

Contrelle[®] Activgard

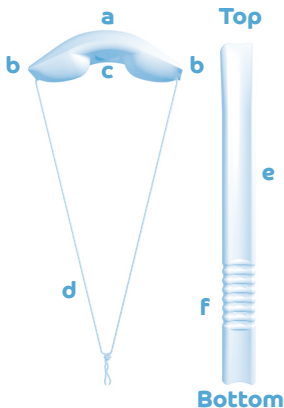
Bladder support for women

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

Contrelle® Activgard is a Class IIa single use device for treating women over the age of 18 years who are experiencing Stress Urinary Incontinence (SUI) and Mixed Urinary Incontinence (MUI) where SUI is predominant. SUI is when women leak on effort or exertion, or on sneezing, laughing, coughing, lifting, or exercise.

- a.** Contrelle® Activgard
- b.** Wings
- c.** Central depression
- d.** String
- e.** Applicator
- f.** Placement grooves



CLINICAL BENEFITS

Contrelle® Activgard is a discreet device inserted into the vagina to support the urethra and bladder neck to prevent or reduce the loss of urine due to SUI. 1 in 3 women experience SUI and physical exercise can exacerbate symptoms. These symptoms adversely affect a woman's quality of life.

Contrelle® Activgard is made of a soft comfortable foam. When positioned in the vagina it supports the bladder neck and urethra, preventing SUI. It does not stop you from emptying your bladder, so you can go to the toilet as normal with Contrelle® Activgard in place, without the need to remove during and afterwards.

DEVICE USE

Each Contrelle® Activgard can be used for up to 16 hours a day or just when running, swimming, taking exercise or other sporting activities. Each Contrelle® Activgard can only be used once. It is recommended to change Contrelle® Activgard when convenient after swimming.

The Contrelle® Activgard should be changed every 4 to 6 hours during menstruation. Do not use Contrelle® Activgard at the same time as a tampon or instead of a tampon. You should use the applicator to insert Contrelle® Activgard. Do not use anything other than the applicator to insert the Contrelle® Activgard.

Some women may find a small amount of water-based lubrication gel (available at any chemists) can make insertion easier.

CONTRAINDICATIONS

Before you use Contrelle® Activgard check this list carefully and DO NOT use if you:

- are under the age of 18 years
- are pregnant, or have given birth in the last 3 months
- are suffering from any infection or irritation in the vagina
- have suffered from TSS (Toxic Shock Syndrome)
- have had any pelvic surgery in the last 6 months
- are undergoing any therapy for pelvic malignancy
- have moderate to severe vaginal prolapse
- have urinary or vaginal infections
- have significant or bothersome vaginal dryness
- have problems with manual dexterity which could cause insertion or removal issues
- are male

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WARNINGS AND PRECAUTIONS

The following Warnings and Precautions should be considered before using Contrelle® Activgard.

- Once the Contrelle® Activgard pouch has been opened use immediately. Do not store unwrapped
- Keep Contrelle® Activgard out of direct sunlight
- Do not use Contrelle® Activgard if the packaging is open or damaged
- Do not insert more than one Contrelle® Activgard at a time
- Do not use Contrelle® Activgard with any other vaginal device including tampons, mooncups and pessaries
- You can use Contrelle® Activgard when you have an Intrauterine device (coil) fitted though we recommend you speak to your doctor or healthcare professional to confirm suitability
- Do not use Contrelle® Activgard during sexual intercourse
- Do not use a single device for more than 16 hours
- Do not use a single device for more than 6 hours during menstruation
- Do not use the device for more than 16 hours in any 24-hour period
- Do not use Contrelle® Activgard more than once. DO NOT REUSE. You risk potential harm of infection and / or irritation if device is used more than once
- Do not insert Contrelle® Activgard into the anus or the urethra

Do not use Contrelle® Activgard and applicator any way other than that described in the accompanying instructions.

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HOW TO USE CONTRELLE® ACTIVGARD

1. Before you start, read the instructions carefully.

Have this leaflet available in a convenient place so you can read it as you follow each step. Give yourself plenty of time until you become familiar with the use of Contrelle® Activgard.

2. Size Selection

Start with the sizing kit.

Size 1 – Small

Size 2 - Medium

Size 3 - Large

Contrelle® Activgard is available in three sizes to enable women to find and use the most comfortable size which provides optimal results. It is recommended to start with Size 2. Once inserted you should feel comfortable and you should experience little or no urine leakage when you are active or when you cough. If Size 2 is not comfortable try Size 1.

If leakage occurs when using Size 2 or the device moves change to Size 3.

We recommend you should walk for 15 minutes, cough, jump or run to check for any leakage and movement. Some women may experience slight initial discomfort until they get used to the product.

3. Preparation

- a.** Wash your hands thoroughly before opening the package and pouch.
- b.** To open, tear pouch at either end, remove Contrelle® Activgard from pouch. Do not use scissors or you could risk cutting the string.
- c.** Hold Contrelle® Activgard in one hand by the wings and place under luke warm or cold running water, so the water is hitting the top of the arch for approximately 15 seconds.
- d.** Keep under running water for a further 30 seconds, while gently and evenly applying pressure to the wings using both hands, squeezing together 10 times to ensure the foam is thoroughly saturated. The foam device will become softer and will expand in size by approximately 30%. [When saturated

with water before use, Contrelle® Activgard does not absorb natural moisture from the vagina]. Once fully saturated squeeze out any excess water.

- e. Remove applicator from reusable protective sleeve.
- f. Place the string loop around the bottom of the applicator (close to the placement grooves) with the knot in the middle of the hollow. Pull the Contrelle® Activgard foam device to the top of the applicator so the central depression fits onto the top of the applicator. Always place the string on the bottom of the applicator first, as this makes it easier to place on the applicator.

4. Insertion

- a. Relax and find a comfortable position that makes it easy to insert Contrelle® Activgard. Hold the applicator between finger and thumb on the placement grooves and place Contrelle® Activgard at the opening of the vagina with the wings front to back, **not side to side towards your thighs**. The placement grooves on the applicator will help you correctly position Contrelle® Activgard, and help guide depth of placement. Everyone is different and you will find which position works best for you in terms of number of grooves outside the body.
- b. Part the labia with one hand and insert the Contrelle® Activgard into the vagina until your fingers touch your body. Every woman is individual, and you may need to tilt the angle of insertion.
- c. Ease the string off the bottom of the applicator and withdraw the applicator, leaving the string outside your body.
- d. Wash the applicator, carefully dry and store in the protective sleeve ready for future use.
- e. Wash your hands after insertion.
- f. Contrelle® Activgard should now be comfortably in place in the vagina, with the wings pressing gently against the urethra and rectum. Please note that the Contrelle® Activgard will only work when it has been correctly positioned in the vagina. After one or two uses it will become easy to position, and as easy as inserting a tampon. In case of any difficulties consult your healthcare professional.

3a.



3b.



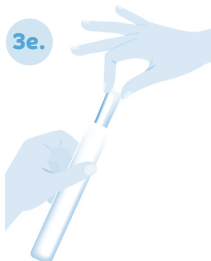
3c.



3d.



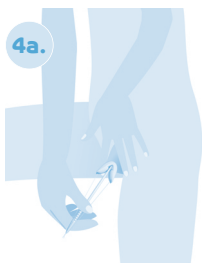
3e.



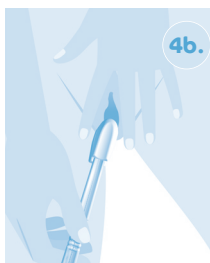
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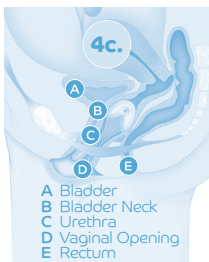
4a.



4b.



4c.



- A Bladder
- B Bladder Neck
- C Urethra
- D Vaginal Opening
- E Rectum

5. Removal

- a. ALWAYS remove Contrelle® Activgard after 16 hours or when you have finished sporting activities and always before going to bed.
- b. To remove the Contrelle® Activgard, pull gently downwards on the string.
- c. Wrap Contrelle® Activgard in tissue and dispose of in normal household waste. Do not flush it down the toilet. Do not re-use Contrelle® Activgard.
- e. Wash hands after removal.

WHEN TO CONSULT YOUR DOCTOR OR HEALTHCARE PROFESSIONAL

If you experience any of the following contact your Doctor or Health Professional:

- Difficulty inserting or removing Contrelle® Activgard
- Bleeding not related to your monthly period
- Irritation, discomfort, or pain
- Pain or burning when urinating
- If symptoms persist and Contrelle® Activgard does not reduce your bladder leakage. You may have a different type of incontinence that is not Stress Urinary Incontinence (SUI) or Mixed Urinary Incontinence (MUI).
- You can use Contrelle® Activgard when you have an Intrauterine device (coil) fitted though we recommend you speak to your doctor or healthcare professional to confirm suitability.

TOXIC SHOCK SYNDROME (TSS)

TSS, is a very rare condition caused by the bacterium, *Staphylococcus aureus*. About half the cases registered occur among menstruating women who use tampons. Most cases are found among younger women who use highly absorbent tampons.

There have been no reported issues of TSS with the use of Contrelle® Activgard. When Contrelle® Activgard has been fully saturated with water before use, it absorbs no moisture from the vagina. Although the risk of TSS is very small, it is important to be able to recognise the symptoms as the condition is serious and should receive immediate treatment.





TOXIC SHOCK SYNDROME (TSS)

Know the TSS symptoms. TSS can feel a lot like flu, and symptoms can vary from person to person, but most commonly the symptoms are:










- high temperature (usually exceeding 39°C, 102°F)
- a sunburn-like rash
- diarrhoea
- vomiting
- a sore throat and dizziness

If you should experience these symptoms, remove Contrelle® Activgard and contact your doctor or health professional immediately. Inform your doctor or health professional that you have been using Contrelle® Activgard.

SYMBOL MEANINGS

 Viveca Biomed Ltd Unit 1 & 2, Wansbeck Network Centre, Wansbeck Business Park, Ashington, Northumberland NE63 8QU	
EC REP CS Lifesciences Europe Limited 3 Inns Quay, Dublin 7, Ireland	
REF	Catalogue Number
LOT	Lot / Batch Number
	Date of Manufacture
	Consult instructions for use
	Do not re-use

SYMBOL MEANINGS

	Product supplied non-sterile
	Do not use if packaging damaged
	Protect from sunlight
	Keep dry
	Do not use for more than 16 hours in any 24-hour period
	EC Certified Product with Notified Body Number
	Indicates that the product is a Medical Device
	Contrelle® Activgard Device Size, Number describes size variant (Small - 1, Medium - 2, Large - 3)
	
www.contrelle.com	

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