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Document No.	IFU En	Title	Information For Use
Issue	04	Date	01-04-08

IncoStress[®] Instructions For Use

IncoStress[®] is latex free.

IncoStress[®] has been developed to provide positive results to the majority of adult women of all ages who suffer with urinary stress incontinence

Intended purpose of IncoStress[®]

IncoStress[®] is designed for adult women of all ages who suffer with urinary stress incontinence only.

Note: IncoStress[®] is a medical device for stress urine incontinence only. Other degrees of incontinence or bladder problems should be discussed with your doctor first.

How it works

IncoStress[®] is worn inside the vagina, it naturally places pressure against the urethra (the tube that allows loss of urine from the bladder). This gentle pressure controls the involuntary loss of urine and restores the natural anatomical position of the bladder, thus, preventing stress incontinence.

Its unique shape allows the pelvic floor muscles to be gently exercised, which over a period of time may help strengthen them. It is not a pelvic exerciser and the user is recommended to carry out pelvic floor muscle exercises also.

Inserting

IncoStress[®] is inserted into the vagina using the same method as inserting a tampon. Find the most comfortable position for you to begin.

Before you insert IncoStress[®]

- Empty your bladder and wash your hands.
- Remove IncoStress[®] from the packaging and wash in clean water using non-perfumed soap.
- Normally you should not need lubrication as your body produces it naturally. If you should need extra lubrication use **ONLY WATER BASED LUBRICANTS** and **only** lubricate the top end of IncoStress[®].

Picture 1: Insert IncoStress[®] into the vagina (thick part first) as high as it will allow. In some cases the thin tail will be completely inside the vagina, it will always be within easy reach to remove. You may feel the presence of IncoStress[®], but it should not be uncomfortable. However, if you do feel any discomfort, remove, wash and re-insert

Picture 2: IncoStress in position, demonstrating the support of the bladder and urethra.

Removing

Relax the pelvic muscles, gently pull out IncoStress[®] using the tail.

If you find it difficult to retain IncoStress[®], there may be other medical conditions which contribute or it may be that your pelvic muscles are too weak to hold IncoStress[®]. In this case we recommend you use IncoStress[®] during sleeping hours as your pelvic muscles can work whilst asleep, helping them regain strength naturally over a period of time.

If you have any doubts, we strongly recommend you seek professional medical advice.

Usage

IncoStress[®] is to be removed, cleaned and inspected daily. It may be used up to a month.

This is a class IIa medical device and as such, must be replaced within 30 days after the package is initially opened. C&G Medicare Ltd will not take any responsibility if this product has been used outside recommendations contained in these instructions.

IncoStress[®] may be used during sleep.

Not to be used more than 8 hours continuously. After 8 hours remove, wash and leave out of the body for a minimum of 1 hour.

IncoStress[®] may be removed as many times as you feel necessary during the 8 hours period.

It is recommended that IncoStress[®] be removed before one opens the bowels and before urinating.

Cleaning, Inspection and Replacement

Visually inspect for any signs of discolouration, wear or damage daily. IncoStress[®] must be replaced one month after initial opening of the package or sooner as required.

Do not clean using alcohol, bleach or any other chemicals

Do not place in the dishwasher

Do not place in the microwave

Do not steam

Disposal

IncoStress[®] can be disposed of by simply wrapping in tissue or toilet paper and disposing with normal household waste. It must **not** be flushed down the toilet as it is **not** biodegradable and may cause blockages.

Warning and Contraindications

IncoStress[®] is made from Non Toxic Medical Grade Silicone.

Should you find you have any sensitivity to this material or are allergic, you must stop using the product immediately and consult your doctor.

Toxic Shock Syndrome (TSS) is a rare but a serious illness, it can be treated if recognised early.

Symptoms of TSS

Sudden high fever (usually over 39°C/102°F), vomiting, diarrhoea, sunburn like rash, sore throat, dizziness or fainting.

Not all these symptoms may be present at once.

In the unlikely event that you have these symptoms during use of the IncoStress, remove it immediately and consult your doctor.

Important

IncoStress[®] has been researched and designed explicitly for the intended purpose as stated in these instructions for use, and must NOT be used outside of these instructions for any other purpose.

IncoStress[®] is a SINGLE PATIENT USE product and must NOT be interchanged between patients.

IncoStress[®] must NOT be left in place any longer than 8 hours without removal, cleaning and inspection.

IncoStress[®] must NOT be flushed down a toilet.

IncoStress[®] must NOT be used during menstruation and never use a tampon at the same time.

IncoStress[®] must NOT be used if you are or think you are pregnant.

DO NOT USE IncoStress[®] if you have any urine, bladder or vaginal infections.

DO NOT USE IncoStress[®] if you have any known allergies to any sort of silicone.

For further information visit www.incostress.com

Manufactured in the UK by C&G Medicare Ltd.

Registered office: 5 Spoonbill Close, Glamorgan CF36 3UR

C&G Medicare Ltd is constantly aware of keeping our customers satisfied.

Your feedback is important to us. Email: info@incostress.com

Thank you for taking the time to let us know.

Revision History

Issue	Date	Revision
00		Original Issue see original IFU
01	20-07-07	Complete new info sheet produced.
02	25-08-07	See highlighted area for changes, all ® symbols are subscript. Pictures a,b,c have been removed. Instructions for picture 3 and 4 have been removed.
03	01-04-08	See highlighted areas for changes

Dated: 2010