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

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in tum, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

SAFETY

This section contains important safety information. Boston Scientific requires that you read and understand all warnings, cautions, precautions and the operator’s manual prior to using the Rezūm System.

WARNINGs

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

Familiarity 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 by or on the order of a physician (or properly licensed practitioners).

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: 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 Verumatum: Prior to each treatment, know where the verumatum is in relation to the tip of the needle. All treatments should be placed proximal to the verumatum.

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: 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 cause 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 re-use, 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.

External Surface of Sterile Water Vial: The exterior of the 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 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 bag is 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®, InnoView® 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 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 ≤ 80 cc.

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

THE REZŪM SYSTEM OVERVIEW

The Rezūm System is designed to treat patients with bothersome urinary symptoms associated with BPH. The Rezūm System utilizes radiofrequency current to generate “wet” thermal energy in the form of water vapor, which is then injected into the transition zone and/or median lobe of the prostate tissue in controlled 9-second doses. The vapor that is injected into the prostate tissue rapidly disperses through the interstitial space between the tissue cells. As the vapor 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 vapor condensation process also causes a rapid collapse of vasculature in the treatment zone, resulting in a bloodless procedure.

Following thermal therapy for BPH, small pieces of coagulated tissue may slough off and be expelled via urination. This sloughing process may continue for a few months post-procedure depending on the rate of healing.

CONTENTS

The Rezūm System consists of the following:
• Rezūm Generator (reusable)
• Rezūm Delivery Device Kit (disposable)

REZŪM GENERATOR

The portable Rezūm Generator is provided with the following reusable components (Figure 1):
• Generator
• One Power Cord

Figure 1. Rezūm Generator.

REZŪM DELIVERY DEVICE KIT

The Rezūm Delivery Device Kit contains the following disposable components:
• One sterile Delivery Device with cable and tubing
• One sterile Syringe
• One sterile Spike Adaptor
• One Sterile Water Vial

Rezūm Delivery Device Component Functions and Specifications (Table 1).
Figure 2. Delivery Device Components.

Table 1. Functional Description of the Delivery Device

<table>
<thead>
<tr>
<th>Description</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Shaft</td>
<td>Provides enclosed channel for needle, vapor tubing, rigid scope lens and flush irrigation.</td>
</tr>
<tr>
<td>B. Tip</td>
<td>Guides shaft into treatment area and houses needle.</td>
</tr>
<tr>
<td>C. Needle</td>
<td>Inserted into the targeted prostate tissue to deliver vapor treatment.</td>
</tr>
<tr>
<td>D. RF Cable</td>
<td>The RF cable is the energy line and connections for the switches and thermocouples.</td>
</tr>
<tr>
<td>E. Saline Flush Line</td>
<td>Provides saline flush for irrigation through the Delivery Device.</td>
</tr>
<tr>
<td>F. Water Line</td>
<td>Line to move water into the Delivery Device.</td>
</tr>
<tr>
<td>G. Drain Line</td>
<td>Line to allow urine to be drained from the bladder.</td>
</tr>
<tr>
<td>H. Rigid Cystoscope Lens Port</td>
<td>Provides secure connection of rigid cystoscope lens in Delivery Device.</td>
</tr>
<tr>
<td>I. Flush Activation Button</td>
<td>Provides saline flush (normal, high). Top, front button (white).</td>
</tr>
<tr>
<td>J. Needle Deployment Button</td>
<td>Located behind the flush button, deploys the needle into the prostate tissue. Top, back button (grey).</td>
</tr>
<tr>
<td>K. Vapor Activation Button</td>
<td>Activates vapor after needle has been deployed. Bottom button (blue).</td>
</tr>
<tr>
<td>L. Needle Retraction Button</td>
<td>Retracts needle back into Delivery Device shaft. Grey button located on the underside of the nose cone.</td>
</tr>
<tr>
<td>M. Nose Cone Release Pin</td>
<td>Detaches shaft from Delivery Device to allow the safe manual retraction of needle into shaft if Needle Retraction Button fails.</td>
</tr>
</tbody>
</table>

THE REZUM PROCEDURE
User Supplied Materials
Other materials that are typically required for the Rezūm™ System procedure include, but are not limited to, the following items.

- Cart or sturdy surface for the Rezūm Generator
- Prep tray
- Topical antiseptic (e.g. Betadine)
- Patient drape
- Disposable underpads (e.g. Chux)
- Gauze squares
- Lidocaine gel anesthetic or water-soluble lubricating gel
- Saline supply at room temperature (1 L, 2 L, 3 L, 4 L, 5 L or 500 ml)
- IV pole for Saline supply
- 4 mm, 30 degree, 30 cm Storz®, InnoView® or Richard-Wolf® rigid cystoscope lens
- Light source and cord
- Video camera and display; recorder optional
- Drain bucket
- Hemostat

Preparing the Patient
1. Prior to the procedure, administer physician-preferred pain and/or anti-anxiety medication. If using oral medications, allow sufficient time for the medications to reach peak levels.
Set Up the Rezūm™ Delivery Device

1. Remove the Delivery Device RF cable and plug into generator, ensuring white dot on the top of the plug is aligned with red dot on the generator port (Figure 6).

2. Ensure needle has retracted on Delivery Device.

3. Remove Saline Flush Line and Water Line from tray.

4. Place the Saline Flush Line in the Saline Pump. Ensure Saline Flush Line is seated such that the Saline Pump door can close smoothly. Align the color indicators on the generator and saline flush line (Figure 7).

5. Close Saline Pump door prior to attaching Saline Flush Line tip to the Saline bag.

6. Remove cap from tip of Saline Flush Line and attach to the saline source (Figure 8). Ensure clamp on Saline Flush Line is open.

7. Remove Spike Adaptor and Sterile Water Vial from Syringe. Do not coat the lens itself, as this may impede visualization (Figure 11).

8. Load the filled Syringe into the Syringe cradle (Figure 9).

Note: If Saline Flush Line tip is attached to saline bag prior to placing Saline Flush Line in the Saline Pump and closing the Saline Pump door, saline may leak.

9. Remove cap from Water Line luer and connect Syringe to Water Line by twisting the luer on the prefilled Syringe. Pressure relief valve on Water Line should be pointing down.

10. Using sterile technique, close clamp on Drain Line to ensure saline flows through Delivery Device during the procedure (Figure 10).

Warning: 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.

Note: Prime the Delivery Device using the following steps (Figure 12):
1. Confirm the Generator display is showing the Therapy Screen. Perform the Rez

2. Pull in Flush Activation Button (1) and Needle Deployment Button (2) until needle is deployed. Release both buttons once needle is deployed. C. Pull in Vapor Activation Button (3) and hold to activate the vapor until the display screen indicates the priming cycle is complete (approximately 30 seconds).

D. Toward the end of the priming cycle, visually verify vapor is coming out of the needle tip. E. When priming cycle is complete, release the Vapor Activation Button and retract the needle by pushing upward on the Needle Retraction Button.

Caution: 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.

F. If the Vapor Activation Button is released before the end of the priming cycle, repeat the priming cycle (steps A to E).

G. If priming cycle is not successfully completed, repeat steps a to e or replace Delivery Device.

Perform the Pre-Treatment Vapor Cycle

1. Activate idle feature by running a pre-treatment vapor cycle. Idle feature heats coil to keep water in a ready state so vapor delivery is immediate. If this step is not completed, condensation may build up between treatments, which may lead to insufficient treatment.

2. Pull in Flush Activation Button (1) Needle Deployment Button (2) and then Vapor Activation (3) (Figure 12).

3. During pre-treatment vapor cycle, observe flush exiting tip.

4. When pre-treatment vapor cycle is complete, release the Vapor Activation Button and retract the needle by pushing upward on the Needle Retraction Button.

Note: Pre-treatment vapor cycle must be completed prior to inserting Delivery Device into the patient.

Perform the Rezûm™ Vapor Treatment

1. Confirm the Generator display is showing the Therapy Screen.

2. Coat the shaft of the Delivery Device with water-soluble lubricating or anesthetizing gel.

3. Attach light cord and video camera to the scope lens.

4. Using finger, activate the saline flush by applying gentle pressure to the Flush Activation Button.

5. Carefully insert the Delivery Device into the urethra through the meatus.

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

Warning: Ensure needle is fully retracted by viewing needle position through scope lens. If needle is not retracted prior to insertion of the Delivery Device, damage to urethra may occur.

Warning: No modification of this equipment is allowed. Do not attempt to service or maintain the generator while in use with a patient.

6. While examining prostatic urethra, locate the apex of the prostate and the bladder. A TRUS and/or cystoscopy prior to the procedure can help obtain prostate measurements to determine the appropriate number of treatments.

7. Estimate the prostatic treatment length (i.e. from bladder neck to verumontanum). This length is considered the vapor treatment zone (Figure 13).

G. If priming cycle is not successfully completed, repeat steps a to e or replace Delivery Device.

8. Based on the length of the vapor treatment zone, determine the number of treatments per lobe (Table 2). A treatment consists of a single 9-second delivery of vapor.

Table 2. Guidelines for determining the number of treatments (lateral lobe).

<table>
<thead>
<tr>
<th>Distance from Bladder Neck to Veru</th>
<th>Estimated Number of Treatments per Lobe</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 2.0 cm</td>
<td>1-2</td>
</tr>
<tr>
<td>2.0 – 3.0 cm</td>
<td>2-3</td>
</tr>
<tr>
<td>&gt; 3.0 cm</td>
<td>3-4</td>
</tr>
</tbody>
</table>

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

Note: A maximum number of 15 full treatments can be delivered with each Delivery Device.

9. If a median lobe is present and judged to be in need of treatment, deliver one treatment if median lobe is < 2 cm and two or more treatments if median lobe is > 2 cm. If central zone hyperplasia contributes to an elevated bladder neck with a prostatic urethral ≥ 35 degrees, as evidenced by sagittal TRUS, deliver one treatment for an enlarged central zone < 2 cm and two treatments for an enlarged central zone > 2 cm.

Caution: 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 nc 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.

10. Start the procedure by positioning the tip of the device just inside the bladder. Rotate the Delivery Device 90 degrees (horizontal) and bring device shaft just off floor of urethra.

11. While maintaining the 90 degree rotation, pull Delivery Device back into the urethra and position 1 cm back from the bladder neck. If treatment occurs within 1 cm of the bladder neck, short-term irritative symptoms may be experienced by the patient. Place the distal tip of the Delivery Device shaft against the lateral urethral wall.

Note: Optimal placement for the vapor treatment is in the crest of the lateral lobe. Ensure the shaft of the device is not close to the anterior surface, as this may lead to a sub-optimal treatment.

Note: On occasion, patient prostatic anatomy may restrict the Delivery Device tip from reaching the bladder neck. This may be due to an elevated bladder neck from central zone hyperplasia or a median lobe. On these occasions, do not force the device through tissue. Ensure the Delivery Device tip is proximal to the verumontanum and treat the bulk of the lateral lobe proximal to the verumontanum. Advance the Delivery Device in 1 cm increments toward the bladder neck to deliver subsequent vapor treatments. This may relax the tissue to allow the Delivery Device to reach the bladder neck. If the Delivery Device still cannot reach the bladder neck, treat the area that is proximal to the verumontanum.

12. Stabilize the Delivery Device before deploying the needle and remain completely still throughout the treatment.

13. While holding the Flush Activation Button, continue to pull in the Needle Deployment Button until the needle is deployed.

14. Visually verify the needle is fully inserted into the prostate by inspecting to see if the black depth marker just proximal to the emitter holes is not visible (no black should be seen).

Warning: 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 nc 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.

15. Using finger, pull in Vapor Activation Button and hold to activate the vapor until treatment cycle is complete.

Caution: 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, 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.

Note: When the vapor treatment begins, the Rezûm System automatically tracks the time until the programmed treatment is complete and then automatically shuts off the vapor. Vapor can be stopped prior to treatment completion if Vapor Activation Button is released.

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

16. The display screen will show each individual treatment time and count the number of full treatments that were completed.

17. Release Vapor Activation button and push upward on the Needle Retraction Button to retract the needle.

Warning: 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.

18. Reposition the Delivery Device for the next treatment by moving the device tip approximately 1 cm distal to the previous needle placement. The objective is to create contiguous, overlapping lesions, 1 cm apart, and running parallel to the prostatic urethra.

19. Maintain device rotation at 90 degrees between treatments to avoid losing sight of previous treatment location.

20. Follow the natural slope of the urethra to avoid being too close to the ceiling, i.e. too anterior. Center the needle between the floor and ceiling of the urethra and target the bulk of the adenoma directly if it is not centered.
METHOD FOR MANUAL NEEDLE RETRACTION

In the event the Needle Retraction Button fails to retract the needle fully into the Delivery Device shaft, follow the steps below to manually retract the needle into the Delivery Device shaft before removing the Delivery Device from the urethra. This should not occur under normal use and is designed only as a backup in case of device malfunction.

1. Disconnect Delivery Device Electrical Cable from the Generator.
2. Using a hemostat or other device, pull down and remove the release pin located below the nose cone to disengage the shaft assembly from the Delivery Device handle (Figure 15).

Note: As the handle is being withdrawn, if the distal end of the needle body (in the handle) detaches from the handle and the proximal end of the needle is not drawn into the shaft tip, pull on the beige, right-angled plastic tube protruding from the shaft to manually retract the proximal end of the needle into the shaft tip (Fig. 17).

4. While maintaining the needle tip within the shaft, remove Delivery Device from patient.
5. If treatment is incomplete, re-start procedure with new Delivery Device and complete procedure.

Warning: Do not remove device from the patient if the needle is not fully retracted. In case of incomplete needle retraction, manually retract needle before removing the device from the patient. Do not attempt to reassemble device for reuse after manual needle retraction.

METHOD FOR DRAINING THE BLADDER

If necessary during treatment, the bladder can be drained through the Delivery Device.

1. Ensure needle is retracted.
2. Place the tip of the Delivery Device in the bladder to drain.
3. Unclamp the drain line.
4. Remove scope lens to expedite draining of the bladder.
5. Select Drain Bladder on Generator to reset Saline Instilled.
6. When finished draining the bladder, reclamp the drain line.

STORAGE, HANDLING, AND DISPOSAL

Rigid Cystoscope Lens

Refer to the rigid cystoscope lens packaging insert instructions for use for care, cleaning and handling.

Resum™ Delivery Device

The Delivery Device is shipped sterile. If the package sterile barrier is broken or missing, do not use the product. The Delivery Device must not be reused or re-sterilized. It is for single use only.

The Delivery Device is packaged for easy transfer to the sterile field. The Delivery Device should be handled with care at all times. The storage area should have good ventilation, store in a cool, dry, dark place.

After use, discard the Delivery Device in accordance with local environmental regulations for biohazards material.
REPORTED ADVERSE EVENTS

A summary of the adverse events reported and adjudicated in the Rezùm™ II Pivotal study at treatment out through report date of February 9, 2019 is presented in the table below. After unblinding at 3 months, the primary study endpoint, control subjects who elected to proceed were requalified by inclusion criteria and eligible to participate in a crossover study to receive thermal therapy. There were no unanticipated adverse device effects or reports of de novo erectile dysfunction, rectal wall injury, or fistula. Fifty-seven percent of the Treatment and Crossover subjects did not report any procedure or device related AE. Eighty percent of the adverse events reported occurred within the first 30 days post-procedure and were typically of short duration. There was a total of 6 procedure and/or device related Serious Adverse Events (SAE) reported in a total of 4 Treatment and Crossover subjects. One subject experienced extended urinary retention due to untreated intravesical lobe protrusion. A second subject had an allergic reaction to Xanax and was admitted to the hospital for nausea and vomiting. A third subject experienced bladder neck contracture and bladder calculi, which resolved within 30 days. A fourth subject was diagnosed with urosepsis following cystoscopy, which resolved with medication.

As of February 9, 2019, 88% of the adverse events have resolved. The remaining ongoing events listed will be assessed at the patients’ next clinical study follow up visits. Events will be updated annually out to five years.

Table 2. All Adjudicated Procedure and/or Device Related AEs for Treatment and Crossover Subjects Through 4 Year Follow-up

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Procedure or Device Related AEs</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Resolved AEs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dysuria</td>
<td>17%</td>
<td>14%</td>
<td>4%</td>
<td>0%</td>
<td>97%</td>
</tr>
<tr>
<td>Hematuria, Gross</td>
<td>12%</td>
<td>11%</td>
<td>1%</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>Hematospermia</td>
<td>6%</td>
<td>6%</td>
<td>&lt;1%</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>Urinary Frequency</td>
<td>6%</td>
<td>5%</td>
<td>1%</td>
<td>0%</td>
<td>82%</td>
</tr>
<tr>
<td>Decrease in Ejaculatory Volume</td>
<td>5%</td>
<td>4%</td>
<td>&lt;1%</td>
<td>0%</td>
<td>33%</td>
</tr>
<tr>
<td>UTI, Suspected</td>
<td>5%</td>
<td>4%</td>
<td>1%</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>Urinary Retention</td>
<td>5%</td>
<td>&lt;1%</td>
<td>4%</td>
<td>&lt;1%</td>
<td>100%</td>
</tr>
<tr>
<td>Urinary Urgency</td>
<td>5%</td>
<td>3%</td>
<td>2%</td>
<td>0%</td>
<td>78%</td>
</tr>
<tr>
<td>Anecalculation</td>
<td>3%</td>
<td>2%</td>
<td>&lt;1%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Terminal Dribbling</td>
<td>2%</td>
<td>2%</td>
<td>&lt;1%</td>
<td>0%</td>
<td>60%</td>
</tr>
<tr>
<td>UTI, Culture Proven</td>
<td>2%</td>
<td>1%</td>
<td>2%</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>Epididymitis</td>
<td>2%</td>
<td>&lt;1%</td>
<td>2%</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>Erectile Dysfunction, Worsening</td>
<td>2%</td>
<td>2%</td>
<td>&lt;1%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Gross Hematuria with Clots</td>
<td>2%</td>
<td>1%</td>
<td>&lt;1%</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>Hematuria, Intermittent uncomplicated</td>
<td>2%</td>
<td>1%</td>
<td>&lt;1%</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>Incomplete Voiding</td>
<td>2%</td>
<td>&lt;1%</td>
<td>1%</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>Pain/Discomfort with Ejaculation</td>
<td>2%</td>
<td>0%</td>
<td>2%</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>Pain/Discomfort, Pelvic</td>
<td>2%</td>
<td>1%</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
<td>100%</td>
</tr>
<tr>
<td>Pain/Discomfort, Perine</td>
<td>2%</td>
<td>2%</td>
<td>0%</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>Poor Stream</td>
<td>2%</td>
<td>2%</td>
<td>0%</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>Prostatitis</td>
<td>2%</td>
<td>1%</td>
<td>1%</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>Splayed Stream</td>
<td>2%</td>
<td>&lt;1%</td>
<td>1%</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>Urethral Stricture</td>
<td>2%</td>
<td>0%</td>
<td>2%</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>Gross Hematuria with retention</td>
<td>1%</td>
<td>0%</td>
<td>1%</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>Hematuria, Micro</td>
<td>1%</td>
<td>1%</td>
<td>0%</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>Urinary Incontinence, Urge</td>
<td>1%</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>Urinary Tract Infection (UTI)</td>
<td>1%</td>
<td>1%</td>
<td>0%</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>Total</td>
<td>43%</td>
<td>36%</td>
<td>21%</td>
<td>2%</td>
<td>89%</td>
</tr>
</tbody>
</table>

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 orgasmic 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.

PIVOTAL CLINICAL STUDY SUMMARY

Efficacy

The Rezùm II Study was a multicenter, randomized, controlled, double-blinded study comparing the improvement in BPH symptoms at baseline and at 3 months post-procedure, as measured by IPSS, for subjects in the Treatment Arm as compared to subjects in the Control Arm. The Treatment Arm consisted of subjects receiving injections of water vapor into targeted zones of the prostate. The Control Arm consisted of subjects receiving a rigid cystoscopy with simulated active treatment sounds. The Treatment Arm demonstrated clinically, and statistically, significant mean improvement as compared to the Control Arm. The difference between the two arms was highly significant and the pre-specified, 3-month primary endpoint was met (p < 0.0001).

The graphs below summarize the Treatment Arm outcomes through 4 years for IPSS, Qmax, and Quality of Life.

Graph 1. Mean IPSS Over Time.

Graph 2. Mean Qmax (ml/sec) Over Time (voided volume ≥ 125 ml)

Graph 3. Mean QoL Over Time.

*Changes relative to baseline are significant, p < 0.001.

Caution: 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.
Other Potential Adverse Events

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.

Pain Management

The clinical study did not require specific medications to be used and investigators were instructed to use their clinical judgment in determining what medications, if any, to use on a subject-by-subject basis. Of the 196 subjects treated in the study 135 (69%) received oral sedation, 41 (21%) received a prostate block, and 20 (10%) received IV sedation.

Table 4. Types of Medication Used.

<table>
<thead>
<tr>
<th>Types of Medication</th>
<th># of Subjects (N=196)</th>
<th>Percentage of Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral Pain Medication</td>
<td>135</td>
<td>69%</td>
</tr>
<tr>
<td>Prostate Block</td>
<td>41</td>
<td>21%</td>
</tr>
<tr>
<td>IV Sedation</td>
<td>20</td>
<td>10%</td>
</tr>
</tbody>
</table>

Catheterization

Catheterization occurred prior to discharge in 90% of subjects (122 subjects) in the Treatment Arm and 20% of subjects (12 subjects) in the Control Arm. Of the 122 subjects in the Treatment Arm who were catheterized immediately post-procedure, 68% (83 subjects) were catheterized due to “physician discretion.” The mean duration of immediate post-procedure catheterization was 3.4 days for subjects in the Treatment Arm and 0.9 days for subjects in the Control Arm. This difference in catheterization rates for the two arms of the Study is to be expected due to the fact subjects in the Treatment Arm received thermal vapor treatments resulting in anticipated inflammatory healing effect.

Table 5. Catheterization.

<table>
<thead>
<tr>
<th>Subjects with catheterization performed</th>
<th>Treatment (N=135)</th>
<th>Control (N=61)</th>
</tr>
</thead>
<tbody>
<tr>
<td># of Subjects</td>
<td>135</td>
<td>61</td>
</tr>
<tr>
<td>Percentage</td>
<td>90.4% (122/135)</td>
<td>19.7% (12/61)</td>
</tr>
<tr>
<td>Duration of catheterization, days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± Std (N)</td>
<td>3.4 ± 3.2 (123)</td>
<td>0.9 ± 0.8 (12)</td>
</tr>
<tr>
<td>Median (Min - Max)</td>
<td>2.9 (0.0 - 30.9)</td>
<td>0.9 (0.0 - 2.0)</td>
</tr>
</tbody>
</table>

Four subjects with a treated median lobe were re-catheterized due to retention for an average of 5 days. An additional 3 subjects were re-catheterized due to multiple cystoscopic examinations outside of the protocol during the early tissue healing phase (first 90 days post-procedure).

Subsequent Treatments

Out of 188 subjects treated in the Treatment Arm, and Crossover group 9 subjects (5%) sought alternative treatment options within 4 years post initial Rezūm™ treatment.

Graph 4. Subsequent Retreatment (Cumulative).

Supplier's Declaration of Conformity

Unique Identifier: Rezūm M006D2201-003 GTIN 08714729992547 G2200-003 GTIN 0855357006003

Responsible Party – U.S. Contact Information

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
508-382-9555
www.bostonscientific.com

FCC Compliance Statement: This device complies with Part 18 of the FCC Rules

For further information, see FCC web site for a complete description of all requirements.