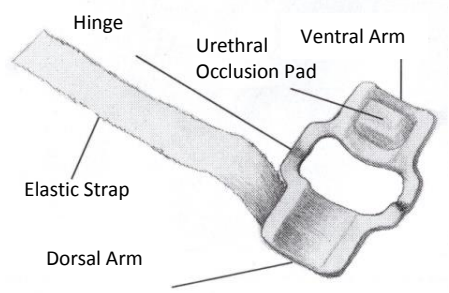
Male Continence Device Physician Instructions for Use

The C3® male continence device is an externally applied occlusive device intended for the control of incontinence in males. The device consists of a cradle which is hinged in the mid-portion. The cradle and hinge are constructed of semi-rigid plastic and coated with foam on the inner surface. The hinged portion of the device contains an opening of sufficient diameter to allow it to be placed over the penis. One arm of the cradle (ventral arm) contains a urethral occlusion pad on the inner surface and the other arm (dorsal arm) has an elastic strap attached to the outer surface. The penis is placed through the opening in the hinge of the device so that the foam surface will be in contact with the penile shaft. With the dorsal cradle arm positioned over the dorsal surface of the penile shaft, the elastic strap is secured to hold the device snugly in place. When the device is positioned in this manner, sufficient force is applied to hold the device in place and to allow the urethral occlusion pad to occlude the urethra.



The device is available in two sizes. The regular size fits a penile circumference of 6.0 to 10.0 cm at the base of the penis. The large size accommodates a penile circumference greater than 10.0 cm at the base of the penis.

Indications

The C3® male continence device is intended for management of incontinence in males who are considered candidates for an external urethral occlusive device.

Contraindications

Do not use in patients with unresolved adverse side effects from prior use of an external incontinence device.

Do not use in patients with pre-existing skin conditions or other medical conditions which would predispose them to developing adverse affects from using an external urethral occlusive device.

Do not use in patients with indwelling urinary catheters or implanted penile prosthetic devices.

Warnings

Patients using this device must be instructed regarding an appropriate bladder management program. The device should be removed and the bladder emptied at a minimum of once every 4 hours. Do not urinate without opening or removing the device. Discontinue use if skin reaction or irritation, pain, swelling, pressure sores or other signs of decreased penile circulation occur. Discontinue if pain or other difficulties with urination occur.

Precautions

Use with caution in patients with decreased mental capacity, decreased sensation of the genital organs or ongoing urinary tract infection. Do not use the C3® male continence device if it becomes wet or damaged. Attempts to wash the device will cause it to degrade. Discard the C3® device and replace when soiled.

Caution

Federal (U.S.A.) law restricts this device to sale or use by and on the order of a physician.

Side Effects and Complications

Potential risks and complications include, but may not be limited to, pain, swelling, erosion, pressure sores, reaction or irritation of the skin and tissues underlying or surrounding the device or the entire penis. Continued use of the device in the presence of adverse effects may result in more serious complications.

Replacement/Reuse

The C3® continence device is disposable. The device should be discarded if the foam becomes compressed or soiled, the strap loses its holding ability, or the strap detaches from the cradle.

Expected Results

The C3® male continence device is intended for men who are incontinent due to decreased bladder outflow resistance. The presence of any unstable bladder contractions will decrease the success achieved with the device. A patient learning and adjustment period of approximately one week is required. During this time, the patient should be encouraged to experiment with the position of the device on his penis, as well as the adjustment of the fastening strap for optimal comfort and efficacy. The amount of control achieved by an individual patient is related to the severity of his incontinence, motivation and concomitant use of a program to moderate fluid intake and empty the bladder on a schedule if appropriate. Patients with mild to moderate incontinence will achieve the best results with the device. In patients with severe leakage, the optimal result may be a significant reduction in the size and/or the number of pads used. To optimize results, especially in severely incontinent men, have the patient keep a diary to characterize the relationship of incontinent episodes with the fluid intake and bladder emptying. Once this is done, a schedule for moderating fluid intake and bladder emptying may be found to be appropriate.

Instructions for Use

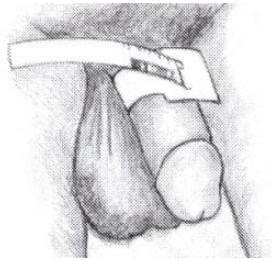
Size Selection

Use a measuring tape to determine the appropriate sized device as follows:

1. Wrap the measuring tape around the base of the penis at its widest girth.

2. Gently pull the tabs in the direction of the arrows until the tape rests around the penile shaft. Do not pull the tape so tightly that it deforms the penis. This will result in incorrect sizing.

3. Observe the shading zone that appears in the window between the arrows



Positioning the Device

1. With the white foam side of the C3® device facing toward the body, place the penis through the opening in the hinge.

2. Position the lower arm of the device so that the urethral occlusion pad is positioned against the urethra, midline on the bottom of the penile shaft.

Figure 3

3. Place the upper arm along the top of the penile shaft. (see figure 3.)

4. Secure the device by strapping the elastic strap around the penis. Secure the elastic strap so that the device is comfortably snug. Take caution not to pinch the skin between the elastic strap and the external portion of the device. (see figure 4.)

5. To urinate or remove the C3® device, the elastic strap must be opened and loosened.

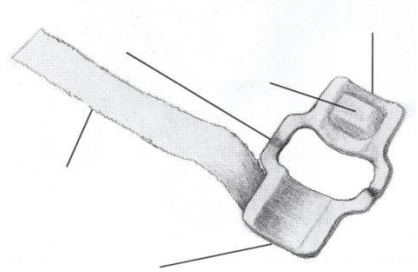
Figure 4

Do not urinate without opening the plastic strap.

C3 Male Continence Device Patient Instructions for Use

The C3® device is an external male continence device that is applied to your penis to prevent of decrease episodes of incontinence (involuntary loss of urine).

A diagram of the C3® device is shown in Figure 1. The device is made of semi-rigid plastic with foam on the inside. It consists of a cradle with a hinge in the middle. The cradle has an upper (2) and a lower (3) arm. The upper arm has an elastic strap (4) on the outside. The elastic strap is used to hold the device in place on your penis. The lower arm has a urethral occlusion pad (5) on the inner surface. The urethra, the tube which carries urine out of your body, is located on the underside of your penis close to the skin.



When the device is in place on your penis, the urethral occlusion pad presses on the urethra of prevent involuntary loss of urine.
The device comes in two sizes. Your doctor will determine which size is appropriate for you to use.

Important things you should know

Caution:

The device should only be used under the direction and supervision of your doctor. Do not use the device until your doctor has instructed you regarding the proper use of the device.

Some of the complications which could occur from use of the device are pain, swelling, pressure sores, reaction or irritation of the penis or tissues underlying of surrounding the device, difficulties or pain during urination. If these or any other symptoms related to the use of this device occur, discontinue use and contact your doctor.

The C3® is a disposable device. The number of days you can use depends on how wet and soiled it gets and soiled it gets and on normal wear. If you notice the foam padding becoming compressed or soiled, of if the strap loses its holding ability or detaches from the cradle, it is time to discard it and use a new C3®.

You must follow a program to empty your bladder while using this device your doctor will give you directions for a program which is suitable for you. If not, the C3® device should be opened or removed and you should empty your bladder at least once every four hours when the device is in place.

Instructions for Use

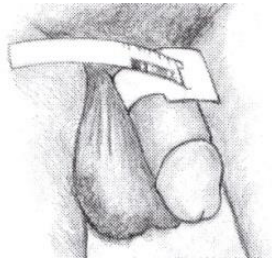
Size Selection

Use a measuring tape to determine the appropriate sized device as follows:

1. Wrap the measuring tape around the base of the penis at its widest girth.

2. Gently pull the tabs in the direction of the arrows until the tape rests around the penile shaft. Do not pull the tape so tightly that it deforms the penis. This will result in incorrect sizing.

3. Observe the shading zone that appears in the window between the arrows



Positioning the Device

1. With the white foam side of the C3® device facing toward the body, place the penis through the opening in the hinge. (See figure)

2. Position the lower arm of the device so that urethral occlusion pad is positioned against the urethra, midline on the bottom of the penile shaft. (see figure)

3. Place the upper arm along the top of the penile shaft. (see figure 2)

4. Secure the device by strapping the elastic strap around the penis. Secure the elastic strap so that the device is comfortably snug. Take caution not to pinch the skin between the elastic strap and the external portion of the device. (see figure 3)

5. To urinate or remove the C3® device, the elastic strap must be opened and loosened. Do not urinate without opening the plastic strap.

Do not urinate without opening or removing the device.

European Distribution:

mtm medical | technology | marketing

Waffenschmiedweg 30a
86911 Diessen Germany
Tel.: +49 (0)8807-91138
Fax: +49 (0) 8807-940899
e-mail: sl.mtm-med.com
Internet: www.mtm-med.com

Manufacturer:

personalmed
advancing pelvic health®

Redmond, WA 98052 | USA

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