

JOYDIVISION international AG

Rudolf-Diesel-Weg 10
30419 Hannover
Germany

Muenster, November the 21st 2012

Dermatological and gynaecological expertise on a
clinical-gynaecological application test
with subsequent questionnaire

Soft Tampons

Client :	JOYDIVISION international AG Rudolf-Diesel-Weg 10 30419 Hannover Germany
Test subjects :	20 female adult test persons, healthy skin
Test period :	8 – 12 weeks
Test area:	vaginal
Application frequency:	depending on requirements within 2 – 3 menstruations

1. AIM OF THE ASSESSMENT

The purpose of this study was to examine the tolerability of **Soft Tampons** in groups according to clinical-dermatological and clinical-gynaecological test criteria.

2. MATERIAL AND METHODS

The subjects were able to consult the dermatologist or gynaecologist taking care of the test at any time in case if objective or subjective skin changes were noticed.

Before the commencement of the trial, all participants were dermatologically and gynaecologically examined. Only subjects without any pathological disorders were included in the test group.

The subjects were advised to use 3 to 6 Soft Tampons depending on requirements and possibilities within 2 or 3 menstruations and if possible while swimming, sauna or sexual intercourses.

3. PANELLISTS

The test panel does include 20 adult, female panelists in healthy general condition.

3.1 INCLUSION CRITERIA

- Subjects with healthy skin in the test area aged 18 years and older
- Subjects with normal and regular menstruation
- should do also during the menstruation physical exercises and if possible agree to have sexual intercourses while using the Soft Tampons

3.2 EXCLUSION CRITERIA

- severe or chronic skin inflammation
- serious inner or chronic diseases
- intake of drugs that possibly can interfere with skin reactions (Glucocorticoids, antiallergics, topical immuno modulator, etc.)
- application of pharmaceutical products and skin care products with active ingredients until 7-10 days before testing
- severe allergies or occurred severe side effects after usage of cosmetic products
- sunbath or usage of tanning bed during the study period
- known cancer
- pregnancy or lactation period
- pathological changes of vulva or vagina
- current medicinal treatment of vulva or vagina
- recurrent mycosis
- atopy
- toxic shock syndrome in anamnesis
- anatomical abnormalities like uterus prolapses or similar

• 3.3 TEST SUBJECTS

No.	Name	Gender	Age	Skin type
1.	Ni. Ac.	f	29	normal
2.	Sa. Al.	f	46	dry
3.	Da. Be.	f	36	dry
4.	Be. Es.	f	46	normal
5.	Ja.-So. Fa.	f	19	dry
6.	Si. Fa.	f	42	normal
7.	Jo. Ga.	f	36	dry
8.	Al. Gr.	f	23	normal
9.	Br. Gr.	f	43	sensitive
10.	Sa. Ha.-Al.	f	38	normal
11.	Si. Kö.	f	51	dry
12.	Fr. Pe.	f	50	dry
13.	Ch. Ra.	f	24	normal
14.	An. Ro.	f	35	dry/oily
15.	Fr. Sa.	f	41	dry/sensitive
16.	Ja. Sch.	f	30	normal
17.	Me. Sch.	f	32	combination skin
18.	Ma. Sch.-Mo.	f	26	dry
19.	Si. Se.	f	34	normal
20.	Be. Th.	f	19	normal

4. DERMATOLOGICAL AND GYNAECOLOGICAL EXAMINATIONS

1. At the beginning of the study

All of the 20 female participants were determined to have healthy skin and mucous skin by dermatological and gynaecological standard and criteria. No pathological skin disorder was detected.

2. During the study

No complaint of any pathological disorder was reported during the course of the 12-week application study with the usage of 3 – 6 Soft Tampons. Pathological skin changes did not occur. Interruptions or medical intervention were not necessary.

3. At the end of the study

At the final dermatological and gynaecological examination at the end of the study none of the 20 panelists showed any pathological skin changes. The product was well-tolerated, no evidence of any pathological skin disorders could be detected.

5. DERMATOLOGICAL AND GYNACOLOGICAL ASSESSMENT CRITERIA

1. Redness (Erythema)
2. Oedema
3. Fissures
4. Dryness
5. Pruritus
6. Pathological alteration of vulva or vagina

Scale of dermatological and gynaecological clinical assessment:

0 = no reaction

1 = slight local irritation

2 = slight expanded reaction

3 = clear local irritation

4 = clear local irritation and oedema strong

5 = clear local infiltration and alteration of skin or mucosa

6. RESULTS OF GYNAECOLOGIC EXAMINATION

Panelist	Access examination	Comments	Final examination	Comments
1.	0	-	0	-
2.	0	-	0	-
3.	0	-	0	-
4.	0	-	0	-
5.	0	-	0	-
6.	0	-	0	-
7.	0	-	0	-
8.	0	-	0	-
9.	0	-	0	-
10.	0	-	0	-
11.	0	-	0	-
12.	0	-	0	-
13.	0	-	0	-
14.	0	-	0	-
15.	0	-	0	-
16.	0	-	0	-
17.	0	-	0	-
18.	0	-	0	-
19.	0	-	0	-
20.	0	-	0	-

Dr. med. Dr. rer. nat. Wolfgang-Christof Burkart
 Specialist in gynaecology

7. RESULTS OF THE DERMATOLOGICAL ANALYSIS

Panelists	Access examination	Comments	Final examination	Comments
1.	0	-	0	-
2.	0	-	0	-
3.	0	-	0	-
4.	0	-	0	-
5.	0	-	0	-
6.	0	-	0	-
7.	0	-	0	-
8.	0	-	0	-
9.	0	-	0	-
10.	0	-	0	-
11.	0	-	0	-
12.	0	-	0	-
13.	0	-	0	-
14.	0	-	0	-
15.	0	-	0	-
16.	0	-	0	-
17.	0	-	0	-
18.	0	-	0	-
19.	0	-	0	-
20.	0	-	0	-

8. SUBJECTIVE ASSESSMENT CRITERIA

1. overall assessment of the product
2. subjective impression on the handling of the product

9. QUESTIONNAIRE – EVALUATION

BEFORE THE APPLICATION

1. Did you already know Soft Tampons before? If yes, wherefrom?

- [0 x] friends
- [0 x] internet
- [0 x] journals/press
- [0 x] pharmacy
- [0 x] drugstore
- [0 x] other:
- [20 x] no

2. What kind of sanitary products do you use usually during the menstruation?

- [20 x] tampons
- [5 x] sanitary napkins/Panty liner
- [0 x] other (please comment)

3. Describe the first impression before the application of the Soft Tampons in headwords. Which three attributes are coming spontaneously into your mind? (e.g. modern, fancy, high quality, boring)

- [1 x] good idea! Modern and cool, doubts if it works
- [1 x] fancy, practical, interesting idea
- [1 x] eccentric, practical, stylish
- [1 x] modern, cool, Oh my god, what is this?
- [1 x] exciting, very promising, modern
- [1 x] modern
- [1 x] sweet idea, modern
- [1 x] modern, hygienic
- [1 x] funny, cute
- [1 x] modern, particular, new
- [1 x] modern, particular, complicated
- [1 x] big, interesting, hygienic packaging
- [1 x] interesting, very promising, maybe insecure
- [1 x] funny, cool, new
- [1 x] unlikely, new not inspiring confidence
- [1 x] large, soft, curious
- [1 x] rather large, modern, particular form
- [1 x] elastic, large, different
- [2 x] no statement

4. Which advantages do you expect of the Soft Tampons in comparison to „traditional“ tampons? (multiple answers possible)

- [10 x] a more intimate experience of the menstruation, as nothing is visible (no filament)
 [6 x] more freedom for a more hygienic amorous play during the menstruation
 [9 x] sports without any restrictions
 [14 x] discreet wearing e.g. in the sauna or while swimming
 [13 x] „not“ noticeable wearing comfort
 [1 x] other (please comment)

Comment:

- [1 x] in case of the hygienic intimate experiences it has to be awaited
 [1 x] higher absorbency than a normal tampon

5. Do you avoid sexual intercourses during the menstruation?

- [9 x] yes
 [4 x] no
 [7 x] unwillingly, but due to hygienic reasons yes

6. According to you what kind of requirements must be fulfilled by such a product? What would be purchasing decisive?

	very important	important	medium	less important	not important
Wearing comfort	1 [18 x]	2 [2 x]	3 [0 x]	4 [0 x]	5 [0 x]
More freedom with complete discretion	1 [4 x]	2 [13 x]	3 [2 x]	4 [1 x]	5 [0 x]
Hygiene	1 [15 x]	2 [4 x]	3 [1 x]	4 [0 x]	5 [0 x]
Design	1 [0 x]	2 [0 x]	3 [9 x]	4 [6 x]	5 [5 x]
Simple introduction	1 [8 x]	2 [12 x]	3 [0 x]	4 [0 x]	5 [0 x]
Easy removal	1 [10 x]	2 [10 x]	3 [0 x]	4 [0 x]	5 [0 x]
Material	1 [3 x]	2 [8 x]	3 [7 x]	4 [2 x]	5 [0 x]
Costs	1 [2 x]	2 [12 x]	3 [4 x]	4 [2 x]	5 [0 x]
Claims	1 [1 x]	2 [2 x]	3 [10 x]	4 [6 x]	5 [1 x]
Usage instruction	1 [2 x]	2 [5 x]	3 [9 x]	4 [2 x]	5 [2 x]
Packaging	1 [1 x]	2 [1 x]	3 [10 x]	4 [5 x]	5 [3 x]
Availability	1 [3 x]	2 [11 x]	3 [6 x]	4 [0 x]	5 [0 x]
Environmental safety	1 [1 x]	2 [11 x]	3 [5 x]	4 [3 x]	5 [0 x]

Others:

AFTER THE APPLICATION

**7. In which of the situations mentioned below did you use the Soft Tampons?
(multiple responses possible)**

- [19 x] sports
- [14 x] swimming
- [5 x] sauna
- [12 x] sexual intercoursess

**8. In case you have had sexual intercoursess while wearing the Soft Tampon,
did you notice it? If yes, please describe it briefly.**

- [8 x] I had no sexual intercoursess
- [9 x] no, I didn't notice the Soft Tampon.
- [3 x] yes, my partner or I did notice it:

Comment:

- [1 x] the thought that the tampon is present was already annoying
- [1 x] my partner did notice a resistance
- [1 x] my partner did notice it, but I didn't

**9. Did you experience any problems while introducing or removing the Soft
Tampon? If yes, please describe it briefly. (multiple responses possible)**

- [10 x] no, I had no problems
- [2 x] yes, while introducing.
- [9 x] yes while removing.

Comment:

- [1 x] it was slightly difficult to grab it
- [1 x] after getting used to it, it worked perfectly
- [1 x] for the removal it was slightly problematic to grab the tampon and to remove it
- [1 x] the description for the removal of the Soft Tampon is rather simple but in practice it is not possible. I never found the notch and I always had to search and pick with two fingers
- [1 x] after the sexual intercoursess I couldn't remove the tampon
- [1 x] not as easy as with normal tampons
- [1 x] the introduction was due to the size very difficult, I had to push hard to remove the tampon, which was especially difficult after swimming because it took too long
- [1 x] the Soft Tampon slipped too deep after sexual intercoursess, in general I couldn't use the notch because I couldn't grab it
- [1 x] I didn't like the removal that much
- [1 x] problems with finding the notch
- [1 x] the intended notch is not easy to recognize or to feel, only with many patients and many attempts I found it, the removal is not hygienic

10. Did you feel restricted during physical exercises? If yes, please describe it briefly.

[16 x] no, I had no problems.

[4 x] yes, because:

Comment:

[1 x] the Soft Tampons absorbed not enough, I wore additionally sanitary napkins

[1 x] the tampon was every now and then noticeable, especially while exercises

[1 x] I was permanently tensed

[1 x] once the tampon didn't work, but beside this everything was good

11. Would you say, that you were able to move more freely and unburdened due to the Soft Tampons without disturbing filaments?

[10 x] yes

[10 x] no

Comment:

[1 x] I don't feel the filament usually

[1 x] if I wear only underwear I don't have to check if the filament is visible

[1 x] that no filament disturbs is a big advantage, but nevertheless I did not like the wearing comfort

[1 x] because I was afraid that the tampon would drop out if it is full

[1 x] the Soft Tampon was not better than a normal tampon while jogging

[1 x] the fear that something could leak was bigger because nothing was noticeable although one knew that something is there

12. What kind of difference did you notice in comparison to usual tampons (e.g. tampons mini)?

[3 x] no noticeable difference

[8 x] better wearing comfort

[3 x] worse wearing comfort

[12 x] pleasantly soft and almost not noticeable

[2 x] better absorbency

[6 x] worse absorbency

[2 x] Other:

Comment:

[1 x] good absorbency, I did not expect this, even in case of strong bleedings

[1 x] complicated usage

[1 x] I don't notice tampon mini, but I noticed the Soft Tampons, the wearing comfort is bad

[1 x] the Soft Tampons are more comfortable for the later days

[1 x] it ran down the legs after 2 hours

[1 x] easy introduction, the opening of the packaging is easier than the opening of usual tampons

13. How often and how long did you use the Soft Tampon in average? Please comment briefly. (multiple answers possible)

- [15 x] every day during the menstruation at least once, according to the instruction
 [0 x] every day during the menstruation at least once, but longer than recommended
 [6 x] every day during the menstruation at least once, but shorter than recommended
 [2 x] others:

Comment:

- [1 x] once overnight and the absorbency was surprisingly good
 [1 x] during swimming, exercises and sexual intercourses
 [1 x] in case of a strong menstruation, the additional usage of sanitary napkins was necessary, as the tampons don't absorb fluids very well
 [1 x] the third tampon unintended longer, it had to be removed by the gynaecologist
 [1 x] only during the activities
 [1 x] since I was swimming every day I could use the tampons as instructed; after sexual intercourses I removed the tampons directly, I don't know why but the feeling was kind of annoying
 [1 x] shorter than recommended because the Soft Tampon was not that absorbent

14. Please rate the enclosed usage instruction regarding the following points:

	very good	good	medium	bad	very bad
Information content	1 [5 x]	2 [15 x]	3 [0 x]	4 [0 x]	5 [0 x]
Comprehension	1 [5 x]	2 [15 x]	3 [0 x]	4 [0 x]	5 [0 x]
Design/Presentation	1 [5 x]	2 [10 x]	3 [5 x]	4 [0 x]	5 [0 x]
Clear arrangements	1 [1 x]	2 [17 x]	3 [2 x]	4 [0 x]	5 [0 x]
Overall impression	1 [2 x]	2 [18 x]	3 [0 x]	4 [0 x]	5 [0 x]

15. How do you rate the Soft Tampons after the application test with your own words? What would you wish?

- [1 x] I was very satisfied with the tampons, I didn't expect this
 [1 x] a small bag for the disposal would be good, otherwise a good idea
 [1 x] I was more or less satisfied, I had only some problems during the removal
 [1 x] very pleasant, it could be a little bit smaller (in comparison to conventional tampons)
 [1 x] in case of the removal there is a little bit precariousness, but despite this I felt free during e.g. physical exercises
 [1 x] a better technique for the removal would be of advantage I would still use it during sexual intercourses but not otherwise
 [1 x] the tampons need to have a higher absorbency, the wearing comfort is not very comfortable

- [1 x] the wearing comfort was strange, maybe because it felt strange and annoying, I would prefer a normal tampons with e.g. a shorter filament
 [1 x] not that large, this would make the introduction easier
 [1 x] that they would be offered in a higher amount, since I would like to use them always, beside this I think they are good because they are very comfortable
 [1 x] actually good, absorbency and removal improvable
 [1 x] need to be changed too often, otherwise perfect, not leaky
 [1 x] simple introduction and removal
 [1 x] higher absorbency, bag for disposal would be good
 [1 x] the wearing comfort during the day and during physical exercises was pleasant, only the removal was difficult and a bag for the disposal would be good
 [5 x] no statement

16. How satisfied have you been with the Soft Tampons regarding:

	very good	good	medium	bay	very bad
Quality	1 [2 x]	2 [15 x]	3 [1 x]	4 [2 x]	5 [0 x]
Introduction	1 [2 x]	2 [13 x]	3 [2 x]	4 [3 x]	5 [0 x]
Removal	1 [0 x]	2 [5 x]	3 [8 x]	4 [4 x]	5 [3 x]
Material	1 [0 x]	2 [9 x]	3 [8 x]	4 [3 x]	5 [0 x]
Hygiene	1 [2 x]	2 [7 x]	3 [5 x]	4 [5 x]	5 [1 x]
Form	1 [4 x]	2 [10 x]	3 [4 x]	4 [2 x]	5 [0 x]
Packaging	1 [1 x]	2 [15 x]	3 [3 x]	4 [1 x]	5 [0 x]
Overall impression	1 [0 x]	2 [10 x]	3 [7 x]	4 [3 x]	5 [0 x]

17. Which proposals, wishes and suggestions for the improvement of the product do you have? Please be creative and support us to optimize our products for you! Please describe briefly:

I like less:

- [1 x] the removal, not very clean for the hands
- [1 x] no small bags for the disposal
- [1 x] the size
- [1 x] the form
- [1 x] still the precariousness (e.g. baths) how long such a tampons works
- [1 x] the mechanism of the removal
- [1 x] absorbency
- [1 x] quality
- [1 x] during the removal my complete hand was full of blood
- [1 x] the wearing comfort was strange, maybe it was due to the strange and annoying feeling
- [1 x] introduction and removal
- [1 x] the notch was rather useless, because the tampons are also without this easy to remove
- [1 x] the function for the removal and the absorbency
- [1 x] the removal and the disposal
- [1 x] the big packaging was rather unhandy for a woman's bag
- [1 x] the complicated removal
- [1 x] not that absorbent, color
- [1 x] the notch for the removal
- [2 x] no statement

I liked very much:

- [1 x] the absorbency and pleasant wearing comfort, better than normal tampons, does not dry the vagina
- [1 x] no filament which may be contaminated with urine
- [1 x] no filament, color, wearing comfort during physical exercises
- [1 x] no filament, that it works perfectly well during sexual intercourses
- [1 x] the freedom to leave the water in the swimming bath without thinking about the filament
- [1 x] no filament
- [1 x] die optic
- [1 x] that no filament is visible
- [1 x] the wearing comfort and the high absorbency
- [2 x] the wearing comfort
- [2 x] the wearing comfort is perfect
- [1 x] no filament
- [1 x] almost not noticeable during the usage, no annoying filament
- [5 x] no statement

I would wish:

- [1 x] a clean removal, unfortunately not possible without a filament
- [1 x] a slightly smaller form
- [1 x] smaller (different) form
- [1 x] improvement of the removing mechanism
- [1 x] higher absorbency
- [1 x] a normal tampon with e.g. a shorter filament
- [1 x] that the introduction and the removal would be easier
- [1 x] higher amount per package and cheaper and good environmental safety during the production
- [1 x] optimization of the above mentioned points
- [1 x] that the tampons are available in a smaller package
- [1 x] bag for the disposal
- [9 x] no statement

18. Is your first impression of the product confirmed? Is the description appropriate? Are your expectations complied? Please describe briefly the impression you had after the application of the Soft Tampons (in comparison to your first impression) in headwords.

- [1 x] I did not expect the tampons to be that comfortable and pleasant to wear, I am very convinced
- [1 x] the introduction was easier than expected
- [1 x] first skeptical, but I was positively surprised by the wearing comfort, which I did not expect due to the form, no expectations
- [1 x] before the application I was afraid that I could not remove the tampons, this did not come true, simple usage
- [1 x] the first impression didn't come true, the expectations came true, good and modern
- [1 x] practical in swimming baths, during sexual intercourses unnecessary, good for sports
- [1 x] the introduction and the wearing were better than expected but the removal was disappointing
- [1 x] description good, I am not satisfied (absorbency)
- [1 x] the optic is good, the removal was too complicated, not hygienic, not very absorbent
- [1 x] easy introduction, no problems during the removal
- [1 x] for my menstruation not absorbent enough
- [1 x] good idea, expectations came true, wearing comfort disappointing, otherwise is the description correct
- [1 x] impression is confirmed, expectation came not true, I expected problems during the introduction and the removal
- [1 x] it is a very interesting product in a handy packaging with a high wearing comfort
- [1 x] the product is more reliable than expected, but during strong menstruation not recommendable
- [1 x] it is a novelty, at least for the sexual intercourses I liked the tampons, since I don't do physical exercises that often and don't go swimming that often normal tampons are sufficient for these activities
- [1 x] the product keeps what it promises

- [1 x] my first impression is correct, that the tampons are difficult to remove, I was positively surprised by the wearing comfort
- [1 x] I did expect more, not technically mature yet
- [1 x] because of the form I was skeptical, but I was positively surprised from the introduction, the removal was as expected not very easy

19. Would you continue to use the Soft Tampons?

- [7 x] yes
 - [1 x] yes, for physical exercises und swimming
 - [1 x] depends on the costs
 - [1 x] for the sauna and maybe for sexual intercourses
- [7 x] yes and I would recommend them as well
- [6 x] no, because:
 - [1 x] absorbency (the tampon was full after half an hour)
 - [1 x] the removal is too unhygienic, tampons with a filament for the removal are way more uncomplicated
 - [1 x] the fear that I can't remove it
 - [1 x] for me is the wearing comfort very important and this is not as comfortable as with normal tampons
 - [1 x] I think it is too complicated
 - [1 x] they are very pleasant for the usage and the packaging is hygienic

20. The Soft Tampons are supposed for special moments during the menstruation, on which you wish more freedom and more space for movements. Do you agree with this statement? Where do you see the advantages of the Soft Tampons?

- [1 x] during physical exercises more comfortable, during swimming and sauna more discreet
- [1 x] fast and good introduction
- [1 x] yes, since there are no restrictions during swimming and sports, the tampon is not noticeable since there is no filament
- [1 x] no filament, very good for sauna
- [1 x] yes, in the swimming bath
- [1 x] yes, absolutely, because it is also not noticeable for the man
- [1 x] I don't agree, it is too unhygienic, the only advantage is the optic
- [1 x] yes, that the tampons don't have a filament and are noticeable lighter
- [1 x] I don't need it, I am not convinced
- [1 x] in principle I agree, the particularity that no filament is visible
- [1 x] no, it should be easier but it isn't
- [1 x] high wearing comfort, because the tampons is not noticeable
- [1 x] perfect wearing comfort
- [1 x] yes, I agree because despite the menstruations sexual intercourses are possible
- [1 x] the only particularity I see is that the tampons are without a filament

- [1 x] I see the particular feature during swimming and/or sauna (no filament)
- [1 x] I agree with the statement that it is not visible (no filament)
- [1 x] yes, especially during physical exercises and swimming very comfortable
- [2 x] no statement

21. With which claim would you make advertisement?

- [1 x] for swimming, sauna and physical exercises more pleasant for the woman
- [1 x] discreet, invisible, simple usage
- [1 x] fluffy, light, Soft Tampons!
- [1 x] From now on every day sauna
- [1 x] ? I don't know !
- [1 x] intimate, discreet, everything possible
- [1 x] lighter, better, more freedom!!!
- [1 x] Nowadays the heart is carried in the trouser
- [1 x] For more intimacy for special days
- [1 x] more freedom, easygoing during physical exercises
- [1 x] Soft Tampons, because the life of a woman is already too difficult or Soft Tampons try the difference or Soft Tampons everything else was yesterday
- [1 x] Just escape from worries
- [1 x] Soft Tampons are for every moment perfect!!!
- [7 x] no statement

- Application test
- Soft Tampons

10. ASSESSMENT OF RESULTS

All of the 20 study participants tolerated the product **Soft Tampons** very well during the course of the four-week application test under dermatological-clinical and clinical-gynaecological criteria. There were no undesired or even pathological skin reactions in the test area if the product was used as recommended. One subjects had problems with the removal after sexual intercourses and had to visit the gynaecologist. Since she went too late to the gynaecologist, she used the tampon longer than recommended and a minor colpitis had developed which had to be medicinal treated. According to gynaecological-specialist's opinion this reaction can't be directly correlated with to the product and may occur always if a tampon or Soft Tampon is used longer than recommended.

It can therefore be concluded that the recommended use of the product in practice does not lead to any undesired skin reactions due to any skin irritant or sensitizing characteristics of the product.

From a dermatological and gynaecological point of view it can be concluded that the test product

Soft Tampons

was tolerated

very well

in an application test with repeated use of the product under clinical-dermatological and gynaecological conditions



Dr. med. Werner Voss

Specialist in Dermatology,
Venerology, Allergology,
Phlebology and
Environmental medicine

Dr. med. Gerrit Schlippe

Specialist in Dermatology,
and Venereology.
Allergology