METRIC

A-A-54999
15 February 1994

COMMERCIAL ITEM DESCRIPTION

NEPHROSTOMY SET, PERCUTANEOUS, 10 Fr Pigtail Catheter

The General Services Administration has authorized the use of this Commercial Item Description.

This Commercial Item Description covers a sterile, disposable, percutaneous pigtail nephrostomy set.

Salient characteristics:

Material. The pigtail catheter shall be fabricated from polyurethane. The dilators shall be fabricated from polyethylene. The tubing and stopcock shall be fabricated from transparent polyvinyl chloride. The disc shall be fabricated from silicone. The needles and stylets shall be fabricated from Class 3 stainless steel in accordance with American Society for Testing and Materials (ASTM) F899. The guide wire shall be fabricated from polytetrafluorethylene coated stainless steel. The plastic shall meet the requirements of the United States Pharmacopeia (USP) for Class II plastics.

Style, design and dimensions. The nephrostomy set shall consist of the following:

One radiopaque 10 French pigtail catheter with six sideports. The catheter shall be 30 cm (11.8 inches) ± 2.5 cm (1 inch) long.

One size 14 French connecting tube 30 cm (11.8 inches) ± 2.5 cm (1 inch) long with integral drainage bag connector

One - one way stopcock.

Six radiopaque dilators sizes 6,7,8,9,10 and 12 French. The dilators shall be 20 cm (7 9 inches) ± 2.5 cm (1 inch) long

One 18 gauge and one 22 gauge needle Each needle shall be 20 cm (7 9 inches) ± 2 5 cm (1 inch) long and shall be supplied with a stylet

One retention disc with pull tie

One guide wire The guide wire shall be 80 cm (31.5 inches) ± 5 cm (2 inches) long with a 3 mm (0.12 inch) ± 0 5 mm (0.02 inch) J-style safety tip. The wire shall have a 0 97 mm (0.038 inch) ± 0 09 mm (0.003 inch) diameter.

The catheter, tubing and dilators shall be radiopaque in accordance with ASTM F640

Non-toxic and pyrogen-free The nephrostomy set shall be non-toxic and pyrogen-free when tested in accordance with the United States Pharmacopeia (USP).

Sterility The nephrostomy set shall be tested for sterility in accordance with the USP or the Association for the Advancement of Medical Instrumentation (AAMI) requirements Sterility assurance level shall be 0 0001

Workmanship. The nephrostomy set shall be free from defects which detract from its appearance or impair its serviceability.

Unit Each (EA). One nephrostomy set, together with detailed directions for use, as specified, constitutes one unit. The nephrostomy set shall be supplied in a sealed peel-open package capable of maintaining sterility of the contents unless package is damaged or opened.

QUALITY ASSURANCE PROVISIONS.

Responsibility for inspection Unless otherwise specified in the contract or purchase order, the contractor is responsible for the performance of all inspection requirements as specified herein. Except as otherwise specified in the contract or purchase order, the contractor may use his own or any facilities suitable for the performance of the inspection requirements specified herein, unless disapproved by the Government. The Government reserves the right to perform any of the inspections set forth in the specification where such inspections are deemed necessary to assure supplies and services conform to prescribed

Records. Records of examinations and tests performed by or for the contractor shall be maintained by the contractor and made available to the Government upon request, at any time, or from time to time, during the performance of the contract and for a period of three years after delivery of the supplies to which such records relate.

Inspection. Inspection, as used herein, is defined as both examination (such as visual or auditory investigation without the use of special laboratory appliances or procedures) and testing (determination by technical means of physical and chemical properties) of the item.

Examination. Examination shall be conducted to determine compliance with specification requirements.

Sampling for examination Sampling for examination shall be conducted in accordance with MIL-STD-105 and as specified. Unit of product for examination purposes shall be one nephrostomy set as specified. Sampling shall be inspection level II with an Acceptable Quality Level (AQL) of 1.0.

Tests. Tests shall be conducted to determine compliance with specification requirements. Where feasible, the same sample shall be used for the determination of two or more test characteristics.

Sampling for tests. Sampling for tests shall be conducted in accordance with MIL-STD-105 and as specified. Unit of product for test purposes shall be one nephrostomy set. Sampling shall be inspection level S-2 with and AQL of 1.0.

Contractor certification. The contractor shall certify and maintain substantiating evidence that the product offered meets the salient characteristics of this Commercial Item Description, and that the product conforms to the producers' own drawings, specifications, standards, and quality assurance practices. The government reserves the right to require proof of such conformance prior to first delivery and thereafter as may be otherwise provided for under the provisions of the contract.

Metric products. Products manufactured to metric dimensions will be considered on an equal basis with those manufactured using inch-pound units, providing they fall within the tolerances specified using conversion tables contained in the latest revision of Federal Standard No. 376, and all other requirements of this document are met.

If a product is manufactured to metric dimensions and those dimensions exceed the tolerances specified in the inch/pound units, a request should be made to the contracting officer to determine if the product is acceptable

The contracting officer has the option of accepting or rejecting the product.

Regulatory requirements

Federal Food, Drug, and Cosmetic Act. If the product covered by this document has been determined by the U.S. Food and Drug Administration to be under its jurisdiction, the offeror/contractor shall comply, and be responsible for compliance by its subcontractors/suppliers, with the requirements of the Federal Food, Drug, and Cosmetic Act, as amended, and regulations promulgated thereunder. In addition, the offeror/contractor shall comply, and be responsible for compliance by its subcontractors/suppliers, with the requirements of all other applicable Federal, State, and local statutes, ordinances, and regulations

Recovered materials. The offeror/contractor is encouraged to use recovered material in accordance with Federal Acquisition Regulation Subpart 23.4 to the maximum extent practical.

Preservation, packaging, packing, labeling, and marking Unless otherwise specified, preservation, packaging, and packing shall be to a degree of protection to preclude damage to containers and/or contents thereof under normal shipping conditions, handling, etc , involving shipment from the supply source to the receiving activity, plus reshipment from receiving activity, and shall conform to applicable carrier's rules and regulations. Intermediate and exterior package quantities and labeling and marking shall be as specified in the contract and/or order.

Ordering data Intermediate/exterior package quantities and labeling and marking must be specified in the contract and/or order.

NOTE: The following National Stock Number and its respective Item Identification is covered by this document:

NATIONAL STOCK NUMBER	ITEM IDENTIFICATION
6515-01-189-7073	NEPHROSTOMY SET, PERCUTANEOUS, 10 Fr. Pigtail Catheter, Six Dilators Two 20 cm needles, Sterile, Disposable

MILITARY INTERESTS:

Custodians:

Army-MD
Navy-MS
Air Force-03

PREPARING ACTIVITY:

DoD-MB

Agent:

DLA-DM

CIVIL AGENCY COORDINATING ACTIVITIES:

VA-OSS
USPHS
FDA-MPQAS

Project No 6515-5747
Location:\word\mark\NEPH(mab)

STANDARDIZATION DOCUMENT IMPROVEMENT PROPOSAL

INSTRUCTIONS

1 The preparing activity must complete blocks 1, 2, 3, and 8. In block 1, both the document number and revision letter should be given.

2 The submitter of this form must complete blocks 4, 5, 6, and 7.

3 The preparing activity must provide a reply within 30 days from receipt of the form.

NOTE: This form may not be used to request copies of documents, nor to request waivers, or clarification of requirements on current contracts. Comments submitted on this form do not constitute or imply authorization to waive any portion of the referenced document(s) or to amend contractual requirements.

I RECOMMEND A CHANGE:	1. DOCUMENT NUMBER: A-A-54999	2. DOCUMENT DATE (YYMMDD): 95/02/15

3. DOCUMENT TITLE: NEPHROSTOMY SET, PERCUTANEOUS, 10 Fr Pigtail Catheter

4. NATURE OF CHANGE (Identify paragraph number and include proposed rewrite, if possible. Attach extra sheets as needed.)

5. REASON FOR RECOMMENDATION

6. SUBMITTER

a. NAME (Last, First, Middle Initial)	b. ORGANIZATION	
c. ADDRESS (Include Zip Code)	d. TELEPHONE (Include Area Code) (1) Commercial (2) AUTOVON (If applicable)	7. DATE SUBMITTED (YYMMDD)

8. PREPARING ACTIVITY

a. NAME: Defense Personnel Support Center ATTN: DPSC-MAP	b. TELEPHONE (Include Area Code) (1) Commercial: (215) 737-8431 (2) AUTOVON: 444-8431
c. ADDRESS (Include Zip Code) 2800 [illegible] Philadelphia, PA [illegible]	IF YOU DO NOT RECEIVE A REPLY WITHIN 45 DAYS CONTACT: Defense Quality and Standardization Office 5203 Leesburg Pike, Suite 1403, Falls Church, VA 22041-3466 Telephone (703) 756-2340 AUTOVON 289-2340

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