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SAFETY BRIEF

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Snap-Lock Beads Danger Analysis

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ABSTRACT

A tragic accident occurred when a 16 month old child fell face down and an oblong plastic toy snap-lock bead lodged in his throat obstructing his airway. Approaches utilized in the danger analysis include safety and medical literature review, codes and standards research, accident statistics survey, and evaluation of alternative snap-lock beads designs. Results of the danger analysis indicate that there are technically and economically feasible design alternatives which prevent the snap-lock beads from blocking the user's airway.

INTRODUCTION

The airway of a 16 month old child became blocked when he fell face down with a chain of two plastic toy snap-lock beads in his mouth. When the child's mother attempted to pull the snap-lock beads from her child's mouth, the beads separated with the mother holding onto one bead while the other bead remained lodged in the child's throat. The child's mother was unable to dislodge the remaining bead from her child's throat so a tracheotomy was performed to remove the 3.49 cm (1.375 in.) diameter oblong bead shown in Fig. 1.

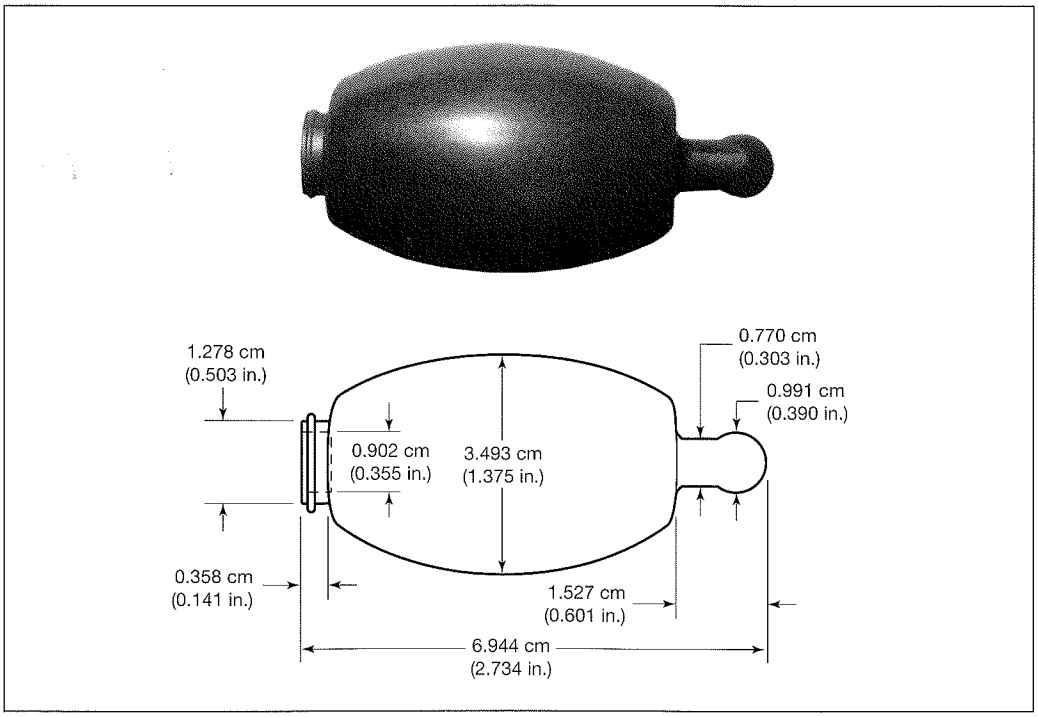

Figure 1 - Oblong Bead

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Table 1 - Size of Products Involved in Choking Incidents
(Number of Fatalities and Non-Fatalities by Diameter)

	Diameter – cm (in.)								
	Total Known	< 2.54 < (1.00)	2.54 - 3.02 (1.00 - 1.19)	3.05 - 3.28 (1.20 - 1.29)	3.30 - 3.53 (1.30 - 1.39)	3.56 - 3.78 (1.40 - 1.49)	3.81 - 4.04 (1.50 - 1.59)	4.06 - 4.29 (1.60 - 1.69)	> 4.29 > (1.69)
Total	136	5	44	9	3	6	60	4	5
Fatalities	18	2	8	3	–	–	4	1	–
Non-Fatalities	118	3	36	6	3	6	56	3	5

Note: If product was not exactly round, dimension quoted is largest dimension of width or height.

Source: U.S. Consumer Product Safety Commision
Directorate for Epidemiology/EPHF

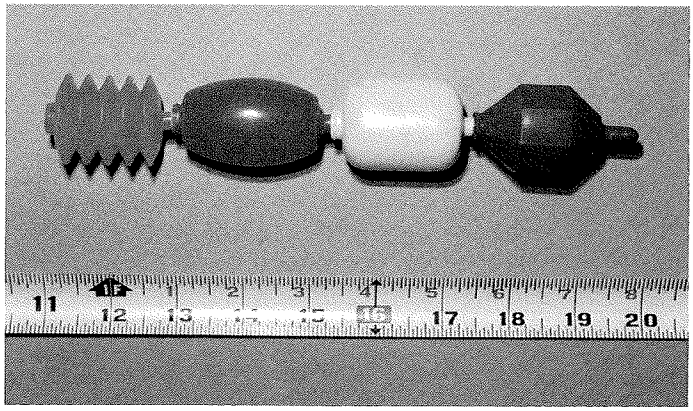


Figure 2 - Snap-Lock Beads Chain

The subject oblong snap-lock bead was part of a set of different shaped beads which can be snapped together to form a chain as depicted in Fig. 2 and then pulled apart. The manufacturer has received notice of at least two other similar accidents involving snap lock beads lodging in children's throats both of which resulted in fatalities. The manufacturer has also received numerous accounts of the male portion of the snap-lock beads breaking off and being placed into children's mouths.

Three to four months prior to the purchase of the subject snap-lock beads, the manufacturer decided to enlarge the diameter of the snap-lock beads up to 4.45 cm (1.75 in.) to reduce the probability of the tip breaking off and to reduce the probability of a child getting a whole bead in its mouth. Three to four months after the purchase of the subject snap lock beads and two months before the subject accident, production began on the enlarged 4.45 cm (1.75 in.) diameter snap-lock beads. The manufacturer's policy was to sell the existing inventory of the smaller 3.49 cm (1.375 in.) snap-lock beads, which included the subject snap-lock beads, even after the decision was made to increase the diameter to 4.45 cm (1.75 in.) for safety reasons. The goal of this investigation is to make toy designers and users more aware of the small parts asphyxiation hazard and to identify failure prevention design alternatives to help reduce the number of these injuries.

ACCIDENT STATISTICS

The U.S. Consumer Product Safety Commission (CPSC) Directorate for Epidemiology, Division of Human Factors, has performed a human factors analysis of choking incidents in children (1). According to this CPSC study, there were 136 choking incidents involving children from one month to four years of age, including 18 fatalities, where the diameter of the object was specified as presented in Table 1. A review of Table 1 indicates that almost two-thirds of the objects involved in choking incidents studied were larger than 3.18 cm (1.25 in.). The CPSC concluded that the 3.18 cm (1.25 in.) diameter is not adequate to prevent penetration of an object into the mouth.

The interaction between human and product characteristics was assessed by comparing the CPSC incident reports with the medical literature. The CPSC study indicates that in general, objects with diameters of 4.19 cm (1.65 in.) or less, having smooth surfaces and flared or spherical ends, are choking children. It appears that these sizes and configurations were most often implicated in choking incidents for the following reasons (1):

1. Objects with diameters of 4.19 cm (1.65 in.) or less are small enough to be inserted into the mouth.

2. Smooth objects are more likely than rough objects to be sucked on since they are comfortable in the mouth. Once in the mouth, this smooth surface easily slides in the throat.

3. These diameters are too large to be ingested into the passageway to the stomach or inhaled into the passageway to the lungs. Therefore, the object lodges in the pharynx, restricting or completely interrupting respiration.

4. If an object is large enough and shaped such that it can lodge in the pharynx, the protective reflexes become ineffective. The gag reflex cannot function, because the throat tissue surrounds the spherical or flared end, prohibiting expulsion of the object. The swallowing

reflex cannot be invoked as the object is too large to enter the esophagus. The cough reflex cannot function because air first must be taken into the lungs before it can have enough force to expel an object. The object blocks air from coming into the lungs. Since the objects are rounded, they are especially effective in blocking off the airway, since the throat easily molds to their contours, forming a complete seal. Objects that are compressible are even more effective at blocking off the air passage, as they, in turn, can conform to the throat's contours.

LITERATURE REVIEW

A review of the medical and safety literature addressing the characteristics of objects that cause choking in children was conducted to analyze object sizes associated with toy choking injuries. Table 2 presented by Rimell et. al. (2) displays the diameter of a computer-simulated ring allowing passage of 101 three-dimensional objects causing children's asphyxiation deaths. An examination of Table 2 indicates that the maximum diameter object in the study causing a child asphyxiation death is 4.44 cm (1.75 in.). The Bendix Study to Determine the Size of Toy/Toy Parts Which Caused Suffocation (3) issued an opinion that toy/toy parts/objects from 5 mm (0.197 in.) to 44 mm (1.73 in.) in greatest diameter can produce fatal obstruction of the oral pharyngeal tracts. The findings of the research on small parts aspiration, ingestion, and choking in small children by Rider and Wilson (4) indicate that the maximum diameter object associated with fatality was 4.44 cm (1.75 in.). According to the Consumer Reports Toy Buying Guide (5), some toy safety analysts believe that objects would have to be 4.44 cm (1.75 in.) in diameter to be fully safe.

*Table 2 - Diameter of Computer-Simulated Ring Allowing Passage of 101 Three-Dimensional Objects Causing Children's Asphixiation Deaths**

Diameter of Virtual Ring, cm (in.)	Spheres, No. (%) (n = 31)	Nonspheres, No. (%) (n = 70)
0.13 (0.05)	0	0
0.38 (0.15)	0	1 (1.4)
0.63 (0.25)	1 (3.2)	5 (7.1)
0.89 (0.35)	0	22 (31.4)
1.14 (0.45)	0	10 (14.3)
1.4 (0.55)	0	3 (4.3)
1.65 (0.65)	23 (74.2)	2 (2.9)
1.9 (0.75)	1 (3.2)	17 (24.3)
2.16 (0.85)	0	0
2.41 (0.95)	0	2 (2.9)
2.67 (1.05)	1 (3.0)	2 (2.9)
2.91 (1.15)	1 (3.0)	0
3.17 (1.25)	1 (3.0)	4 (5.7)
3.43 (1.35)	0	0
3.68 (1.45)	1 (3.0)	2 (2.9)
3.94 (1.55)	0	0
4.19 (1.65)	0	0
4.44 (1.75)	2 (6.1)	0
4.69 (1.85)	0	0
4.94 (1.95)	0	0
5.18 (2.04)	0	0
Total	**31 (99.8)**	**70 (100.1)**

* Data from Inchcape Testing Services Risk analysis and Management, Moonachie, NJ. The numbers in the Spheres and Nonspheres columns are the numbers of objects that passed through the computer-simulated ring of that diameter.

Nowak and Casamassimo (6) report that the Little People line of products (Fisher Price Inc., Aurora, NY) was modified in 1991 to a larger size following reports of choking incidents. Prior to 1991, the width of the toy was 24 mm (0.945 in.) which could easily fit in an infant's mouth. The new Little People toy is 40.4 mm (1.59 in.) in diameter which exceeds any of the mean measurements for oral openings obtained, as shown in Table 3.

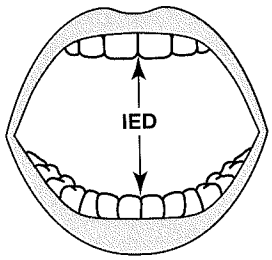
CODES AND STANDARDS

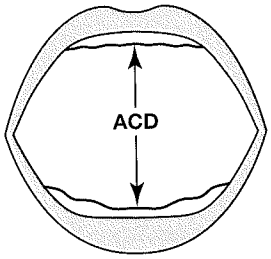
A truncated right cylinder with a 3.18 cm (1.25 in.) diameter as depicted in Fig. 3 was specified by the Voluntary Product Standard on Toy Safety, ANSI/VPS PS 72-76 (7), to act as a go/no go small parts test gauge for toys intended for use by children aged 36 months or less. This 3.18 cm (1.25 in.) diameter small parts cylinder has been adopted by the CPSC as published in Part 1501 - Method for Identifying Toys and Other Articles Intended for Use by Children Under 3 Years of Age Which Present Choking, Aspiration, or Ingestion Hazards Because of Small Parts (8). In addition, the American Society for Testing and Materials (ASTM) incorporates the 3.18 cm (1.25 in.) diameter small parts cylinder into its Standard Consumer Safety Specification on Toy Safety, ASTM F963-86 (9).

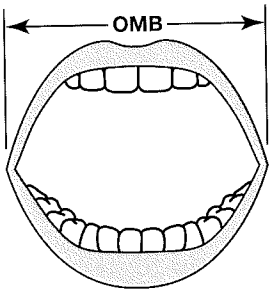
Opposition to the 3.18 cm (1.25 in.) small parts test cylinder was presented by the New York State Attorney General's Office together with the Consumer Federation of America by filing a petition asking that the small parts test cylinder be modified and enlarged to require a minimum 42.7 mm (1.68 in.) diameter (10). Responding to an Advance Notice of Proposed Rulemaking on small parts choking hazards in the Federal Register, comments from five special interest or consumer groups, a safety consultant, three members of the medical community, and one toy premium distributor were that the current test cylinder is inadequate. Suggestions for improvements included adopting a supplemental test fixture with a suggested diameter ranging from 42.7 mm (1.68 in.) to 45.0 mm (1.77 in.) (11).

Alternative small parts diameter recommendations have been published. A review by the CPSC of selected fatal and serious non-fatal choking incidents involving products intended for use by children under three (except for balloons) and of the sizes of objects involved in these incidents indicates that a test device with a circular opening of approximately 42.7 mm to 45.7 mm (1.68 in. to 1.80 in.) would eliminate nearly all of the objects involved in these incidents (12). The CPSC requires that pacifiers cannot be completely drawn through a test fixture with an opening of 42.7 mm (1.68 in.) as illustrated in Fig. 4 as published in Part 1511 - Requirements for Pacifiers (13). Standard Consumer Safety Specification on Toy Safety, ASTM F963-86 (9), specifies a supplemental test fixture for rattles, squeeze toys, and teethers which contains a 42.7 mm (1.68 in.)

Table 3 - Oral Opening, Alveolar Crest Distance, and Mouth Breadth by Age - mm (in.)







Age Groups	IED - Incisal Edge Distance (Maximum Opening)	ACD - Alveolar Crest Distance (No teeth, Maximum Opening)	OMB - Open Mouth Breadth (Maximum)
6 wk			
Mean	—	26.9 (1.059)	28.5 (1.122)
S.D.	—	3.9 (0.154)	3.9 (0.154)
Range	—	20.0 - 39.0 (0.787 - 1.535)	20.0 - 35.5 (0.787 - 1.398)
No.	—	46	46
6 mo			
Mean	—	33.3 (1.311)	32.1 (1.264)
S.D.	—	3.9 (0.154)	4.3 (0.169)
Range	—	25.0 - 42.0 (0.984 - 1.65)	20.0 - 40.0 (0.787 - 1.575)
No.	—	73	73
12 mo			
Mean	35.5 (1.398)	28.7 (1.130)	35.7 (1.406)
S.D.	4.4 (0.173)	5.7 (0.224)	4.4 (0.173)
Range	25.0 - 45.5 (0.984 - 1.791)	22.9 - 36.0 (0.902 - 1.417)	30.0 - 50.0 (1.181 - 1.969)
No.	58	4	62
18 mo			
Mean	36.1 (1.421)	—	36.7 (1.445)
S.D.	4.0 (0.157)	—	5.2 (0.205)
Range	28.5 - 47.0 (1.122 - 1.850)	—	30.0 - 55.0 (1.181 - 2.165)
No.	61	—	61
24 mo			
Mean	36.1 (1.421)	—	37.3 (1.469)
S.D.	4.1 (0.161)	—	5.2 (0.205)
Range	25.0 - 46.5 (0.984 - 1.831)	—	25.0 - 50.0 (0.984 - 1.969)
No.	58	—	58
30 mo			
Mean	36.9 (1.453)	—	37.5 (1.476)
S.D.	4.7 (0.185)	—	4.9 (0.193)
Range	25.0 - 48.5 (0.984 - 1.909)	—	22.0 - 45.0 (0.886 - 1.772)
No.	62	—	62
36 mo			
Mean	35.7 (1.406)	—	36.9 (1.453)
S.D.	4.5 (0.177)	—	5.4 (0.213)
Range	24.0 - 46.5 (0.945 - 1.831)	—	26.0 - 55.0 (1.024 - 2.165)
No.	60	—	60

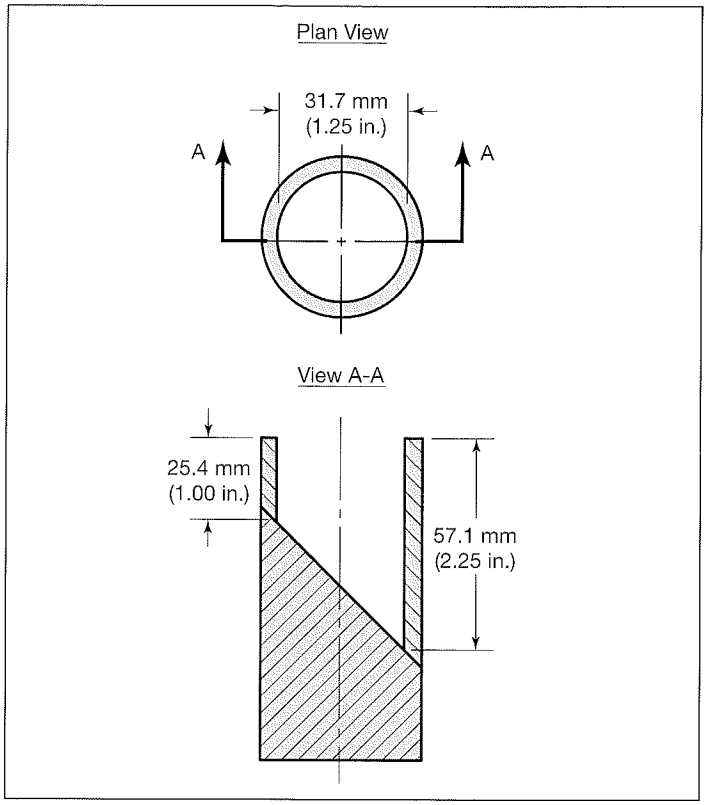


Figure 3 - Small Parts Cylinder

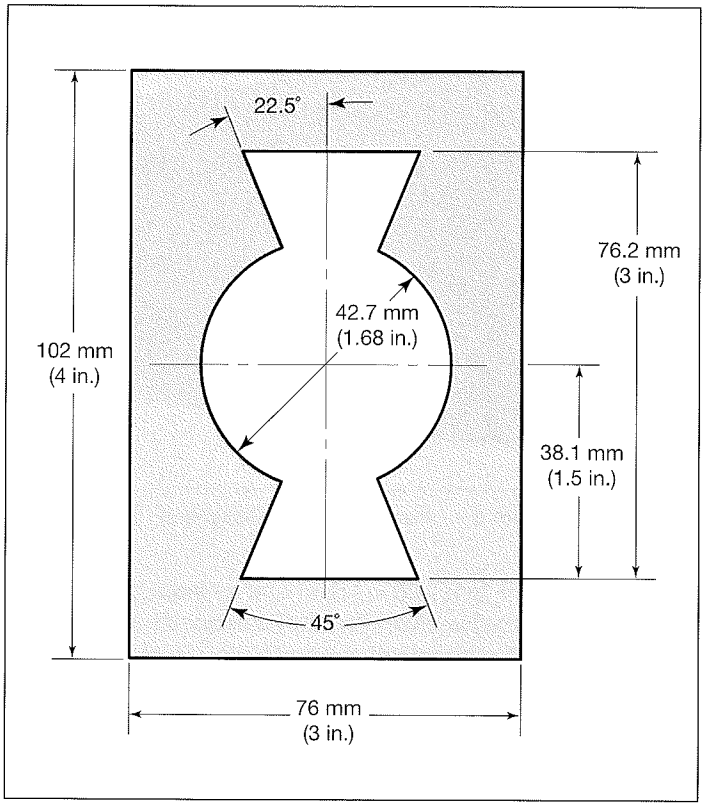


Figure 4 - Pacifier Test Fixture

diameter opening. In addition to the U.S. rattle fixture requirements, Japan drafted amendments which state that a fixture having a circular opening with a 45.0 mm (1.77 in.) diameter would be used to screen spherical portions of toys (1). Furthermore, according to Banned Toys and Other Banned Articles Intended for Use by Children, any ball intended for children under three years of age is banned if it passes in any orientation entirely through a circular hole with a diameter of 44.4 mm (1.75 in.) in a rigid template 6 mm (0.25 in.) thick (14).

DESIGN ALTERNATIVES

Increase Diameter

Based upon the accident statistics survey, literature review, and codes and standards research, increasing the diameter of the subject 3.49 cm (1.375 in.) snap-lock beads would be a feasible design change to restrict the bead from blocking the airway of a 16 month old child. It should be noted that the diameter of an exemplar oblong snap-lock bead provided to the author measured 3.299 cm (1.299 in.). The consensus in the literature studied suggests a recommended diameter of approximately 4.45 cm (1.75 in.) for the snap-lock beads. Indeed, the manufacturer of the 3.49 cm (1.375 in.) diameter snap-lock beads began producing 4.45 cm (1.75 in.) diameter snap-lock beads before the subject accident and has not changed this diameter since.

Ventilation

Incorporating ventilation features into the design of the snap-lock beads would allow sufficient air flow to prevent asphyxiation if the beads enter the child's airway. Pen caps utilize various forms of safety vents to prevent asphyxiation if the cap enters the user's airway (15). In addition, pacifier guards or shields are required to contain at least two vent holes symmetrically located, each at least 5 mm (0.20 in.) in minor dimension (13).

Shape

Modifying the shape of the snap-lock beads is a design alternative which would prevent total blockage of a child's airway if the bead is inserted in the child's mouth. The CPSC human factors analysis associated with choking incidents in children indicates that smooth objects such as a toy telephone receiver were implicated more often than rough objects such as a toy giraffe head with bumps for ears, horns, nose, and mouth (1). Rimell et. al. (2) found that cubes with diameters greater than 3.17 cm (1.25 in.) did not occlude the airway totally, regardless of the angle at which they were placed in the oropharynx. Some pen cap designs utilize a clip that forms an air channel to prevent asphyxiation if the cap enters the user's airway (15). In the case of the snap-lock bead design, creating a scalloped shape as in Fig. 5 forms an air passageway if the bead lodges in the child's airway.

Compressibility

According to the CPSC human factors analysis associated with choking incidents in children, compressibility and flexibility must also be considered, as all of the squeeze toys, several of the pacifier shields, and some of the teethers involved in choking incidents were compressible or flexible (1). Since children have the ability to suck, gum, bite, or squeeze, they may compress or flex objects larger in diameter than the mouth so that these objects can fit into the mouth. Indeed, the subject oblong 3.49 cm (1.375 in.) snap-lock bead can be compressed

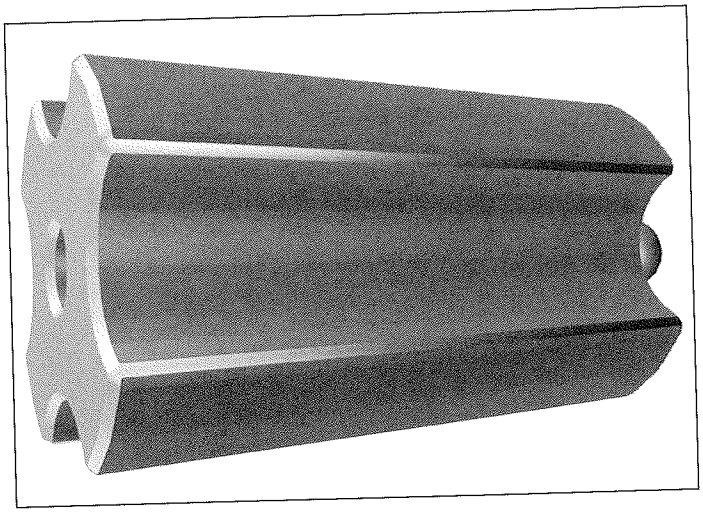


Figure 5 - Bead with Air Passageway

into a hollow 3.18 cm (1.25 in.) diameter cylinder. As reported in the CPSC hazard analysis on injuries associated with small objects, over half of the deaths reported for which the consistency of the object was known involved pliable objects. This finding may indicate that there is a greater risk of death associated with pliable objects (16). Increasing the rigidity of the snap-lock bead structure can be effective in reducing the capability of the bead to compress into a child's mouth and completely block the airway by conforming to the throat's contours.

Taste/Texture

At four to five months of age, the mouth is one of the most important sources of sensory inputs as children explore their world by manually bringing things into their mouths for manipulation and exploration (1). Choking incidents continue to occur until about three years of age because these children have not developed the cognitive ability and probably not the physical ability to pull the toy out of the mouth and throat once that toy becomes entrapped (1). According to a CPSC analysis of choking-related hazards associated with children's products, about 85% of the victim children typically put non-food objects in their mouths (17). Where reported, about one-half of the victims were described as frequently putting objects in their mouths and about one-half as sometimes or never doing this. Almost two-thirds of the victims under age three were described as having frequent mouthing behavior, and over three-fourths of the victims three years and over were described as sometimes or never doing this. Furthermore, children who have large objects in their mouths may roll or fall onto their faces, thereby forcing these objects into their throats (1).

To address this tendency of children to put objects in their mouths, it has been suggested by Baker et. al. that a bitter-tasting substance be used on the surface of balloons to reduce the appeal of chewing on them (18). Similarly, a non-toxic, non-pleasing substance or texture could be placed on the surface of the snap-lock beads to discourage children from placing the beads in their mouths. Smoother objects offer less friction than textured objects, making them more likely to move to the back of the mouth and down into the airway passages (19).

Warnings

Some of the manufacturer's product literature and packaging for the snap-lock beads shows the beads inserted into a child's mouth. In addition, some of the manufacturer's literature and packaging for the snap-lock beads states that they are chewable, a perfect teething toy, and too big to swallow. This product literature and packaging implies that the manufacturer encourages and intends for children to mouth the snap-lock beads. The manufacturer's product literature and packaging for the snap-lock beads did not contain any warnings regarding the asphyxiation danger associated with the beads blocking a child's airway. In addition, the snap-lock beads do not possess any on-product warnings. Labeling requirements for certain toys are set forth in the Standard Safety Specification on Toy Safety, ASTM F963-92 (20). Some elements of these labeling requirements include the following:

1. Signal word
2. Statement of the hazard
3. Color contrast
4. Legibility and discernability
5. Age grading
6. Promotional materials shall not use words, statements, or other graphic material that is inconsistent in any way with cautionary labeling, age grading, or instructions for the use of the toy.

It should be noted that warnings are considered the third priority of the Safety Hierarchy (21), whereas attempting to eliminate the snap-lock beads asphyxiation danger through design is considered to be the first priority.

An example of the use of warnings regarding choking risks associated with small objects is the Fisher-Price Little People. According to a Fisher-Price Family Alert Program (22), Fisher-Price began to market "Play Family" playsets in 1965. Some were labeled for children one year old and above, while others specified a minimum of two years of age. From 1971 until 1991, all playsets were labeled with a two-year minimum age. In 1986, the North American Play Family line was renamed "Little People." That same year, in addition to the two-year minimum age, a warning was added to each package that said, "Regardless of age, this product is not intended for children who still put objects in their mouths." In 1988, the Little People figures were made larger, allowing Fisher-Price to reduce the minimum age restriction from two years to 18 months.

CONCLUSIONS

The current 3.18 cm (1.25 in.) diameter small parts test fixture does not eliminate objects which can enter the mouth and obstruct the airway by blocking the mouth and upper throat. Thus these types of choking incidents continue to occur (19). Even though the subject 3.49 cm (1.375 in.) diameter oblong snap-lock bead will not fit entirely within the 3.18 cm (1.25 in.)

diameter small parts cylinder because of interference with the sloped cross-member, it has been clearly documented that the bead is capable of producing serious injury and death if it blocks a child's airway. Following reports of choking incidents, the snap-lock beads manufacturer ultimately changed the design by increasing the beads size in a similar fashion to the increased size of the Little People toy. Results of this investigation indicate that there are technically and economically feasible design alternatives which would restrict the snap–lock beads from completely blocking a child's airway and would allow sufficient air flow to prevent asphyxiation.

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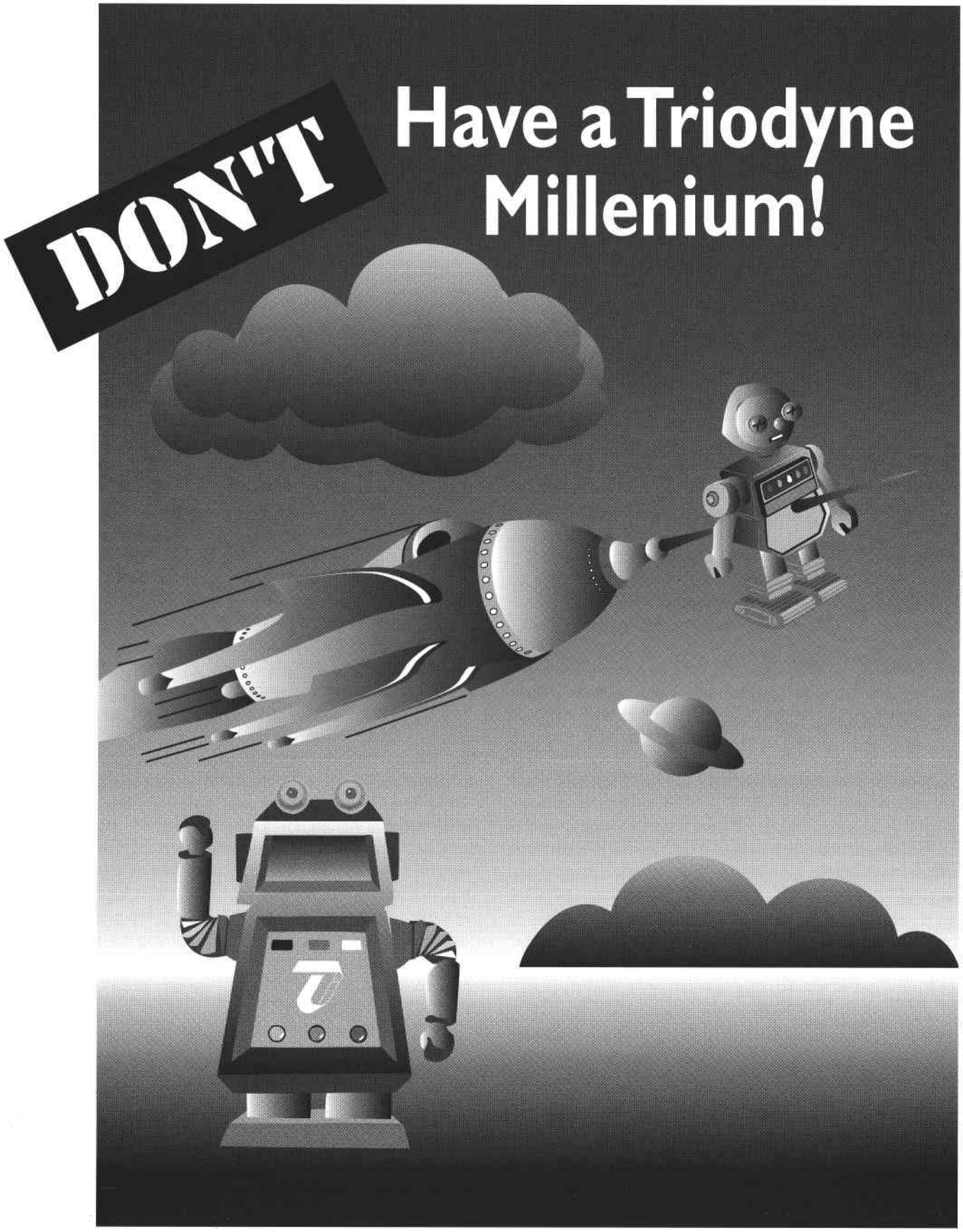
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