

A-A-53939
21 March 1990

COMMERCIAL ITEM DESCRIPTION

POINT, ENDODONTIC, AUXILIARY, Gutta-Percha

The General Services Administration has authorized the use of this Commercial Item Description as a replacement for MIL-P-37991(DLA-DM) which is cancelled.

This commercial item description covers auxiliary (conventional) gutta-percha endodontic points.

Salient characteristics:

General. The auxiliary gutta-percha endodontic points shall be in accordance with American National Standards Institute (ANSI)/American Dental Association (ADA) No. 57, Type I Class 2 for Endodontic Filling Materials with the following additions and exceptions. The points shall be of the following sizes:

XF	(Extra-fine)
FF	(Fine-fine)
MF	(Medium-fine)
F	(Fine)
FM	(Fine-medium)
M	(Medium)
L	(Large)

A point set shall be comprised of XF, F, M, and L.

Material. The polymeric material shall be high grade gutta-percha or balata which shall be washed and treated to remove impurities and provide a uniform, clean, non-toxic point. A filler containing barium sulfate for radiopacity shall be uniformly distributed in the finished point. All ingredients, including color additive, shall be of a high quality suitable for use in the formulation of endodontic points.

AMSC N/A

FSC 6520

DISTRIBUTION STATEMENT A. Approved for public release; distribution is unlimited.

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Style, design, size, and dimensions. The points shall be designed for use in filling pulp canals in endodontic procedures. The points shall be uniformly tapered. The points shall be machine rolled or hand rolled to the required dimensions.

The overall length of the point shall be 28-32 mm. The non-operative end of the point shall be flattened and shall have a serrated or grooved surface pattern. The flattened end shall be 2-4 mm in length, and at least 1/2 the diameter of the point 3 mm from the tip.

Working properties. The gutta-percha points furnished shall be of such formulation and process as to provide a complete sealing of the prepared root canal when used in endodontic procedures. The working properties of the points shall exhibit cohesive strength, toughness and flexibility without brittleness.

Certification-Acceptability. The points shall be certified or acceptable by the American Dental Association. At time of award of contract, the manufacturer shall furnish, upon request, a certificate and data showing that the brand of material to be furnished is the same in quality and brand as that appearing on the list of acceptable or certified materials. Compliance with this certification requirement does not absolve the manufacturer from complete compliance with the other requirements of this specification.

Color. The color of the points shall be pink.

Radiopacity. The radiopacity requirement of ANSI/ADA No. 57 shall apply. Testing for radiopacity shall be as specified under tests.

Delivery schedule. No more than 2 months shall have elapsed from date of manufacture of the points to date of delivery to the Government.

Shelf life. The points shall comply with requirements of this specification for no less than 18 months from date of delivery, when stored at 35 to 46 degrees fahrenheit. The inspection test date shall be 18 months from date of manufacture.

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Toxicity. The manufacturer shall submit a statement that the points have no toxic effects on the normal, healthy person when used for the purpose intended.

Workmanship. Points shall be free of curled or twisted portions and shall have a smooth surface free from foreign matter and defects. The points shall show no defects which detract from their appearance or impair their serviceability.

Unit. Package (PG). One package containing one hundred endodontic points of one size only, as specified, constitutes one unit.

Set (SE). One point set containing 25 extra-fine points, 25 fine points, 25 medium points and 25 large points in a compartmentalized container, as specified, constitutes one unit.

Unit package. The points shall be packaged in a rigid container designed to prevent damage during shipment or storage.

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 requirements.

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 the Government's 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.

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Sampling for examination. Sampling for examination shall be conducted in accordance with MIL-STD-105, at an inspection level of S-4, with an AQL of 2.5 (percent defective). The unit of product for examination shall be one point for each package sampled.

Examination. The points shall be examined to determine compliance with all requirements specified herein. Points shall be examined for defects, including but not limited to, those listed below.

Defects

Points are not clean.

Style and design not as specified.

Color of points not as specified.

Tapered length surface not smooth rolled finish.

Laminations cracks or voids present.

Twisted or curled sections present.

Size not as specified.

Sampling for tests. Sampling for tests shall be conducted in accordance with MIL-STD-105, at an inspection level of S-1, with an AQL of 1.0 (percent defective). The unit of product for tests purposes shall be one point from each package sampled.

Tests. Tests to include dimensions, 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. There shall be two determinations per lot or batch number. Each determination shall be the average of specimens when averaging is specified in testing procedure.

Dimensions. The points shall be tested for dimensions in accordance with ANSI/ADA No. 57

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Radiopacity. The points shall be tested for radiopacity in accordance with ANSI/ADA No. 57. The test for radiopacity shall be performed on the first lot or batch of a contract or purchase order. For the remaining lots or batches of the same contract or purchase order, the contractor may provide certification of compliance with the radiopacity requirement specified herein, provided that the remaining lots or batches are composed of the same formulation and manufactured identically as the first lot or batch originally tested for radiopacity.

Contractor certification. The contractor shall certify that the product offered meets the salient characteristics of this description and 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.

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 Public Law 94-580, as amended, and as implemented for 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.

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NOTE: The following National Stock Numbers are covered by this document:

<u>NATIONAL STOCK NUMBER</u>	<u>ITEM IDENTIFICATION</u>
6520-01-180-6991	POINT, ENDODONTIC, Large, Auxiliary, Gutta-Percha, 100s
6520-01-180-6692	POINT, ENDODONTIC, Fine, Auxiliary, Gutta-Percha, 100s
6520-01-180-6993	POINT ENDODONTIC, Fine-Fine, Auxiliary, Gutta-Percha, 100s
6520-01-182-4633	POINT ENDODONTIC, Fine-Medium, Auxiliary, Gutta-Percha, 100s
6520-01-182-4634	POINT ENDODONTIC, Medium-Fine, Auxiliary, Gutta-Percha, 100s
6520-01-184-1580	POINT ENDODONTIC, Medium, Auxiliary, Gutta-Percha, 100s
6520-01-185-8460	POINT ENDODONTIC, Extra-Fine, Auxiliary, Gutta-Percha, 100s
6520-01-221-9026	POINT SET, ENDODONTIC, Gutta-Percha, Auxiliary

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

MILITARY INTEREST:

Preparing Activity:

Custodians:

DoD-MB

Army-MD

AGENT:

Navy-MS

Air Force - 03

DLA-DM

CIVIL AGENCY COORDINATING ACTIVITIES:

VA-OSS

PHS

FDA-MPQAS

Project No. 6520-2283
Location: NCR SYS ENDOC

INSTRUCTIONS: In a continuing effort to make our standardization documents better, the DoD provides this form for use in submitting comments and suggestions for improvements. All users of military standardization documents are invited to provide suggestions. This form may be detached, folded along the lines indicated, taped along the loose edge (*DO NOT STAPLE*), and mailed. In block 5, be as specific as possible about particular problem areas such as wording which required interpretation, was too rigid, restrictive, loose, ambiguous, or was incompatible, and give proposed wording changes which would alleviate the problems. Enter in block 6 any remarks not related to a specific paragraph of the document. If block 7 is filled out, an acknowledgement will be mailed to you within 30 days to let you know that your comments were received and are being considered.

NOTE This form may not be used to request copies of documents, nor to request waivers, deviations, or clarification of specification 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.

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STANDARDIZATION DOCUMENT IMPROVEMENT PROPOSAL

(See Instructions - Reverse Side)

1. DOCUMENT NUMBER
A-A-53939

2. DOCUMENT TITLE
Point, Endontic, Auxiliary, Gutta-Percha

3a. NAME OF SUBMITTING ORGANIZATION

4 TYPE OF ORGANIZATION (Mark one)

VENDOR

USER

MANUFACTURER

OTHER (Specify) _____

3b. ADDRESS (Street, City, State, ZIP Code)

5 PROBLEM AREAS

a. Paragraph Number and Wording

b. Recommended Wording

c. Reason/Rationale for Recommendation

6 REMARKS

7a. NAME OF SUBMITTER (Last, First MI) - Optional

b. WORK TELEPHONE NUMBER (Include Area Code) - Optional

c. MAILING ADDRESS (Street, City, State ZIP Code) - Optional

8. DATE OF SUBMISSION (YYMMDD)

(TO DETACH THIS FORM, CUT ALONG THIS LINE.)