

## DEVICE USE

Each Contrelle® Activgard can be used for up to 16 hours a day or just when running, swimming, taking exercise or engaging in 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.

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 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
- are male

## 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 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 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.
- 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.

### 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. 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. 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 or you feel the device moves with Size 1 try Size 2.

If significant leakage still occurs when using Size 2 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.

Contrelle® Activgard should always be easy to insert. A small amount of water-based lubricant should provide added comfort to insert. If it feels too tight when you try to insert the device – STOP and try a smaller size. If you continue it could be difficult to remove.

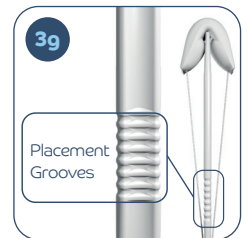
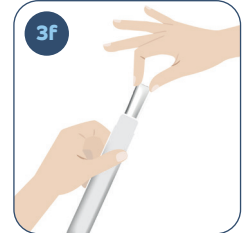
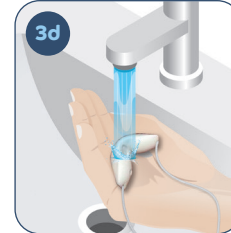
If you are new to Contrelle you may feel the device for the first few times of use/experience slight initial discomfort. After this initial period you should feel comfortable with Contrelle in place and many users will not feel the device.

### 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. Make sure the string is damp too. Squeeze it 9 or 10 times to make sure it is properly saturated as then it will not absorb moisture from the vagina.
- 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 placement 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

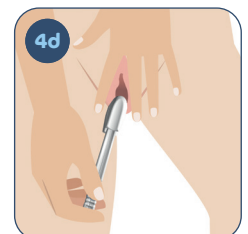
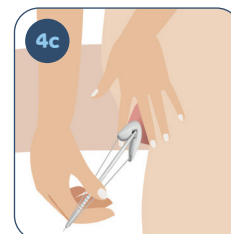
or nudge onto the top of the applicator without resistance.

- 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.

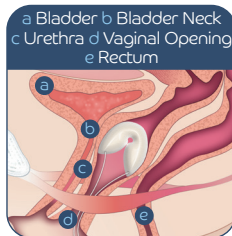
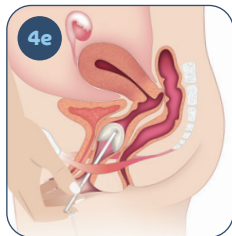


### 4. Insertion

- 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 then 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 **foam wings front to back, not side to side towards your thighs.**
- Part the labia with one hand and insert the Contrelle® Activgard device into the vagina. You may need to tilt the angle of insertion. The placement grooves on the applicator will help you correctly position Contrelle® Activgard and help guide depth of placement. We recommend inserting to the first placement groove on the applicator for the first few uses. Everyone is individual and you will find which position works best for you in terms of number of grooves outside the body. Please note that inserting too far can make it more difficult to remove the device. If whilst establishing the best position you are increasing the depth of insertion past the first groove, please do this gradually and carefully. Never force the device. As a guide, if you are familiar with inserting a tampon, Contrelle should sit slightly lower than a tampon.
- Ease the string off the bottom of the applicator and withdraw the applicator, leaving the string outside your body.
- Wash the applicator, dry and store in the protective sleeve ready for future use.
- Wash your hands after insertion.

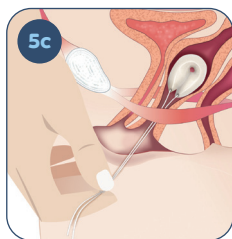
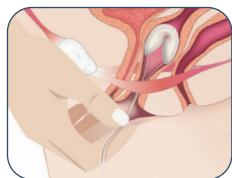


h. Contrelle® Activgard should now be comfortably in place in the vagina, with the wings pressing gently against the urethra and rectum. Please note that the Contrelle® Activgard will only work when it has been correctly positioned in the vagina. After one or two uses it will become easy to position, and as easy as inserting a tampon. In case of any difficulties consult your healthcare professional or contact our clinical support team. Email [info@contrelle.com](mailto:info@contrelle.com)



## 5. 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.
- 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.



## 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	Name and Address 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

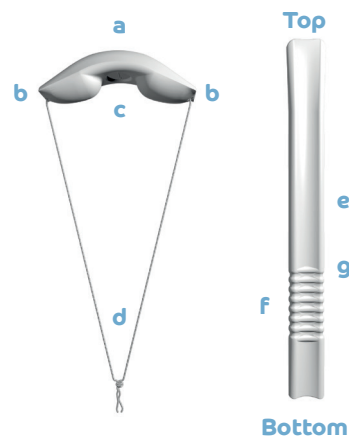
## INSTRUCTIONS FOR USE

## 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.

Stress urinary incontinence occurs when women leak when sneezing, laughing, coughing, lifting, exercise or other exertion, which puts the bladder under pressure. SUI can affect up to 1 in 3 women adversely impacting a woman's quality of life.

- Contrelle® Activgard
- Wings
- Central depression
- String
- Applicator
- Placement grooves
- First groove



## CLINICAL BENEFITS

Contrelle® Activgard is a clinically researched medical device for treating women who are experiencing bladder leakage caused by SUI. It is made of soft body compatible foam which is inserted into the vagina using an applicator. It sits comfortably inside the vagina to support the bladder neck and urethra, and gently helps improve the angle of the bladder neck to help stop bladder leaks due to 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 replace afterwards.