

## DEVICE USE

**Each Contrelle® Activgard can only be used once.** A single Contrelle® Activgard can be used for up to 16 hours a day or just during activities such as running, swimming, taking exercise or other sporting activities. 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.

Always use the applicator to insert Contrelle® Activgard. Do not use anything other than the applicator to insert the Contrelle® Activgard.

For new users or women with some vaginal dryness we recommend using a water-based lubrication gel (available at most pharmacies) as this can make insertion and removal 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 current urinary or vaginal infections
- have untreated vaginal dryness which causes irritation without speaking to a healthcare professional
- have problems with manual dexterity which could cause insertion or removal issues
- were born with male anatomy

## WARNINGS AND PRECAUTIONS

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

- **Do not use Contrelle® Activgard more than once. DO NOT REUSE.** You risk potential harm of infection and / or irritation if the device is used more than once
- 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 package 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, moon cups and vaginal pessaries for prolapse
- 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 6 hours during menstruation
- Do not use a single device for more than 16 hours in any 24-hour period
- 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

## 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. For new users, please have some water-based lubricant available. We understand the concept of a bladder support will be new to some users. It's important

to relax before trying to insert or remove Contrelle® Activgard, otherwise your muscles will be tense. You may find it easier to insert the device when sat on the toilet, as this can help relax the pelvic floor muscles.

### 2. Start with the sizing kit

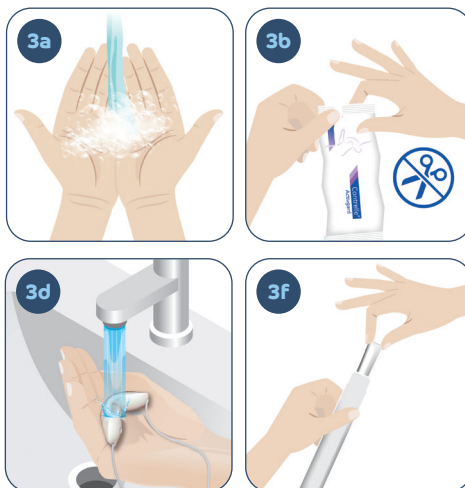
The sizing kit contains all three sizes.

**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. The size you need is **not** related to how much you weigh, how tall you are, how much you leak or how strong your pelvic floor is. It's about finding the right size, which is a combination of the fit for the size and shape of your vagina, as well as the amount of support needed for the bladder to help stop leaks. There is no benefit in trying a size which is too large as it will not provide better results in stopping leakage. It will also be too tight to easily insert and will make removal difficult.

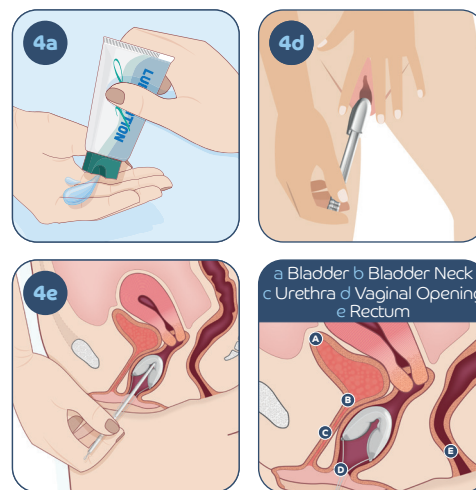
It is recommended to start with Size 1.

### 3. Preparation



- Wash your hands thoroughly before opening the package and pouch.
- To open, tear pouch at either end, remove Contrelle® Activgard from pouch. Do not use scissors or you will risk cutting the string.
- Take care when handling Contrelle® Activgard – make sure that you do not damage the foam with your fingernails.
- Soak Contrelle® Activgard thoroughly under running cold water holding in the palm of your hand, whilst at the same time slowly squeezing the device 10 times or more until the device is fully saturated. This should take at least 30 seconds. The foam device will expand in size by about a third in all dimensions and be smooth and even in appearance. If the device appears misshapen continue to run under water and to squeeze until it is even and smooth. You cannot over saturate the foam. When the device is properly saturated it will not absorb moisture from the vagina and is easier to put on the applicator.
- When saturated, squeeze out any excess water.
- Remove applicator from reusable protective sleeve.
- Place the string loop around the **BOTTOM** of the applicator (close to the grooves) with the knot in the middle of the hollow. **ALWAYS PLACE THE STRING ON THE BOTTOM OF THE APPLICATOR FIRST. DO NOT PUT THE FOAM DEVICE ON THE TOP OF THE APPLICATOR FIRST** as this will apply too much stress to the device and potentially cause it to tear.
- Once the string is in place, gently slide the Contrelle® Activgard foam device onto the top of the applicator, using your finger and thumb, so the central depression fits onto the top of the applicator. **DO NOT FORCE** the foam Activgard device onto the applicator – it should easily slide or nudge onto the top of the applicator without resistance.
- Always check the Contrelle® Activgard foam device for any possible damage/tears before you insert. If there is any damage do not use the device.

### 4. Insertion



- We recommend using a **water-based lubricant** gel at the entrance of the vagina to ease insertion. You may find you don't need this after the first few uses.
- It is important to relax so your muscles are not tense. Taking a deep breath can help and find a comfortable position that makes it easy to insert Contrelle® Activgard.
- Hold the applicator between finger and thumb on the grooves with both placed over the string. Place Contrelle® Activgard at the opening of the vagina with the foam wings **front to back, not side to side towards your thighs.**
- Part the labia (the lips at the vaginal opening) with one hand and insert the Contrelle® Activgard device into the vagina. You may need to tilt the angle of insertion. The device is designed to sit in the middle of the vagina to support the bladder. For most women Contrelle® Activgard should therefore not be pushed up as far as a tampon, as this may cause difficulties with removal and will make the product ineffective. We recommend for new users to start inserting the device to the first groove of the applicator. However, for maximum benefit, you may need the device to be slightly lower or higher depending on your anatomy. If higher, never insert to the top of the vaginal canal where the cervix sits. Whilst inserting the device, you should feel no pain or resistance. Never force the device, and insert slowly and gradually. Using a small amount of water-based lubricant at the vaginal opening can help with insertion. Finding the right position may require adjustments whilst you are getting used to the product. It is important to remember every woman is different so the optimal depth of insertion will vary, and you will find which position works for you.
- Ease the string off the bottom of the applicator and withdraw the applicator, leaving the string outside your body.
- Wash the applicator with soap and water, dry and store in the protective sleeve ready for future use.
- Wash your hands after insertion.
- Contrelle® Activgard should now be comfortably in place in the vagina. Please note that 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 or questions contact your Healthcare Professional or our Clinical Support Team. Email [info@contrelle.com](mailto:info@contrelle.com)

### 5. Size selection

For new users to find the best size, we recommend starting with size 1.

Once inserted you should feel comfortable and you should experience little or no urine leakage when you are active or when you cough, and the device should not move. If you still experience leakage, this could be due to the positioning rather than size. Before trying a larger size check the device isn't positioned too high, by gently pulling on both strings to slightly lower the position of

Contrelle® Activgard.

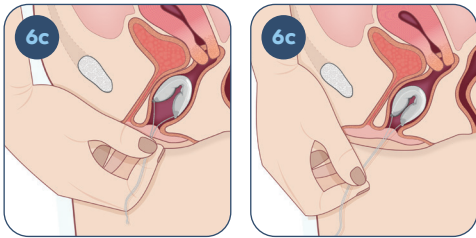
If this doesn't help and you still experience leakage or you feel the device moves with Size 1 try Size 2. If significant leakage still occurs when using Size 2, again try adjusting the positioning.

If you still experience leakage or the device moves change to Size 3.

We recommend you should walk for at least 30 minutes, cough, jump or run to check for any leakage and movement.

#### 6. Removal

- ALWAYS** remove Contrelle® Activgard after 16 hours or when you have finished sporting activities and **ALWAYS** before going to bed.
- We recommend using a water-based lubrication gel to ease removal. Some women find they don't need this after the first few uses. Apply the gel inside the vagina.
- Relax** and hold both strings evenly together (either side of the knot), as close as possible to the body, then gently and slowly ease the device out of the vagina. By pulling both strings gently together with equal pressure you pull the wings together for ease of removal. Using Contrelle® Activgard may need some practice. It is important to always relax – do not become stressed or tense as this will tighten your muscles and make removal difficult. Take your time, relax and take a break if needed. Some women find removing Contrelle® Activgard easier using a squatting or lying position or whilst sitting on the toilet.
- 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.
- Wash hands after removal.



#### TROUBLESHOOTING

##### The device is slipping

- Use a water-based lubricant at the vaginal opening rather than on the product. Make sure you only use water-based lubricants.
- Try a larger or alternative size.
- Try inserting the product slightly higher.
- If using vaginal oestrogen cream, gel or suppository, wait a few hours prior to inserting the device.

##### I cannot insert the product comfortably

- Try sitting on the toilet and inhaling to relax the pelvic floor muscles during insertion.
- Use a water-based lubricant.
- Ensure you have started with the smallest size.

##### The device is not working

- Draw the device slightly lower so that it sits only just above the pelvic floor muscles and is not pushed in as far as a tampon.
- Try inserting the device slightly deeper.
- Try a larger or alternative size.

If you have any questions or difficulties, contact your Healthcare Professional or our Clinical Support Team at [info@contrelle.com](mailto:info@contrelle.com)

#### 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.

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

 <b>Viveca Biomed Ltd</b> Unit 1 & 2, Wansbeck Network Centre, Wansbeck Business Park, Ashington, Northumberland NE63 8QU		Name and Address of legal Manufacturer
	<b>CS Lifesciences Europe Ltd</b> The Black Church, St. Mary's Place Dublin 7, D07 P4AX Ireland <a href="mailto:eurep@cslifesciences.com">eurep@cslifesciences.com</a>	Name, Address and Email of European Authorised Representative
	Catalogue Number	
	Lot / Batch Number	
	Expiry Date / Use By Date	
	Consult instructions for use	
	Do not re-use	
	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)	
		Contrelle® Activgard Applicator
<a href="http://www.contrelle.com">www.contrelle.com</a>		Website

# Contrelle® Activgard

Bladder support for women

## INSTRUCTIONS FOR USE

### PLEASE READ

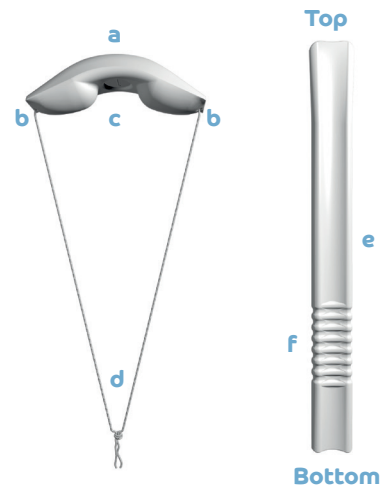


#### DEVICE DESCRIPTION

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.

Activities such as sneezing, laughing, coughing, lifting, exercise or other exertion can put the bladder under pressure, leading to a leak. These bladder leaks are known as stress urinary incontinence. SUI can affect up to 1 in 3 women, adversely impacting their quality of life.

- Contrelle® Activgard
- Wings
- Central depression
- String
- Applicator
- Grooves



#### CLINICAL BENEFITS

Contrelle® Activgard is a clinically researched medical device for women who experience bladder leakage. It is made from soft body compatible foam, which is inserted into the vagina using an applicator.

From within the vagina, it supports and stabilises the bladder neck and urethra (the tube which empties the bladder) whilst also gently improving the angle of the bladder neck.

This helps stop urine leakage. Whilst wearing Contrelle® Activgard you can empty your bladder as normal, without needing to remove the device.

ART-0004 rev05 v5