CoreFlow®

COREFLOW® SOFT STENT
INSTRUCTION FOR USE
ENGLISH

DEVICE DESCRIPTION

The product CoreFlow® Soft Stent is a device for management of bladder outlet obstruction.

- Enables sphincter-controlled continence and is suitable for patients with urinary retention.
- Temporarily de-obstructs the prostatic urethra.
- Two-piece innovative design simplifies the introduction and allows initial use as a normal indwelling catheter.
- Designed with a balloon at its proximal end for bladder anchor and coil in the distal section to keep it from migrating.

The product CoreFlow® Soft Stent is a catheter with two functions:

- Work just as an indwelling Foley catheter.
- When the lower part is removed by a pulling force, the upper part functions as a short catheter for the prostatic urethra. The micturition functions normally and the external sphincter is closed after micturition.

CoreFlow® Soft Stent principle:

- The CoreFlow® Soft Stent is a soft stent that consists of two parts, referred to as the front section and rear section, see figure 1. The two parts can be separated by a simple operation.
- The diameter of the front section is 20 Fr/Ch/6.7 mm and the diameter of the rear section is 16 Fr/Ch/5.3 mm.
- The CoreFlow® Soft Stent has a balloon at its proximal end to anchor it in the bladder and a drainage lumen.
- The separation of the CoreFlow® Soft Stent occurs between 30 and 50 mm below the anchoring balloon depending on the length of the device.
- The balloon is inflated with sterile water or sterile saline solution using a medical syringe connected with a luer taper to the balloon inflation valve.
- A catheter connector with or without a urinary bag can be attached to the drainage funnel.

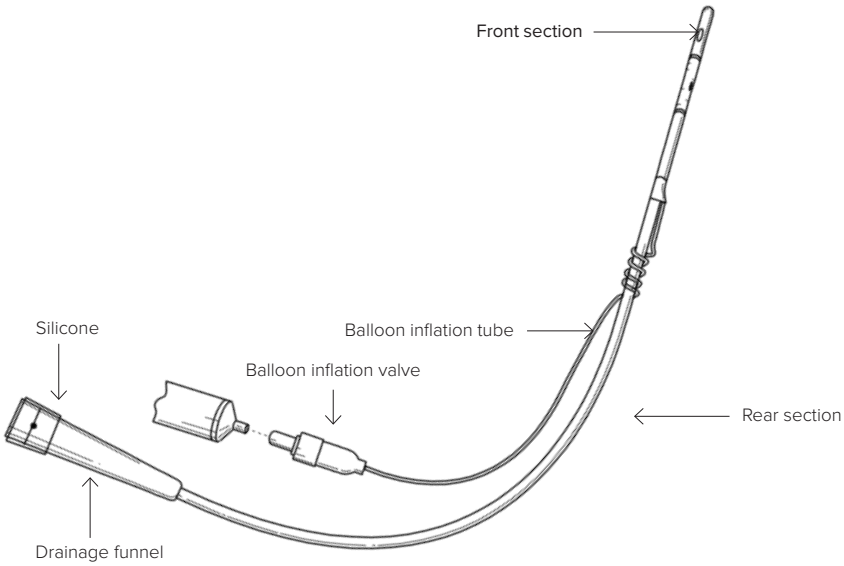

Figure 1

- The balloon inflation tube forms a spiral 25 mm below the front section. The spiral has the function of a second anchor and prevents the CoreFlow® Soft Stent from sliding up into the bladder.
- A thread is attached to the front section and runs through the drainage lumen. When the front and the rear section of the CoreFlow® Soft Stent are connected the two sections are held together with this thread. The thread is covered by a silicone layer on the funnel part to prevent leakage.
- The CoreFlow® Soft Stent is only for usage during a maximum of 29 days.
- The CoreFlow® Soft Stent is delivered sterile and ready to use.

INTENDED PURPOSE

Intended use

Temporarily resolve obstruction of the prostatic urethra.

Intended user profile

Male patients with urinary retention. Stent length 30 mm for prostate length >30 mm. Stent length 40 mm for prostate length >40 mm. Stent length 50 mm for prostate length >50 mm.

Intended use environment

Hospitals, health care centers and home environment.

INDICATIONS

- Post all active BPE/BPH treatments.
- Patients in need for indwelling catheters (not only limited to patients waiting for final treatment).
- Diagnostic tool to pre-check continence and mimic micturition after an attended active treatment (TURP/TUMT) by temporary relieving prostate obstruction (not only limited to cerebral cause).
- Patients using Clean Intermittent Self-catheterisation (CISC)

CONTRAINDICATIONS

- History of urinary tract disease including urethral stricture, bladder neck contracture, bladder, or kidney stones, other significant urological condition, or abnormal urethral anatomy.
- History of difficult urethral catheterization (need of cystoscopy before stent application).
- Current bleeding
- Urinary incontinence
- Prostatic length 30 mm or shorter

PRECAUTIONS

There is a risk for complications if the CoreFlow® Soft Stent is not handled carefully and correctly. The risk for complications can be minimized by using the product as described in this instruction for use.

Consider the patients status of hematuria and coagulum before using the CoreFlow® Soft Stent after TUMT:

- If the patient is showing signs of pronounced bleeding or presence of coagulum, the bladder should be flushed with large amounts of solution through a normal Foley catheter or the CoreFlow® Soft Stent before removing the rear section. If pronounced bleeding does not subside the CoreFlow® Soft Stent should not be used.
- If there are minor or moderate signs of bleeding, there is no need of flushing since urine counteracts the formation of coagulum due to its fibrinolytic effect.

Damaged packaging

Damaged packaging means that the CoreFlow® Soft Stent is no longer sterile. Non-sterile products must not be used.

Decreased performance

Verify that all parts of the rear section, including the protruding connection tube, are removed when separating the CoreFlow® Soft Stent.

Infection risk

Verify that all remaining parts of the CoreFlow® Soft Stent are removed from the patient after use.

Risk of problems when removing the CoreFlow® Soft Stent

If the knot on the thread is removed by mistake, the thread may be pulled out of the front section of the catheter (stent) thus making it difficult to remove the CoreFlow® Soft Stent from the patient. The stent can always in this situation, as an alternative, be removed by pulling the thin silicon balloon inflation tube after emptying the balloon.

SIDE EFFECTS

- Urethritis – local irritation of the urethral mucosa and secondary urge sensation.
- Minor leakages with dripping after voiding and the need for a pad to harbor the thread and the tiny tube if this occurs.

ADVERSE EVENTS

Mechanical problems with insertion

Mechanical problems related to the insertion and the positioning of the CoreFlow® Soft Stent device. Placement of the device meet the same difficulties you experience placing an ordinary Foley catheter. By using double amount of lubricant and anesthetic jelly and waiting for > 5 minutes the device will normally slide easily into the urinary bladder. However, problems related to the placement of the device and/or correction of the position after placement occurs occasionally. Some of these problems should be accounted for on the learning curve, which always is present when a new technique is introduced.

Displacement of the device

Displacement of the device usually seems to be relatively easy for the patient to adjust by application of slight traction on the blue thread. As with all mechanical devices in the lower urinary tract, irritation caused by the device itself can also be seen.

REPORTABILITY

Any serious incident that has occurred in relation to the medical device shall be reported to ProstaLund AB and to the authority having jurisdiction in your locale.

DIRECTIONS FOR USE

Selecting correct length

1. Measuring the prostatic length using TRUS according to Figure 2

The different CoreFlow® Soft Stent item numbers have different lengths (see Table 1) of the catheter part that will reside inside the prostate. The CoreFlow® Soft Stent version selected should be chosen to match the patient's prostatic anatomy. From TRUS measurements of the prostate dimensions, see Figure 2, use the measurement of the prostatic urethra length as a guide to which active length of the CoreFlow® Soft Stent to be chosen. Note that if the CoreFlow® Soft Stent is used post TUMT or after other heat-based therapies it may be necessary to take the increased length due to swelling of the prostate into consideration.

SAGITAL VIEW

Figure 2. Illustration showing how to place TRUS markers to measure the Prostatic Urethra Length.

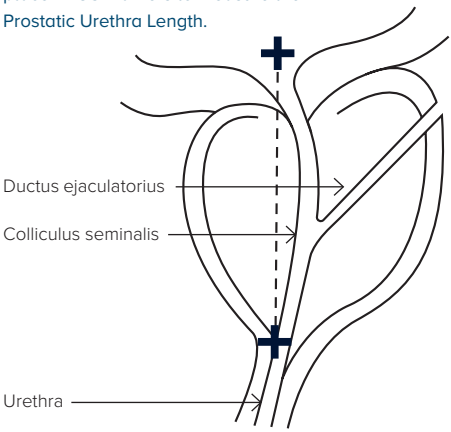

Table 1

Length of CoreFlow® Soft Stent [mm]	Article number
30	BNC 819130
40	BNC 819140
50	BNC 819150

Inserting the CoreFlow® Soft Stent

1. Check that the sterile packaging is unbroken and remove the CoreFlow® Soft Stent from the sterile packaging. Handle it as a sterile product.
2. Examine the CoreFlow® Soft Stent. In particular, check the balloon for leakage by inflating it with 10 ml of air. If there is any sign of damage discard the CoreFlow® Soft Stent and continue the session with a new sterile catheter.
3. Insert double amount of anesthetic gel into the patient's urethra and keep it in place with a penis clamp > 5 minutes.
4. Insert the CoreFlow® Soft Stent into the urethra and into the bladder and fill the balloon with 10 ml of saline solution through the balloon inflation valve on the balloon inflation tube. The bladder will empty through a drainage lumen when the CoreFlow® Soft Stent is inserted correctly.

5. Gently stretch the CoreFlow® Soft Stent until the balloon reaches the bladder neck.

Removing the rear section

1. Before separating the rear part, the bladder can be filled with fluid. This will facilitate the tests below where the patients' micturition is tested. Fill the bladder slowly with saline solution until the patient feels urge.

2. Remove the silicone layer from the drainage funnel. Pull the loop of the thread over the funnel according to **Figure 3**.

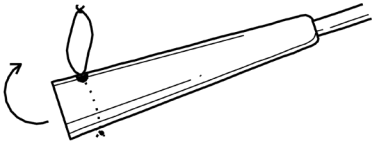

Figure 3

3. Carefully remove the rear section of the catheter by pulling lightly. Note! Only pull the catheter part and not the balloon inflation tube or the thread. Verify that all parts of the rear section, including the protruding connection tube have been removed, see **Figure 4**.

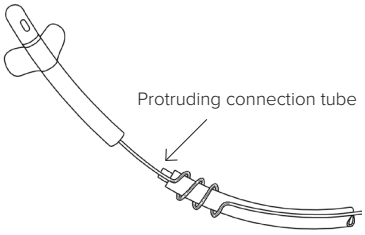

Figure 4

4. Place two overhand tight knots on the part of the balloon inflation tube exiting from the meatus to make sure that the balloon filling cannot leak. Position the knots close to the balloon inflation valve e.g. far away from the urethral meatus to prevent discomfort during nightly erections. The overhand knot is illustrated in **Figure 5**. Cut off the part of the tube with the balloon inflation valve below the knots.

5. Instruct the patient of the function of the CoreFlow® Soft Stent including how to reposition the front section (stent) if it has migrated partly into the bladder and how to micturate by using the thread.

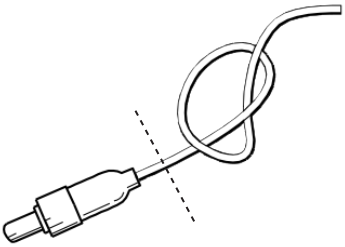

Figure 5

Confirm that the patient has received and fully understands the patient information.

6. Let the patient stay under your direct supervision before you let him home in order to see if he can micturate satisfactorily and is continent. Confirm that the patient can micturate by pulling the rear end of the front section just below the sphincter, and that the micturition ceases when the thread is released.

Removing the CoreFlow® Soft Stent

1. Cut off the balloon inflation tube close above the knots to let the balloon fluid out by self-pressure.

2. Carefully remove the front section of the CoreFlow® Soft Stent placed in the prostatic urethra by pulling the thread while keeping the balloon inflation tube gently stretched.

3. Verify that all remaining parts of the CoreFlow® Soft Stent are removed from the patient after use.

4. Dispose the CoreFlow® Soft Stent after use in accordance with the applicable routines.

5. Verify that the patient can micturate spontaneously before letting him home.

SAFE DISPOSAL

Dispose of the catheter after use in accordance with established hospital routines.

STORAGE AND HANDLING

The CoreFlow® Soft Stent is a disposable sterile product intended for single use only. It is sterilized using ethylene oxide and is to be used before the expiry date stated on the product label. The CoreFlow® Soft Stent shall be stored in a clean and dry environment at a temperature between 10 – 30°C. Relative humidity (non-condensing) shall be between 10 – 80% R.H

SYMBOLS

 Manufacturer

 Read instructions for use

 Date of expiry

 Sterilized by Ethylene oxide

 Balloon capacity

 Length of the stent

 Diameter at the front of the catheter

 Article number

 Batch number

 Do not re-use. Single use device

 Medical Device

 Temperature range

 Relative Humidity range

 Do not use if product sterile barrier system or its packaging is comprised

 Singel sterile barrier system with protective packaging outside

ORDERING INFORMATION	
Device	**Article number**
CoreFlow® Soft stent Length of stent 30 mm	BNC 819130
CoreFlow® Soft stent Length of stent 40 mm	BNC 819140
CoreFlow® Soft stent Length of stent 50 mm	BNC 819150

ProstaLund®

CONTACT INFORMATION

ProstaLund AB
Scheelevägen 19
SE-223 63 Lund
Tel: +46 (0)46 12 09 08
E-post: info@prostalund.com
www.prostalund.se
www.coreflow.se

Medical Device CE 0123