

## Retrospective pilot study evaluating a new device, the Coreflow® – Soft Stent

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### Objective

In a retrospective study the use of a new temporary stent – CoreFlow® Soft Stent-was evaluated in 51 patients. This new device was used instead of an ordinary indwelling catheter post microwave treatment of BPH using the Prostalund CoreTherm device

### Method

51 consecutive patients were included in the study. The device is shown in Figure 1. The device comes in different lengths of the stent part. The suitable length was determined using TRUS prior to the treatment. After the microwave treatment, the CoreFlow® was introduced in a similar way as an ordinary Foley catheter, see Figure 2. The bladder was flushed through the device and then filled with saline solution. The device's rear part was then separated with the stent part positioned in the prostatic urethra and the "pull-thread" and balloon tube running through the urethra and ending outside the meatus, see Figure 3.

After placement, the patients performed a voiding test to demonstrate:

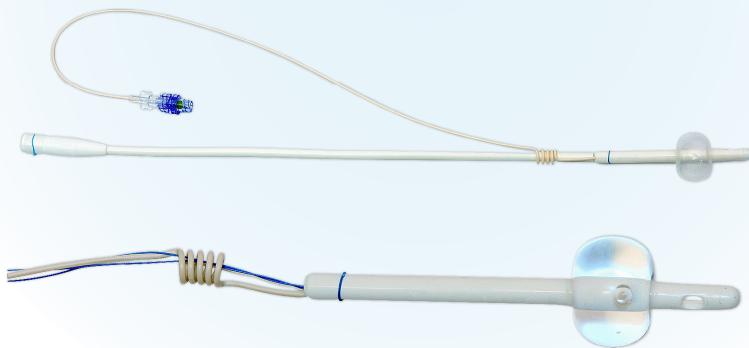
- sphincter controlled voiding function
- continence
- that the self-catheterization mechanism functioned by forcing the external sphincter to open by using the "pull-thread" of the device, see Figure 4.

### Results

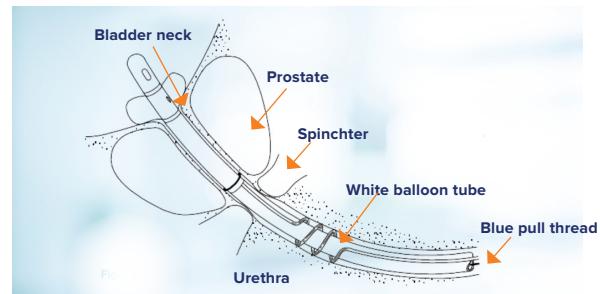
The CoreFlow® was found to be very easy to place and remove. One out of 51 patients needed to have the stent removed prematurely due to a blockage in the drainage canal. Most of the patients needed to slightly reposition the stent using the pull thread the first couple of days after the microwave treatment. Some patients also needed to use the "pull-thread" to perform self-catheterization the first days after the procedure. No patients developed symptomatic UTI during the use of the stent. One patient had a positive urine culture after the removal of the stent.

### Conclusion

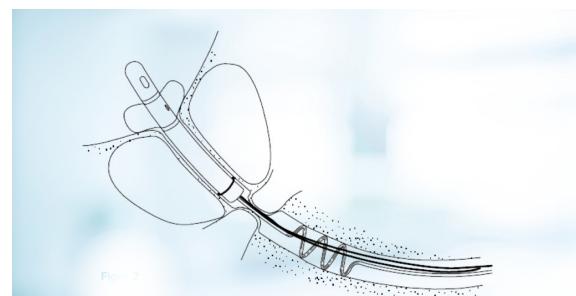
The initial experience indicates that the device can successfully be used post microwave treatment to replace an indwelling catheter. The CoreFlow® seems to have a large potential in lowering the risk of UTIs post invasive procedures like microwave therapy as well as improving health related quality of life aspects.



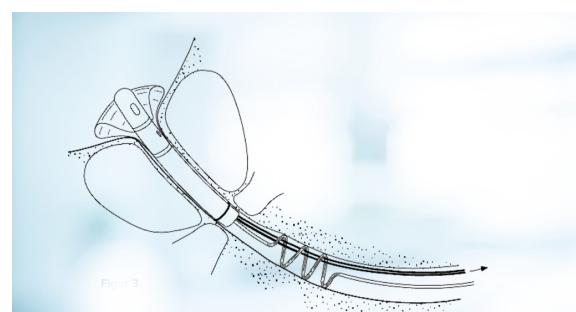
**Figure 1.** Pictures of CoreFlow® - Soft Stent. The top picture shows the device prior to separation of the lower part. The bottom picture shows the upper - i.e. the stent part of the device. The stent is anchored at the bladder neck with the balloon and below the external sphincter with the coil.



**Figure 2.** Schematic showing the CoreFlow® during insertion. Inserted as an ordinary Foley catheter.



**Figure 3.** Sphincter controlled voiding is possible with CoreFlow® in place as a stent in the prostatic urethra.



**Figure 4.** Self-catheterization using the "pull-thread" mechanism. The balloon is made of a soft material allowing it to be compressed when force is applied. The rear part of the stent thereby opens a flow channel past the sphincter. When the "pull-thread" is released the stent is repositioned by the balloon returning to its original shape.

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