



DEVICE:

Bakane Incontinence Control Device (B.I.C.D.)

INDICATIONS:

Urinary Incontinence, Severe Urinary Urgency

CONTRAINDICATIONS:

Severe penile deformity. Patient's on anticoagulants. Vascular insufficiency or problems with blood circulation. Use of blood thinning medications are relative contraindications. Also, patients who have penile deformity, such as Peyronie's disease, the B.I.C.D. should be used with caution.

USE:

The one size usually fits all B.I.C.D. is meant to be used for severe urinary urgency or urinary incontinence. The B.I.C.D. straps around the penis so that the Pressure Push Tab 'T' compresses the urethra. It is recommended that the user makes himself familiar with the B.I.C.D.. The B.I.C.D. consists of Strap 'S,' Button 'B,' Strap Gate 'G,' Elevation 'E,' Pressure Push Tab 'T,' and Soft Lining 'L.' The Pressure Push Tab and Button mechanisms are covered by Soft Lining 'L' and cannot be seen. The Button 'B' on the lower aspect of the B.I.C.D. operates the Pressure Push Tab. When the Button is pressed, the Pressure Push Tab elevates and you can see the convexity of the inner soft lining and Elevation of point 'E.' When the button is pressed again, the point 'E' comes down, the inner lining becomes flat. It is recommended that the Pressure Push Tab is moved to the elevated position and then the B.I.C.D. be placed around the penis. Extreme care should be exercised when placing the B.I.C.D. around the penis to make sure that the penile skin does not get trapped between the Strap 'S,' and the Strap Gate, 'G.' Placing a piece of gauze around the penis can help prevent trapping of the skin. Once the Strap Gate is engaged, the B.I.C.D. can be tightened around the penis. It is not necessary to make the B.I.C.D. very tight, just light pressure is sufficient to prevent the user from leaking urine. The B.I.C.D. should be comfortable for the user to wear.

The B.I.C.D. should not be left in place for extended periods. The B.I.C.D. should be periodically loosened during use. During the period the B.I.C.D. is in use, the wearer can urinate without having to remove the B.I.C.D. from around the penis. Slight pressure on the sides will create a gap between the penis and the Pressure Push Tab and by itself may be sufficient to allow

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USE (CONTINUED):

urination. Additional relief can be obtained by pressing the Button 'B' in this position while maintaining side pressure. If necessary, the Strap 'S' can be loosened by elevating the Tie Mechanism 'M.' Once urination is achieved, maintain pressure on the sides, then press Button 'B.' Then release the side pressure. The strap can now be re-tightened if necessary.

PRECAUTIONS:

Care should be taken to prevent trapping of the skin between the Strap 'S' and the Strap Gate 'G.' The B.I.C.D. should not be left on for extended periods. It is important that all of these instructions are received from the physician and the user must become fully conversant with the use of this B.I.C.D. and its release mechanisms.

Properly used, the B.I.C.D. will give trouble free use for control of incontinence or urgency. The B.I.C.D. is washable, but care should be taken to prevent fluids from entering the push button mechanism.

SIMPLE STEPS:

1. Push in Button 'B' to elevate 'P.'
2. Position 'P' under the urethra.
3. Engage Strap 'S' in gate 'G' taking care to keep the penile skin clear of the gate.
4. Tighten the B.I.C.D. to a comfortable position.

TO RELEASE:

1. Compress the B.I.C.D. from the sides, then press the push Button 'B' to depress 'P.'
2. If necessary, loosen the Tie Mechanism 'M.'

AFTER URINATION:

1. Compress from both sides.
2. Press Button 'B'
3. Let go side compression
4. Tighten B.I.C.D. as needed



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