



American National Standard/
American Dental Association
Specification No. 58

Root Canal Files, Type H (Hedstrom)

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**AMERICAN NATIONAL STANDARD AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 58 FOR
ROOT CANAL FILES, TYPE H (HEDSTROM)**

The Council on Scientific Affairs of the American Dental Association has approved revised American Dental Association Specification No. 58 for Root Canal Files, Type H (Hedstrom). This and other specifications for dental materials, instruments and equipment are being formulated by working groups of the ADA Standards Committee on Dental Products (formerly Accredited Standards Committee MD156 for Dental Materials, Instruments and Equipment). The Committee has representation from all interests in the United States in the standardization of materials, instruments and equipment in dentistry. The Council has adopted the specifications, showing professional recognition of their usefulness in dentistry, and has forwarded them to the American National Standards Institute with a recommendation that the specifications be approved as American National Standards. The American National Standards Institute granted approval of ADA Specification No. 58 as an American National Standard April 2004. It becomes effective April 2005.

The Council thanks the working group members and the organizations with which they were affiliated at the time the specification was developed:

Frank Lentine (Chairman), Lentine Enterprises, Ltd., Taylor, MI; Neill Luebke (Secretary), Brookfield, WI; Richard Geary, American Dental Association, Chicago, IL; Gerald Glickman, University of Texas-Houston; Lonnie Graybill, Miltex Instrument Company, Inc., York, PA; John Ingle, American Association of Endodontists, San Diego, CA; Siegfried Kiesewetter, Miltex Instrument Company, Inc., York, PA; Michael Sobotka, Charles B. Schwed Co., Key Gardens, NY; Lars Spangberg, University of Connecticut, Farmington, CT; and Timothy Svec, University of Texas, Houston, TX.

**AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION
NO. 58 FOR ROOT CANAL FILES. TYPE H (HEDSTROM)**

FOREWORD

(This foreword does not form a part of ANSI/ADA Specification No. 58 for Root Canal Files, Type H [Hedstrom]).

Combined efforts with the International Organization for Standardization (ISO) working group on Root Canal Instruments, TC 106/SC4/WG9 resulted in modernization of the requirements and test methods which influenced the Standards Committee for Dental Products (SCDP) working group WG 4.27 to prepare this document.

This third revision to the specification includes conversion of units to SI type throughout the specification. Other sections that were revised are:

- Compliance –Reorganized to locate specific requirements with the individual test since the criteria was different.
- Inspection- Added requirement for visual inspection.
- Procedures – Added detailed test methods for the measurement of diameters, taper, tip dimensions, and length measurements. Also, added optical comparator to the equipment list.
- Sterilization/Corrosion – Retained only the Boil test for corrosion testing. The steam autoclave and dry heat tests were relocated to Sterilization (5.3.2.1) under Handles (5.3) and prior to the procedure for the resistance to fracture by twisting and the stiffness tests.
- Preparation for delivery – The entire section was revised using update specification styling. A note was added to explain color designation system. The marking section was expanded to agree with the new revision to ANSI/ADA Specification No. 28 for Root Canal Instruments, Files and Reamers.
- Tables – Tables 1 and 4 were combined into a new Table 1.

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NO. 58 FOR ROOT CANAL FILES, TYPE H (HEDSTROM)**

1 SCOPE AND CLASSIFICATION

1.1 Scope

This specification is for endodontic Hedstrom files for hand use only having a working part taper of 2% (0.02 millimeter per millimeter of length) as used in endodontic preparation or shaping operations.

1.2 Types

The instruments covered by this specification shall be of the following types:

Type III. Hedstrom Files (FDI/ISO Root Canal Files Type H)

2 APPLICABLE SPECIFICATIONS AND REGULATIONS

The following documents form a part of this specification:

2.1 Specifications

ANS Metric Practice, ZZ10.1-1976.

ASTM B16 for free-cutting brass.

2.2 Regulations

Quality Systems Requirements (QSR) issued by the Food and Drug Administration.

3 REQUIREMENTS

3.1 Dimension

3.1.1 Diameters

The diameters designated as D_0 , D_3 and D_{16} for all sizes of Hedstrom files shall be as shown in Table 1 and Figure 1 with an allowable tolerance for all diameters when tested as specified in 5.2.2.1

3.1.2 Taper

The taper of the cutting portion of the Hedstrom file shall be 0.02 mm per millimeter of cutting length when tested as specified in 5.2.2.2.

3.1.3 Tip

The tip length of the instrument shall be the development of an included angle of 75° with an allowable tolerance of $\pm 15^{\circ}$ for all instruments as shown in Fig. 1 when tested as specified in 5.2.2.3. Shape of tip is optional.

3.1.4 Lengths

The length of the cutting portion of the instrument shall not be less than 16 mm. The length of the