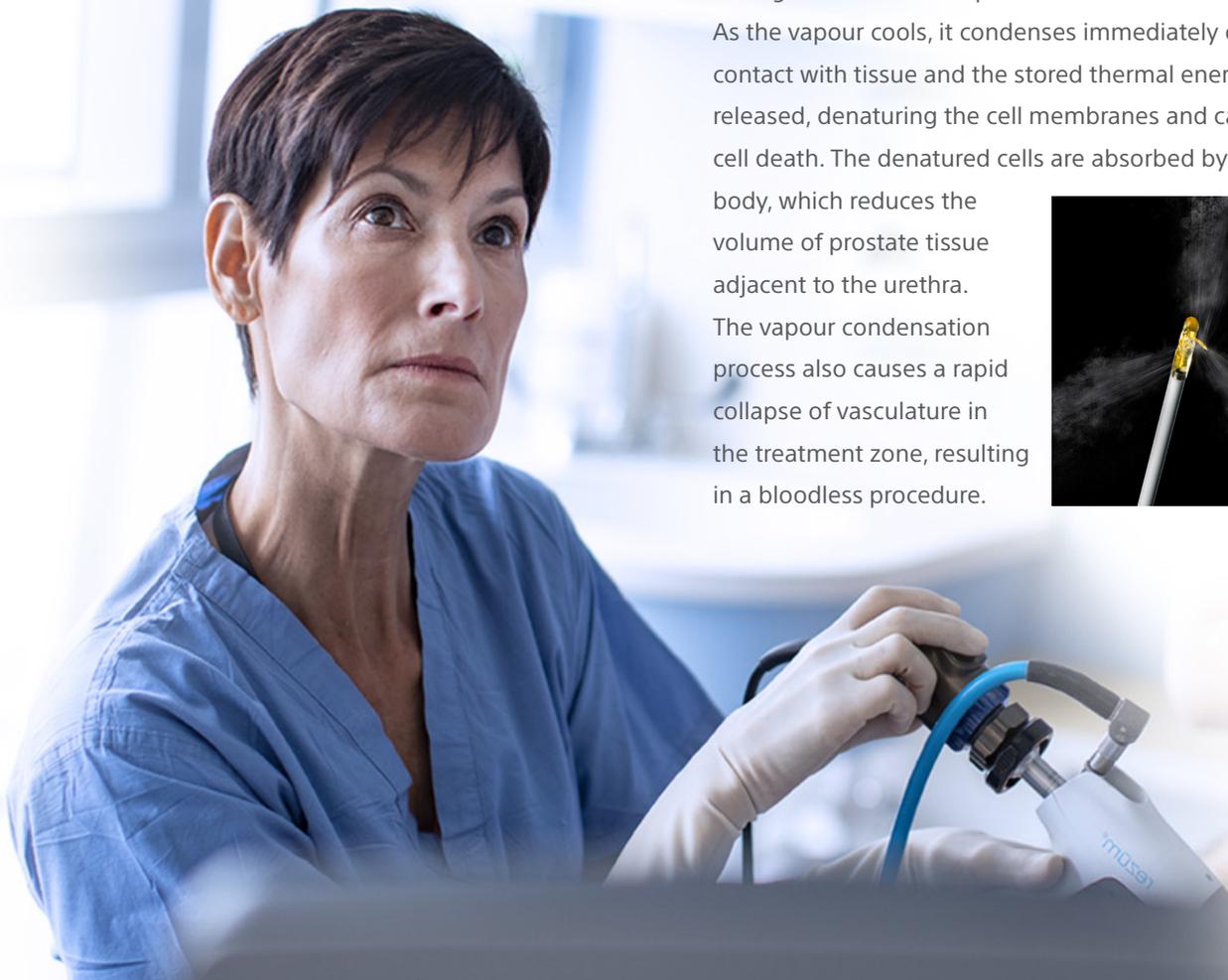


Rezūm™ Water Vapour Therapy: A Step-by-Step Guide

Overview

The Rezūm System is intended to relieve symptoms, remove obstructions, and reduce prostate tissue associated with benign prostatic hyperplasia (BPH). It is indicated for men with a prostate volume $\geq 30\text{cm}^3$. The Rezūm System is also indicated for treatment of prostate with hyperplasia of the central zone and/or a median lobe.

The Rezūm System utilizes radiofrequency current to generate “wet” thermal energy in the form of water vapour, which is then injected into the transition zone and/or median lobe of the prostate tissue in controlled 9-second doses. (See image below.) The vapour that is injected into the prostate tissue rapidly disperses through the interstitial space between the tissue cells. As the vapour cools, it condenses immediately on contact with tissue and the stored thermal energy is released, denaturing the cell membranes and causing cell death. The denatured cells are absorbed by the body, which reduces the volume of prostate tissue adjacent to the urethra. The vapour condensation process also causes a rapid collapse of vasculature in the treatment zone, resulting in a bloodless procedure.



Preparing the Patient

Prior to the procedure, you will administer pain and/or anti-anxiety medication and will instruct the patient to completely void their bladder. Then, the patient will be prepared and draped using standard cystoscopy guidelines and placed in the lithotomy position.

Performing the Procedure

The Rezūm™ System treatment is performed in eight steps.



1. You will first start with priming the device prior to patient contact. This is done by performing one vapour treatment outside the patient. This will remove condensed water from the shaft and activates the idle feature to keep vapour in a ready state.



2. You will insert the Delivery Device and assess the prostatic anatomy.



3. Once inserted, you will consider the vapour treatment zone by measuring fields of view (FOV) between the bladder neck and verumontanum.



4. Then, you will position the Delivery Device and deploy the needle to deliver the vapour treatment.



5. Vapour treatment is then activated while holding the Delivery Device steady. The needle is retracted following the vapour treatment. Each treatment is 9 seconds.

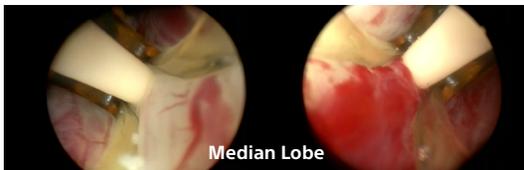


When the vapour treatment begins, the Rezūm System automatically tracks the time until the programmed treatment is complete and then automatically shuts off the vapour. Vapour can be stopped prior to treatment completion if the Vapour Activation Button is released.

6. You can then deliver subsequent vapour treatments 1 cm apart until proximal end of the verumontanum.



7. Once complete, you can then treat the median lobe or central zone hyperplasia, if needed.



8. Finally, you will perform a final assessment of the prostatic urethra and bladder and withdraw the device.



Once you are ready to start offering the Rezūm System in your practice, Boston Scientific will work with you to complete a mandatory one-day training course that will equip you to successfully be able to treat your patients with water vapour therapy utilizing the Rezūm System.

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