, mini, micro, low profile)
e. intended location of implantation (e.g. chest, brachial)
f. number of septums (e.g. single, double)
g. catheter:
    i. size, in French gauge; (e.g. 5Fr, 8Fr)
    ii. length, in centimetres
    iii. number of lumens (e.g. single, double)
    iv. material of construction (e.g. polyurethane, silicone)
    v. open or closed catheter (valve/non-valve)
h. chamber/port body:
    i. base diameter, in millimetres
    ii. septum diameter, in millimetres.
    iii. materials of construction (e.g. titanium, plastic, silicone, polysulfone)
    iv. internal volume in millilitres
    v. maximum number of punctures advised (e.g. 1000, 1500, 2000)
    vi. and/or dwell time of TIVAD

Additional Information

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

a. whether the product is marked as single use on the external packaging
b. a list of insertion kit contents and component dimensions
c. whether catheter is pre-connected or not pre-connected in kit
d. insertion technique required (e.g. Seldinger, surgical, ultrasound guided venepuncture)
e. whether insertion kit contains an introducer
    i. size of introducer in French gauge
f. maximum flow rate for rapid infusion TIVADs, in millilitres per minute
g. whether the TIVAD is recommended for use with a power injector, and if so:
    i. the recommended pressure rating, in PSI
    ii. the recommended injection rate, in millilitres per second; and
    iii. the recommended number of power injections or dwell time.

h. whether the TIVAD is:
    i. MRI compatible
    ii. CT compatible
    iii. lipid compatible

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Out of Scope

i. TIVADs with wireless monitoring or smart/active technology

Category 23 - Pre-Filled Saline Syringe for Intravenous Catheter Flush

A range of sterile pre-filled saline syringes for intravenous catheter flush is required to meet patient clinical needs.
The Therapeutic Goods Administration consider pre-filled saline syringes for intravenous catheter flush to be a medical device.

Out of Scope

a. Pre-Filled syringes that contain any solution other than 0.9% sodium chloride
b. Pre-Filled syringes made from glass
c. Pre-Filled syringes for use outside of the intravascular space

Mandatory Criteria

Pre-filled saline syringes for intravenous catheter flush must:

a. have lot number, expiration date and filled volume printed on syringe/label; and
b. have a syringe diameter of 10ml to prevent catheter damage.
c. have a luer lock connection
d. contain 0.9% sodium chloride solution only
e. comply with Australian Pharmaceutical / TGA guidelines on medicine labelling.

Desirable Criteria

Clinical Attributes

For each pre-filled saline syringe for intravenous catheter flush offered, Tenderers shall provide the following information in the Tender Response Worksheet:

a. brand name
b. whether product has sterile fluid path and solution (sterile fluid path); and
c. whether product also has a sterile external syringe surface (externally sterile)
d. contains latex or latex free
e. DEHP %
f. syringe capacity in millilitres (e.g.10ml)
g. filled volume of normal saline in syringe in millilitres (e.g.3ml, 5ml, 10ml)

Category 24 - IV Arm Boards

A range of arm boards (for use in securing intravenous and arterial cannula and immobilising limbs during IV therapy/arterial line monitoring) is required to meet clinical needs for adult, paediatric and neonatal patients.

Desirable Criteria
Preference will be given to IV arm boards that:

a. Have sustainable options (Preference)
b. For Paediatric arm boards, preference will be given to arm boards with artwork or graphics

Clinical Attributes

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

a. brand name
b. sterile or non-sterile
    i. whether additional components are available for replacement (e.g. foam pad replacement, strap replacement)
c. single use or reusable
    i. if reusable, how many times arm board can be reused
c. contains latex or latex free
d. size (e.g. neonatal, infant, paediatric, adult)
e. dimensions, in millimetres (e.g. 100mm x 30mm)
f. materials of construction (e.g. foam, aluminium, polyvinyl chloride, vinyl)
g. integral securing features (where applicable):
    i. dimensions, in millimetres (e.g. 50mm x 10mm)
    ii. method of securement (e.g. hook and loop fasteners, tape, foam/fabric strap)
h. whether arm board is bendable/flexible
i. whether arm board is designed for arterial line/cannula or intravenous line/cannula use
j. whether arm board is padded or has a hard surface

Additional Information
For each arm board, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

a. whether the product is marked as single use on the external packaging
b. whether the arm board is:
    i. MRI compatible

Out of Scope
a. IV arm boards that are custom made by Health Services

Appendices

Appendix 1 - Category and Subcategory List

Product Category	Product Subcategory
01- Peripheral Intravenous Cannulae	01.01 Peripheral IV Cannula, Safety
	01.02 Peripheral IV Cannula, Non-Safety
02- Winged Intravenous and Subcutaneous Devices	02.01 Winged IV Device, Infusion Set with Tubing, Safety
	02.02 Winged IV Device, Infusion Set with Tubing, Non-Safety
03- Peripherally Inserted Central Catheters	03.01 PICC, Single Lumen, Non-Power Injectable
	03.02 PICC, Multiple Lumen, Non-Power Injectable
	03.03 PICC, Single Lumen, Power Injectable
	03.04 PICC, Multiple Lumen, Power Injectable
04 - Central Venous Catheters and Guidewires	04.01 Central Venous Catheterisation Kit, Uncoated
	04.02 Central Venous Catheterisation Kit, Antimicrobial Coated
	04.03 Central Venous Catheterisation Kit, Antibiotic Coated
	04.04 Guidewire for Central Venous Catheters
	04.05 Central Venous Catheter, Uncoated, Power Injectable
	04.06 Central Venous Catheter, Uncoated, Non-Power Injectable
	04.07 Central Venous Catheter, Coated, Power Injectable
	04.08 Central Venous Catheter, Coated, Non-Power Injectable
05- Gravity Intravenous Administration Sets	05.01 Gravity IV Administration Set, Without Integral Hand Pump
	05.02 Gravity IV Administration Set, With Integral Hand Pump, Single Spike
	05.03 Gravity IV Administration Set, With Integral Hand Pump, Double Spike

	05.04 Gravity IV Administration Set, Without Integral Burette
	05.05 Gravity IV Administration Set, With Integral Burette
	05.06 Gravity IV Administration Set, Safety, Secondary Infusion Set
	05.07 IV Spike
	05.08 Blood Filter
06- Burettes	06.01 Burette
07- Intravenous Extension Tubing	07.01 IV Extension Tubing, Luer Lock, Macrobore
	07.02 IV Extension Tubing, Luer Lock, Microbore
	07.03 IV Extension Tubing, Luer Lock, Macrobore, Low Sorb Line
	07.04 IV Extension Tubin, Luer Lock, Microbore, Low Sorb Line
08- Single Lumen IV Extension Sets and Filters	08.01 Single Lumen IV Extension Set
	8.02 IV Filter
09- Multi Lumen IV Adaptors	09.01 Multi Lumen Adaptor, Needleless Luer Access
10- Needleless Connectors	10.01 Needleless Connector, Negative Displacement
	10.02 Needleless Connector, Neutral Displacement
	10.03 Needleless Connector, Positive Displacement
	10.04 Needleless Connector, Anti-Reflux / Anti-Siphon Valve
11- Intravenous Access Port Caps	11.01 IV Access Port Cap, Non-Antimicrobial
	11.02 IV Access Port Caps, Antimicrobial
12- Stopcocks	12.01 Stopcock, Closed Luer Access, Without Tubing
	12.02 Stopcock, Closed Luer Access, With Tubing
	12.03 Stopcock, Open Luer Access, Without Tubing

	12.04 Stopcock, Open Luer Access, With Tubing
	12.05 Stopcock, Closed and Open Luer Access, Without Tubing
	12.06 Stopcock, Closed and Open Luer Access, With Tubing
13- Port Access Needles	13.01 Port Access Needle, Non-Powered, Safety, Closed Luer Access
	13.02 Port Access Needle, Non-Powered, Safety, Open Luer Access
	13.03 Port Access Needle, Non-Powered, Safety, Open and Closed Luer Access
	13.04 Port Access Needle, Non-Powered, Non-Safety, Closed Luer Access
	13.05 Port Access Needle, Non-Powered, Non-Safety, Open Luer Access
	13.06 Port Access Needle, Non-Powered, Non-Safety, Open and Closed Luer Access
	13.07 Port Access Needle, Powered, Safety, Closed Luer Access
	13.08 Port Access Needle, Powered, Safety, Open Luer Access
	13.09 Port Access Needle, Powered, Safety, Open & Closed Luer Access
	13.10 Port Access Needle, Powered, Non-Safety, Closed Luer Access
	13.11 Port Access Needle, Powered, Non-Safety, Open Luer Access
14- Antiseptic Skin Preparation Swab Sticks, Wipes & Applicators	14.01 Antiseptic Skin Preparation, Chlorhexidine Gluconate, Applicator
	14.02 Antiseptic Skin Preparation, Isopropyl Alcohol, Applicator
	14.03 Antiseptic Skin Preparation, Povidone-Iodine, Applicator

	14.04 Antiseptic Skin Preparation, Chlorhexidine Gluconate, Swab Stick
	14.05 Antiseptic Skin Preparation, Isopropyl Alcohol, Swab Stick
	14.06 Antiseptic Skin Preparation, Povidone-Iodine, Swab Stick
	14.07 Antiseptic Skin Preparation, Chlorhexidine Gluconate, Wipe
	14.08 Antiseptic Skin Preparation, Isopropyl Alcohol, Wipe
	14.09 Antiseptic Skin Preparation, Povidone-Iodine, Wipe
15- IV START KITS	15.01 IV Start Kits, Basic Pack
	15.02 IV Start Kit, with one-or-two Additional Components
	15.03 IV Start Kit, with more-than-two Additional Components
16- Non-Powered Ambulatory Infusion Devices	16.01 Non-Powered Ambulatory Infusion Device
	16.02 Non-Powered Ambulatory Infusion Device, Kit
17 - Closed System Transfer Devices	17.01 Closed System Transfer Devices, Vial Spike
	17.02 Closed System Transfer Devices, Bag Spike, Without Integrated Infusion Line
	17.03 Closed System Transfer Device, Bag Spikes, With Integrated Infusion Line
	17.04 Closed System Transfer Device, Accessories
18 - Acute Haemofiltration Catheters	18.01 Acute Haemofiltration Catheter, Uncoated
	18.02 Acute Haemofiltration Catheterisation Kit, Uncoated

	18.03 Acute Haemofiltration Catheter, Coated
	18.04 Acute Haemofiltration Catheterisation Kit, Coated
19 - Midline Catheters	19.01 Midline Catheter, Single Lumen, Non-Power Injectable
	19.02 Midline Catheter, Multiple Lumen, Non-Power Injectable
	19.03 Midline Catheter, Single Lumen, Power Injectable
	19.04 Midline Catheter, Multiple Lumen, Power Injectable
	19.05 Midline Catheter, Accessories
20 - Intraosseous Needles & Drivers	20.01 Intraosseous Needle, Manual
	20.02 Intraosseous Needle, Powered
	20.03 Driver for Intraosseous Needle
21 - Neural Connector Devices	21.01 Neural Connector, Spinal and Epidural Needle
	21.02 Neural Connector, Syringe
	21.03 Neural Connector, Epidural Catheter
	21.04 Neural Connector, Filter
	21.05 Neural Connector, Catheter Connector
	21.06 Neural Connector, Catheter Fixation Device
	21.07 Neural Connector, Spinal and Epidural Kit
	21.08 Neural Connector, Spinal Manometer
	21.09 Neural Connector, Extension Tubing
22 - Totally Implantable Venous Access Devices (TIVADs)	22.01 TIVAD, Non-Power Injectable, Single Septum
	22.02 TIVAD, Non-Power Injectable, Double Septum
	22.03 TIVAD, Power Injectable
23 - Pre-Filled Saline Syringe for IV Catheter Flush	23.01 Pre-Filled Saline Syringe for Intravenous Catheter Flush, Sterile Fluid Path, Non-Externally Sterile
	23.02 Pre-Filled Saline Syringe for Intravenous Catheter Flush, Sterile Fluid Path, Externally Sterile
24 – IV Arm Board	24.01 IV Arm Board, Bendable
	24.02 IV Arm Board, Inflexible

Appendix 2 - Compliance Requirements

Australian and International Standards

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

For each standard listed, Respondent are to ensure the latest publication of each standard is used.

Standard Number	Standard Name
5369: 2023	Reprocessing of reusable medical devices and other devices in health and non-health related facilities.
NATIONAL STANDARD 3 – PREVENTING AND CONTROLLING HEALTHCARE ASSOCIATED INFECTIONS	National Safety and Quality Health Service Standards (NSQHSS) by Australian Commission on Safety and Quality in Health Care (ACSQHC).
ISO 13485:2016	Medical Devices Quality Management System. References Table of Subcategory Definitions; last review 2020
ISO 7864 : 2016	Sterile hypodermic needles for single use - Requirements and test methods
ISO 15747: 2018	Plastic containers for intravenous injections
ISO 8536 - 4: 2019	Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed
ISO 8536 – 10: 2015	Infusion equipment for medical use – Part 10: Accessories for fluid lines for single use with pressure infusion equipment
ISO 1135 – 4: 2015	Transfusion equipment for medical use – Part 4: Transfusion sets for single use, gravity feed
ISO 10555 – 1: 2023	Intravascular catheters – Part 1: General requirements
ISO 10555 – 3: 2013	Intravascular catheters – sterile and single-use catheters – Part 3: Central venous catheters
ISO 10555 – 5: 2013	Intravascular catheters – sterile and single-use catheters – Part 5: Over-needle peripheral catheters

Standard Number	Standard Name
ISO 10555-6:2015	Intravascular catheters - Sterile and single-use catheters - Part 6: Subcutaneous implanted ports
ISO 10555 – 7: 2023	Intravascular catheters – sterile and single-use catheters – Part 7: Peripherally inserted central catheters
ISO 18250 – 6: 2019	Medical devices – Connectors for reservoir delivery systems for healthcare applications – Part 6: Neural applications
ISO 18250 – 7: 2018	Medical devices – Connectors for reservoir delivery systems for healthcare applications – Part 7: Connectors for Intravascular infusion
ISO 10993 – 10: 2021	Biological evaluation of medical devices – Part 10: Tests for skin sensitization
ISO 28620: 2020	Medical devices – Non-electrically driven portable infusion devices
ISO 11070: 2014	Sterile single-use intravascular introducers, dilators and guidewires
ISO 23908: 2011	Sharps injury protection – Requirements and test methods – Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
ISO 9626: 2016	Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods
ISO 6009: 2016	Hypodermic needles for single use – colour coding for identification
ISO 8871 – 5: 2016	Elastomeric parts for parenteral and for devices for pharmaceutical use – Part 5: Functional requirements and testing
ISO 80369 – 20: 2015	Small bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods
ISO 20698: 2018	Catheter systems for neuraxial application – Sterile and single use catheters and accessories
ISO 80369 – 1: 2018	Small bore connectors for liquids and gases in healthcare applications – Part 1: General requirements
ISO 80369 – 6: 2016	Small bore connectors for liquids and gases in healthcare applications – Part 6: Connectors for neuraxial applications

Standard Number	Standard Name
ISO 80369 – 7: 2021	Small bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications
ISO 16054:2019	Implants for surgery - Minimum data sets for surgical implants

Guidelines and Other References

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

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

EVIQ, Central Venous Access Devices, 2010, last reviewed 2023

Guidelines for the prevention of bloodstream infections and other infections associated with the use of intravascular catheters: part I: peripheral catheters, World Health Organisation (2024)

Legislation

a. Therapeutic Goods Administration, Uniform Recall Procedure for Therapeutic Goods, (V2.3 June 2022), Commonwealth of Australia.

b. Therapeutic Goods Administration (2023), Australian Regulatory Guidelines for Medical Devices.

c. Therapeutic Goods Administration (2022), Medical Device Patient Information Leaflets and Implant Cards (including acceptance of Implementation Plans), (V1.9, October 2022)

d. Therapeutic Goods Administration (2023), Guidance on boundary and combination products: Medicines, medical devices and biologicals, (V2.0, December 2023)