



American National Standard/
American Dental Association
Specification No. 101

Root Canal Instruments: General Requirements

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**AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION
SPECIFICATION NO. 101 FOR ROOT CANAL INSTRUMENT: GENERAL REQUIREMENTS**

The Council on Scientific Affairs of the American Dental Association has approved American Dental Association Specification No. 101 for Root Canal Instrument: General Requirements. 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. 101 as an American National Standard on August 21, 2001. This standard becomes effective August 21, 2002.

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

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FOREWORD

(This foreword does not form a part of revised ANSI/ADA Specification No. 101 for Root Canal Instruments: General Requirements.)

The ADA SCDP (formally ASC MD 156) working group WG 4.27 initiated a New Work Item in April, 1996 with a scope for "Root canal cleaning and shaping instruments having designs which are not included within current standards. New standard will provide requirements for size identification, minimum performance levels, package labels and instructions". The work project was approved April 30, 1997 and the first working draft was prepared for circulation to the working group on January 31, 1998.

Fatigue testing of instruments intended for mechanical operation was included in the first draft. The working group adopted testing procedures proposed for ANSI/ADA Specification No. 95 for Root Canal Enlargers. Subsequently several papers were published concerning various test methods for fatigue testing NiTi instruments and various shaped instruments with differing results. After two attempts to initiate a round robin study, the working group determined that selection of a suitable test procedure was premature.

In order to advance the work of the standard already concluded, the working group agreed to submit the document for approval with the understanding that we would continue to monitor the ongoing work on fatigue testing of the new types of instruments. When data indicates that a suitable, universally acceptable test procedure is identified, we will initiate the necessary new work proposal for a revision or addendum to include this important requirement.

Meanwhile this document includes:

- Definitions for flexible instrument, guided tip instrument and tip portion of the instrument;
- Dimensional requirements and designations which are inclusive of any taper or shape; and
- Modified twisting and bending data tables that compensate for the effect of tapers other than the current standard of 0.02 (2%).

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1 SCOPE AND FIELD OF APPLICATION

This standard specifies requirements and test methods for hand or mechanically operated instruments for root canal shaping and cleaning having designs or materials which are not included within the provisions of ANSI/ADA Specification Nos. 28 and 58. Generally this specification includes root-canal instruments having 2% tapers with diameter sizes not included within Specifications Nos. 28 and 58; root-canal instruments having tapers other than 2%; and root-canal instruments having other shapes. The purpose of this specification is to provide a document to identify methods for size and product designation, safety considerations, for example, minimum requirements for fracture forces, flexibility, and instructions/labeling. Areas such as effects of sterilization processes on the instrument will be investigated for inclusion.

2 REFERENCES

ANSI/ADA Specification No. 28 for Endodontic Files and Reamers
ANSI/ADA Specification No. 58 for Root Canal Files, Type H
ANSI/ADA Specification No. 71 for Root Canal Filling Condensers and Spreaders
ANSI/ADA Specification No. 95 for Root Canal Enlargers
ISO 1797 Dental rotary instruments – shanks

3 DEFINITIONS

- 3.1 **Flexible instrument.** When tested as described in section 6., Resistance to bending, the average value of the tested samples shall be 65%, or less, of the value listed in the appropriate bending or stiffness table of referenced specifications or Table 3 of this specification.
- 3.2 **Guided tip instrument.** An instrument with a tip that guides access within a root canal.
- 3.3 **Tip portion of the instrument.** The segment of the instrument which is intended as the point, which has an included angle from 60° to 90° and whose shape may be conical or flat sided whose end is pointed or truncated.

4 REQUIREMENTS

- 4.1 **Material.** The working portion of the instruments and the handle portion materials shall be left to the discretion of the manufacturer.
- 4.2 **Dimensional requirements.** The dimensions are given in millimeters. The nominal diameter and taper dimensional requirements of the instruments shall be left to the discretion of the manufacturer. Instruments having shanks for mechanical operation shall meet the requirements of ISO 1797. The allowable tolerance for the identified diameters shall be less than 50 % of the difference between the next smaller and/or the next larger instrument of the available brand sizes. Figure 1 illustrates typical instruments. Testing shall be carried out in accordance with Clauses 6.1 to 6.3.