ANSI/ADA Specification No. 58
Approved: February 2010

American National Standard/American Dental Association
Specification No. 58

Root Canal Files, Type H (Hedstrom)

ADA American Dental Association®
Council on Scientific Affairs

2010

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 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 on February 25, 2010.

The Council thanks the members of Working Group 4.27 and the organizations with which they were affiliated at the time the specification was developed:

Frank Lentine (chairman), Lentine Enterprises, Ltd, Taylor, MI;

Timothy Svec (secretary), Tigard, OR;

Dave Clement, University of Oklahoma, Oklahoma City;

Gerald Glickman, Baylor College of Dentistry, Dallas, TX;

Lonnie Graybill, Miltex Corporation, York, PA;

Jeffrey W. Hutter, Boston University, MA;

John Ingle, American Association of Endodontists, San Diego, CA;

Neil Luebke, Brookfield, WI;

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Michael Sobotka, Charles B. Schwed Company, Key Gardens, NY; and

Lars Spangberg, University of Connecticut, Farmington.

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FOREWORD

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

ANSI/ADA Specification No. 58-2010, the fourth revision of this specification, cancels and replaces ANSI/ADA Specification No. 58-2004, the third revision of this specification.

This revision has been developed by SCDP Working Group 4.27 to allow a tolerance for diameters for sizes 70 to 140 of ± 0.04 instead of ± 0.03. The purpose of this revision is to bring this specification into agreement with ANSI/ADA Specification No. 28 for Root Canal Files and Reamers, Type K.

The boiling water portion of the corrosion test procedure has been eliminated because the effects of water are adequately covered by the autoclave test.

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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.

I.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 standards contain provisions, which, through reference in this text, constitute provisions of this specification. At the time of publication, the editions indicated were vaild. Since all standards are subject to revision, parties to agreements based on this specification are encouraged to investingate the possibility of applying the most recent edition of the specification or standard listed.

2.1 Specifications

ANS Metric Practice, ZZ10.1-1976.

(American National Standards are available from the American National Standards Institute, 25 West 43rd St., New York, NY 10036 or www.ansi.org).

ASTM B16 for free-cutting brass.

(ASTM standards are available from ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428 or www.astm.org).

2.2 Regulations

FDA Quality System Requirements. (CFR Title 21, Subchapter H-Medical Devices, Part 820, Quality System Regulation. Subpart B-Quality System Requirements).

(Available from the U.S. Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-0001 or www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1&subpartNode=21:8.0.1.1.12.2)

3 TERMS AND DEFINITIONS

3.1 Operative part – portion of the instrument from the tip to the handle or shank.

3.2 Working part – portion of the instrument with an active cutting surface.

3.3 Handle – part of the instrument to be manipulated by the user by hand.