

September 27, 2024

Ms. Joan Lawrence, ASTM F15.22 Subcommittee Chair Mr. Jos Huxley, ASTM F15.22 Task Group Chair Ms. Carol Pollack-Nelson, F15.77 Subcommittee Chair Mr. Alan Kaufman, F15.77 Subcommittee Chair ASTM International 100 Barr Harbor Drive West Conshohocken, PA 19428

Dear Ms. Lawrence, Mr. Huxley, Ms. Pollack-Nelson, and Mr. Kaufman:

The U.S. Consumer Product Safety Commission (CPSC) staff is aware of an incident involving a child injured due to the internal interaction of ingested magnets, which warrants further discussion with ASTM subcommittees F15.22 and F15.77 given your focus on toy and magnet safety.<sup>1</sup>

According to IDI 210824CBB1805, in August 2021, a 10-year-old female swallowed 17 small, spherical magnets from a magnet set. An upper endoscopy to retrieve the magnets was unsuccessful, and a series of x-rays showed the magnets progressing through the victim's gastrointestinal tract. As a result, the victim was discharged from the emergency room. The victim returned to the hospital three days later exhibiting lower right quadrant pain and was admitted. A CT-scan showed 17 small magnets arranged in a ring, which had adhered around a fold in the bowel in the cecum. The 17 magnets were eventually removed using biopsy forceps during a colonoscopy, and the victim was discharged. The full redacted IDI can be viewed under enclosure 1.

CPSC staff acquired the 17 magnets removed from the victim and measured the diameters and the flux densities in accordance with the procedures in ASTM F963-23, *Standard Consumer Safety Specification for Toy Safety,* section 8.25. The average diameter was 2.48 mm, and the average flux density was 3.10 kG. The flux indices were then calculated with an average of 46.38 kG<sup>2</sup> mm<sup>2</sup>, as shown in table 1, enclosure 2. All the magnets measured below the current limit of 50 kG<sup>2</sup> mm<sup>2</sup>.

Specifically, the Safety Standard for Magnets, 16 C.F.R. part 1262, specifies the following limit regarding magnet size and attractive force:

Each loose or separable magnet in a *subject magnet product* that fits entirely within the

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<sup>&</sup>lt;sup>1</sup> The views in this letter are those of the staff and have not been reviewed or approved by, and may not reflect the views of, the Commission.



cylinder described in <u>16 CFR 1501.4</u> must have a flux index of less than 50 kG<sup>2</sup> mm<sup>2</sup> when tested in accordance with the method described in § 1262.4.

16 C.F.R. § 1262.3. These requirements are identical to the requirements called out in ASTM F963-23.

In CPSC staff's briefing package supporting the Notice of Proposed Rulemaking (NPR) for the Safety Standard for Magnets,<sup>2</sup> staff discussed and requested public comments regarding the magnetic flux index limit and the test methodology, among other considerations. Staff raised concern that the limit might not be stringent enough to prevent internal interaction injuries.

CPSC testing of a small sample of subject magnet products suggests that magnets with a flux index lower than (*i.e.*, weaker than) 50 kG<sup>2</sup> mm<sup>2</sup> may be capable of causing internal interaction injuries, indicating that a flux index limit lower than 50 kG<sup>2</sup> mm<sup>2</sup> may be appropriate to address the internal interaction hazard; however, this testing did not provide conclusive evidence that magnets weaker than 50 kG<sup>2</sup> mm<sup>2</sup> present an internal interaction hazard.

For example, staff described a magnet internal interaction incident for which staff was unable to measure the exact magnets ingested, but did measure other magnets from the same set, and found the other magnets to be below the limit. In another example, staff described the perforation of a child's nasal septum by two 2.5 mm diameter, neodymium spherical magnets. In staff's testing of 2.5 mm diameter, neodymium spherical magnets to the flux index typically measures around 30 to 58 kG<sup>2</sup> mm<sup>2</sup>.

Given the available data at that time, and the long-standing international acceptance of the limit, 16 C.F.R. part 1262, *Safety Standard for Magnets*, ultimately specified the above limit.

Based on CPSC staff's testing of the incident magnets involved in IDI 210824CBB1805, staff is concerned that this incident demonstrates the 50 kG<sup>2</sup> mm<sup>2</sup> limit is insufficient to protect consumers from the magnet internal interaction hazard. As mentioned above, the flux indices of all involved magnets tested below the limit, and medical intervention was required for safe removal to prevent a painful injury possibly becoming more serious. Staff requests that ASTM schedule a meeting in the next two months to discuss the redacted IDI and consider a safer limit for magnet toys, which might also be relevant to other magnets subject to CPSC's Safety Standard for Magnets, 16 C.F.R. part 1262.

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<sup>&</sup>lt;sup>2</sup> See October 18, 2021, "Commission Briefing Package: Proposed Rule- Safety Standard for Magnets," via the URL: <u>https://www.cpsc.gov/s3fs-public/Proposed-Rule-Safety-Standard-for-Magnets.pdf?VersionId=2XizI5izY10vQRVazWpkqdJHXg5vzRY\_</u>.



Thank you for your continued work to revise and improve consumer product safety through ASTM F963 and F3458.

Sincerely,

Benjamin Mordecai

Benjamin Mordecai, Mechanical Engineer Project Manager, ASTM F963 Directorate for Laboratory Sciences

sHarsanyi

Stephen Harsanyi Engineering Psychologist, Directorate for Engineering Sciences

Cc: Molly Lynyak, ASTM F15 Staff Manager Don Mays, ASTM F15 Chair Jacqueline Campbell, CPSC Voluntary Standards Coordinator Daniel Taxier, Children's Program Manager

Enclosure(s):

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Enclosure 1

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1. Task Number		2. lı	nvestigator's ID								
210824CBB1805			9085		EPIDEMIOLOGIC						
3. Office Code	4. Date of Acc	ident 5. D	Date Initiated		INVESTIGATION						
800	YR MO D	AY	YR MO DAY		REPORT						
000	2021 06										
6. Synopsis of Accident or Complaint UPC On August 2021 a ten-year-old female intentionally swallowed 17 small, spherical magnets after her											
mother told her not to	b. The victim wa	as admitted to t	he hospital that da	ay, and disc	harged the ne	ext, after an					
upper endoscopy to r	etrieve the ma	gnets was unsu	uccessful and seria	al X-Rays sh	howed the ma	agnets					
progressing through	the victim's gas	stro-intestinal tra	act. On the evenin	g of August	: 🛄, 2021, the	e victim					
returned to the hospit	al with lower ri	ght quadrant pa	ain and was admit	ted the follo	wing day afte	r a CI-scan					
magnets were remov	ed using a bior	osv forcep durin	ng a colonoscopy (	on August	. 2021 and t	he victim was					
discharged later that	day.		.9		,						
**** Please see next page for addendum note information ****											
7. Location (Home, Scl	nool, etc)	8. C	City		9. State						
0 - UNKNOWN			UNKNOWN								
10A. First Product		10B. Trade/B	rand Name		10C. Model Number						
1345 - BUILDING	SETS				UNF	UNKNOWN					
10D. Manufacturer Na	me and Addres	S									
11A. Second Product		11B. Trade/B	rand Name	11C. Mo	del Number						
0		NONE		NON	NONE						
11D. Manufacturer Name and Address											
NONE											
12A. Hispanic or Latino 12B. Race					12C. Race S	12C. Race Source					
	Other:										
42. Are of Vistim	14 Cov		45 Dispessition	16 Iniury Diagnosia							
13. Age of Victim	14. Sex	nale	4 - Hospitaliz	ed (admitte	d 41 - Ingested F O						
17 Body Part(s)	18 Respor	dent	19 Type of Invest		20 Time Sn						
Involved	it. Respor	luent	15. Type of invest	ilgation	20. Time Sp (Operatio	onal / Travel)					
0 - INTERNAL	1 - Vict	im/Complainan	t 2 - Telephone	е	14.00	0.00					
21. Exhibit(s)	1. Exhibit(s) 22. Case S			23. S	Sample Collection Number						
9 - Multiple Exhibit	s			)							
24. Permission to Disclose Name (Non NEISS Cases Only)											
Yes	( No		Yes for Manuf.	Only	Verbal	<b>Written</b>					
25. Review Date	26. Reviewed	Ву	<u> </u>	- 27. Regiona	al Office Direc	tor					
09/30/2021	9093	-		Beverly	y J. Kohen						
28. Distribution				29. Source	Document Number						
Amelia Hairston-P	orter; Grace El	man; Madeleine	e Mietus; Michelle								
Guice; Stephen Ha	arsanyi										

IDI 210824CBB1805

On 10/ /2021, we processed the following addendum request.

To the 182, we added Sample to the Sample box (block 23) on the 182.

To the report narrative, we added the following under the "SAMPLE" heading: The incident magnets were collected and submitted under Sample Collection Report **Collection** after the investigation was completed.

We have completed this requested addendum.

Narrative

on

#### **INCIDENT SUMMARY**

8/ /2021 describing an incident involving a ten-year-old female who swallowed a chain of magnets. Efforts to reach the victim's parents were unsuccessful as they did not respond to outreach efforts, (see Exhibit 1). (NOTE: The complainant declined to provide the victim's parents' names or contact information citing privacy concerns; but stated that he would reach out to them and request that a parent contact the CPSC Investigator. No contact was ever made. Their names and contact information were located via Internet searches and outreach efforts were made, but no response was received.) As the victim's parents were not interviewed, most pre-incident, incident and additional information requested is unknown and post-incident information after the victim's discharge from the reporting hospital is unknown. The information contained in this report is based solely on information contained in the victim's medical records and on the limited information known and provided by the reporting doctor (see Exhibits 1, 3 and 4); as such, this investigation is being submitted as an abbreviated IDI.

### **INCIDENT PRODUCT IDENTIFICATION**

The incident product consisted of **Sector** spherical spherical magnets, each measuring approximately .2 X .2 X .2 cm. It is unknown where or when the magnet set was purchased or how many magnets were in the set. The Emergency Room doctor stated that the victim's mother reported that they had been packaged in a plastic box at the time of purchase.

Manufacturer:

*Model / Item #:* Unknown

Color:

UPC: Unknown

**NOTE:** There is a discrepancy regarding the brand of magnets involved in this incident as the Emergency Room doctor identified **and the set of the set of** 

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the victim's mother advised h	im that the original product packaging	g was discarded. It is
suspected, but could not be co	onfirmed, that	as they appear in
the victim's medical records a	re being used as a generic term to de	scribe small magnets and
not as a brand name. The ide	ntification of the involved magnets	in
this report is based on reporte	ed statements made by both the viction	m and the victim's mother to
the complainant which identif	ied the incident magnets	

## ADDITIONAL E-ASSIGNMENT QUESTIONS

The requested questions for this investigation are attached as Exhibit 2.

## PRE-INCIDENT

The 10-year-old female victim lives at home with her mother, father, a younger brother (age unknown) and an older sister (age unknown). The victim's medical records called out that the victim's father

history of anxiety, depression and aggressive behavior and was on fluoxetine, hydroxyzine, and melatonin, it was also noted that this history was deemed to be "non-contributing" to the subject incident.

Shortly prior to the incident the 10-year-old female victim had been disciplined by her mother (reason why unknown) and had been instructed by her mother not to swallow magnets. It is unclear if the victim was seen handling the magnets or what prompted the victim's mother to issue that specific instruction to the victim.

## **INCIDENT**

At approximately **and the set of the set of** 

## POST INCIDENT

The victim informed her mother that she had swallowed the magnets approximately three hours after the incident. The victim's mother immediately contacted the victim's primary care physician who advised her to take the victim to a local emergency room. The victim's mother transported the victim to a local emergency room where the first X-Ray taken revealed "15-17 magnets adhered in a chain in the proximal GI tract" (see Exhibit 4); the victim was subsequently transferred to the reporting hospital for further evaluation of the "foreign body ingestion". The medical records reviewed reveal that the victim arrived at, and was admitted to, the reporting hospital at **Context of Context of Co** 

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victim was "active", "not in acute distress" and that her bowel sounds were normal, there was no distension of the abdomen and there were no masses noted.

The first X-ray taken at the admitting hospital showed the presentation of the magnets essentially unchanged from the previous X-Ray in a "string-like pattern". At a number on August , 2021, the victim underwent an upper endoscopy to remove the incident magnets. The endoscopy was unsuccessful as the report notes that there was "no visualized foreign body" during the procedure; it was suspected that the magnets had moved farther down in the victim's gastro-intestinal tract. Hospital staff continued to monitor the victim, a series of X-Rays were taken which showed the magnets progressing through the victim's gastro-intestinal track and laxatives were administered to "clean-out" the victim's bowels. The final X-Ray taken during this admission notes "the progression of the magnets into likely the sigmoid colon", (see Exhibit 4). The victim was discharged to home at for a nugust 2021 in "stable clinical condition" without having passed the magnets. The victim's parents were advised to monitor the victim's stool for the magnets and to return in two days if the magnets had not yet passed. The victim's mother monitored the victim's stool for the magnets, but it is unclear if she sought further medical assistance within two-days as advised.

On the evening of August , 2021, the victim's mother brought the victim back to the local hospital emergency room as the victim was complaining of lower right quadrant pain in her abdomen. The local hospital took an X-Ray and, after determining the magnets were also presenting in the lower right quadrant of the victim's body, transferred her a second time to the reporting hospital. The victim was admitted to the reporting hospital on August 2021 after a CT-scan of the victim's pelvis with IV contrast, done under general anesthesia, showed "17 small magnets arranged in a ring adherent around fold of bowel in cecum" (see Exhibit 4).

The victim was admitted, laxatives were administered to the victim and hospital staff continued to monitor the victim. The victim's medical records note that she presented with no blood in the stool and that she was eating and drinking; the only complaint noted was the lower right quadrant pain. At **Section** on August **1**, 2021 the victim underwent a pediatric colonoscopy under general anesthesia to remove the magnets. The victim's medical records note that the incident magnets "were removed using a biopsy forcep w/o any difficulty", (see Exhibit 4). The victim was discharged, with instructions to follow-up with her primary care physician, at **1** on August **2** 2021 after an X-Ray of her abdomen, taken earlier that day at **1**, ruled out a retained foreign body post colonoscopy removal of the 17 magnets. It is unknown what further medical care, if any, the victim received as a result of this incident.

The complainant believes the incident magnets present a substantial hazard and would like to see all small magnet sets banned. The complainant opined and noted, "The continued manufacture, distribution, and sale of any rare-earth magnet sets products represents a reckless disregard for human health and life, and had a direct impact on our patient, who was

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Narrative

subjected to serial radiographs, upper endoscopy, and colonoscopy, and who was at risk for death from perforation of the gastrointestinal tract."

#### SAMPLE

The incident magnets will be available to collect from the pathology department of the involved hospital on a currently unknown future date. The magnets are currently being stored off-site and had to be requested to be returned to the involved pathology department to facilitate the sample collection, (see Exhibit 1).

Added by addendum on 10/2021: The incident magnets were collected and submitted under Sample Collection Report address after the investigation was completed.

#### **EXHIBITS**

Exhibit 1: Identification of Parties (5 pages) [EXCLUDED]

Exhibit 2: Additional E-Assignment Questions (3 pages)

Exhibit 3: Images received via text message from the complainant / **CONFIDENTIAL** (4 pages) [EXCLUDED]

Exhibit 4: Victim's Medical Records / CONFIDENTIAL (77 pages) [EXCLUDED]

# **Additional E-Assignment Questions**

**NOTE:** As attempts to reach the victim's parent were unsuccessful, the information contained in this Exhibit is based solely on information appearing in victim's medical records (see Exhibit 4) and from limited information known by the complainant doctor; as such, much of the requested information is unknown.

## 1. Acquire/verify background information

- What was the victim's age at the time of the incident? 10
- How many magnets were ingested? 17 Over what period of time? All at once
- What was/were the size(s) and shape(s) (*e.g.*, spheres, cubes) of the ingested magnet(s)?
  .2 X .2 X .2 cm spheres
- Where was the product usually stored? **Unknown** Were the magnets regularly kept in a container provided by the manufacturer? **Unknown**
- Who owned the magnet(s)? What was the owner's age? If it was purchased for a child under 14, did the caregiver (*e.g.*, parent) believe it was appropriate for the child? Why or why not? Was the caregiver aware of other children who had played with the product or similar products? Did the caregiver intend for others to have access to the product as well? **All Unknown**
- Prior to the incident, was the caregiver aware of any risks or dangers associated with the product? **Unknown** Specify what the caregiver knew and from what source(s).

### 2. Describe the ingestion scenario

- Where was the victim at the time of ingestion? **Unknown**
- What was the victim doing when s/he ingested the magnets (*e.g.*, playing, experimenting, mimicking piercings)? **Intentionally defying her mother.** Did the victim explain why they ingested the magnets (*e.g.*, intentional, accidental)? **Intentional.** Did they see this behavior online, in magazines, from friends, etc.? **Unknown**
- How did the victim acquire the magnets? Did the victim have a full set? Were the magnets in the manufacturer-provided container or packaging when the victim acquired the magnets? All Unknown
- Was the victim seen handling the product before the incident? Unknown
- How did the caregiver find out about the ingestion? The victim told her she had swallowed them. When? Approximately 2 <sup>1</sup>/<sub>2</sub>-3 hours after the incident. What actions were taken upon learning of the ingestion? The victim's mother called the victim's

#### primary care physician.

- 3. Describe the symptoms and treatment from discovery of the problem through resolution
  - Did the victim have symptoms after ingestion? Not immediately. Describe the symptoms, including the timeline of symptoms. The victim complained of lower right abdominal pain on day 5 after the ingestion which is what brought her back to the ER. Prior to day 5, the victim did not complain of any symptoms.
  - Did the caregiver contact medical professionals on behalf of the victim? If yes,
    - Was the caregiver aware that magnets were ingested prior to contacting medical professionals? Yes
    - How much time passed between ingestion of the magnet(s) and contacting medical professionals? 2 1/2-3 hours
    - How many visits did the victim make to medical professionals because of the magnet ingestion? **Unclear from the medical records received and reviewed.**
    - Was the victim hospitalized because of the magnet ingestion? Yes For how long?
      2 days, but not consecutively; the victim was admitted from 8/2/21-8/2/21
      and again from 8/2/21 to 8/2/21.
    - What did medical professionals do for the victim? Took serial X-Ray images to track the course of the magnets, did a CT of the pelvis with IV contrast under general anesthesia, attempted to "clean out" the bowels with the pelvis with the pel
  - Has the victim recovered? **Unknown** What was the length of time between ingestion and recovery? **6 days** Indicate if future treatment or follow-up is/was needed. **Unknown**
  - Did the caregiver or medical professionals initially misunderstand the cause of the symptoms? No. If yes, please specify, including any delays between the ingestion and correct diagnosis.

## 4. **Describe the product**

- What was the name of the product? **Unknown** Who was the manufacturer? What was the brand?
- How many magnets were in the product? **Unknown.** Did the consumer own multiple products/sets? **Unknown.**
- What size(s) and shape(s) (*e.g.*, spheres, cubes) were the magnet(s) in the product? **.2** X **.2** Cm spheres
- How was the product packaged (*e.g.*, pouch, tin, plastic box)? Plastic box. Were there instructions? **Unknown** Were there any warnings or age labels with the product? **Unknown** Please specify.

- Where was the product purchased, and in what section of the store/website (*e.g.*, toys, office supplies)? **Unknown.** If purchased online, give details about what the website looked like.
- Please also take note of the date of manufacture, date of purchase, model/serial numbers, cost, marketing, and any other information you can collect about the product. All unknown.

#### 5. Acquire pertinent documents and samples

- Obtain photos of the product and the incident sample including the package. Attached within Exhibit 3. If the hospital provided the ingested magnets, please advise the hospital that the magnets be placed in a plastic medical container and sealed with a medical evidence tape before transferring to CPSC. \*\*\*Sample Pending\*\*\*
- Obtain a copy of the purchase receipt or invoice if the victim's family still has it (if the magnets were online, the receipt is usually in the purchaser's email). Not available.
- Obtain medical records associated with the incident (*e.g.*, x-ray images, hospital records, surgeons' reports, photos). Obtain information on the location(s) of the ingested magnets prior to removal (*e.g.*, stomach, small intestine, large intestine, etc.) and details of any specific medical intervention procedures needed and any specific injuries incurred (*e.g.*, ulcers, perforations, twisted bowel (volvulus injury) and treatments needed (*e.g.*, bowel resection)). Medical records are appended as Exhibit 4.
- Obtain records of any reports the caregiver made to sources such as the manufacturer, retailer, CPSC, media, and the police. **Unknown.**



## Enclosure 2

Sub (#)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Magnet Color	Blue	Teal	Teal	Teal	Teal	Teal	Blue	Teal	Teal	Teal	Blue	Blue	Blue	Teal	Blue	Blue	Blue
Magnet Diameter (mm)	2.50	2.48	2.50	2.48	2.50	2.42	2.47	2.47	2.44	2.50	2.47	2.49	2.50	2.46	2.49	2.51	2.50
Magnet Pole Area (mm <sup>2</sup> )	4.91	4.83	4.91	4.83	4.91	4.60	4.79	4.79	4.67	4.91	4.79	4.87	4.91	4.75	4.87	4.95	4.91
Flux Density (kG)	3.08	3.11	3.17	3.04	3.12	3.14	3.17	3.09	3.17	3.11	3.14	2.98	3.09	3.01	3.03	3.04	3.17
Flux Index (kG <sup>2</sup> mm <sup>2</sup> )	46.54	46.70	49.30	44.62	47.76	45.33	48.13	45.73	46.96	47.45	47.22	43.22	46.85	43.04	44.68	45.71	49.30

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