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

Sex toys — Exigences relatives à la conception et à la sécurité des produits destinés à être mis en contact direct avec les organes génitaux, l'anus ou les deux

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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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 Project Committee ISO/PC 325, *Sex Toys – Design and safety requirements for products in direct contact with genitalia, the anus or both.*

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. These products are in touch with physically sensitive parts of the body. It may be embarrassing for the users to report issues concerning these products. 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 document aims to ensure that the design of sex toys minimizes the risk of injuries to the user for reasonable and foreseeable use, that the materials are safe to use in contact with genitalia, the anus or both, and also that there is sufficient and correct information provided to the user.

The requirements in this document are intended for manufacturers of sex toys. However, all parties in the supply chain may benefit from using this document as guidance.

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

1 Scope

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

This document covers only manufactured 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, cosmetics or assistive products for example lubricants, massage oil.

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.

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

ISO 7010, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
sex toy
manufactured product intended for sexual stimulation or to enhance sexual pleasure

Note 1 to entry: Excluded: products classified as medical devices, cosmetics or assistive products; for example, lubricants, massage oil, intimate gels/sprays, and food supplements.

3.2
intended use
use for which a product is intended according to the specifications, instructions, and information provided by the *manufacturer* (3.4)

[SOURCE: ISO 14971:2019, 3.6 — modified, process and service deleted, alternative term deleted]

3.3
risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO/IEC Guide 51:2014, 3.9]

3.4
manufacturer
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 1 to entry: 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 2 to entry: Importing a product constitutes the same legal responsibility as of a manufacturer.

3.5
sharp edge
accessible edge of a *sex toy* (3.1) which presents an unreasonable risk of injury during *intended use* (3.2) and *reasonably foreseeable misuse* (3.6)

[SOURCE: ISO 8124-1:2018, 3.33 — modified, sex toy, intended and misuse updated, hazardous deleted]

3.6
reasonably foreseeable misuse
use of a product in a way not intended by the *manufacturer* (3.4) but which can result from readily predictable human behaviour

Note 1 to entry: Reasonably foreseeable misuse can be intentional or unintentional.

[SOURCE: ISO 14971:2019, 3.15 — modified, system deleted, note 1 to entry deleted]

3.7
foreseeable use
use of a product that is capable of being known or anticipated in advance based on a *manufacturer's* (3.4) best knowledge about the product

[SOURCE: ISO 10377:2013, 2.6 — modified, supplier's is changed to manufacturer's]

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.

The risk analysis process shall include:

— Risk assessment

— Documentation of the risk assessment

— Periodical review

— Post market control

Guidance on risk analysis is described in Annex A.

4.2 Risk analysis process

The manufacturer shall establish, document, and maintain throughout the product's lifecycle 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 in the post-market phase.

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

4.3 Risk assessment

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.

Each risk evaluation shall be reviewed periodically, based on user feedback, post-market surveillance and new scientific literature. Any modification or change to the product requires a new risk evaluation.

The manufacturer shall ensure that the person or team performing the risk assessment are competent to do so.

4.4 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.

Continuous assessment of product safety can be done via customer feedback. The data can be used to further improve the products, relating to, for example material and design safety.

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.

NOTE Design includes all aspects of the product including, shape, size, materials, packaging, and user information.

5.1.1 Anal use products

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. They shall be designed with considerations based on the normal anatomy and physiology of the human anus and rectum. See Annex B for guidance.

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.

NOTE 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.

5.2 Mechanical hazards

5.2.1 Prevention of retention

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

5.2.1.1 Anal use products

A sex toy shall have sufficient mechanisms and design features to prevent them from being inserted further than intended to prevent retention in the anus or rectum during its intended use. The effectiveness of these design features shall be tested and documented. The flexibility of the product and the base-to-neck ratio should be considered.

EXAMPLE 1 Anal plugs, anal beads, anal dildos.

Medium and large products shall have design features making it possible for medical professionals to extract if retained, by using tools and instruments commonly used for medical procedures. See Table B.2.

EXAMPLE 2 Loops, strings, or accessible edges.

5.2.1.2 Non-anal use products

Sex toys not intended for anal use, but which can be misused as such, shall have clear information in the user information of the intended purpose and how not to use the product.

Manufacturers should consider adding design features making retrieval possible for foreseeable anal retention.

5.2.2 Products for genital enclosure

A sex toy intended for enclosing genitals for example, penile rigidity 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 which may pose a risk when not properly fixed it shall have a locking mechanism which ensures that the parts stay in place during use and are only released when unlocked.

EXAMPLE Sex machine with replaceable dildos, battery compartments.

5.3 Vibration

Hazards to the user 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.

Mains powered products shall include an automatic time limit or clearly state maximum time of duration of use.

NOTE Manufacturers can consider standards relating to the effects of vibration, for example ISO 5349-1, ISO 5349-2, ISO 20643.

5.4 Electrical safety

The manufacturer shall consider the electrical safety of the product during the design phase, based on intended use and reasonably foreseeable misuse.

This includes the charger and charging of the product.

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.

NOTE A qualified third party can be a certified laboratory.

5.5 Surface temperature

For products with surface heating features, the risk analysis shall identify hazards and evaluate the risks associated with the surface temperature of parts which come into contact with the human body during the intended use.

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

NOTE ISO 13732-1 states thresholds for burn.

The heating element shall be designed so it automatically turns off before the temperature of the surface exceeds 48 °C, taking into account temperature inertia.

The manufacturer should take into account a reasonable ambient temperature up to 30 °C and if the product is intended to be used internally or externally.

5.6 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.

5.7 Surfaces, corners, edges, and protruding parts

If not required for the intended function of the product, all accessible parts intended to be in contact with genitalia, the anus, or both shall be smooth and be free from burrs and sharp edges.

NOTE See ISO 8124-1:2018,4.6, 4.7, 5.8, 5.9, E.11 for information.

6 Materials

6.1 General

Manufacturers should consider environmental aspects of materials used and production methods without compromising the user's safety.

6.2 Material safety

The manufacturer shall make sure that no chemicals in quantities known to be harmful for the user are used in the products.

The manufacturer shall establish a Restricted Substance List (RSL) including limits of substances that shall not be present in the materials that come into contact with mucosa.

The manufacturer should establish, implement, and maintain a procedure to identify the applicable laws and regulations of the countries where the products are manufactured, imported, distributed and sold, in order to ensure that applicable legal requirements are taken into account.

See Annex C for guidance on creating a Restricted Substance List.

All material safety information shall be made available during a procurement process.

6.3 Biocompatibility

Sex toys are products with repeated contact with mucosa and possibly compromised tissue. Manufacturers shall make sure that the materials, that come into contact with mucosa during intended use are biocompatible.

For sex toys, only in vitro methods shall be used.

NOTE There are different ways to make sure that materials are biocompatible. For example, one way can be to test the finished product according to the ISO 10993 series. The most relevant parts for sex toys of the ISO 10993 series are ISO 10993-5, ISO 10993-10 Annex C[1)], and ISO 10993-23 Clause 6. Another way can be to use only materials, including additives and colouring have been tested according to that series or food contact approved.

Testing shall be done by an accredited laboratory. The laboratory shall conform with the requirements in ISO/IEC 17025. The results shall be interpreted by a toxicologist or another qualified expert.

6.4 Cleaning and maintenance

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

7 User information

7.1 General

User information shall include all information directed to the consumer.

Symbols may be used. If relating to the safe use of the product these shall be in correspondence with ISO 7000 or ISO 7010 (https://www.iso.org/obp/ui).

Marketing information shall be consistent with product information.

The distributor should ensure that the consumer information is available in a language understood by the users.

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 electrically powered

— Lot, batch, or serial number, as far as possible, or if this is not possible it shall be on the product package

7.3 Packaging

Information on the product packaging shall at least include:

— Description of product functionality and intended use

— Specification of material intended to be in contact with genitalia, anus/rectum, or both

— State or use symbol “Contains natural rubber latex” (if applicable)

— Information about battery and/or charging (if applicable)

— Information on what is included or needed items which are excluded

1) Under preparation. Stage at the time of publication: ISO/FDIS 10993-10.

EXAMPLE 1 Battery, adapter, charging equipment, lubricants.

— Compliance with this document, if applicable

— If the product is not intended for internal or anal use it shall be stated on the packaging

EXAMPLE 2 Not for Internal Use/Not for Anal Use.

7.4 Additional user information

Information on or inside the product packaging shall at least include:

— Operating instructions

— Storage instructions

— Cleaning instructions

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

— Contact information of the manufacturer which shall include name, postal address, and may include website and email

— Information about compatibility with other materials (lubricants, oils, etc.)

— Warranty information

— Disposal instructions

— 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 1 Material damage, malfunctioning product, product heating up etc.

— Handling of information transmitted by the product

EXAMPLE 2 Wireless products.

— Recommendation to keep the user information for reference

Annex A
(informative)

Guidance on risk management

A.1 General

The following checklist is intended to help the manufacturer to identify risks and evaluate them, in order to make a safe product.

There are other standards and guidelines that go into more detail regarding risk management. The manufacturer is encouraged to study them. For example: ISO 14791, ISO 31000, ISO 10377, EU general risk assessment methodology.

A.2 Risk assessment phases and steps

Table A.1 — Risk assessment phases and steps

Risk assessment phases	Risk assessment steps
a) Risk identification	1. Defining the product 2. Identifying the hazard(s)
b) Risk analysis	3. Describing how the hazard may harm the user(s) 4. Describing the potential harm
c) Risk evaluation	5. Determining the severity of harm 6. Determining the probability of occurrence 7. Determining the risk level by combining the severity of harm and the probability of occurrence

A.2.1 Interpretation of risk assessment steps

1. Defining the product – key features e.g. the intended use, the material, shape and geometry
2. Identifying the hazard(s) – see Table A.2 in A.3, literature review and consulting experts
3. Describing how the hazard may harm the user(s) – consider different scenarios both for intended use and reasonably foreseeable misuse
4. Describing the potential harm – describe what harm the hazard may cause based on studies, reports, literature and expert opinions, and input from market surveillance
5. Determining the severity of harm – based on results from b) 3 and b) 4 in Table A.1 make an estimation:

— High – severe injury, permanent disability, or disease

— Medium – injury which requires medical treatment

— Low – discomfort, no injury or health issue

6. Determining the probability of occurrence:

— Very high – more likely to occur than not

EXAMPLE 1 User placing the batteries in the wrong polarity or user not reading user information.

— Medium high – the event will be expected to occur sometimes

EXAMPLE 2 Use of incompatible lubricant or cleaning agent.

— Medium low – the event may occur sometimes

EXAMPLE 3 Misuse of clitoral bullet vibrator for anal use or unable to remove penile rigidity ring.

— Low – little or no chance of occurrence

7. Determining the risk level by combining the severity of harm and the probability of occurrence, see Table A.3 Risk evaluation matrix in A.4

A.3 Risk analysis checklist for potential hazards

The following questions and categories should always be considered when doing a risk analysis. The manufacturer is responsible for the comprehensive risk analysis based on the product and its intended use.

The list below can be used as guidelines for consideration. The list is not comprehensive.

Table A.2 — Checklist for potential hazards

General criteria	What are the reasonably foreseeable hazards and misuse? Is the reasonably foreseeable misuse of the product documented? Is the intended use of the product documented?
Physical hazards	Is there a risk of retention in intended or unintended orifice? Are there any sharp edges? Is there a risk of trapping or pinching? Risk of excessive vibration? Risk of using products not intended for anal use for anal use? Risk of overheating? Are there any other physical hazards?
Removable parts	Are there any removable parts that can be hazardous? Loss of critical components?
Biocompatibility	Risk for skin irritation and sensitization? Risk of contamination? Risk of leaching harmful substances? Does the product contain natural rubber latex or other known allergens?
Biological (Microbiological) evaluation	Are there any risks of pathogen contamination throughout supply chain? Are the cleaning and maintenance instructions complete and clear? Are risk associated with sharing a product communicated?

Table A.2 *(continued)*

Degradation of components	Are the materials compatible with the intended use of the product? Are there risks associated with degradation of the material? Are there risks associated with wear and tear of components?
User information	Are the warnings complete? Are identified risks communicated in the user information?
Transportation/Storage	Is transportation and storage conditions appropriate for each product?

A.4 Risk evaluation

For every identified risk there needs to be an evaluation. The table below can be used to categorize the risks.

Table A.3 — Risk evaluation matrix

		Probability of occurrence			
		High	**Medium high**	**Medium low**	**Low**
Severity of harm	**High**	Risk level - Very high	Risk level - Very high	Risk level - High	Risk level - Moderate
	Medium	Risk level - High	Risk level - Moderate	Risk level - Moderate	Risk level - Low
	Low	Risk level - Low	Risk level - Low	Risk level - Low	Risk level - Low

Each risk evaluation should be reviewed periodically, based on user feedback, post-market surveillance and new scientific literature. Any modification or change to the product will require a new risk evaluation.

The manufacturer should identify the warning signs and risk symptoms which indicate that the risk has occurred or will occur.

A.4.1 Risk level assessment

After determining the probability of occurrence and severity of harm, the risk should be assigned to a risk level. The risk levels should be assessed according to the principles below.

— Very high is totally unacceptable. The product should not be placed on the market in the current design.

— High is not acceptable, and the product should be redesigned.

— Moderate risks should be mitigated by redesign and/or warnings in user information.

— Low is acceptable.

The manufacturer should carry out risk mitigation action(s) (e.g. redesign, user warning, supply chain control, change of raw material) to ensure the revaluated risk level is low and minimized as far as possible.

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 is the base for some of the requirements listed 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 anaesthesia, 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 mm to 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 in the years 1950–2009, mostly from case reports [3]. 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 B.1).

Table B.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
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)
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. The classification in Table B.2 is a general guide based on the normal anatomy and physiology of the human anus and rectum.

Table B.2 — Product size classification

	Small	Medium	Large
Total length	≤ 4 cm	≤ 12 cm	> 12 cm
Diameter	≤ 2,5 cm at widest insertable point	≤ 3,5 cm at widest insertable point	> 3,5 cm at widest insertable point

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 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.

NOTE If a product doesn't fit into any of the 3 proposed size categories, the largest dimension will be considered to classify the size of the toy (e.g. a toy having a 4 cm diameter and 10 cm length will be classified as size large).

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 cm to 2,5 cm [3].

The risk of perforation is low as pressure on adjacent tissue is low. The risk of sphincter injury is also 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 to 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 position 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 cm to 3,5 cm. This estimate is not precise: dilation under anaesthesia without preserved pain reaction to dilation could increase the risk of sphincter damage compared with the setting of consensual sexual arousal. There is a considerable disagreement between current (2019) sexual practice and this recommendation based on the available medical literature.

B.4 Large

Large objects are longer than 12 cm, and the centre of the object will risk pivoting the object from a position by the sacrum into the abdomen (sigmoid position). 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).