ANSI/ADA Specification No. 125-2009/ISO 16409:2006

Approved: March 2009



American National Standard/American Dental Association **Specification No. 125**

Manual Interdental Brushes

Identical adoption of ISO 16409:2006, *Dentistry – Oral hygiene products – Manual interdental brushes.*

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This is a preview of "ANSI/ADA 125-2009". Click here to purchase the full version from the ANSI store.

INTERDENTAL BRUSHES

The Council on Scientific Affairs of the American Dental Association has approved American Dental Association Specification No. 125 for Manual Interdental Brushes. 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. 125 as an American National Standard on March 31, 2009.

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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INTERDENTAL BRUSHES

FOREWORD

(This Foreword does not form a part of ANSI/ADA specification No. 125 for Manual Interdental Brushes).

This specification is an identical adoption of ISO 16409:2006 Dentistry – Oral hygiene products – Manual interdental brushes. ADA SCDP Working Group No. 7.43 on Interdental Brushes examined the specification and found it acceptable for adoption as ANSI/ADA specification No. 125.

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INTERDENTAL BRUSHES

1 SCOPE

This specification specifies requirements and test methods for performance criteria for manual interdental brushes with a round cross-section of the brush head. It also specifies the accompanying information, such as the manufacturer's instructions for use and labelling of the packaging.

This specification is not applicable to powered interdental brushes, manual toothbrushes, dental floss, tapes, and strings, nor is it applicable to interdental cleaners that do not include filaments.

2 NORMATIVE REFERENCES

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942, Dentistry — Vocabulary

(Copies of ISO standards may be obtained from the American Dental Association, 211 E Chicago, IL, 60611 or www.adacatalog.org).

3 TERMS AND DEFINITIONS

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

- **Manual interdental brush** hand-powered device composed of filaments emanating radially from a stem, intended for cleaning of interdental surfaces.
- **3.2** Interdental brush head portion of manual interdental brush, which passes in and out of spaces between the teeth to clean the exposed surfaces.

NOTE: The brush head can be fixed or removable, but is fixed during use.

- 3.3 Interdental brush handle portion of manual interdental brush which holds the stem of the manual interdental brush
- 3.4 **Stem** central support structure of the manual interdental brush head, usually composed of twisted wire, which secures the filaments.

NOTE: The stem is secured in the handle or in a connector, or fulfils the function of a handle itself.

- 3.5 **Filament –** single strand attached to the stem.
- 3.6 Stem retention force force required to remove the stem from the interdental brush handle holding it.
- 3.7 **Passage hole diameter –** minimum diameter of a hole through which a manual interdental brush head can pass without stem deformation.
- 3.8 Brush size index of brush sizes determined by the passage hole diameter.

4 CLASSIFICATION

Manual interdental brushes shall be classified as follows:

Type 1: replacement heads may be mounted into a handle;