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SAFETY BRIEF

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PEN CAP FAILURE ANALYSIS AND PREVENTION

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ABSTRACT

A tragic accident occurred when a young child swallowed the interior component of a two piece highlighter pen cap which obstructed his airway. Approaches utilized in the failure analysis include dynamic testing, accident statistics survey, safety literature research, and a review of alternative pen cap designs. Results of the analysis indicate that there are technically and economically feasible pen cap design alternatives on the market and in the literature which allow sufficient airflow to prevent asphyxiation if the cap enters the user's airway.

INTRODUCTION

A young child was asphyxiated when he ingested the interior component of a two piece highlighter pen cap, obstructing his airway. At the time of the accident, the child pulled the cap from the pen body shown in Fig.1 and a piece of the cap flew into his mouth. A tracheotomy was performed to remove the aspirated foreign body depicted in Fig. 2 from the child's throat.

Figure 1 - Pen Body and Cap

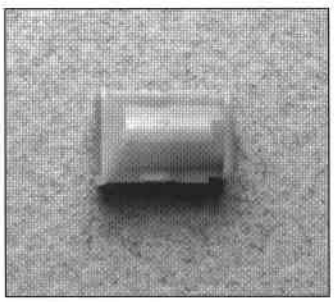

Figure 2 - Aspirated Foreign Body

The two components of the highlighter pen cap shown in Fig. 3 were formed by a press fit. There were no other mechanical fasteners joining the two pen cap components together. Consequently, dynamic testing of the highlighter pen conducted by pulling the cap from the pen body revealed situations where the pen body would be held in one hand, the exterior pen cap component would remain in the other hand, and the interior pen cap component would be catapulted into the air.

After the production of the subject highlighter pen, the manufacturer changed the design by incorporating an aperture into the interior component of the pen cap as shown in

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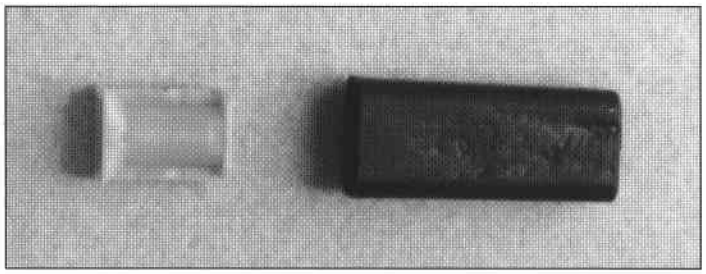

Figure 3 - Pen Cap Component in Separated Condition

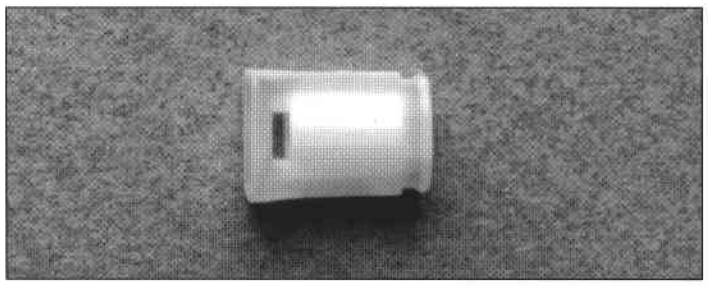

Figure 4 - Pen Cap Interior with Aperature

Fig. 4 which will allow sufficient air flow to prevent asphyxiation if it enters the user's airway. This modified design is in conformance with British Standard BS 7272:1990 (1) and International Standard ISO 11540:1993 (2) which call for pen caps to allow some air to pass through if they become lodged in the windpipe. The goal of this investigation is to make pen designers and users more aware of the pen cap 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) has compiled accident statistics associated with pen caps through the National Electronic Injury Surveillance System (NEISS) which also describes the details of these injuries (3). The death certificate files, comment files, and reported incident files from the CPSC from 1974 to 1994 contain dozens of asphyxiation injuries due to children swallowing pen caps. In addition to the CPSC accident statistics, the safety and medical literature (4-10) has described injuries involving pen caps in the airways of children. In Australia, 31 children were hospitalized in a 6 year period after swallowing pen tops (9). In the United Kingdom, 9 children were asphyxiated by pen tops between 1970 and 1984 (9). No such deaths have occurred since the U.K. adopted the international safety standard (9). Despite the reported injuries related to children swallowing pen caps, the CPSC decided to take no action (9).

STANDARDS

BS 7272:1990, British Standard Specification for Safety Caps for Writing and Marking Instruments (1), and ISO 11540:1993, Caps for Writing and Marking Instruments Intended for Use by Children up to 14 Years of Age - Safety Requirements (2), have been developed to minimize the risk of suffocation for children who might accidentally swallow a pen cap. The foreword of BS 7272:1990 (1) states the following:

"This standard attempts to minimize the risk to children of asphyxiation due to the accidental inhalation of pen caps which subsequently lodge below the larynx and so block the trachea.

Children should be actively discouraged from sucking, chewing or otherwise putting pen caps in their mouths. It should, however, be recognized that despite any discouragement that they may receive, children will suck, chew or otherwise put pen caps in their mouths. This British Standard is a secondary safety measure designed to minimize a risk that might be avoided altogether. Another way of minimizing this risk is to make pens without detachable caps whenever possible.

In the preparation of this standard, the Technical Committee has recognized that whilst it is possible to identify the age range of the children who are most at risk, it has not been possible to identify with certainty any writing instruments with detachable caps that would never be accessible to children and hence never pose a risk. It is, however, acknowledged that certain products are not designed for use by children and such items should be clearly labelled to that effect."

The foreword of ISO 11540:1993 (2) states the following:

> **"International Standard ISO 11540 was prepared by the British Standards Institution (as BS 7272:1990) and was adopted, under a special 'fast-track procedure,' by Technical Committee ISO/TC 10, Technical drawings, product definition and related documentation, in parallel with its approval by the ISO member bodies."**

In general, the caps shall comply with either the cap size, vent area, or air flow requirements as appropriate. The cap size requirement of ISO 11540:1993 contains the following specifications:

1. When a cap is presented with its main axis perpendicular to a ring gauge of diameter 16 + 0.05 mm and part of the cap enters that gauge, at least 5 mm of the length of the cap shall not pass freely through it as illustrated in Fig. 5.

2. Caps which comply with this requirement are deemed to be too large to present an inhalation hazard.

The vent area requirement of ISO 11540:1993 contains the following specifications:

1. A continuous air passage of at least 6.8 mm^2 shall extend for the length of the cap body. The cross-sectional area of the continuous air passage, if not

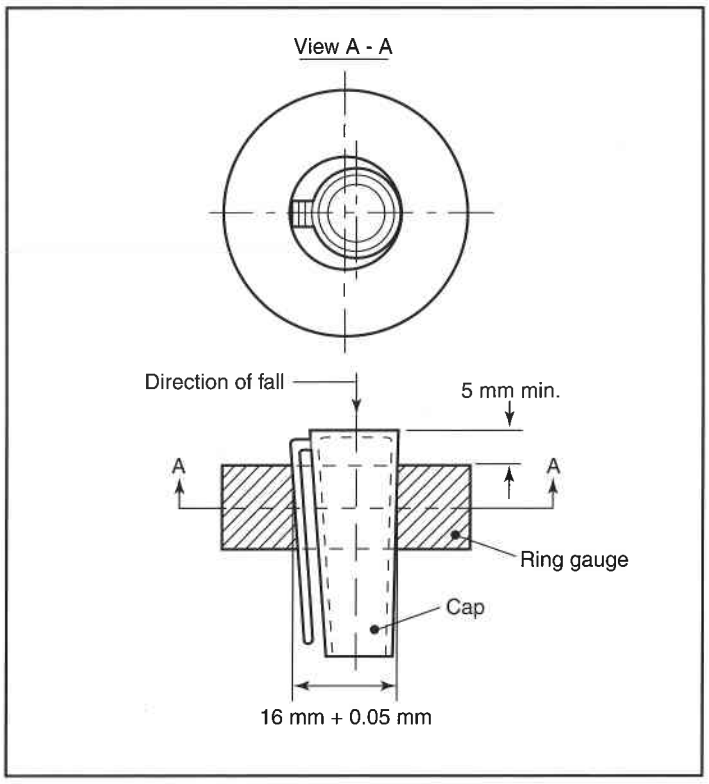

Figure 5 - Cap Size Requirement

entirely enclosed, shall be that area that would be encompassed by a thin piece of cotton thread wrapped tautly around any section perpendicular to the main axis or to the largest dimension (see Fig. 6).

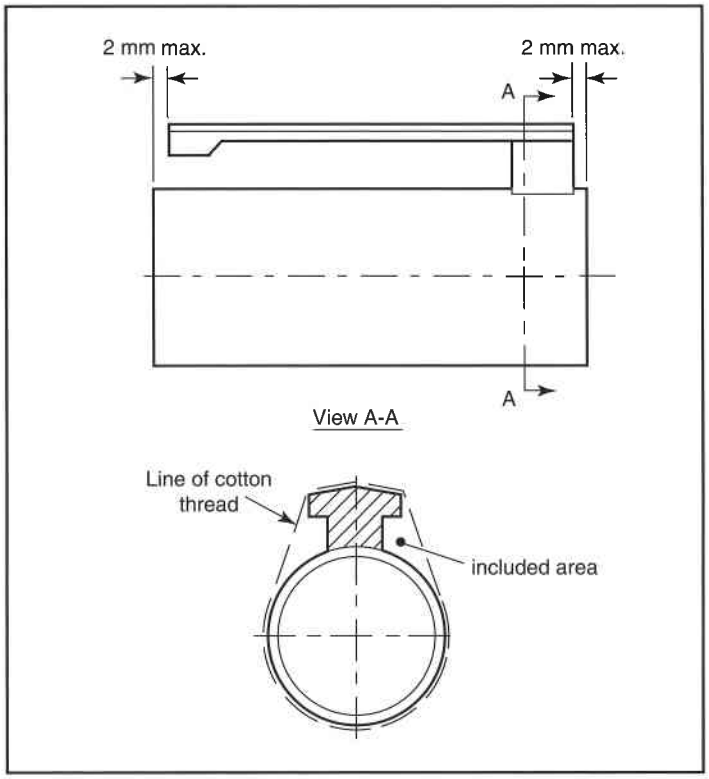

Figure 6 - Sectional View of Cap with Clip

2. Where a clip or other protrusion is the means of providing the air passage, it shall be securely fixed and shall not be more than 2 mm short of either end of the cap body. However, the clip may extend any distance beyond the end of the cap body.

3. Caps complying with this requirement are deemed not to present an asphyxiation hazard.

The air flow requirement of ISO 11540:1993 contains the following specifications:

1. Caps shall permit a minimum air flow of 8 l/min measured at room temperature with a maximum pressure difference of 1.33 kPa when tested using the apparatus shown in Fig. 7.

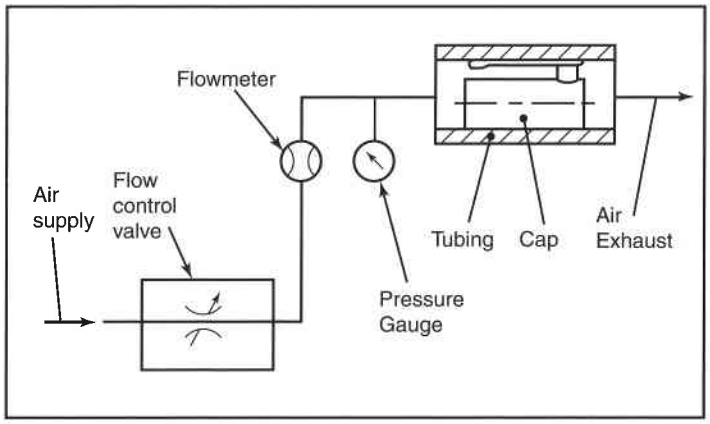

Figure 7 - Air Flow Test Apparatus

2. A single circular orifice with a cross-sectional area of approximately 3.4 mm² can be expected to satisfy this criterion, but multiple smaller orifices may require a larger total cross-sectional area.

ALTERNATIVE PEN CAP DESIGNS

A survey of the patent literature (11-22) has revealed alternative pen cap designs which allow sufficient airflow to prevent asphyxiation if the cap enters the user's airway. These safer designs include a hole in the top, a clip that forms an air channel, and an inner and outer cap with an air passage between the two as illustrated in Fig. 8 (14). It should be noted that although some of these patents were assigned prior to publication of BS 7272:1990 and ISO 11540:1993, the majority of these patents were assigned in the early 1990's. A collection of alternative pen caps with safety vents currently on the market is depicted in Fig. 9.

CONCLUSIONS

Although U.S. pen manufacturers are not obligated to follow the international safety standards, there are some

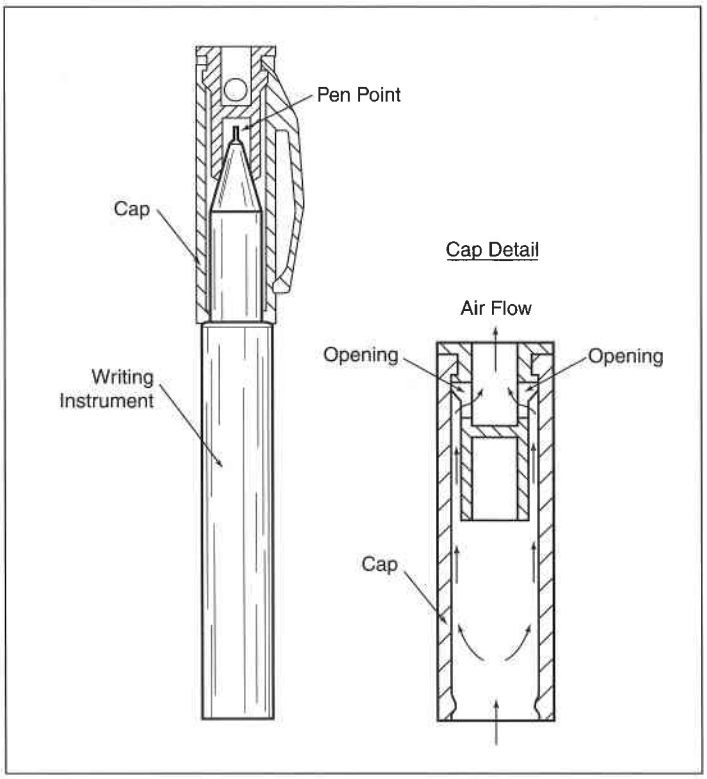

Figure 8 - Writing Instrument Cap with Safety Vent

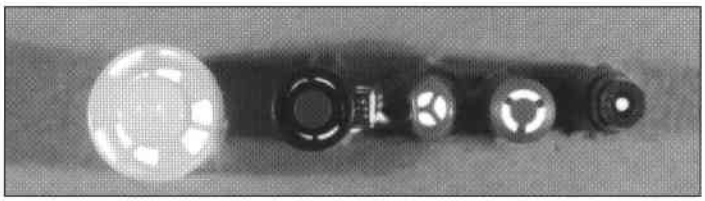

Figure 9 - Pen Caps with Safety Vents

who do. Consequently, it is common to see pens with the safer caps alongside nearly identical pens with the old style caps, such as the subject cap, in stores. Typically, the user cannot differentiate between the pens which comply with the international safety standards and those which do not. In addition, a survey of pens which do not comply with the international safety standards revealed that these pens generally do not contain warnings and instructions regarding the danger of asphyxiation from their caps. The Safety Hierarchy (23) would suggest that attempting to eliminate the pen cap asphyxiation danger through design is the first priority; warning of this danger is the third priority. Results of this investigation indicate that there are technically and economically feasible design alternatives on the market and in the literature which allow sufficient air flow to prevent asphyxiation if the cap enters the user's airway.

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