INSTRUCTIONS FOR USE: URETHROGRAPHY CLAMP

BERNA RING ® URETHROGRAPHY DEVICE

MD

INDICATIONS

Urethrography continues to be the main imaging technique for the morphological and functional study of the male urethra. It is divided into Retrograde Urethrography (RUG) and Voiding Cystourethrography (VCUG).

RUG is indicated to assess strictures, fistulous tracts, diverticula, or other anomalies of the anterior urethra, as well as to classify urethral traumas.

VCUG is indicated to evaluate anomalies of the posterior urethra (strictures, fistulae, or diverticula) and the bladder (tumors, malformations, diverticula, or vesicoureteral reflux).

To visualize periurethral tissues, new imaging techniques are necessary: Sonourethrography (SUG) and Urethrography-Magnetic Resonance (U-MR).

B-Ring® is a medical device specifically designed by expert clinicians and indicated for performing any of these procedures.

Its advantages include the easy handling of the device, that it does not cause discomfort to the patient, and that it can be used in cases with alterations in the urethromeatal region: strictures, malformations (e.g., hypospadias) or previous surgery (e.g., meatotomy).

In RUG, it is recommended to introduce the contrast by gravity infusion, using a small-diameter urethral catheter without a balloon, and placing the bottle with iodinated contrast 2m from the floor, which allows the bladder to be retrogradely filled in approximately 10 min and the VCUG to be performed without the need for bladder catheterization.

Gravity infusion is also advised for retrogradely introducing physiological saline solution in SUG and contrast (gadolinium) in U-MR, with the advantage that it avoids the examiner from having to manipulate syringes.

DESCRIPTION

Aprobado por técnico responsable. Approved by the Qualified Person
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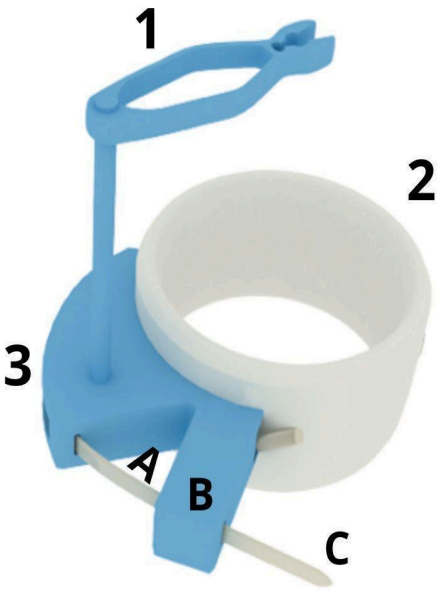
B-Ring® is a Class I medical device for the diagnostic imaging of anomalies in the male urethra. Its use is restricted to qualified professionals (Physician or Nursing personnel). The device is a clamp system that features three main elements in its design: catheter clip, padded ring, and rigid base.



1. **CATHETER CLIP (*PINZA PORTASONDA*):** It has two holes for fixing a 10 Fr or 6 Fr catheter (in case of urethromeatal stricture).

2. **PADDED RING (*ANILLO ACOLCHADO*):** When the strap is pulled, it reduces its diameter and applies external compression.

3. **RIGID BASE (*BASE RÍGIDA*):** The V-notch (A), the grip mark (B), and the strap (C) are located here.

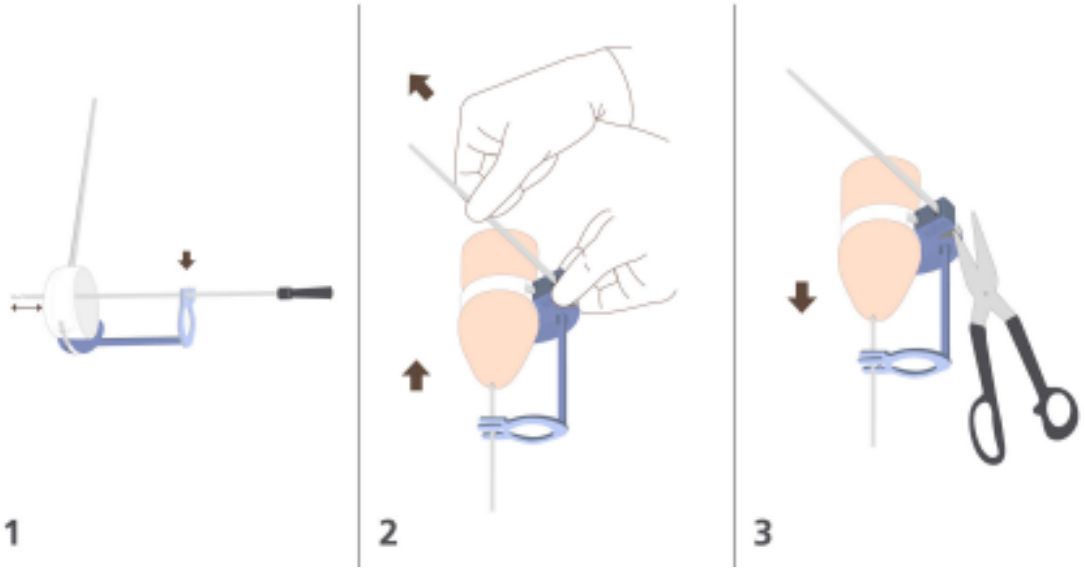
INSTRUCTIONS FOR USE

B-Ring® is used along with a pre-lubricated urethral catheter connected to an infusion system. The procedure can be divided into three steps: connection, compression, and removal.

1. **Connection:** The catheter is connected to the infusion system and is fixed in the device's catheter clip after checking that its tip is separated about 2cm from the padded ring, to prevent the contrast outlet holes from being obstructed when compression is applied.

2. **Compression:** If there is a foreskin, it is retracted, and the glans is cleaned with povidone-iodine (Betadine®). After purging the infusion-catheter system, the device-catheter is introduced until the ring is positioned in the coronal sulcus. The strap is progressively and carefully pulled while holding the device at the grip mark until no contrast extravasation is observed. The retrograde study is then performed.

3. **Removal:** The strap is cut with scissors at the V-notch, which allows the compression of the ring to be released and the device-catheter to be easily removed. The voiding study is then performed.



CONTRAINDICATIONS

Allergy to iodinated contrast and acute urinary infections.

WARNINGS

The use of B-Ring® is not recommended in the pediatric population (< 12 years) and caution should be exercised when using it in the following situations:

1. Phimosis and Paraphimosis.
2. Dermatitis and superficial wounds in the balanopreputial region.
3. In cases where more than 20 minutes are needed for the retrograde filling of the bladder, it is recommended to release the external compression and remove the device to stop ischemia and venous congestion of the glans.
4. Do not use in patients recently operated on the urethra (< 6 weeks).
5. **DO NOT USE IN CASE OF DETERIORATION OF THE PROTECTIVE PACKAGING.**

STORAGE CONDITIONS

Store the product at room temperature and in a dry place, protected from humidity

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