



American National Standard/
American Dental Association
Specification No. 85, Part 1

Disposable Prophylaxis Angles

ADA American
Dental
Association®
Council on
Scientific Affairs

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Reaffirmed: December 2009

**AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 85 –
PART 1 FOR DISPOSABLE PROPHY ANGLES**

The Council on Scientific Affairs of the American Dental Association has approved American Dental Association Specification No. 85 – Part 1 for Disposable Prophylaxis Angles. 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. 85 – Part 1 as an American National Standard on August 25, 2004.

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 ANSI/ADA Specification No 85 – Part 1 for Disposable Prophylaxis Angles).

ANSI/ADA Specification No. 85 – Part 1 was developed by ADA SCDP Working Group WG 4.30 on Prophylaxis Angles.

Suggestions for improvement of this specification will be welcome. Send comments to:
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1 SCOPE

This specification covers disposable prophy angles suitable for a dental hygienist or a dentist to use in conjunction with a doriot style handpiece during the final stages of a dental cleaning, also known as a polish.

1.1 Purpose

The purpose of this standard is to provide general requirements for disposable prophy angles to assure that to the extent safety and performance efficiency can be controlled by device design, they are effective for their intended use and the risks of injury to the patient and dental professional are minimized.

2 NORMATIVE REFERENCES

ISO 10993-1, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing

(ISO Standards are available from the American National Standards Institute, 25 W. 43rd St., New York, NY 10036).

3 DEFINITIONS

For the purposes of this specification, the following definitions shall apply.

3.1 **Disposable Prophyl Angle (DPA):** Dental devices driven by dental motors through a doriot attachment intended to be used only once and then discarded.

3.2 **Final Packaging:** A retail selling unit.

4 TYPES

This specification covers three types of disposable prophy angles:

Type I. Disposable prophy angle with cup attachment.

Type II. Disposable prophy angle with brush attachment.

Type III. Disposable prophy angle with other attachments.

5 REQUIREMENTS

5.1 Biocompatibility

All material used to construct the angle shall be for use in the oral cavity. This includes, but is not limited to colorant oxides, plastics, rubber and lubricants, whether made of synthetic or natural compounds. Test in accordance with ISO 10993.

5.2 General

The disposable prophy angle shall not exhibit any defects that would negatively impact its intended use, safety or performance. The disposable prophy angle shall be able to perform during an entire polishing procedure under normal intended operation. Satisfactory completion of sections 8.1 and 8.2 of this specification will meet this requirement.