



American National Standard/
American Dental Association
Standard No. 178

Orthodontic Anchor Screws

Identical adoption of ISO 19023:2018, *Dentistry — Orthodontic anchor screws*

ADA American
Dental
Association®

Standards Committee on Dental Products

2019

**AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION
STANDARD NO. 178 FOR ORTHODONTIC ANCHOR SCREWS**

The ADA Standards Committee on Dental Products (SCDP) has approved ANSI/ADA Standard No. 178 for Orthodontic Anchor Screws. This and other standards for dental materials, instruments and equipment are being formulated by working groups of the ADA SCDP. The Committee has representation from all interests in the United States in the standardization of materials, instruments and equipment in dentistry. The Committee has adopted the standards, showing professional recognition of their usefulness in dentistry, and has forwarded them to the American National Standards Institute with a recommendation that the standards be approved as American National Standards. The American National Standards Institute granted approval of ADA Standard No. 178 as an American National Standard on August 26, 2019.

The ADA Standards Committee on Dental Products thanks the members of Working Group 1.7 on Orthodontic Products and the organizations with which they were affiliated at the time the standard was developed:

Jerry Horn (chairman), Individual Representative, San Diego, CA;
Michael Adjodha, U.S. Food and Drug Administration, Rockville, MD;
William Brantley, Ohio State University, Columbus;
Leon Laub, Rocky Mountain Orthodontists, Denver, CO;
Spiro Megremis, American Dental Association, Chicago, IL;
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Orlando Sarria, Ultimate Wireforms, Inc., Bristol, CT.

**AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 178
FOR ORTHODONTIC ANCHOR SCREWS**

FOREWORD

(This Foreword does not form a part of ANSI/ADA Standard No. 178 for Orthodontic Anchor Screws).

This standard is an identical adoption of ISO 19023:2018, Dentistry – Orthodontic anchor screws. ADA SCDP Working Group No. 1.7 on Orthodontic Products examined the international standard and found it acceptable for identical adoption as ANSI/ADA Standard No. 178.

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Introduction

Orthodontic anchor screws for temporary skeletal anchorage of orthodontic appliances are considered as auxiliary orthodontic devices.

Orthodontic anchor screws are medical devices used in dentistry. Unlike implants, such as endosseous dental implants, which are intended to remain permanently inside the bone and where, therefore, osseointegration is desired, orthodontic anchor screws are removed at the end of the orthodontic treatment. Insertion and removal of orthodontic anchor screws require the appropriate instruments and adapters.

This document has been developed as a result of the difficulty often encountered by clinicians to make meaningful comparisons between orthodontic anchor screws using the information currently available from manufacturers and suppliers.

Thus the purpose of this document is to facilitate communication between manufacturers and clinicians which will allow comparison between various orthodontic anchor screws.

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological hazard are not included in this document, but it is recommended that, for the assessment of possible biological or toxicological hazards, reference should be made to ANSI/ADA Standard No. 41, ISO 10993-1 and ISO 7405.

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1 Scope

This document specifies requirements and test methods for orthodontic anchor screws used in orthodontic treatment.

This document gives details of methods to compare physical and mechanical properties of orthodontic anchor screws together with test methods and packaging and labelling information.

NOTE Orthodontic anchor screws are used to provide temporary intraoral skeletal anchorage during orthodontic treatment and are removed at the end of the orthodontic treatment. Similar to endosseous dental implants, they are, therefore inserted into the maxillo-facial bone structures.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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*

ISO 5832-2, *Implants for surgery — Metallic materials — Part 2: Unalloyed titanium*

ISO 5832-3, *Implants for surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

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

ASTM F67, *Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)*

ASTM F136, *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*

ASTM F543-17, *Standard Specification and Test Methods for Metallic Medical Bone Screws*

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

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at <https://www.electropedia.org/>

— ISO Online browsing platform: available at <https://www.iso.org/obp>