ANSI/ADA Specification No. 105-2010/ISO 21606:2007 Approved: January 2010



American National Standard/American Dental Association Specification No. 105

# Orthodontic Elastomeric Materials

Identical adoption of ISO 21606:2007, *Dentistry – Elastomeric auxiliaries for use in orthodontics.* 

ADA American Dental Association<sup>®</sup> Council on Scientific Affairs

2010

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# AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 105 FOR ORTHODONTIC ELASTOMERIC MATERIALS

The Council on Scientific Affairs of the American Dental Association has approved American Dental Association Specification No. 105 for Orthodontic Elastomeric Materials. 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. 105 as an American National Standard on January 8, 2010.

The Council thanks the members of Working Group 1.7 and the organizations with which they were affiliated at the time the specification was developed:

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## AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 105 FOR ORTHODONTIC ELASTOMERIC MATERIALS

#### FOREWORD

(This Foreword does not form a part of ANSI/ADA Specification No. 105 for Orthodontic Elastomeric Materials).

This specification is an identical adoption of ISO 21606:2007, *Dentistry – Elastomeric auxiliaries for use in orthodontics*. ADA SCDP Working Group No. 1.7 on Orthodontic Products examined the international standard and found it acceptable for identical adoption as ANSI/ADA Specification No. 105.

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this specification, but it is recommended that in assessing possible biological hazards reference should be made to ISO 10993-1 and ISO 7405.

## AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 105 FOR ORTHODONTIC ELASTOMERIC MATERIALS

1 SCOPE

This specification is applicable to all elastomeric auxiliaries including orthodontic elastics, elastomeric bands, chains, links, thread and ligatures used for orthodontics both inside and outside the mouth, in conjunction with fixed and removable appliances.

#### 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 1942:2009 Dentistry — Vocabulary

ISO 3696:1987, Water for analytical use - Specification and test methods

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

(ISO standards for dentistry are available from the American Dental Association, Department of Standards, 211 E. Chicago Ave., Chicago, IL 60611 or www.adacatalog.org. Other ISO standards are available from the American National Standards Institute, 25 W. 43<sup>rd</sup> St., New York, NY 10036 or www.ansi.org).

#### 3 TERMS AND DEFINITIONS

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

- 3.1 **Orthodontic elastics –** intra-oral and extra-oral elastomeric rings used to apply forces to teeth.
- 3.2 Orthodontic thread elastomeric thread (may be hollow) of constant cross-section used to apply forces to teeth.
- **3.3** Orthodontic elastomeric chain interconnected elastomeric rings or a multi-perforated elastomeric band used to apply forces to teeth.
- 3.4 **Orthodontic elastomeric ligatures –** elastomeric rings used to retain wires to orthodontic attachments.
- 3.5 Orthodontic elastomeric separators elastomeric products used to open interproximal spaces between teeth.
- **3.6** Link length *L*, distance between the centres of the holes of adjacent links of orthodontic elastomeric chains. See Figure 1.
- 3.7 Test length length of elastomeric units for units under five links:
  - Five links for chains;
  - 20 mm loop circumference for thread;
  - Diameter of elastomeric ring without load.

See Figure 1.