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First Edition

# DRAFT TANZANIA STANDARD

## Textiles – Menstrual Tampons — Specification

Draft for Stakeholders' comments

DRAFT TANZANIA STANDARD

## Foreword

This Draft Tanzania Standard lays down basic requirements for menstrual tampons in order to assist the manufacturers to produce goods of defined quality and help in safe – guarding health and interests of consumers.

This Draft Tanzania Standard specifies materials, performance test for absorptive capacity, the strength of withdrawal cord, a microbial count to detect possible contamination during manufacture, instructions for hygienic use, and information about Toxic shock syndrome (TSS) and its warning symptoms.

During the preparation of this Draft Tanzania Standard, reference was made to the following document.

*KS 1534: 2000 - Specification for menstrual tampons.*

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## 1. Scope

This Draft Tanzania Standard specifies requirements and test methods for scented, scented deodorized, non-scented and non-scented deodorized menstrual tampons.

## 2. Normative references

The following referenced documents are indispensable for the application 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.

TZS 26, Textiles — Determination of conductivity, pH, water soluble matter, chloride and sulphate in aqueous extracts.
TZS 278, Textiles – Absorbent cotton gauze – Specifications.
TZS 279 - EAS 96, Sanitary towels — Specification.
TZS 1823 - ISO 21149, Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria.
TZS 1825, Cosmetics — Microbiology — Detection of Escherichia coli.
TZS 1826 - ISO 22717, Cosmetics — Microbiology — Detection of pseudomonas aeruginosa.
TZS 1827 - ISO 22718, Cosmetics — Microbiology — Detection of staphylococcus aureus.
TZS 1830 - ISO 18416, Cosmetics — Microbiology — Detection of candida albicans.
ISO 10993, Biological evaluation of medical Device Part 10: Test for irritation and sensitization.

## 3. Terms and definitions

For the purposes of this Draft Tanzania Standard, the following definitions shall apply.

### 3.1 aseptic technique

The exercise of special procedures for maintaining sterility of equipment, media and suchlike, or the purity of cultures by eliminating adventitious contamination and for protecting the operator and environment.

### 3.2 batch

Quantity of tampons which, as far as practicable, consists of material or items of single type, grade, class, absorptive capacity and composition, and which has been manufactured under essentially the same conditions in a specified period of time.

### 3.3 contamination

The undesirable transfer of organisms from one person, material or environment to another.

### 3.4 disinfectant

An agent that is used for disinfection.

### 3.5 disinfection

A process intended to kill or remove micro-organisms, but which cannot usually kill bacterial spores

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**3.6 menstrual tampon**

A product made of permissible materials (see 5.1) that is inserted into the vagina and used to absorb menstrual discharge

**3.7 Scented or scented deodorized Menstrual Tampon**

**a Tampon which** has scent (i.e., fragrance materials) added for aesthetic purposes (scented menstrual tampon) or for deodorizing purposes (scented deodorized menstrual tampon). This generic type of device includes sterile scented menstrual Tampon used for medically indicated conditions, but does not include menstrual tampon treated with added antimicrobial agents or other drugs.

**3.8** Unscented or unscented deodorized Menstrual Tampon

**a Tampon which** has no scent i.e., fragrance materials (unscented menstrual tampon) or may contain deodorized material for deodorizing purposes (unscented deodorized menstrual tampon). This generic type of device includes sterile unscented menstrual Tampon used for medically indicated conditions, but does not include menstrual tampon treated with added antimicrobial agents or other drugs.

**3.9 unit pack**

The pack enclosing a single tampon and applicator, where provided.

**3.10 primary pack**

The pack containing one or more unit packs.

**3.11 supply pack**

The pack that is supplied to the consumer. It may be the primary pack, or contain one or more primary packs.

**3.12 transport pack**

The pack intended for transportation of one or more supply packs.

**3.13 sterilization**

A process that is intended to kill or remove all types of micro-organisms; with an acceptably low probability of a micro-organism surviving on any article.

Note 1: Throughout this standard, the term “tampon” is to be taken to mean “menstrual tampon”.

## 4. Materials

### 4.1 Permissible materials

Tampons shall be manufactured from cellulosic materials (such as cotton and viscose rayon), or synthetic textile polymers, either singly or in combination, provided that adequate testing does not demonstrate a hazard. Polyester foam shall be not used. Carboxy-methylcellulose (CMC) shall be not added to tampons.

Note 2: Although in-vitro studies have indicated that polyester foam and not CMC may be responsible for enhancing the production of TSST-1 toxin under certain test conditions, high absorbency per se has been implicated in some epidemiological studies. It was therefore decided to prohibit the use of polyester foam, and to prohibit the addition of CMC to tampons. This requirement is in recognition of the fact that, although naturally occurring low background

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levels may be present, CMC is not added to tampons as there are consumer concern about this substance. Concern has also been expressed about acrylate modified rayons. Where such materials are used, evidence is required that no demonstrable hazard exists.

### 4.2 Freedom from toxic and irritant effect

Tampons shall not contain ingredients in sufficient concentration to cause a toxic or irritant reaction when used as directed. This can be tested in accordance to ISO 10993 -10

### 4.3 Freedom from impurities

No foreign matter shall be evident when the material is visually inspected.

### 4.4 Ether soluble substances

#### 4.4.1 Requirement

When the tampon material, excluding the withdrawal cord, is tested in accordance with TZS 278 with diethyl ether as solvent, and two 5 g samples as described in 4.4.2, the material shall contain less than 0.5% soluble substances.

#### 4.4.2 Test specimen

Prepare the test specimen as follows:

a) Avoiding contamination, tear two or more tampons apart, removing the withdrawal cord from the body of the tampon. This may require the use of a cutting device as some tampons have the withdrawal cord sewn to the body of the tampon.

b) Remove sufficient fibrous material to make up a pooled specimen of mass approximately 5 g.

**4.5** The manufacturer should declare the type of the tampon and if scented or uncented deodorized and the chemicals, scent or fragrance used.

## 5. REQUIREMENTS

The requirements of the Tampon shall be as specified in Table 1

### 5.1 Length of withdrawal cord

The length of the withdrawal cord hanging free from the tampon shall be not less than 80 mm.

### 5.2 Applicator

The applicator, where provided, shall be smooth and designed to minimize risk of trauma.

### 5.3 Absorptive capacity

Each batch of tampons shall be classified into one of the absorbency ranges given in Table 1.

When tested in accordance with Annex A, the classified absorbency range for a batch of tampons shall be the range into which at least 90 per cent of the estimated population of that batch fall.

### 5.4 Pull strength of withdrawal cord and its attachment point

When tested in accordance with the method described in Annex B, the pull strength of the withdrawal cord and its attachment point shall be such that the mean force required to break or detach the cord shall not be less than 28 N. No value for an individual cord shall be less than 22.4 N.

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### 5.5 Water repellency of withdrawal cord

When tested in accordance with Annex C, the withdrawal cord shall not sink completely beneath the surface of the water.

### 5.6 Microbiological requirements

#### 5.6.1 Microbial content

The microbiological limits for Tampons shall be as given in Table 2 when tested in accordance with the test methods prescribed therein.

## 6. PACKAGING

Packaging of the tampon shall comply with the following requirements:

a) Each tampon shall be packed in a closed unit pack capable of maintaining product quality until opened by the consumer.

b) The unit pack shall be packed in a primary pack, which is sufficiently robust to protect the tampons against damage during normal transport and normal storage. The primary pack shall be designed, overwrapped or sealed, so that tampering can be easily detected.

c) The primary pack shall contain an information leaflet in accordance with Clause 8.

## 7. MARKING

Each Primary packs shall be permanently and legibly marked with the following information:

a) Name of the product;

b) Name and address of the manufacturer/Trade mark;

c) Country of origin;

d) the batch number of the tampons which may be immediately preceded by the words “Batch No.”, “Lot No.” or by words or symbols having a similar meaning;

e) The word scented, scented deodorized, unscented or unscented deodorized menstrual tampon

f) The tampons shall be labelled appropriate to the absorbency range e.g. “approximately 11 g absorbency, suitable for medium flow.

g) Tampon instructions for use
   - insertion/ removal instructions,
   - Limit of wear time, - it shall not be worn for more than eight hours.
   - Disposal sign,

h) The following warning in letters having height of not less than 1.0 mm, with the word "IMPORTANT" in capitals,

   **IMPORTANT** Tampon use has been associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and keep the enclosed information.

## 8. INFORMATION LEAFLET

A leaflet containing the following information shall be enclosed in each primary pack:

a) detailed instructions for use including the need for hygiene and care in insertion;

b) information about Toxic Shock Syndrome;

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c) the wording of the information on TSS shall be acceptable to the relevant regulatory authority in the country of supply.

Note 4: an example of wording that was regarded as suitable for inclusion on the leaflet is given in Annex E.

**Table 1 – Performance requirements for Tampons**

| SN | Characteristics | Requirement | Test Method |
|---|---|---|---|
| 1 | Length of withdrawal cord, min | 80mm | Measure by ruler TZS 44 |
| 2 | Pull strength of withdrawal cord and its attachment point | | |
| | i) mean force required to break or detach the cord, N, min | 28 | Annex B |
| | ii) value for an individual cord, N, min | 22.4 | |
| 3 | Absorptivity capacity (absorbency range) | | Annex A |
| | i) 12-16 | Approximately 14 g absorbency Suitable for heavy flow | |
| | ii) 9-13 | Approximately 11 g absorbency Suitable for medium flow | |
| | iii) 6-10 | Approximately 6 g absorbency Suitable for light flow | |
| 4 | pH value….. | 5.5 – 8.5 | TZS 26 |
| 5 | Quantity ( Number of pieces) | As declared | Visual |

**Table 2 – Microbiological limits for Menstrual Tampon**

| S/N | Quality | Requirement, cfu/g | Test method |
|---|---|---|---|
| 1 | Total viable count | <10 | TZS 1823 |
| 2 | *Pseudomonas Aeruginosa* | No detectable per gram of sample | TZS 1826 |
| 3 | *Staphylococcus Aureus* | <10 | TZS 1827 |
| 4 | *Candida Albicans* | No detectable per gram of sample | TZS 1830 |
| 5 | *Escherichia Coli* | No detectable per gram of sample | TZS 1825 |

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# Annex A
# (normative)
# Method for measuring absorptive capacity

## A.1 Scope

This annex sets out a method for measuring the absorptive capacity of a tampon under counter pressure.

## A.2 Principle

A tampon of known mass is inserted into an artificial vagina (syngina) and allowed to take up water until saturated. It is then removed and its mass is again determined.

## A.3 Apparatus

The following apparatus is required:

a) syngina capable of exerting a controlled pressure of 2 kPa above atmosphere (see Note and Clause A.4);

Note 5: The pressure of the human vagina in the rest position amounts to about 1.35 kPa to 2.70 kPa irrespective of filling rate. The constant pressure used in this test is the mean value.

b) pair of tongs;

c) glass stirring rod;

d) balance accurate to 0.01 g;

e) condom of the appropriate length, width, and thickness. The condom shall not contain silicone oil lubricant as this may alter the absorption properties of the tampon. Condoms that are unlubricated or that contain corn starch powder shall be used;

f) burette;

g) funnel.

**A.4 Description of operation of syngina** (see Figures A.1 and A.2)

Air pressure of the incoming air is reduced to about 100 kPa before proceeding via throttle valve (1) to the Tpiece (2). At this point it will be further reduced in accordance with the lower edge of the immersion pipe (3) and the filling level ($h_1$) of the water level container (4).

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This controlled pressure acts on the three-way cock (22) and the syngina (8) and on the surface of the liquid in the water level container (4). Pressure on the liquid in (14) causes it to rise in the riser pipe (15) to a height $h_2$ (equal to *h),* which can be read on the scale (16). Thus the pressure acting on the condom and hence the tampon can be read from this scale.

This pressure can be increased by opening inlet (5) and allowing water to flow into container (4) thereby increasing height $h_1$. Alternatively, pressure can be reduced by opening outlet (6) and allowing water to flow from container (4) thereby decreasing height $h_1$. Pressure relief is realized via the three-way cock (22) by turning it appropriately.

## A.5 Test specimens

Select the required number of tampons at random from one homogeneous batch for use in this procedure. Should a test be invalid in accordance with Clause A.8, draw the necessary additional tampons from the same batch at random to complete the required number of valid tests.

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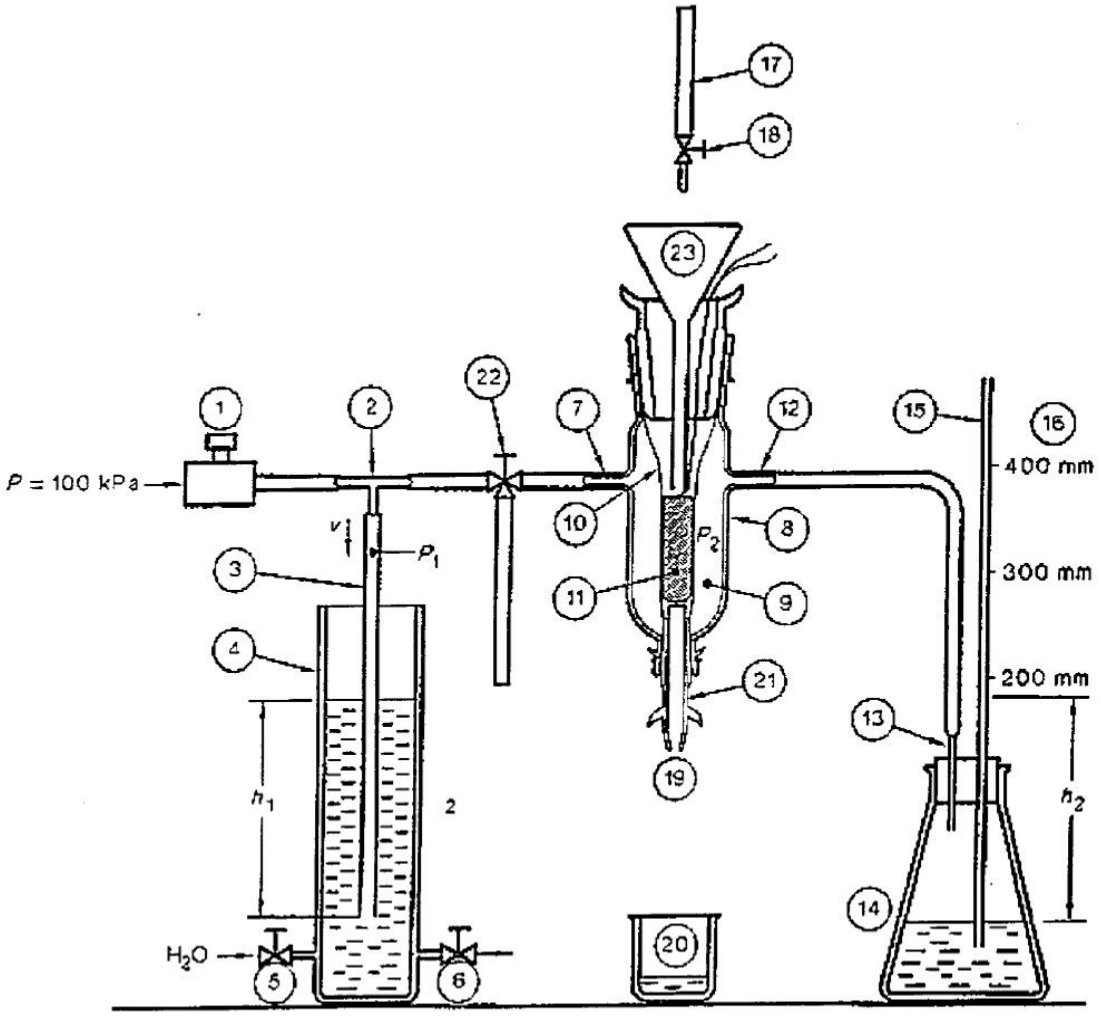


**Fig A.1 – Typical Syngina and test apparatus.**

**KEY**

1- Viable throttle valve for regulation of the overflow speed 'V '.
2- T – piece.
3- Immersion for producing the test pressure p.
4- Water level container.
5- Inlet cock - for adjustment for the;
6- Outlet cock – Immersion depth.
7- Connection to the Syngina.
8- Syngina.
9- Space with pressure $P_2$ act on 10;
10- Condom contracts around tampon (11);
11- Tampon to be tested.
12- Outlet pipe.
13- Connection to the level container.
14- Level container.
15- Riser pipe.
16- Scale.
17- Burette.
18- Burette cock.
19- Overflow opening of the Syngina.
20- Glass beaker.
21- Support pipe.
22- Three-way cock.
23- Funnel.

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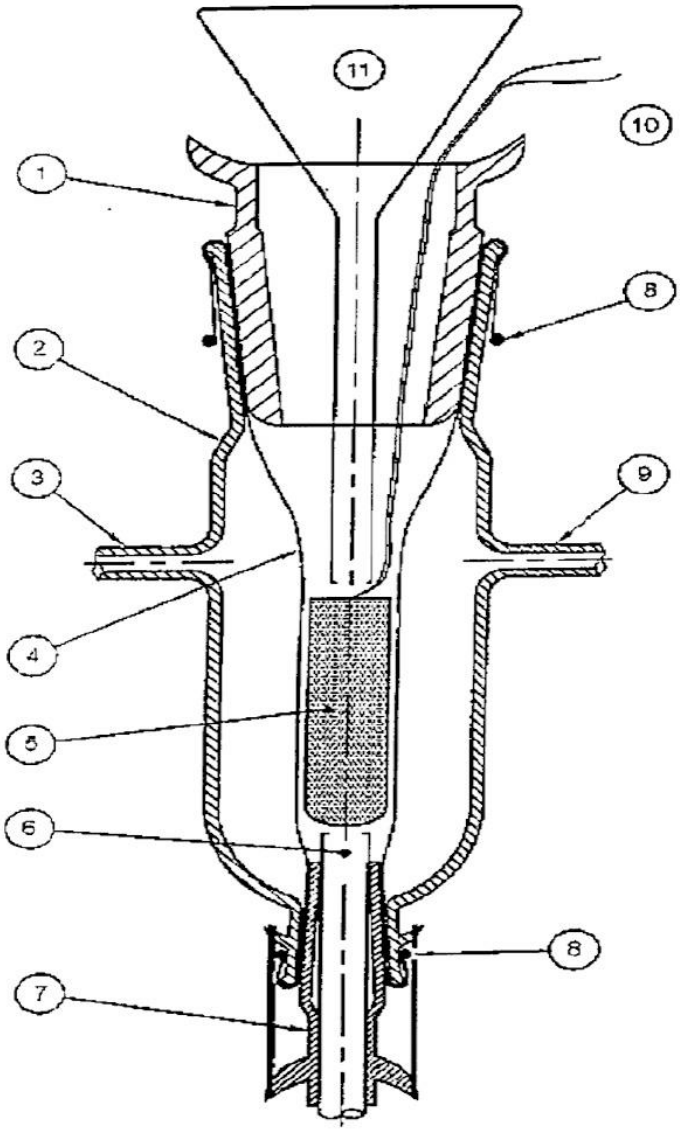


**Fig A.2 – Detail of syngina.**

1- Glass stopper.
2- Syngina.
3- Connection to syngina.
4- Condom contracts around tampon (5).
5- Tampon.
6- Outlet pipe.
7- Support band holding condom in place.
8- Rubber bands holding condom in place.
9- Connection to level container.
10- Withdrawal cord.
11- Funnel.

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## A.6 Procedure

The procedure shall be as follows:

a) condition the wrapped tampons for at least 12 h at 20 ± 2°C and 65 ± 5% relative humidity.

b) prepare the syngina with a condom as indicated in Clause A.4 and Figure A.2. Remove the teat of the condom to allow the outlet pipe to penetrate;

c) unwrap one tampon, remove the applicator where provided, and extend the withdrawal cord away from the body of the tampon;

d) determine the mass of the tampon and record ($M_1$);

e) insert the tampon into the syngina, positioning it carefully by using the stirring rod, as shown in Figure A.2.

f) insert the tip of the burette into the funnel which is in turn inserted into the condom approximately 10 mm above the tampon;

g) apply a constant pressure of 2 kPa above atmospheric pressure to the outer surface of the condom and hence to the tampon contained within it;

h) deliver water from the burette to the tampon at a rate of between 1.5 mLs and 1.8 mLs until the first drop of water appears at the bottom of the syngina;

i) turn off the water flow and let any excess water drip off the tampon;

j) reduce pressure on the condom and hence on the tampon to atmospheric pressure using the three-way cock (22);

k) remove the tampon from the syngina, ensuring that no water is lost;

l) determine the mass of the saturated tampon and record ($M_2$);

m) calculate the absorptive capacity of the tampon in grams of water, as follows:

$$\text{Absorptive capacity} = M_2 - M_1. \quad \ldots \text{A.6(1)};$$

n) repeat steps d) to m) until the required number of valid tests have been performed.

Note 5 - The maximum number of tests to be carried out before a new condom is fitted is 25.

## A.7 Invalid test

A test shall be considered invalid in the following instances:

a) pressure exerted on the tampon is reduced due to a hole in the condom becoming apparent during the test;

b) tampon expands longitudinally forcing the top of the condom open. A new condom is inserted in the syngina in every such case and the determination is repeated.

## A.8 Test report

The test report shall contain the following information:

the highest and lowest absorptive capacity results in grams of water per tampon;

a) the number of tampons tested;

b) the absorbency range, as given in Table 1, into which 90% of the estimated population fall;

c) reference to this test method in this Annex A.

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# Annex B
(normative)
# Method for testing the strength of the withdrawal cord and its attachment to the tampon

## B.1 Scope
This annex sets out a method for determining the strength of the withdrawal cord and its attachment to the tampon in both wet and dry conditions.

## B.2 Principle
Tampon is supported in a holder leaving the withdrawal cord free. The holder containing the tampon is rigidly supported while an increasing force is applied to the withdrawal cord until either the cord breaks or it is detached from the body of the tampon.
Figure B.1 gives a diagrammatic sketch of the arrangement.

## B.3 Apparatus
a) Tensile testing machine complying with the following:

i the machine shall comply with requirements of machines as specified in ISO 7500-1 except that the error in measurement of length shall not exceed 1.0 mm;
ii the machine shall provide means for indicating the force applied to the test specimen clearly and continuously on a dial scale or chart. It shall also provide means for indicating the force required to break or detach the cord;
iii the capacity of the machine or the range selected shall be such that the force required to break the test specimen shall be not less than 10% of the machine capacity;
iv the machine shall be capable of extending the specimen at a constant rate of 200 ± 25 mm/min;
v the force measuring mechanism of the machine shall allow little or no movement of the fixed jaws in the direction of the applied force;
vi the fixed and moving jaws of the machine shall be in same plane, parallel to one another and at right angles to the direction of application of the force;
vii the jaws of the machine shall be so constructed so as not damage the test specimen.

Note **5:** Suitable packaging materials or embedding techniques may be used whenever necessary to prevent test specimens slipping in the jaws.

b) Two holders (see Figure B.2 having internal diameters of 26 ± 1 mm and 29 ± 1 mm, respectively.

Note 6: The example of a holder shown in Figure B.2 will introduce a small error as the applied force will be slightly offset. This error is typically <1 %. The flat plate of that holder gall be offset to allow easy insertion of the tampon.

c) A wire 200 mm long with the end bent to form a hook as shown in Figure B 3. If optional slotted holders are used, wire is not required.

d) Timer, capable of measuring 5 min accurately.
e) Beaker of 1 L capacity.
f) Pair of tongs.
g) Distilled or deionized water

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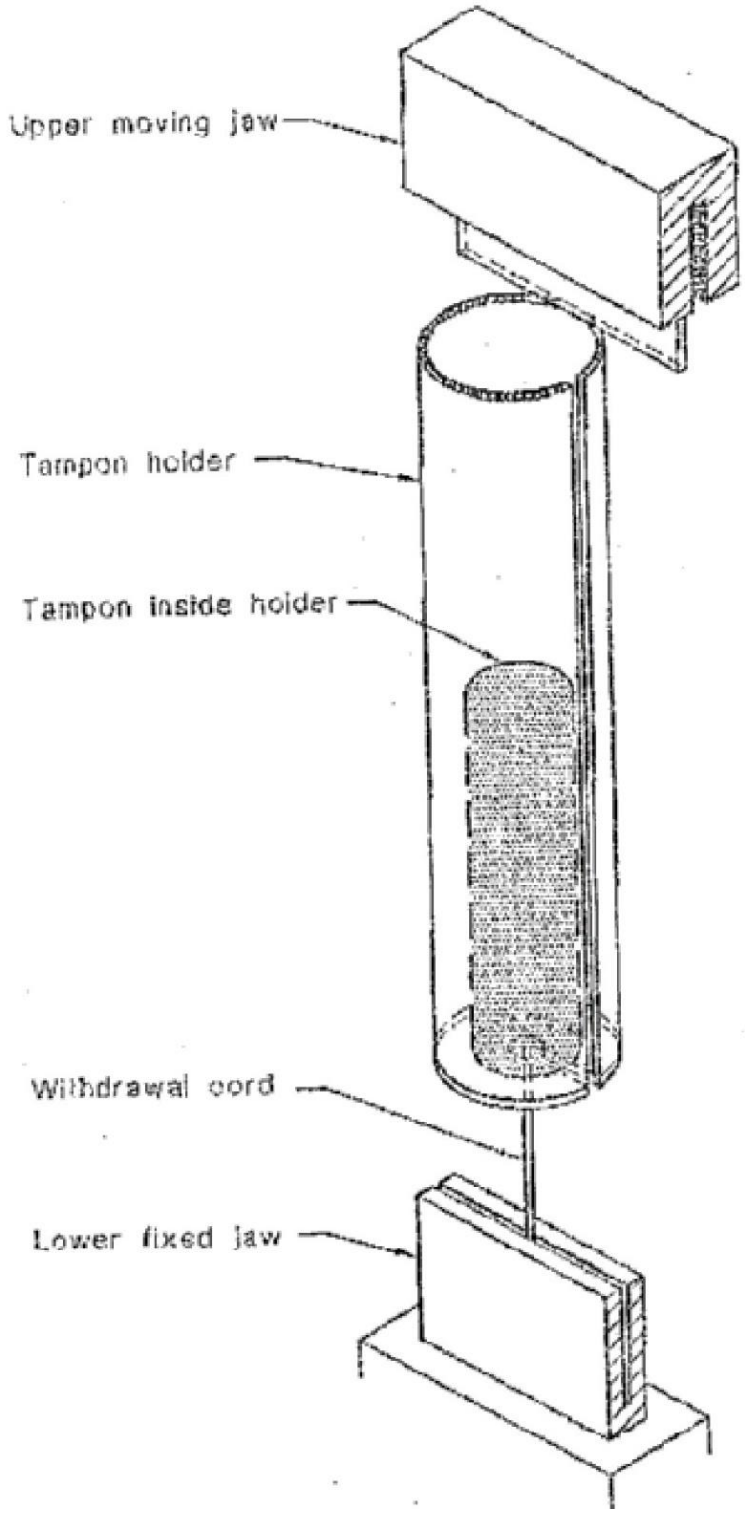


**Figure B.1 — Typical set-up for withdrawal cord attachment test**

### B.4 Test specimens

There shall be 20 unopened tampons at random from one batch. Should a test be invalid in accordance with Clause B.6, the necessary additional test specimens shall be drawn to complete 20 valid tests. Out of the 20 tampons, 10 shall be used for testing in the dry state and 10 for testing in the wet state.

### B.5 Procedure

#### B.5.1 Dry state

The procedure shall be as follows:

a) condition the wrapped tampons for not less than 12 h at 20 ± 2°C and 65 ± 5% relative humidity;

b) unwrap a tampon, remove the applicator where provided, and extend the withdrawal cord away from the body of the tampon;

c) using the hook, which is inserted through the hole in the base of the holder, pull the withdrawal cord through the hole so that the tampon is held within the 26 mm internal diameter holder with cord free (see Figures B.2 and B.3. Alternatively, if the slotted holder is used, the tampon can be threaded into the holder without using the wire hook;

d) place the flange on the holder into the upper jaw of the tensile testing machine. The base of the holder shall be at least 60 mm above the top of the lower jaw;
e) extend the cord so that there are no kinks in it and clamp the lower end in the lower jaw (see Figure B.1);
f) set the machine to give a constant rate of extension of 200 ± 25 mm/min;
g) set the machine in motion and record the force required to either break the cord or detach it from the body of the tampon;
h) repeat steps b) to g) a further nine times;
i) calculate the mean force.

#### B.5.2 Wet state

The procedure shall be as follows:

a) unwrap a tampon, remove the applicator, where provided, and place the tampon in the 1 000 mL beaker in an excess of the water;

b) leave the tampon in the water for at least 5 min;

c) remove the tampon with the tong and gently squeeze to remove excess water;

d) place the tampon in the 29 mm internal diameter holder, inserting the withdrawal cord through the hole in the base.

e) follow steps d) to i) as specified in B.5.1
f)

### B.6 Invalid test

**B.6.1** A test shall be considered invalid if the cord breaks at the point where it enters the lower grips.

**B.6.2** A new tampon is inserted into the holder in each such case and the procedure is repeated.

### B.7 Test report

The report shall contain the following information:

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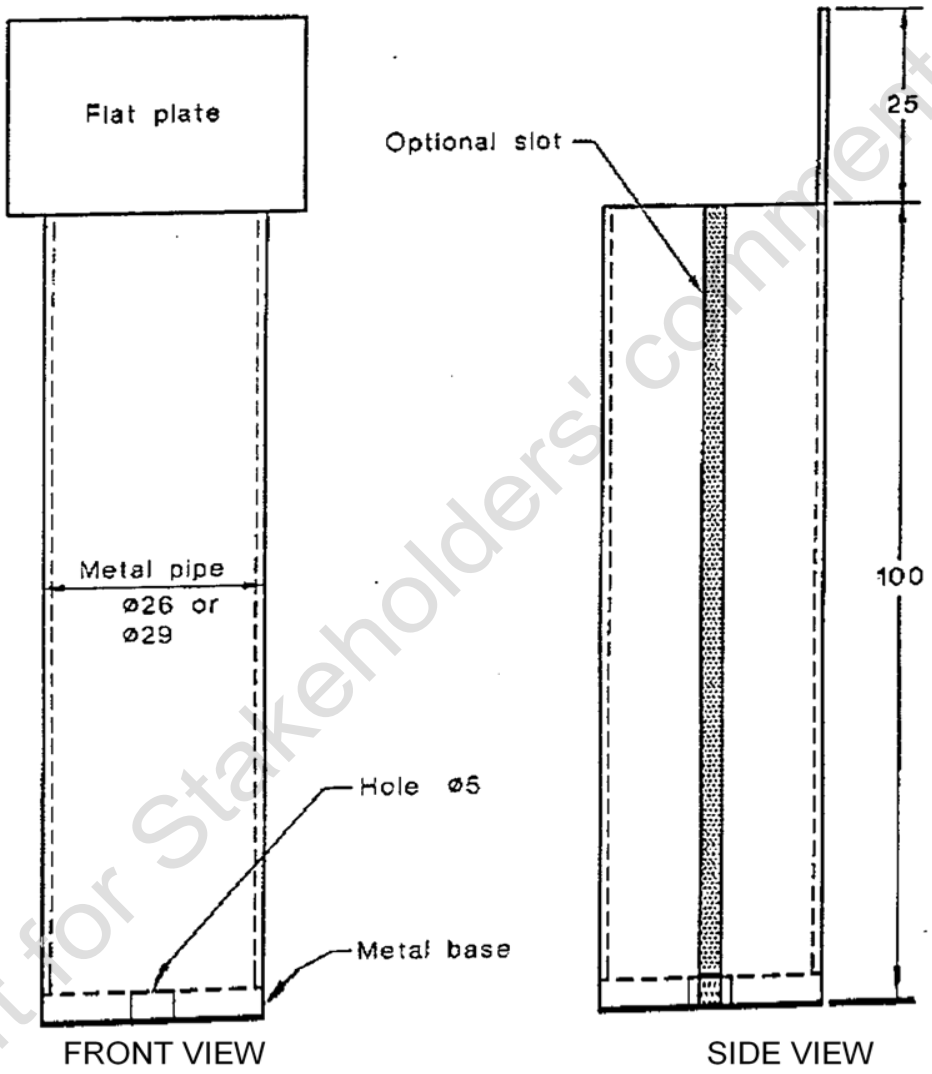
a) For the dry state:
   i) the results of each of the 10 individual tests; and
   ii) the mean force of the 10 tests.
b) For the wet state:
   i) the result of each of the 10 individual tests; and
   ii) the mean force of the 10 tests.

Reference to this test method in this Annex B.

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Note 7: The holder with an internal diameter of 26mm is for use in determining the strength of the attachment cord in the dry state; and the holder with an internal diameter of 29mm is for use in determining the strength of the attachment cord in the wet state.

Fig B.2 – Front and side views of typical tampon holder. (Dimensions in millimetres)

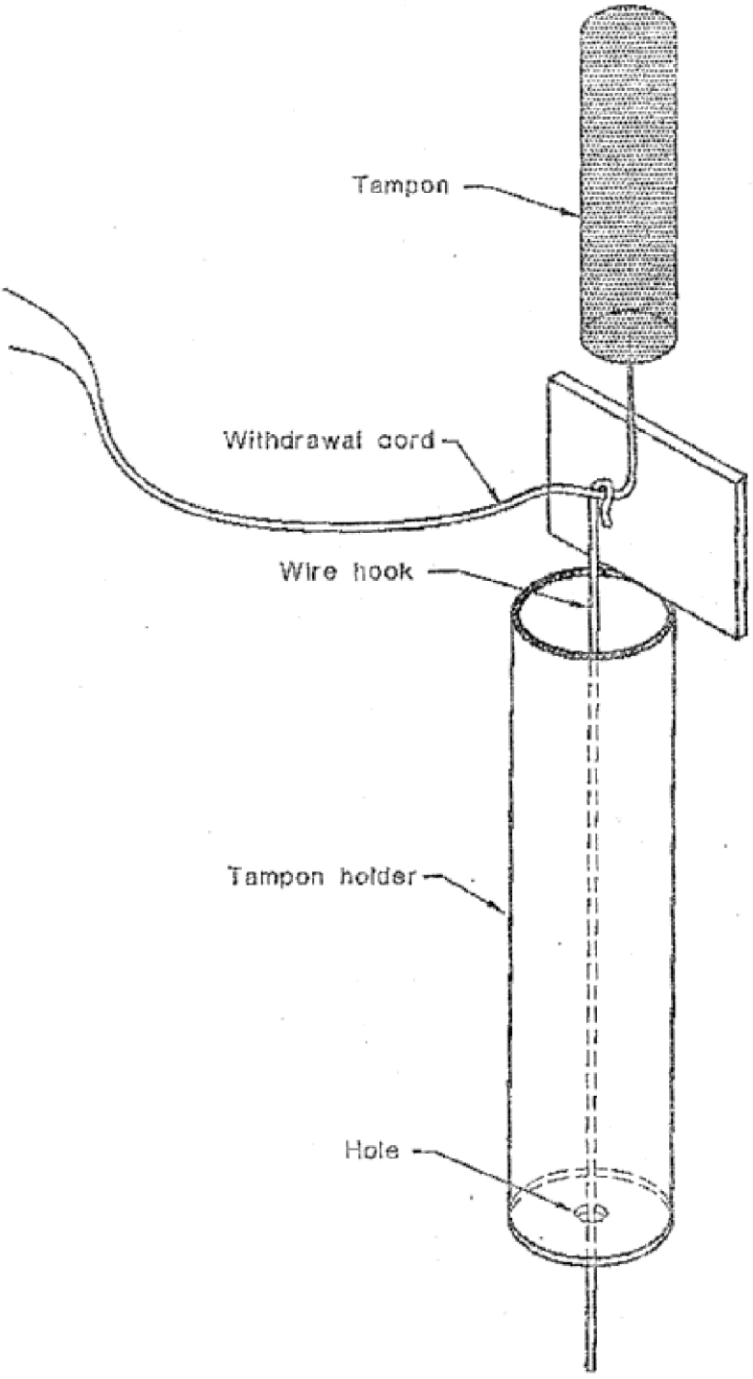


**Figure B.3 — Threading cord through tampon holder**

# Annex C
(normative)
# Method for determining the water repellency of the withdrawal cord

## C.1 Scope
This annex sets out a method for determining water repellency properties of the withdrawal cord.

## C.2 Principle

A section of the withdrawal cord is placed on the surface of water in a beaker. If the repellency of the cord is such that it does not sink in a prescribed time, the cord is determined to have satisfactory water repellency.

## C.3 Apparatus

C.3.1 The **following apparatus shall be required:**

a) five beakers, each of 500 mL minimum capacity, almost filled with tap water;
b) blade or pair of scissors;
c) tweezers;
d) timer, capable of recording time to 5 h;
e) ruler.

## C.4 Test Specimens
Select five unopened tampons at random from one batch.

## C.5 Procedure

C.5.1 The **procedure shall be as follows:**

a) condition the wrapped tampons for at least 12 h at 20 ± 2°C and 65 ± 5% relative humidity;
b) unwrap a tampon, remove the applicator where provided, and, using tweezers, extend the withdrawal cord away from the body of the tampon;
c) using the ruler and scissors or blade, cut a section of the cord approximately 75 mm long;
d) repeat steps b) and c) for each of the other four tampons;
e) again, using tweezers, lightly drop the section of cord taken from each tampon on to the surface of water in a separate beaker;
f) start the timer;
g) after 5 h, examine the beakers to see if the five cord samples are floating on the water surface or have sunk completely beneath the surface.

## C.6 Test report

The test report shall contain the following information:

a) whether or not any of the samples sank completely beneath the water surface;
b) reference to this test method according to this Annex C.

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# Annex D
(normative)
# Method for determining total aerobic microbial count

## D.1 Scope
This annex sets out a method for determining the total aerobic microbial count in tampons and in their applicators, where these are provided.

## D.2 Principle

Samples of tampon and applicator, where provided, are cultured for aerobic bacteria and fungi on appropriate nutrient media and incubated under optimal conditions. The total microbial count per gram is determined separately for the tampon and the applicator.

## D.3 Laboratory practices and precautions

Laboratory practices and precautions for carrying out this test shall comply with the principles set out in EAS 42

## D.4 Apparatus

The following apparatus is required:

a) incubators capable of maintaining a temperature at 32 ± 2°C and 20° to 25°C;

b) laboratory blender;

Note **8:** A 400 mL capacity stomacher type has been found to be appropriate.

c) 80 sterile petri dishes for tampons; 80 sterile petri dishes for applicators, where provided;

d) Colony counter;

e) 10 sterile pipettes for tampons; 10 sterile pipettes for applicators, where provided;

f) sterile stomacher bags;

g) top pan balance, accurate to 0.1 g;

h) disinfectant;

i) scissors;

j) forceps;

k) scalpel blades;

l) tray or sterile petri dishes;

Note 10 The scissors, forceps, scalpel blades and tray are to be provided sterile for each use or are to be dipped in ethanol (see Clause D.5 d)) and flamed between uses.

## D.5 Culture media and reagents

The following culture media and reagents are required:

a) plate count agar (PCA);
b) sabouraud dextrose agar (SDA), with or without 0.0% oxytetracycline (w/v).

Note 11 If used, the oxytetracycline supplement shall be prepared and used as described in the method for oxytetracycline gentamicin glucose yeast extract agar.

c) sterile solution of 0.1 % peptone water with 0.01% Tween 80;

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d) ethanol, 70% (w/w) or greater concentration, for flaming forceps, scissors, blades and tray.

**D.6 Laboratory conditions**

Before commencing the test, carry out the following procedures:

a) switch on laminar flow, disinfect all working surfaces and leave for 15 min;
b) conduct environment control monitoring of the test area to detect background contamination;
c) monitor media for microbial contamination by use of appropriate control plates.

Note 12 One plate from each flask of agar is considered adequate.

**D.7 Test specimen**

Select 10 primary pack at random from one homogeneous batch. From each of these pack remove a single unit pack with forceps. Place samples on a sterile surface, e.g. tray or petri dish. These 10 tampons and their applicators, where provided, make up the test sample and are individually tested.

**D.8 Procedure**

In the laminar flow cabinet, the procedure shall be as follows:

a) tear sterile stomacher bag;
b) aseptically remove the tampon and the applicator, where provided, from the wrapper;
c) dip forceps in ethanol and flame between each transfer;

Note 13 The methodology to be used will depend on the type of wrapping on the tampons.

a) aseptically transfer the tampon to the stomacher bag and weigh it. Repeat for the applicator;

b) add 100 mL of sterile peptone solution (see Clause D.5) to sterile stomacher bag containing the tampon or applicator and process for 1 min;

Note 14 The methods Parts 2 and 8 (for the bacterial count and the fungal count, respectively) shall be followed, other than the incubation times and temperatures;

c) transfer 5.0 mL aliquots of the extract to each of eight petri dishes, taking care to avoid fibres in the extract. Repeat for the applicator, where provided;

Note 15 the testing of four x 5.0 mL aliquots for each of the bacterial and fungal counts is equivalent to testing duplicate 10.0 mL samples.

d) add PCA (approximately 15 mL) into each of the second set of four plates and SDA with or without oxytetracycline (approximately 15 mL) into each of the second set of four plates;
e) mix contents by swirling and allow to set;

Note 16 Because of the extra volume in the plates, care must be taken during swirling so that the contents are not spilt.

f) incubate all PCA plates at 32 ± 2°C for 48 h for aerobic bacteria;
g) incubate all SDA plates at 20°C to 25°C for 5 days for fungi;
h) repeat steps a) to h) for the remaining 9 tampons (and the 10 applicators if provided).

**D.9 Determination of aerobic count**

Determine counts for tampons and applicators separately as follows:

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a) using colony counter, examine all plates and count colonies observed. Do not count fungal colonies that appear on the PCA plates or bacterial colonies that appear on the SDA plates;

b) calculate the bacterial count using the following equation:

Total aerobic bacterial count per gram of tampon or applicator =

$$\left[\frac{\frac{(C_1 + C_2) + (C_3 + C_4)}{2} X\ D}{T}\right]$$

where

$C_1$ is count on PCA plate 1

$C_2$ is count on PCA plate 2

$C_3$ is count on PCA plate 3

$C_4$ is count on PCA plate 4

D is dilution factor of the plates being counted = 10

$T$ is weight of the tampon or applicator, in grams.

c) calculate the fungal count using the following equation:

Total aerobic fungal count per gram of tampon or applicator =

$$\left[\frac{\frac{(C_5 + C_6) + (C_7 + C_8)}{2} X\ D}{T}\right]$$

C

Where

$D$ is dilution factor of the plates being counted = 10

$C_5$ is count on PCA plate 5

$C_6$ is count on PCA plate 6

$C_7$ is count on PCA plate 7

$C_8$ is count on PCA plate 8

$T$ is weight of the tampon or applicator, in grams.

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d) calculate the total aerobic microbial count using the following equation:

Total aerobic microbial count per gram of tampon or applicator = total aerobic bacterial count + total aerobic fungal count.

e) calculate the count per gram of tampon and applicator separately.

### D.10 Test report

The report shall contain the following information:

a) the total aerobic microbial count per gram of each tampon;

b) the total aerobic microbial count per gram of each applicator (if they are provided);

c) reference to this test method, according to this annex D.

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## Annex E
## (informative)
## Example of information on TSS for inclusion in information leaflet

## E.1 Scope

This annex provides an example of the minimum information to be included in the information leaflet, and advice to manufacturers regarding the provision of extra information.

## E.2 Content of leaflet

The leaflet should contain information about:

a) toxic shock syndrome (TSS);
b) precautions for hygiene and comfort when using tampons;
c) instructions for correct use of the product.

An example of wording in Clause E.2 a) and b) above is given in Clause E.3 below. The leaflet should include all of the points in Clause E.3, plus any other information which the manufacturer thinTZS is relevant. An example has not been included in Clause E.2 c), as the instructions are likely to vary from product product and, for many products, are provided by line drawings as well as words.

The expression and organization of the information in the leaflet should be determined by the manufacturer with reference to the requirements of Clause E.4.

## E.3 Example of wording

### E.3.1 Caution — Toxic Shock Syndrome (TSS)

#### E.3.1.1 What is TSS

Toxic shock syndrome (TSS) is a rare but serious illness that may cause death. It is caused by a toxin (a kind of biological poison) which is produced by a type of bacteria (Staphylococcus aureus). These bacteria are found in the nose of about one third of the population. They may also be found on the skin, and occasionally in the vagina, without causing harm.

#### E.3.1.2 Who is at risk

TSS can occur in both males and females of any age but is more common in the young women who use tampons during their period.

#### E.3.1.3 Symptoms of TSS

The early symptoms of TSS may begin suddenly and are similar to the "flue". Remember, early recognition of these symptoms is very important.

- feeling very ill, headache, muscular pains
- high fever and chills. Usually 39°C (102°F) or higher
- vomiting, diarrhoea, or both
- fainting, dizziness, weakness, or confusion
- sunburn — like rash

#### E.3.1.4 What must I do if I think I have TSS

If, during your period or shortly after, you have any of the above symptoms, REMOVE YOUR TAMPON AND SEE A DOCTOR IMMEDIATELY. Remember it is very important to tell the doctor that you have been using tampons.

**E.3.1.4.1** If you have ever had TSS you should not use tampons until you have discussed the matter with a doctor. You may not have developed resistance to the toxin and could get TSS again.

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**E.3.1.5 How does TSS occur**

If the toxin is produced in the vagina or a wound, and absorbed from there into the bloodstream, a person who is not resistant to the toxin may become ill.

**E.3.1.5.1** Most people develop resistance to the toxin (that is the illness is so rare) and in these people there is no harmful effect.

**E.3.1.5.2** The symptoms of TSS may develop rapidly. Early recognition and treatment of these symptoms can usually prevent serious illness.

**E.3.1.6 Do tampons cause TSS**

The simple answer is no. Tampons do not carry the bacteria which cause TSS. However, tampon use has been associated with an increased risk of TSS. Although TSS can occur with the use of tampons of any absorbency, the risk increases with the use of tampons of higher absorbency.

**E.3.1.7 Where can I get more information about TSS**

For more information about Toxic Shock Syndrome, contact the manufacturer or Tanzania Bureau of Standards.

**E.3.1.8 Precautions on tampon use**

**E.3.1.8.1** One should use the lowest absorbency tampon for comfort and level of blood flow. Use only one tampon at a time.

**E.3.1.8.2 Wash** hands before unwrapping and inserting a tampon, and again afterwards.

**E.3.1.8.3** Unwrap a fresh, clean tampon just before use – do not handle it more than necessary or place it on any surface. **E.3.1.8.4 Do** not inset a tampon if it hurts to do so.

**E.3.1.8.5** Removal of the tampon should be easy; if the tampon is dry and difficult to remove, the absorbency is too high or the tampon has not been in place long enough. Tampons should be changed as often as necessary but should not be left longer than 8 hours.

**E.3.1.8.6** Remove the used tampon before inserting the next one and do not forget to remove the last tampon used at the end of your period.

**E.3.1.8.7** Only use a tampon when menstruating.

**E.3.1.8.8** Ask a doctor if it is okay to use tampons if recently given birth, had a caesarean section, a miscarriage, an abortion or any operation on the reproductive system.

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