

Edana Code of Practice for tampons placed on the European market

Version 3: September 2020

Tampon manufacturers in Europe have organized themselves within the Absorbent Hygiene Products Working Group of EDANA, the voice of the nonwovens and related industries in order to coordinate the activities of the tampons manufacturing industry in areas of mutual interest. Member companies represent the dominant share of the production of tampons in the European Union.

This code of practice has been coordinated by Edana and has been in use since 1999. It may be used by any producer or distributor of tampons, and is also made available to national authorities. Please note there is a separate code of practice for the UK which can be found at http://www.ahpma.co.uk/tampon_code_of_practice/



TECHNICAL INTRODUCTION TO THE CODE OF PRACTICE

The sanitary tampon is a device used for absorbing menses inside the female vagina during the menstrual period. The menstrual flow is very variable and can differ from woman to woman and from period to period. Many other factors can affect the quantity of menses, such as age, the type of contraception used, number of children and general health. Tampons are therefore available in a number of different physical sizes and absorbencies to meet the needs of European women.



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1. CONSTRUCTION OF TAMPONS

In Europe there are currently two basic tampon designs: the radially wound pledget or the rectangular/square pad. Both types of tampons are constructed from a tampon band/fibrous fleece, which is typically formed from cotton or viscose rayon fibres or a mixture of both. All tampons are provided with a suitably attached withdrawal cord to ensure safe and efficient removal. Some tampon brands have an additional non-woven layer or coverstock attached to the surface of the tampon, which can aid insertion.

1. **Radially wound pledget:** The tampon band/ fibrous fleece is rolled up like a 'Swiss roll' and then compressed to produce a tampon that expands primarily in the widthways/radial direction.
2. **Rectangular/square pad:** The tampon band/fibrous fleece is in the form of a rectangular or square pad, which is compressed in both the longitudinal and radial directions. This tampon therefore expands in both the longitudinal and widthways directions but predominantly in the longitudinal direction.

All tampons are wrapped in suitable packaging e.g. paper and cellophane or polypropylene to ensure that the hygienic quality of the products are maintained. Some brands of tampons may have a plastic tear strip on the wrapper to aid the opening process.

2. TAMPON USE

There are currently two methods of presenting the tampon to the user:

1. **Digital or non-applicator:** The woman uses her finger to insert the tampon into the vagina.

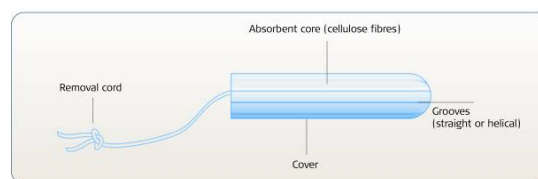


Figure 1: Digital/non-applicator tampon

2. **Applicator:** The tampon is inserted into the vagina using an applicator. The applicator is typically composed of two tubes, an outer and an inner. The applicator may be in compact form so may require assembly. Before insertion, the inner tube of the tampon applicator is partly engaged with the outer tube. In order to insert the tampon the user pushes the inner tube completely inside the outer tube and this expels the tampon into the vagina. Applicators may be made from coated cardboard or plastics such as polyethylene. Some brands are provided with compact applicator forms.

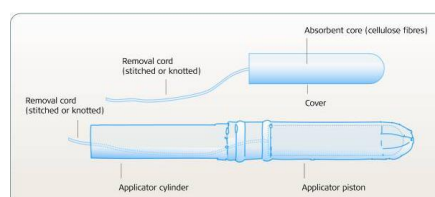


Figure 2: Tampon with Applicator



ELEMENTS OF THE CODE OF PRACTICE

1. HEALTH-RELATED INFORMATION FOR TAMPON PACKS

Each tampon pack must have clear wording to notify the consumer that the pack contains important information regarding menstrual toxic shock syndrome (TSS), a rare but serious illness. The notice should advise the user to read and save the leaflet – (see Annex 1).

The information should be clear and legible and in the language of the country of sale.

2. INFORMATION FOR TAMPON USAGE INSTRUCTIONS

Each pack of tampons must be provided with a clear advice and guidance on the correct use of tampons (see Annex 1).

The information should be clear and in the language of the country of sale.

3. MEASUREMENT OF TAMPON ABSORBENCY

As stated in the Technical Introduction, sanitary tampons are designed to absorb menses. In general women in a light flow situation will use a tampon with a low absorbency whereas a woman in a heavy flow situation will tend to use a tampon with a higher absorbency.

The absorbency of tampons produced by the European tampon industry should be measured using the “Syngina” protocol. This has been published as an EDANA Agreed Test Method, and is available from the Association.

Manufacturers are responsible for developing appropriate sampling plans and statistical protocols to demonstrate compliance to the absorbency system (see Annex 2).

4. ABSORBENCY LABELLING

Each pack of tampons must be labelled with the appropriate number of droplets denoting the range of Syngina tampon absorbency (see Annex 2).

The droplets will be placed in a prominent position either on the front or top of the pack. The droplets will have a minimum size of 3 mm for the smallest packs and will be scaled up as appropriate for larger packs.



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CONSUMER EDUCATION

The industry will continue to provide relevant information on Toxic Shock Syndrome in order to raise the consumers' awareness of the important aspects of this rare but serious illness.

Manufacturers and distributors of tampons will also reference the absorbency labelling system (see Annex 2) in educational material they publish about tampons.

6. REGULATION AND PRODUCT SAFETY

Manufacturers of tampons will continue to meet their obligations under the European General Product Safety Directive 2001/95/EC (published in O.J. L 011, 15.01.2002).

7. DISPOSAL

Manufacturers shall give appropriate disposal advice.

For additional information about the Code of Practice, the Syngina test method or disposal advice, please contact info@edana.org



ANNEX 1

Agreed Minimum Elements of information for Tampon Packs and Usage Instructions

ON THE OUTSIDE OF THE PACKAGE

(example wording below)

“ATTENTION: The enclosed instructions about tampon use include important information regarding menstrual TSS, a rare but serious illness (option: disease). Please read and save it (optional: for your health and hygiene.)”

TO BE INCLUDED IN THE INSTRUCTIONS

Each pack of tampons must be provided with a set of information that provides clear advice and guidance on the use of tampons.

(A) TSS HEALTH INFORMATION MUST :

- Inform consumers about Toxic Shock Syndrome (TSS) – providing both the definition and aetiology of TSS (both menstrual and non-menstrual).
- Inform consumers that TSS is potentially fatal.
- Provide a full description of the symptoms of TSS which may include some or all of the following: a sudden high fever (>39°C), vomiting, diarrhoea, a sunburn-like rash, sore throat, dizziness and/or fainting.
- Inform consumers that the symptoms of TSS may not all occur at the same time
- Instruct the users to seek immediate medical advice if the symptoms of TSS occur, to remove the tampon as a precaution, and to inform their doctor that they are menstruating, they have been using a tampon and might have TSS.
- Advise women that TSS can reoccur and for people who have had TSS we do not advise future use of tampons. If they have had TSS they should consult a doctor before future use of any type of tampon or internal vaginal device.



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(B) GENERAL INSTRUCTIONS SHOULD :

- Advise the user on the method for insertion and withdrawal of the tampon.
- Advise the user to use the lowest absorbency/size to suit their flow.
- Provide a full description of all the absorbencies/sizes available, linking them to the menstrual flow.
- Provide a statement on frequency of use.
- Emphasise the importance of personal hygiene, particularly the washing of hands before and after inserting a tampon.
- Advise the user on length of wear.
- Inform the consumer to only use one tampon at a time
- Advise the user to ensure the removal of the last tampon once menstruation has finished.



ANNEX 2

Agreed Elements for the Absorbency Labelling of Tampon Packs

MANDATORY INFORMATION

A. ON THE OUTSIDE OF THE PACKET

Each pack of tampons must be labelled with the appropriate number of droplets to denote the range of Syngina absorbency.

The droplets should be placed in a prominent position either on the front or top of the pack. The droplets will have a minimum size of 3 mm for the smallest packs and will be scaled up as appropriate for larger packs.

Each set of droplet symbols represents a range of 3g of Syngina absorbency and there are six classes in total (given in table 1).







B. TO BE INCLUDED IN THE INSTRUCTIONS

Manufacturers must include a chart that links the absorbency droplets to the ranges of Syngina absorbency (as shown in table 1).

OPTIONAL (ADDITIONAL) INFORMATION

Manufacturers may continue to use existing size descriptors and/or reference menstrual flow rates as appropriate.

TABLE1: CORRELATION OF DROPLETS WITH SYNGINA ABSORBENCY VALUES

	DROPLETS	GRAMS
1 DROPLET		< 6
2 DROPLETS		6 – 9
3 DROPLETS		9 – 12
4 DROPLETS		12 – 15
5 DROPLETS		15 – 18
6 DROPLETS		18 – 21



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UK Code of Practice for Tampons

There is a separate Code of Practice for tampons which are placed on the UK available at http://www.ahpma.co.uk/tampon_code_of_practice/

Revision History

Version	Changes	Date
Version 3¹	Full revision addressing the content. Main changes comparing to the previous version: Update of the title Update of the Working Group name Addition of an overview of the history of use of the code. Rephrase to make the content clearer. Addition of extra instructions. Addition of a new section, "Disposal advice". Correction of the AHPMA website.	Dec 2020
Version 2	Bibliographical reference to the General Product Safety Directive updated (1992 original to 2001 revision) Version History inserted Changes in design of the document and minor grammatical revisions Reference to version number, and date of update on the cover page Information on how to obtain a copy of the Syngina protocol Insertion of a point of contact for additional information	April 2012
Version 1	Creation	1999

¹ Version 3 Dec 2020
Version 3 Dec 2020

