Rezūm™ Delivery Device Kit for BPH Prescriptive Information

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Warnings

TRAINING: Boston Scientific requires physician training specific to the Rezūm System procedure prior to use. Please contact Boston Scientific for more information.

FAMILIARTY WITH CYSTOSCOPIC PROCEDURES: Users should be familiar with cystoscopic procedures and techniques for treating benign prostatic hyperplasia before using the Rezūm System.

USE UNDER PRESCRIPTION: Federal Law restricts this device to sale and use by or on the order of a physician (or properly licensed practitioner).

TISSUE HEALING AFTER BIOPSY OR PRIOR PROSTATE SURGERY**:** After biopsy or prior prostate surgery, allow tissue to heal (e.g. 30 days) prior to performing Rezūm System procedure.

PRIMING CYCLE: Point the Delivery Device tip away from patient or personnel during the priming cycle. Vapor coming out of the tip is hot and can burn the skin.

FLUSH BUTTON PRESSURE: Excessive pressure while using Flush Activation Button may cause unintended deployment of the needle.

NEEDLE PLACEMENT: Proper placement of the needle is essential. Do not direct the needle downward toward the rectum.

LOCATION OF VERUMONTANUM: Prior to each treatment, know where the verumontanum is in relation to the tip of the shaft. All treatments should be placed proximal to the verumontanum.

NEEDLE TIP: Do not start treatment if the black depth marker on the needle is still visible after needle deployment. If the marker is still visible, push the needle deeper into the prostate until no black is visible through the lens. If unable to position correctly, deliver vapor for ~4 seconds to devascularize the site, then retract needle by pressing upward on the Needle Retraction Button. Reposition Delivery Device approximately 1 cm from the partially treated site and repeat needle deployment steps.

NEEDLE RETRACTION: Prior to starting procedure, the needle should be fully retracted. During procedure, ensure needle is fully retracted by viewing needle position through scope lens. If needle is not retracted prior to repositioning Delivery Device, damage to urethra may occur.

STERILITY/DAMAGED PACKAGING: Do not use the Delivery Device and its contents if the packaging's sterile barrier is broken, the seal is damaged, or the device is damaged.

MANUAL NEEDLE RETRACTION: Do not remove device from the patient if the needle is not fully retracted. In case of incomplete needle retraction, manually retract the needle before removing the device from the patient. For instructions on how to manually retract the needle, see Method for Manual Needle Retraction section. Do not attempt to reassemble device for reuse after manual needle retraction.

SERVICE OR MAINTENANCE WHILE IN USE IN PATIENT: No modification of this equipment is allowed. Do not attempt to service or maintain the Generator while in use with a patient.

URETHRAL STRICTURES: Urethral strictures should be ruled out as a case of obstruction prior to treatment with Rezūm.

Precautions

PRIOR RADIATION: There is no data on the use of this treatment in patients who have undergone prior radiation therapy in the pelvic region.

SINGLE-USE ONLY DEVICE: The Delivery Device is intended for single-use only. Do not reuse, reprocess or resterilize the device. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury or illness.

EXTERIOR SURFACE OF STERILE WATER VIAL: The exterior of the 50 ml Sterile Water Vial is not sterile and should not be placed in the sterile field.

POSITIONING SALINE FLUSH LINE IN SALINE PUMP: Reference indicators on Generator to ensure Saline Flush Line is positioned in the correct direction. If Saline Flush Line is placed in a backwards direction within the Saline Pump, saline will not flow during procedure.

REMAINING SALINE LEVEL IN BAG: Care should be taken during procedure to monitor remaining saline level in bag. If saline bag is empty, patient could experience urethral discomfort due to no flush flow.

MOVEMENT OF DELIVERY DEVICE: Once needle is deployed, hold the Delivery Device steady. Movement of the Delivery Device may stretch tissue and cause vapor to leak into the urethra, possibly causing urethral irritation. Extreme movement may also cause pressure on the needle resulting in difficulty with needle retraction. Needle must be returned to the original insertion position to facilitate retraction.

OVERFILLING OF BLADDER: Care should be taken during procedure to monitor the amount of saline instilled. If bladder is not empty, overfilling of bladder may occur. The Generator helps monitor the amount of saline instilled.

CONTINUED OR WORSENING OF LUTS: During healing phase, patient may experience a continued or worsening of LUTS, which may require the use of a catheter for several days. Cystoscopic intervention during the healing phase may also lead to continued or worsening of LUTS. For more information on these types of events in the clinical study, please refer to the Clinical Summary section of the DFU.

ROOM TEMPERATURE SALINE: Saline should be at room temperature. Do not use cold saline, which may reduce the effectiveness of the therapy.

SCOPE LENS: The Delivery Device is compatible with a 4 mm, 30 degree, 30 cm Storz or Richard-Wolf cystoscopic lens. Use of other scope lenses may impact performance of the Delivery Device.

PRIMING CYCLE: If finger is released from Vapor Activation Button before the priming cycle is complete, vapor will automatically stop and the priming steps will have to be repeated.

VAPOR ACTIVATION: Do not release Vapor Activation button during vapor treatment cycle. If Vapor Activation Button is released before treatment cycle is complete, vapor release will automatically stop, which may lead to partial and incomplete treatment.

AIR BUBBLES IN SYRINGE: Ensure air bubbles are removed from the syringe. If bubbles are trapped in the line, an insufficient treatment may result.

EXCESSIVE TREATMENTS: Treatments in excess of those recommended in the guidelines may lead to prolonged irritative symptoms and/or catheterization.

DISPOSAL INSTRUCTIONS: After use, this product should be treated as a potential biohazard. Handle and dispose of in accordance with acceptable medical practices and applicable local, state and federal guidelines.

Indications for Use

The Rezūm System is intended to relieve symptoms, obstructions, and reduce prostate tissue associated with benign prostatic hyperplasia (BPH). It is indicated for men ≥ 50 years of age with a prostate volume $30cm^3 \leq 80cm^3$. The Rezūm System is also indicated for treatment of prostate with hyperplasia of the central zone and/or a median lobe.

Contraindications

The use of the Rezūm System is contraindicated for the following:

- Patients with a urinary sphincter implant
- Patients who have a penile prosthesis
- Patients who have an active urinary tract infection

ADVERSE EVENTS:

Dysuria, hematuria (gross), hematospermia, urinary frequency, decrease in ejaculatory volume, urinary retention, UTI (suspected), urinary urgency, anejaculation, terminal dribbling, UTI (culture proven), epididymitis, erectile dysfunction (worsening), pain/discomfort (pelvic), prostatitis, urethral stricture, gross hematuria with clots, pain/discomfort with ejaculation, pain/discomfort (penile), poor stream, splayed stream, gross hematuria with retention, hematuria (intermittent uncomplicated), hematuria (micro), incomplete voiding, urinary incontinence (urge), urinary tract infection (UTI).

The following events were reported in <1% of subjects and were mild or moderate in severity unless otherwise indicated: anxiety, bladder neck contracture (severe), bladder stone formation (severe), catheter malfunction, decrease in orgasm pleasure, delay in healing, fever, hesitancy, irritative voiding symptoms, nausea, pain/ discomfort (right testicle, abdomen, leg, other, perineum), prostate perforation, phlebitis of arm, prostatic calculi, pyuria, retrograde ejaculation, urosepsis following cystoscopy (severe), shingles on left lower thigh, urethral injury, urinary incontinence (mixed, stress (resolved)), vomiting, hypotension.

The following adverse events have not been reported in these clinical trials: de novo erectile dysfunction, pelvic abscess, rectal wall injury, and fistula. Delivering a form of thermal therapy or misuse of the device has the potential for producing these adverse effects.