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Международная организация по стандартизации

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Form 4: New Work Item Proposal

Circulation date: 2019-05-18 Closing date for voting: 2019-08-10	Reference number: NA (to be given by Central Secretariat)
Proposer (e.g. ISO member body or A liaison organization) SIS, Swedish Standards Institute	**ISO/TC** ☒ Proposal for a new PC
Secretariat SIS, Swedish Standards Institute	**N** Click here to enter text.

A proposal for a new work item within the scope of an existing committee shall be submitted to the secretariat of that committee with a copy to the Central Secretariat and, in the case of a subcommittee, a copy to the secretariat of the parent technical committee. Proposals not within the scope of an existing committee shall be submitted to the secretariat of the ISO Technical Management Board.

The proposer of a new work item may be a member body of ISO, the secretariat itself, another technical committee or subcommittee, an organization in liaison, the Technical Management Board or one of the advisory groups, or the Secretary-General.

The proposal will be circulated to the P-members of the technical committee or subcommittee for voting, and to the O-members for information.

IMPORTANT NOTE: Proposals without adequate justification risk rejection or referral to originator.
Guidelines for proposing and justifying a new work item are contained **in Annex C of the ISO/IEC Directives, Part 1.**

☒ The proposer has considered the guidance given in the Annex C during the preparation of the NP.

Proposal (to be completed by the proposer)

Title of the proposed deliverable.

English title:

Sex toys — Design and safety requirements for products in direct contact with genitalia, the anus, or both

French title (if available):

Click here to enter text.

(In the case of an amendment, revision or a new part of an existing document, show the reference number and current title)

Scope of the proposed deliverable.

This document specifies safety and user information requirements relating to the materials and design for products intended for sexual use.

This document covers only products that are intended to come in direct contact with genitals and/or the anus.

This document is not primarily intended for products classified as medical devices or assistive products.

Purpose and justification of the proposal*

Click here to enter text.

In a study published 2018 [1] Swedish researchers could see an increase in incidences of objects used for sexual pleasure retained in anus/rectum leading to severe surgical procedures. This finding was also supported by a systematic review based on available data which showed that the cases where patients require surgical extractions has increased across the world. This due the fact that objects used in the anus/rectum where not possible to remove the “natural way”. 40 percent of these objects where noted to be sex toys. However, the authors also suggested that the true figure of sex toy retention is likely even higher than the study suggests, given reluctance to seek care for a potentially embarrassing condition.

Sex toys are being produced, designed and sold globally, it is a global market with consumers across the globe. As there currently are no international standards or regulations specifically for these types of products, each manufacturer and retailer are free to make up their own test method and quality systems, at times based on standards and rules from documents with similar material or safety perspective, but not specific to the intended use of the actual product.

This proposed global standard intended for manufacturers, retailers, medical providers and consumers hopes to reduce incidences where sex toys do to misuse, or accidents cause unnecessary pain for users, save money for the health care sector and enables companies to show conformity. This by stating clear requirements for risk assessment, sufficient user information, outlining safety and quality requirements and providing recommended design considerations.

[1] Dahlberg, M., Nordberg, M., Pieniowski, E. et al. Int J Colorectal Dis (2019) 34: 181. https://doi.org/10.1007/s00384-018-3125-4

Consider the following: Is there a verified market need for the proposal? What problem does this standard solve? What value will the document bring to end-users? See Annex C of the ISO/IEC Directives part 1 for more information.

See the following guidance on justification statements on ISO Connect: https://connect.iso.org/pages/viewpage.action?pageId=27590861

Please select any UN Sustainable Development Goals (SDGs) that this deliverable will support. For more information on SDGs, please visit our website at www.iso.org/SDGs ."

☐ GOAL 1: No Poverty

☐ GOAL 2: Zero Hunger

☒ GOAL 3: Good Health and Well-being

☐ GOAL 4: Quality Education

☐ GOAL 5: Gender Equality

☐ GOAL 6: Clean Water and Sanitation

☐ GOAL 7: Affordable and Clean Energy

☐ GOAL 8: Decent Work and Economic Growth

☒ GOAL 9: Industry, Innovation and Infrastructure

☐ GOAL 10: Reduced Inequality

☐ GOAL 11: Sustainable Cities and Communities

☐ GOAL 12: Responsible Consumption and Production

☐ GOAL 13: Climate Action

☐ GOAL 14: Life Below Water

☐ GOAL 15: Life on Land

☐ GOAL 16: Peace and Justice Strong Institutions

N/A GOAL 17: Partnerships to achieve the Goal

Preparatory work (at a minimum an outline should be included with the proposal)

☒ A draft is attached ☐ An outline is attached ☐ An existing document to serve as initial basis

The proposer or the proposer's organization is prepared to undertake the preparatory work required:

☒ Yes ☐ No

If a draft is attached to this proposal,:

Please select from one of the following options (note that if no option is selected, the default will be the first option):

☐ Draft document will be registered as new project in the committee's work programme (stage 20.00)

☒ Draft document can be registered as a Working Draft (WD – stage 20.20)

☐ Draft document can be registered as a Committee Draft (CD – stage 30.00)

☐ Draft document can be registered as a Draft International Standard (DIS – stage 40.00)

☐ If the attached document is copyrighted or includes copyrighted content, the proposer confirms that copyright permission has been granted for ISO to use this content in compliance with clause 2.13 of the ISO/IEC Directives, Part 1 (see also the Declaration on copyright).

Is this a Management Systems Standard (MSS)?

☐ Yes ☒ No

NOTE: if Yes, the NP along with the Justification study (see Annex SL of the Consolidated ISO Supplement) must be sent to the MSS Task Force secretariat (tmb@iso.org) for approval before the NP ballot can be launched.

Indication(s) of the preferred type or types of deliverable(s) to be produced under the proposal.

☒ International Standard ☐ Technical Specification

☐ Publicly Available Specification

Proposed development track

☐ 18 months* ☐ 24 months ☒ 36 months ☐ 48 months

Note: Good project management is essential to meeting deadlines. A committee may be granted only one extension of up to 9 months for the total project duration (to be approved by the ISO/TMB).

***DIS ballot must be successfully completed within 13 months of the project's registration in order to be eligible for the direct publication process**

Draft project plan (as discussed with committee leadership)

Proposed date for first meeting: 2019-09-02 Stockholm

Dates for key milestones: DIS submission 2021-07-02

Publication 2022-07-02

Known patented items (see ISO/IEC Directives, Part 1 for important guidance)

☐ Yes ☒ No

If "Yes", provide full information as annex

Co-ordination of work: To the best of your knowledge, has this or a similar proposal been submitted to another standards development organization?

☐ Yes ☒ No

If "Yes", please specify which one(s):

Click here to enter text.

A statement from the proposer as to how the proposed work may relate to or impact on existing work, especially existing ISO and IEC deliverables. The proposer should explain how the work differs from apparently similar work, or explain how duplication and conflict will be minimized.

The proposal is specific to sex toys products which are not covered by regulation on medical devices or marketed as assistive products. There is no existing work for these products.

A listing of relevant existing documents at the international, regional and national levels.

Click here to enter text.

Please fill out the relevant parts of the table below to identify relevant affected stakeholder categories and how they will each benefit from or be impacted by the proposed deliverable(s).

	Benefits/impacts	**Examples of organizations/companies to be contacted**
Industry and commerce – large industry	Click here to enter text.	Click here to enter text.
Industry and commerce – SMEs	The proposed standard will give serious producers and retailers a tool to show conformity with a standard specific for their product, which may provide sales arguments and advantage in procurement.	Retailers, producers
Government	Many countries lack regulations of sex toys, this proposed standard can help authorities to regulate and increase quality for consumers. Reduced incidents will reduce cost for the public and private health care systems.	Consumer authorities
Consumers	The proposed standard will benefit consumers as it will be a useful tool for them to ensure the products have gone through a risk analysis and potential risks are mitigated.	Click here to enter text.
Labour	Click here to enter text.	Click here to enter text.
Academic and research bodies	Increased discussion and attention based on the work with this standard may lead to more research on the use of sex toys around the world. Today the research is very limited.	Click here to enter text.
Standards application businesses	Click here to enter text.	Click here to enter text.
Non-governmental organizations	Click here to enter text.	Click here to enter text.
Other (please specify)	Click here to enter text.	Click here to enter text.

Liaisons: A listing of relevant external international organizations or internal parties (other ISO and/or IEC committees) to be engaged as liaisons in the development of the deliverable(s). Liaison with ISO/TC 157 *Non-systemic contraceptives and STI barrier prophylactics*	**Joint/parallel work:** **Possible joint/parallel work with:** ☐ IEC (please specify committee ID) Click here to enter text. ☐ CEN (please specify committee ID) Click here to enter text. ☐ Other (please specify) Click here to enter text.
A listing of relevant countries which are not already P-members of the committee. Note: The committee secretary shall distribute this NP to the countries listed above to see if they wish to participate in this work	
Proposed Project Leader (name and e-mail address) Johan Arrhenius, ja@ticklervibes.com Click here to enter text.	**Name of the Proposer** (include contact information) Anna Sjögren, SIS, Swedish Standards Institute. Anna.sjogren@sis.se
This proposal will be developed by: ☐ An existing Working Group (please specify which one: Click here to enter text.) ☐ A new Working Group (title: Click here to enter text.) (Note: establishment of a new WG must be approved by committee resolution) ☐ The TC/SC directly ☒ To be determined	
Supplementary information relating to the proposal ☒ This proposal relates to a new ISO document; ☐ This proposal relates to the adoption as an active project of an item currently registered as a Preliminary Work Item; ☐ This proposal relates to the re-establishment of a cancelled project as an active project. Other: Click here to enter text.	

Maintenance agencies and registration authorities

☐ This proposal requires the service of a **maintenance agency**. If yes, please identify the potential candidate:
Click here to enter text.

☐ This proposal requires the service of a **registration authority**. If yes, please identify the potential candidate:
Click here to enter text.

NOTE: Selection and appointment of the MA or RA is subject to the procedure outlined in the ISO/IEC Directives, Annex G and Annex H, and the RA policy in the ISO Supplement, Annex SN.

☒ Annex(es) are included with this proposal (give details)

The draft

Additional information/questions

Click here to enter text.

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ISO #####-

ISO TC ###/SC ##/WG #

Secretariat: XXXX

Title Sex toys —Safety requirements for products in direct contact with genitalia, anus or both

WD/CD stage

Warning for WDs and CDs

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

To help you, this guide on writing standards was produced by the ISO/TMB and is available at https://www.iso.org/iso/how-to-write-standards.pdf

A model manuscript of a draft International Standard (known as "The Rice Model") is available at https://www.iso.org/iso/model_document-rice_model.pdf

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee *[or Project Committee]* ISO/TC *[or ISO/PC]* ###, *[name of committee]*, Subcommittee SC ##, *[name of subcommittee]*.

This second/third/… edition cancels and replaces the first/second/… edition (ISO #####:####), which has been technically revised.

The main changes compared to the previous edition are as follows:

— xxx xxxxxxx xxx xxxx

A list of all parts in the ISO ##### series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Sex toys are produced, marketed and sold in most countries in the world. They are a type of product that is in touch with physically sensitive parts of the body and is also a sensitive product for the user to report problems with. Creating an international standard for sex toys regarding design, materials and user information would help both user, producers and re-sellers to make sure that the sex toys on the market are safe to use and that the user has enough information on how to use them correctly.

This standard aims to ensure that the design of sex toys minimizes the risk of injuries to the user, that the materials are safe to use in contact with genitalia/anus or both, and also that there is sufficient and correct information provided to the user. In case incidents occur, due to misuse or inadequate design of sex toys this standard aims to facilitate safe removal of retained products by medical providers.

The requirements in this document are to be followed by manufactures of sex toys. However, all parties in the supply chain may benefit from using this document as guidance.

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Title Sex toys —Safety requirements for products in direct contact with genitalia, anus or both

1 Scope

This document specifies safety and user information requirements relating to the materials and design for products intended for sexual use.

This document covers only products that are intended to come in direct contact with genitals and/or the anus.

This document is not primarily intended for products classified as medical devices or assistive products.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

EN 55014-1 Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: Emission

EN 55014-2 Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 2: Immunity - Product family standard

IEC 60335-1 Household and similar electrical appliances - Safety - Part 1: General requirements

IEC 60335-2-29 Household and similar electrical appliances - Safety - Part 2-29: Particular requirements for battery chargers

ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

3 Terms and definitions

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

3.1 intended use
use for which a product is intended according to the specifications, instructions, and information provided by the manufacturer

Source: ISO 14971:2012 term 2.5 (modified)

3.2 risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO/IEC Guide 51:1999, definition 3.2]

3.3 manufacturer
a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured, or fully refurbished, and markets that device under its name or trademark;

Note to entry 1: Using a third party or subcontractor does not reduce the legal responsibilities of the manufacturer nor does it move legal responsibilities to the third party or subcontractor.

Note to entry 2: Importing a product constitutes the same legal responsibility as of a manufacturer.

4 General requirements for risk management

4.1 General

The safety of the product shall be assessed based on a risk analysis identifying potential risks associated with the intended use of the product, from the design phase until disposal of the product.

4.2 Risk analysis process

The manufacturer shall establish, document, and maintain throughout the life-cycle an ongoing process for identifying hazards associated with a sex toy, estimating and evaluating the associated risks, controlling these risks, and monitoring the effectiveness of the risk controls post market phase.

A risk management and analysis process can be part of the quality management system. That enables early detection of potential risks associated with the product, its intended use and foreseeable misuse.

NOTE: Recommended method for risk analysis is described in Annex A *Based on risk management standards ISO 14971 and others.*

4.3 Risk analysis

The manufacturer shall document any known or foreseeable hazards, or misuse associated with a sex toy. A risk estimation is performed for each hazardous situation identified. For each identified hazardous situation, the associated risk(s) shall be estimated using available information or data. For hazardous situations for which the probability of the occurrence of harm cannot be estimated, the possible consequences shall be listed for use in risk evaluation and risk control. The result of these activities shall be documented.

4.4 Risk analysis criteria

- Physical hazards
- Biocompatibility
- Biological (Micro biological evaluation)
- Use/Misuse
- Degradation of components
- User information
- Transportation/Storage
- Environmental hazards

This list is fundamental, however other criteria may be analysed by the manufacturer.

4.5 Risk mitigation

- Design

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- Production and process control
- User information (including labelling and instructions for use)

4.6 Post market control

The manufacturer shall establish, document and maintain a system to collect and periodically review information about the sex toy in the production and the post market phases. This enables the manufacturer to conduct field corrective actions on individual production batches, if required.

5 Design requirements

5.1 General

All products shall be designed based on the intended use. As an integrated part of the design process, requirement specifications and risk assessment procedures shall be conducted to prevent any harm or discomfort.

Especially products used on or in the anus, shall be designed so that the risk of retaining the product in the anal canal or rectum is minimized. If the product is inserted into the anus, methods of safely extracting it by the user is to be preferred over methods requiring medical expertise.

In case medical expertise is needed to extract retained objects or products, a common problem is that they cannot be grasped with fingers or instruments generally used for anal or rectal medical procedures.

Objects which are not small enough to pass like stool often need surgical attention. Medium sized objects are usually too large to be passed naturally but can be removed if possible to grasp. Large objects are usually difficult to remove because of the force required to extract them is considerable. A large object is also more likely to cause pressure ulceration and perforation of the bowel wall.

In this document small products are maximum 4 cm in length and in diameter no more than 2,5 cm.

Medium size products are maximum 12 cm in length and no more than 3,5 cm in diameter.

Large products are over 12 cm in length and over 3,5 cm in diameter.

5.2 Mechanical hazards

5.2.1 Prevention of retaining

A sex toy shall have sufficient mechanisms and design to prevent retaining in the vagina, anus, or rectum during its intended use or foreseeable misuse.

Manufactures shall make a risk assessment, including considering anatomical design consideration described in Annex B, to find appropriate means of mitigation of the risk of retention. This shall be confirmed by using, as appropriate, references to relevant clinical and/or scientific literature in addition to requirements in this standard.

Medium and large products shall have design features preventing them from being inserted further than intended.

Examples: anal plugs, anal beads, anal dildos

Medium and large products shall have design features making it possible to extract if retained.

Examples: Loops, strings, or accessible edges

5.2.2 Products for genital enclosure

A sex toy intended for enclosing genitals such as, penis ring, chastity devices, etc., shall be safely removable by the user. If genitals are trapped and the user unable to remove the device, the material strength (hardness) and the dimensions of the enclosing part shall allow safe removal with common household tools such as pliers. They shall not require the use of power tools for removal.

5.2.3 Moving and removable parts

If the product is designed with removable parts, these parts shall not be possible to remove without the use of a tool.

Example: sex machine with replaceable dildos

5.3 Vibration

Hazards and nuisance from vibration shall be assessed in the risk analysis.

Manufacturers shall evaluate any vibration from powered sex toys in the intended environment(s) of use.

NOTE: Manufacturers should consider standards relating to the effects of vibration, for example ISO 2631-1; ISO 5349-1; ISO 5349-2

If a product vibrates more than xxx (to be defined) manufactures shall include an automatic time limit or clearly state maximum time of duration.

5.4 Electrical safety

Any product with electrical power shall comply to the following standards EN 55014-1, EN 55014-2, IEC 60335-1, IEC 60335-2-29.

This includes the charging of the product as well.

5.4.1 Electrical stimulation

Products intended to stimulate genitals via electric impulses shall be risk assessed by qualified third party and deemed safe to use.

5.5 Surface temperature

The risk analysis shall identify hazards and evaluate the risks associated with the surface temperature of parts which can come into contact with human body during the intended use.

The maximum surface temperature should not exceed 41 C and shall never exceed 48 C.

If the product exceeds the limit it shall automatically turn off.

NOTE: ISO 13732-1 states thresholds for burn

5.6 Design requirements for products that transmit information

Any product that sends or receives information through wireless technology shall have a visual or audial indicator on the product showing when information is being received or transmitted.

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5.7 Design requirement for wireless remote controlled products

For any remote controlled product the unit that is in touch with the body shall have a clear and simple way to turn it off.

Add requirement on products using radio frequency.

5.8 Surfaces, corners, edges and protruding parts

If not required for the intended function of the product all accessible parts shall be smooth and be free from burrs and sharp edges.

6 Materials

6.1 General

Manufacturers should, whenever possible, use materials that can be recycled for further use and consider other environmental aspects of production, i.e. life-cycle-analysis.

6.2 Biocompatibility and toxicity

For any product or following a significant change to the formulation or manufacturing process, biocompatibility assessments shall be conducted.

The ready-to-use product shall be assessed for biocompatibility.

If the product is supplied with any lubricant, dressing material, or powder, these shall be assessed together with the product.

NOTE: Biocompatibility for medical devices is done in accordance with ISO 10993-1. This standard can be used as a guidance.

Sex toys are surface devices with repeated contact with mucosa and possibly compromised tissue surfaces. The tests shall indicate whether the device produces cytotoxicity, sensitization, or mucosal irritation. Evaluation for cytotoxicity according to ISO 10993-5.

Assessment for irritation and sensitization (delayed contact hypersensitivity) shall be conducted according to (refer to annex in new version of 10993-10 under development by ISO/TC 194/WG 8) The laboratory used for any testing shall comply with the requirements contained in ISO/IEC 17025.

The results shall be interpreted by a qualified toxicologist or any other appropriately qualified expert.

The biological assessment report shall justify that the product is safe for its intended use.

NOTE: It is recommended that the qualified expert is employed by or associated with the testing laboratory.

All data generated in these investigations shall be made available on request in a procurement process.

6.3 Cleaning and maintenance

The manufacturer shall inform the user about cleaning methods and means for the specific products, in accordance with the products intended use.

NOTE: Products intended for anal use require sufficient disinfection after use.

7 User information

7.1 General

User information shall include all information directed to the consumer.

Symbols may be used. If used these shall in correspondence with ISO 7000 (https://www.iso.org/obp/ui)

Marketing information shall be consistent with product information.

7.2 Content of user information on product

Information on the product shall include:

- Clear indication on how to turn the product on and off, if electrical powered
- Lot, batch or serial number, as far as possible, if not possible it shall be on the product package

7.3 Packaging

Information on the product packaging shall include:

- Description of product functionality and intended use, if not self-evident
- Specification of material intended to be in contact with genitalia, anus/rectum or both
- Information about battery and/or charging (if applicable)
- Contact information of the manufacturer, including name, visiting address, telephone and email
- Disposal instructions
- Compliance with this standard, if applicable
- Warnings on how to use or not to use, based on risk assessment

Example: Not for Internal Use/Not for Anal Use etc.

7.4 Additional user information

Information on or inside the product packaging shall include:

- Operating instructions (if applicable)
- Storage instructions
- Cleaning instructions
- Information about compatibility with other materials (lubricants, oils etc)
- Warranty information
- Guidelines/recommendations on maximum usage time/frequency (if applicable)
- Descriptions of physical symptoms when not to use/stop using (if applicable)
- Information on when not to use/consult with physician before using
- Information on when not to use the product

Example: material damage, malfunctioning product, product heating up etc.

- Handling of information transmitted by the product

Example: wireless products

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Annex A
(informative)

Risk analysis method

To be written.

Annex B
(informative)
Design considerations based on anatomy

B.1 Background to problem formulation

The following text is a literature review of data available and the background to why this standardization project emerged and base for the requirements mentioned in this document.

Retained foreign rectal objects can be a cause of emergency hospital admission and may require surgical removal. In addition to sometimes presenting a challenging surgical removal, foreign bodies can cause rectal or anal bleeding, and perforations of the rectum [1], and a classification scheme [2] of these injuries is presented below.

Category 1–Retained foreign body without injury,

Category 2–Non-perforative mucosal laceration,

Category 3–Sphincter injury

Category 4–Recto-sigmoid perforation

Bleeding, perforation, sphincter injury, and mucosal lacerations are managed by the examining physician with a number of techniques, but central to the management is the removal of the foreign body.

Common problems with retained objects are that they cannot be grasped by the medical service provider's fingers or by tools and instruments commonly used for anal or rectal medical procedures. Beyond manual retrieval under local anesthesia, with or without the aid of rigid tubes (anoscope/rectoscope) and forceps, obstetric instruments and vacuum delivery systems, endoscopic methods like flexible sigmoidoscopy/colonoscopy allow access to the entire large bowel and allow close inspection of damage once the foreign body is removed. The armamentarium for endoscopic techniques includes biopsy forceps (closed jaws usually fit in a 2 mm channel through the endoscope, open jaws are 3-7 mm) that can be used to grab, and snares and loops that can be put around objects.

Objects that are difficult to grab onto, i.e., not designed with loops, strings, or accessible edges, which are large enough to pass from the rectum to the sigmoid colon above, or which are too hard to grab with forceps, present challenges for removal. When objects can't be grasped from below, or if perforation of the bowel is suspected, a laparotomy (opening the abdomen through an incision) is sometimes required to evacuate the object or surgically repair the perforated bowel. The use of laparotomy is a last resort for removing objects, but is usually indicated if a perforation into the abdomen is suspected. A systematic review described 193 patients from 1950–2009, mostly from case reports3. The only large, register-based study (648 patients from Japan), reported that laparotomy was required in 15% of patients [4], whereas hospital-based case series report 0% to 50% (Table 1).

Table 1 - Hospital-based case series describing patients with transanally induced retained foreign rectal objects.

Author, year	Country	Time period	Number of patients	Number (%) extraction by transabdominal approach

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Barone 1976	USA	1970-1974	23	0 (0)
Crass 1981	USA	1975-1980	18	4 (22)
Barone 1983	USA	1978-1981	35	1 (3)
Nehme Kingsley 1985	USA	1976-1984	51	1 (2)
Yaman, 1993	Canada	1975-1990	22	0 (0)
Cohen, 1996	USA	1983-1994	48	5 (10)
Kouraklis, 1997	Greece	1981-1994	18	1 (6)
Ooi, 1998	Singapore	1989-1997	30	3 (10)
Biriukov, 2000	Russia	1969-1998	112	5 (4)
Ruiz, 2001	Spain	1980-2000	17	7 (41)
Huang 2003	Taiwan	1997-2000	12	4 (33)
Lake, 2004	USA	1993-2002	87	8 (9)
Clarke, 2005	South Africa	1995-	12	5 (42)
Ayantunde, 2006	UK	2001-2004	16	1 (6)
Rodriguez-Hermosa, 2007	Spain	1997-2004	16	2 (12)
Volpi, 2012	Italy	2007-2010	10	2 (20)
Coskun, 2013	Turkey	1999-2009	15	3 (20)

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Yildiz, 2013	Turkey	1998-2013	25	2 (8)
Cawich, 2017	Trinidad and Tobago	2009-2014	10	5 (50)
Dahlberg, 2018	Sweden	2009-2017	85	8 (9)

To aid in the discussion of sex toy designs and the potential risks in anal use, we present a classification based on the size of the object. This classification is a general guide based on the normal anatomy and physiology of the human anus and rectum.

B.2 Small

Small objects are those that should pass with normal bowel movement. Based on measurements of anal distension, where the passive sphincter stretching begins at 1 cm and increases to 65% of the maximal basal pressure at 3 cm anal distension [5], the dimension of these objects is length 4 cm and in diameter 2-2.5 cm [3].

The risk of perforation is low as pressure on adjacent tissue is low. The risk of sphincter injury must also be considered low.

In the classification above, small objects are mostly at risk of Category 1, i.e., risk of retaining without injury to the user.

B.3 Medium

Medium sized object is between 4 cm and 10-12 cm in their longest dimension. The upper limit for objects defined as medium size are those that risk entering the sigmoid colon from the rectum, as these objects do not fit the pelvis and there are not sufficient counterforces to prevent the object from ascending into the sigmoid colon or upper rectum (upper limit usually approximately 15 cm from the anal verge). Such objects have an increased risk of laparotomy. Objects shorter than approximately 10 cm can adapt a lie perpendicular to the anal canal, but are reached readily with the examiner's fingers, and if they can be grabbed are usually easily removed. With increasing width/thickness the objects become more difficult to control once above the anal canal, as they increasingly fill the lumen of the rectum. The risk of retaining is therefore considerable in the medium sized objects (Category 1), and mitigating design elements could be string or loops that enable endoscopic/rectoscopic evacuation or designs with a marked base or flare that makes inserting the object entirely more difficult.

The risk of perforation (Category 2 and possibly Category 4) in this group increases when the diameter is either small (e.g., leading point with a curvature less than 1 cm in diameter) or large (due to pressure on the intestinal wall). The risk of sphincter injury (Category 3) increases with increasing diameter. As damage to the anal sphincters has been seen in a significant subgroup (16%) upon dilation to 4 cm during medical procedures [4], a safe maximal diameter should not exceed 3-3.5 cm. This estimate is not precise: dilation under anesthesia without preserved pain reaction to dilation could increase the risk of sphincter damage compared with the setting of presumed arousal. There is a considerable disagreement between current (2019) sexual practice and this recommendation based on the available medical literature.

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B.4 Large

Large objects are longer than 12 cm, and the centre of the object will risk pivoting the object from a sacral lie into the abdomen (sigmoid lie). As objects in the rectum follow the basic tilt of the rectum, which is directed backward along the sacrum before turning forward and upward, linear objects beyond approximately 12 cm straighten the rectum upon being inserted, and risk ascending because they do not fit the sacral part of the rectum. As these objects are long enough to displace the intestinal wall and go into the abdominal part of the bowel, they are more difficult to manoeuvre with the rectoscope or endoscope. When such objects are also thick enough to fill the lumen of the intestine, they are difficult to grasp reliably. Exerting enough force through endoscopic instruments onto the object edge, combined with the need for a good hold makes extraction difficult. To prevent retaining, these objects need designs that prevent the object from being fully inserted into through the anus. Flares or large bases are required. The risk of perforation is significant in thick and long objects, as they assert pressure on the bowel wall, both on vigorous insertion and in prolonged retention. The risk of sphincter injury, as described for medium sized objects, increases with increasing diameter, and diameters in excess of 3.5 cm could put the user at risk.

Large objects can subject the user to all of the risks listed above (Category 1-4).

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