



American National Standard/American Dental Association  
**Specification No. 71**

# Root Canal Filling Condensers (Pluggers and Spreaders)

Modified adoption of ISO 3630-3:1994, *Condensers, pluggers and spreaders*.

**ADA** American  
Dental  
Association®  
Council on  
Scientific Affairs

2008

**AMERICAN NATIONAL STANDARD/ AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 71 FOR  
ROOT CANAL FILLING CONDENSERS (PLUGGERS AND SPREADERS)**

The Council on Scientific Affairs of the American Dental Association has approved American Dental Association Specification No. 71 for Root Canal Filling Condensers (Pluggers and Spreaders). 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. 71 as an American National Standard on September 10, 2008.

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; Timothy Svec (Secretary), Tigard, OR; Dave Clement, University of Oklahoma HSC, Oklahoma City; Gerald Glickman, Baylor College of Dentistry, Dallas, TX; Lonnie Graybill, Miltex Corp., York, PA; John Ingle, American Association of Endodontists, San Diego, CA; Nick Lenz, Endodent, Inc., Duarte, CA; Neill Luebke, Brookfield, WI; Randall Maxwell, Dentsply Tulsa Dental Specialties, Tulsa, OK; Spiro Megremis, American Dental Association, Chicago, IL; Michael Sobotka, Charles B. Schwed Co., Kew Gardens, NY; and Lars Spangberg, University of Connecticut, Farmington.

**AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 71 FOR ROOT CANAL FILLING CONDENSERS (PLUGGERS AND SPREADERS)****FOREWORD**

(This foreword is not part of the American National Standard ANSI/ADA Specification No. 71 for Root Canal Filling Condensers (Pluggers and Spreaders)).

This revised specification is a modified adoption of ISO 3630-3:1994, Condensers, pluggers and spreaders. ADA SCDP Working Group 4.27 examined the ISO standard and found it acceptable for adoption as revised ANSI/ADA Specification No. 71, with the following modifications.

The working group updated the specification to include mechanical, rotational or impacting instruments. In doing so, “mechanical” was added where appropriate.

As is common with current root canal instrument specifications, taper sized instrument size presentations have been changed to remove the lengthy descriptions, since tapers different than 2 % are now well known. This allowed removal of the previous Table 2.

The boiling water portion of the corrosion test procedure has been eliminated, since the effects of water are adequately covered during the autoclave test.

In 4.2.1.1, the allowable tolerance for diameters of “ $\pm 0.02$  mm for all diameters” was changed to “ $\pm 0.02$  mm for sizes up to 070 and  $\pm 0.04$  mm for sizes 070 – 140.”

In 4.3, the phrase, “When handles are included as a fixed component of the instrument,” was added to the requirement for handles.

In 4.9, the statement, “Dry heat sterilization requirement is voided for handles made from materials that are affected by dry heat temperatures,” was added to the requirement for heat effects of sterilization.

In 6.3, the phrase, “When handles are included as a fixed component of the instrument,” was added to the requirement for handles.

In 7.2.1., the requirement for lot numbers was changed to, “Each container shall be marked with an appropriate lot and/or date code.”

**Additional note to the Foreword for this Reaffirmation:**

In 2012, the ADA Standards Committee on Dental Products approved a change in the terminology used for standards. ADA standards will no longer utilize the term Specification; standards will now be named as ADA Standards.

With this notice, this ADA Specification is now termed an ADA Standard. Where the term "specification" is used, it should be considered as "standard." It will be re-named as an ADA Standard in its next revision.

## **AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 71 FOR ROOT CANAL FILLING CONDENSERS (PLUGGERS AND SPREADERS)**

### **1 SCOPE AND CLASSIFICATION**

#### **1.1 Scope**

This specification is for root canal instruments for finger, hand, or mechanical operation used to compact root canal filling materials.

#### **1.2 Type**

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

I. Pluggers

II. Spreaders

### **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 valid. Since all standards are subject to revision, parties to agreements based on this specification are encouraged to investigate the possibility of applying the most recent edition of the specification or standard listed.

#### **2.1 Specifications**

ANSI/ADA Specification No. 28 for Root Canal Files and Reamers, Type K.

ANSI/ADA Specification No. 78 for Endodontic Obturating Cones.

ISO 3630, Dental Root Canal Instruments.

(ANSI/ADA specifications and ISO International Standards for dentistry are available from the American Dental Association, 211 East Chicago Ave., Chicago, IL 60611 or [www.ada.org](http://www.ada.org)).

ANS Metric Practice, 2210.1-1976

(American National Standards are available from the American National Standards Institute, 25 West 43<sup>rd</sup> St., New York, NY 10036 or [www.ansi.org](http://www.ansi.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/cfcr/CFRSearch.cfm?CFRPart=820&showFR=1&subpartNode=21:8.0.1.1.1.2.2](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=820&showFR=1&subpartNode=21:8.0.1.1.1.2.2))

### **3 DEFINITIONS**

For the purposes of this Specification, the following definitions apply.

- 3.1 Root-canal filling condenser** – Instrument, the working part of which is cylindrical or tapered, and is circular in cross-section. It is designed to compact the filling material in a root canal in the axial and/or lateral direction. Condensers are commonly used as pluggers or spreaders.