

Designation: D3481 - 06

Standard Test Method for Manual Shelling Two-Piece Child-Resistant Closures That Are Activated by Two Simultaneous Dissimilar Motions¹

This standard is issued under the fixed designation D3481; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

- 1.1 This test method covers the measurement of the force required to separate (or "shell") the snap-fitted outer cap from the inner cap of Type IA, IB, or IC child-resistant closures.
- 1.2 This test method does not measure the force required to separate parts of a child-resistant closure system that were originally "screwed-on" instead of "snapped-on" (for example, pull a cap over or through continuous or multi-start threads when the cap was originally screwed on).
- 1.3 The values stated in SI units are to be regarded as the standard. The inch-pound units given in parentheses are for information only.
- 1.4 This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

2. Referenced Documents

2.1 ASTM Standards:²

D3474 Practice for Calibration and Use of Torque Meters
Used in Packaging Applications

D3475 Classification of Child-Resistant Packages

E105 Practice for Probability Sampling Of Materials

E122 Practice for Calculating Sample Size to Estimate, With Specified Precision, the Average for a Characteristic of a Lot or Process

2.2 Other Documents:

ISO Bulletin 2233 Packaging—Complete, Filled, Transport Packages—Part 2: Conditioning for Testing³

3. Terminology (see Classification D3475)

- 3.1 Definitions:
- 3.1.1 *Type IA child-resistant closure*—a two-piece continuous thread closure requiring a random push down while turning; no orientation of the push down force is necessary.
- 3.1.2 *Type IB child-resistant closure*—a two-piece continuous thread closure requiring a localized squeeze force while turning; the force must be applied to a designated location on the closure skirt.
- 3.1.3 *Type IC child-resistant closure*—a two-piece continuous thread closure requiring a random squeeze while turning; no orientation of the squeeze force is necessary.

4. Summary of Test Method

4.1 This test method measures the force required to pry the outer cap off the inner cap using a fixture having a contact point under the tip of the skirt of the outer cap and leverage being placed on that point and the top of the cap. This procedure is used where a pivotal prying force can be successfully used to separate the components of the closure system. Either a torque wrench or a torque meter can be used as a measuring device.

5. Significance and Use stm-d3481-06

- 5.1 This test method of applying force may be used as a standard test to compare the characteristics of a given design of container/child-resistant closure system with a standard or to compare the characteristics of container/child-resistant closure systems differing in construction.
- 5.2 It may be used to simulate certain manipulations that may be expected to occur in protocol testing⁴ (such as, prying with the teeth or objects in the room, biting, and pulling with the teeth).
- 5.3 This test method may be used to establish performance specifications.

6. Apparatus

6.1 *Testing Machine(s)*:

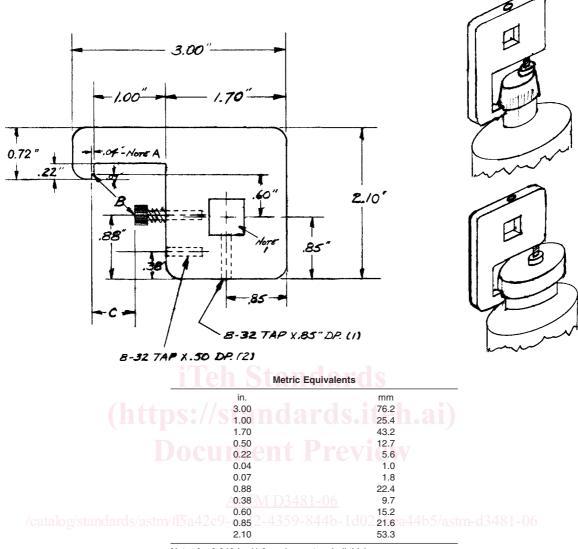
 $^{^{\}rm l}$ This test method is under the jurisdiction of ASTM Committee D10 on Packaging and is the direct responsibility of Subcommittee D10.32 on Consumer, Pharmaceutical and Medical Packaging.

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

³ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

⁴ Consumer Product Safety Commission's Poison Prevention Packaging Act, 1970



Note A-0.040 in. (1.0 mm) or outer shell thickness.

Note B-Maximum 13/4 in. (34 mm)

Note C-Height adjusted with cap screw shown.

Note 1-1/4, 1/2, or 3/4-in. square hole to fit a standard torque

wrench post.

Note 2—Tool made of 1/4-in. metal bar stock.

FIG. 1 Cap Holding Fixture

- 6.1.1 *Torque Meter*—⁵ with a scale that will read with the maximum point reading accuracy within the torque range expected to be measured (for example, use a 0 to 25 T.I.P. torque meter for readings under 25 T.I.P., not a 0 to 100 T.I.P. torque meter).
 - 6.1.2 Torque Wrench, of accepted design and capacity.
 - 6.2 Attachments, Fixtures, etc. (see Fig. 1):
- 6.2.1 *Cap Holding Fixture* with one contact point under the lip of the outer cap skirt and the other point contacting the top

of the cap. The distance between the two contact points should be 34 mm or approximately 13/8 in. (in accordance with page 19 of the Krogman study⁵) or to the farthest side of the cap if less than 34 mm.

- 6.2.2 *Device* for attaching the above tool to a torque wrench or torque meter.
- 6.2.3 *Bottle*, standard size, with corresponding finish to the closure(s) being tested.

7. Sampling

7.1 The number of samples will depend on the desired purpose for which the test is being conducted. However, for a given set of samples, sufficient measurements should be taken

⁵ A digital torque instrument, if used, will have an appropriate design and scale capacity for the container/closure system to be evaluated. Torque results will be available in either electronic display or printout format.