

## The new Gentle Comfort™ Vaginal Cream Applicator

### INTRODUCTION

The Gentle Comfort™ vaginal cream applicator was developed as a direct result of patients' complaints heard in clinical gynecological practice. Patients being treated for vaginitis complained that the standard syringe type vaginal applicator was difficult, uncomfortable and often painful to use. The new Gentle Comfort™ vaginal cream applicator is designed to alleviate these complaints.

It is established that infection, inflammation, or micro trauma of the genital mucosae facilitate infection by HIV. The standard vaginal applicator can be surprisingly traumatic to these delicate mucosae in the presence of vaginitis, or cervicitis, or to the congested mucosae of pregnancy. Gentle Comfort™ vaginal cream applicators are especially designed to minimize the risk of mucosal micro trauma.

The Gentle Comfort™ vaginal cream applicator is INNOVATIVE. The prototype was awarded a Design Institute Award by the South African Bureau of Standards. The applicator is now commercialized.

### DESCRIPTIONS of and COMPARISONS between NEW and OLD APPLICATORS

The easiest way to appreciate the advantages of the new applicator is by comparing it with the old one.

#### 1. THE POINTS

The STANDARD vaginal cream applicator has a blunt rectangular point which is difficult to advance up the vaginal canal for the following reason:

The axis of a person's trunk is in a generally North-South direction. The axis of the vaginal canal runs roughly South East to North West. The weight (gravity) of the abdominal organs therefore bears down on the apposing anterior and posterior vaginal walls and tends to press them together, as does the intra-abdominal pressure caused by the tone of the abdominal musculature. The point of the applicator has to therefore separate the vaginal walls by force. The point has to scrape its way along an inflamed vaginal canal, causing considerable pain in the process.

Many versions of the standard applicator have threads just within the large opening at the point to allow the applicator to be screwed onto a tube of cream. The large opening allows the vaginal mucosa to bulge into the shaft cavity as the applicator advances and the mucosa scrapes over the hard, sharp screw threads which causes even more pain and micro trauma. Some standard applicators flare outwards at the point and so aggravate the situation even further. The GENTLE COMFORT™ vaginal cream applicator has a rounded point which flares backwards to form a wedge-shaped head when viewed from the side. This wedge shape is important. It allows the apposed anterior and posterior vaginal walls to be gently separated without abrasion.

The "bump" below the point serves three functions.

**Firstly:** It forms an ideal shape for the point to gently toboggan along the posterior vaginal wall without abrasion, or discomfort. The point of the applicator cannot "dig in".

**Secondly:** It lifts the opening in the point above (away from) the contact surface with the posterior vaginal wall and so helps to prevent vaginal discharge from being scraped up through the opening into the cavity of the applicator shaft – thus promoting better hygiene.

**Thirdly:** Current applicator fashion seems to be making applicator points narrower and narrower. This is a dangerous trend which increases the risk of an applicator without depth control penetrating through the canal of a multiparous, or incompetent cervix in pregnancy and rupturing the amniotic membranes. The "bump" serves to maintain a safe maximum point diameter. However, when viewed from above, as it is during insertion, the point of the applicator appears fashionably narrow.

#### 2. THE OPENINGS

The STANDARD applicator has a large opening through which much contaminating vaginal detritus may be scraped up into the shaft cavity. The standard applicator is very hard to clean properly without special apparatus. It is precisely because multiple usage of a standard applicator is so unhygienic that multiple applicators had to be introduced for each tube of cream to solve the problem.

The GENTLE COMFORT™ applicator has a relatively small opening which is lifted above the contact surface.

Pick-up of vaginal detrius is reduced, or eliminated. Contact surfaces of the new applicator are easily reached and cleaned. It therefore is much more hygienic to use than the syringe type.

### 3. THE SHAFTS

The STANDARD applicator shaft leaves much to be desired.

(a) It is relatively long and without depth control. If the user inserts it too deeply, the point will collide with the cervix or vaginal vault. This collision may cause pain, or vaginal bleeding. It is particularly dangerous during pregnancy when the cervix is soft and congested. An antepartum haemorrhage of this cause need not be of obstetric significance, but might cause considerable anxiety, expensive investigation, or hospitalization for observation. The risk of penetrating the cervical canal and causing artificial rupture of membranes has already been referred to. Yet the pregnant woman is prone to vaginal Candidiasis. The hormonal milieu of pregnancy causes increased deposition of glycogen in the epithelial cells lining of the vagina. This hyper nutrition may induce overgrowth of *C.albicans* and consequently Candidiasis and a need for antifungal therapy using an applicator. However, many fungicidal products carry a warning to the user in their package inserts to consult their doctor for treatment during pregnancy. The implication seems to be that the doctor needs to insert the applicator, because of the above-mentioned risks!

(b) At the other extreme a user might not insert the applicator deeply enough. This might result from a previous painful collision with the vaginal vault, previous experience of cervical haemorrhage, or simply a degree of vaginismus. In the latter case the user fears that there is not enough room within her vagina to accommodate such a long object and a loaded standard applicator does look pretty long. If the medicament is deposited too superficially in the vagina it will run out through the introitus, be wasted and leave insufficient cream within the vaginal cavity to ensure effective treatment.

(c) The STANDARD applicator shaft is hard, rigid and rectilinear. If the STANDARD applicator is introduced horizontally through the introitus (as many woman are apt to do), the blunt point will collide with the posterior vaginal wall. The reason for this is that the vaginal canal is inclined at an angle to the horizontal – the so-called “angle

of vaginal inclination”. The collision may cause pain, or it may cause the user to assume that the applicator has reached the limit of insertion and cause her to inject the cream prematurely – too shallowly in the vagina.

(d) The STANDARD applicator shaft is relatively narrow, cylindrical and hard. The flange on the syringe is small. If the user’s fingers are contaminated by cream, or moisture, or if her skin is atrophic from advance age, the applicator becomes very slippery and difficult to grasp, or control.

(e) Some STANDARD applicator shafts carry dosage marks. These are always confusing to users, who seldom seem sure of the one they should use.

The GENTLE COMFORT™ applicator is designed to solve all the above problems.

The shaft is of optimum length with depth control. Its length is not visually intimidating. The point will not reach the vaginal vault or cervix in the absence of genital prolaps. Painful vault collisions are eliminated.

Medicament is deposited at an optimal depth in the vagina. The shaft is angled to approximate the angle of vaginal inclination and indicates the correct direction in which the application should be introduced to the user. Posterior wall collisions are avoided. The shaft is soft and flexible. Even if the user introduces the applicator in a direction other than optimal, the shaft will simply flex and the point will glide painlessly along the natural contour of the vaginal wall. The point cannot “dig in”.

The tube of cream upon which the applicator is mounted forms a large comfortable handle to the applicator, ensuring easy and reliable manual control of the applicator during insertion. Compression of the loaded applicator bulb delivers a metered dose of cream into the vagina. A non-return valve prevents any reflux of cream into the tube. There are no confusing marks on the shaft.

### 4. HYGIENE

The STANDARD applicator is designed to be screwed onto, or held against, the neck of the tube of cream, every time it is loaded. The point of the applicator and distal shaft cavity are contaminated by vaginal detrius during applicator insertion. Sterile cream flows over the

contaminated area when the applicator is refilled. The to-and-fro flow of cream into and out of the applicator leads to contamination of the entire cavity of the applicator. This is easily demonstrated experimentally. Multiple usage of a single applicator soon becomes very unhygienic, aesthetically unpleasant and so the need for multiples standard applicators with each tube of cream. In the GENTLE COMFORT™ vaginal cream applicator there is a unidirectional flow of cream. The sterile cream flows out of the tube, through the applicator and into the vagina. The applicator should never be unscrewed from the tube – even during storage – after first usage. The only contamination of cream is that which occurs in the opening of the point. If a little cream is squeezed through the opening and removed with a tissue, good hygiene is maintained. The nose cap prevents contamination of the nose between doses. The contaminated shaft areas are completely accessible and easily cleaned. The Gentle Comfort applicator is very hygienic and a single applicator may therefore be used for multiple doses of cream.

## 5. APPLICATOR INSERTION

Package inserts for the STANDARD applicator invariably illustrate a female figure in supine position with hips and knees flexed ready to insert the applicator through the introitus. As mentioned previously, the intra abdominal pressure apposing the vaginal walls has to be countered by the hard, blunt applicator forcing the vaginal walls apart. Introduction would be most painful and uncomfortable sitting, or standing when maximum abdominal pressure is brought to bear on the vagina. Lying down is the least uncomfortable. However, this means that the user has to find a place to lie down before she can instill the cream. Her arm is not anatomically long enough, when she is supine, to reach the plunger of a loaded syringe held at the angle of vaginal inclination before the introitus, as is so blithely illustrated in most package inserts. If flexure of the user's trunk is impaired by a late second, or third trimester pregnancy which splints her trunk and prevents virtually all flexure then the insertion becomes impossible to achieve. Pathology of hips, knees, back, or arm joints in post menopausal patients makes introduction of the standard applicator, a very undignified and difficult procedure indeed. When using a standard applicator the direction of manipulation is roughly along the long axis of the user's trunk and the arm must be extended beyond its natural reach to manipulate and grasp the plunger.

However, the GENTLE COMFORT™ applicator remains mounted on the tube of cream. When the latter is held

comfortably and naturally in a horizontal position facing the introitus, then the applicator shaft indicates the correct direction for insertion. Movement remains at all times within the anatomical reach of the user's arm. The applicator may easily be introduced whilst standing, or preferably sitting on the edge of a toilet seat, or chair, because the shaft is soft and flexible and has a wedging point to separate the vaginal walls. Virtually undressing is not necessary as is the case with the standard applicator. The procedure is very much easier and more dignified to perform.

## 6. ADVANTAGES OF THE GENTLE COMFORT™ VAGINAL CREAM APPLICATOR

For the user:

- Easier and less undignified to use.
- Less pain of discomfort.
- Less micro trauma to mucosae.
- Improved safety especially in pregnancy.
- Improved hygiene.
- Less wastage of cream.
- Easy to use whilst sitting.
- Not necessary to lie down.

For the pharmaceutical manufacturer:

- Reduced package volume.
- Reduced shelf storage costs in pharmacy and warehouse.
- Reduced transport costs.

For the marketing department:

- Unique patented product.
- Genuine medical improvement.
- Forms a distinguishing feature between Brands – great marketing advantage.

For the environment:

- Reduced environmental pollution. A single applicator to dispose of instead of 6-16 per tube of cream.

## 7. CONCLUSION

The instillation of vaginal cream need no longer be an undignified, difficult, or unpleasant experience for women.

## INITIAL MARKET SURVEY OF THE GENTLE COMFORT™ VAGINAL CREAM APPLICATOR CONDUCTED BY CANT AND ASSOCIATES IN PRETORIA, SOUTH AFRICA

### Females

- 72% of females indicated that conventional vaginal applicators cause discomfort and pain from time to time.
- The main problem which females experience with vaginal applicators at present is the difficulty of insertion thereof.
- 88% of respondents were of the opinion that the new applicator type would be easier to use, safer and more effective.
- 92% of respondents would prefer all creams or ointments to have this new type of applicator supplied as standard.

### Pharmacists

- All pharmacists (100%) were of the opinion that this new type of vaginal applicator would be easier to use by females than the present one is.
- 90% of respondents felt the manufacturers of creams and ointments should offer this new applicator as part of their total product.
- The main advantages which respondents see in this applicator include its ease of use, less damage to the vaginal epithelia and more dignity for ladies.

### Doctors

- 95% of respondents were of the opinion that the vaginal applicators currently on the market do cause discomfort, are not easy to use, or a cause damage to female patients.
- A main cause of complaint is the shape of standard applicators, which are rigid and in some cases sharp edged.

- All the respondents (100%) were of the opinion that this vaginal applicator will be more suitable for female use than is the current situation.
- All the respondents gave their support for this new applicator as long as it will not lead to an increase in costs for the patient.

## DIRECTIONS FOR USING THE NEW GENTLE COMFORT™ VAGINAL CREAM APPLICATOR

1. Puncture the nozzle of the tube of cream.
2. Remove the nose cap from the point of the applicator.
3. Screw the applicator firmly onto the tube of cream.
4. Holding the tube vertically, squeeze the cream into the applicator until it is filled to its tip.
5. Squeeze a little cream onto your fingertip to lubricate the point of the applicator.
6. Sitting on the edge of a toilet seat, or chair, hold the tube in a comfortable horizontal position before the vaginal opening in one hand, with the point of the applicator facing the vagina. Grasp the base of the shaft of the applicator between the forefinger and thumb of your free hand on the finger pads provided and gently guide the applicator shaft into the vagina, until your thumb touches against your body.
7. Compress the applicator bulb between the thumb and first two fingers of the free hand to empty the bulb of cream. It cannot flow back into the tube.
8. Withdraw the applicator shaft from the vagina and clean it using soap and warm water, or a tissue.
9. Replace the nose cap of the applicator and store the tube of cream with the applicator attached – thus keeping the cream clean.
10. To instill the next dose of cream: Remove the nose cap and repeat steps 4-9.

## GENTLE COMFORT™ PRODUCTS ARE PROTECTED BY THE FOLLOWING INTELLECTUAL PROPERTIES

### 1. GENTLE COMFORT™ VAGINAL CREAM APPLICATOR

United States Patent No. US6,537,260 B1  
United States Design Patent No. USD457,627 S  
German Designs Office No. 400 04 156.1  
United Kingdom Patent No. GB 2 351 444 B

### 2. GENTLE COMFORT™ VAGINAL TABLET APPLICATOR

United States Patent No. US 7, 172,573 B1  
United Kingdom Patent No. GB 2 369 063 B  
European Patent No. EP1 214 118 B1  
Designated Contracting States: DE DK FR  
South African Patent No. 2001/9855  
South African Designs Office No. A2000/464

### 3. GENTLE COMFORT™ DIGITAL (FINGER-MOUNTED) TAMPON APPLICATOR

United States Patent No. US 7,186,248 B2  
European Patent Office No. EP 1 423 072 B1

Designated Contracting States:

AT BE BG CH CY CZ DE DK EE ES FI FR GB  
GR IE IT LI LU MC NL PT SE SK TR  
South African Patent No. 2004/2032

### 4. GENTLE COMFORT™ VAGINAL TAMPON

South African Patent No. 2004/1379  
United States and European patents are pending.

## NEW GENTLE COMFORT™ PRODUCTS BEING DEVELOPED

### 1. GENTLE COMFORT™ VAGINAL TABLET APPLICATOR

This applicator follows the design principles and affords the same advantages to the user as the cream applicator does. Tablets are loaded into the reusable tablet applicator by simply inserting the nose of the applicator into a port on a discoid tablet dispenser.

### 2. GENTLE COMFORT™ DIGITAL (FINGER-MOUNTED) VAGINAL TAMPON APPLICATOR

A simple device to hold a loose tampon at the angle of vaginal inclination for insertion. Contact surfaces of tampon are silicone covered to ensure easy painless insertion of a tampon in the correct direction to ensure correct positioning in the vagina. The user's fingers are protected from soiling by menses. Greatly improved hygiene for the user.

### 3. GENTLE COMFORT™ VAGINAL TAMPON

A revolutionary vaginal tampon inserted by applicator to ensure correct placement. Contact surfaces of tampon covered during insertion. Designed to reduce, or eliminate leakage of menses, slipping of tampon, or retrograde menstruation with concomitant pyrexia, nausea and pelvic discomfort. The tampon will have many unique features and may reduce the incidence of endometriosis.