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rezūm™

Delivery Device Kit for BPH

Rx ONLY

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 turn, 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 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 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 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 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®, 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 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 30 cm³ ≤ 80 cm³. 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).

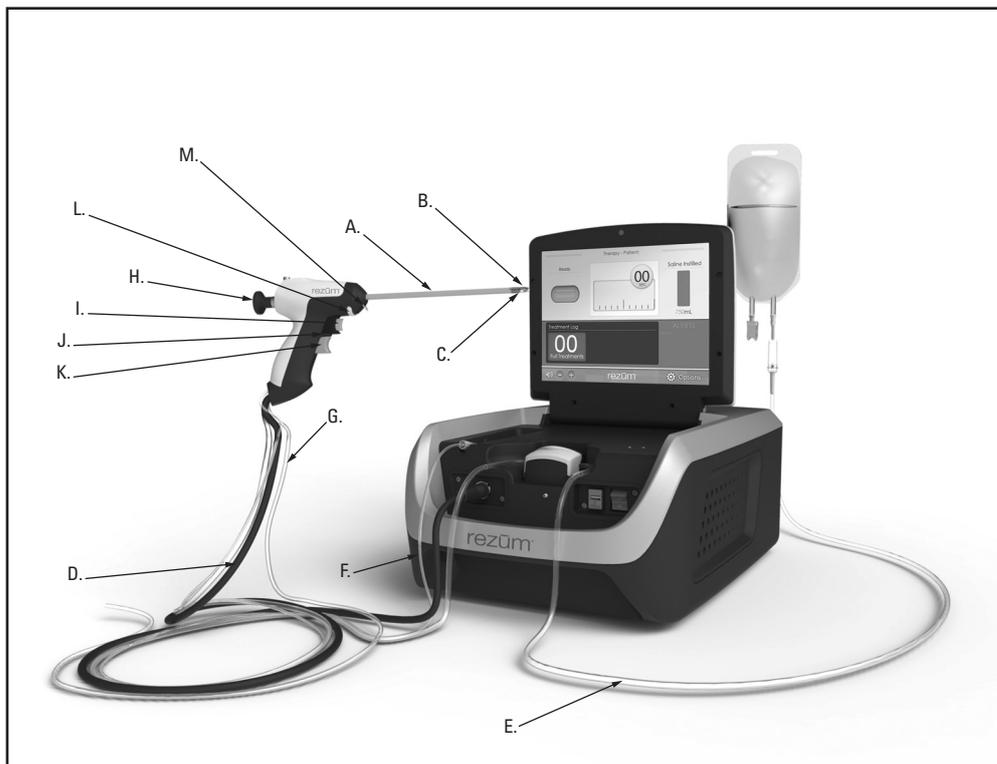


Figure 2. Delivery Device Components.

Table 1. Functional Description of the Delivery Device

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

THE REZŪM 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.

2. Instruct patient to completely void bladder prior to procedure.

Caution: 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.

3. Ten minutes prior to the procedure, prepare and drape the patient using standard cystoscopy guidelines.
4. Place the patient in the lithotomy position. Ensure buttocks are resting at the edge of the table to both enable entry deep enough into the anatomy and also to allow for easier Delivery Device rotation during the procedure.

Power Up the Rezūm Generator

1. Generator should be placed within reach of patient and an electrical outlet to supply power to the unit.
2. Place prep tray or cart near the Generator.
3. Open the display screen.
4. Plug the power cord from the Generator into an electrical outlet (Figure 3).

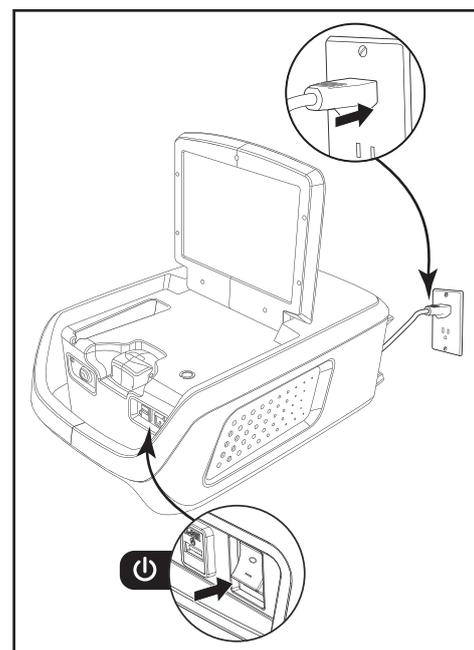


Figure 3. Power up the Rezūm Generator.

5. Turn on the Generator.
6. The Generator is in an inactive state until a valid Delivery Device is connected.

Prepare the Sterile Saline Bag

1. Obtain a brand new bag of saline fluid. 500 mL, 1000 mL, 2000 mL, 3000 mL, 4000 mL and 5000 mL volume options are compatible with the Rezūm Generator.
2. Hang bag on an IV pole (Figure 4).

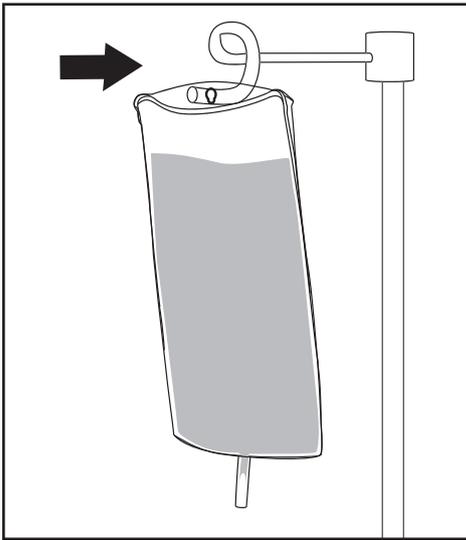


Figure 4. Hang the saline bag on IV pole.

Note: Bag spike is NOT needed; spike is pre-attached to Delivery Device Saline Line Tubing.

Caution: Saline should be at room temperature. Do not use cold saline, as it may reduce the effectiveness of the therapy.

Unpack Contents of Delivery Device Kit

Warning: 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.

Caution: The exterior of the Sterile Water Vial is not sterile and should not be placed in the sterile field.

1. Prior to opening, inspect the integrity of the outside and inside packaging to ensure sterility. Do not use if the packaging is damaged.
2. Lay out sterile field and place lubricating gel in sterile field.
3. Remove the Sterile Water Vial from the corner of the box. Remove the cover from the water vial and wipe with a sterile wipe. Place bottle outside of the sterile field.
4. Using sterile technique, remove the Tyvek® cover from the tray and remove and discard retainer tray.

Prepare the Syringe

1. Using appropriate aseptic practices, remove Syringe and Spike adaptor.
2. Connect Spike adaptor to Syringe. Ensure connection ends remain sterile.
3. Remove protective cover from Spike and insert Spike into Sterile Water Vial.
4. Invert Sterile Water Vial and slowly pull back plunger shaft to fill Syringe (Figure 5). Remove plunger shaft once Syringe is filled.

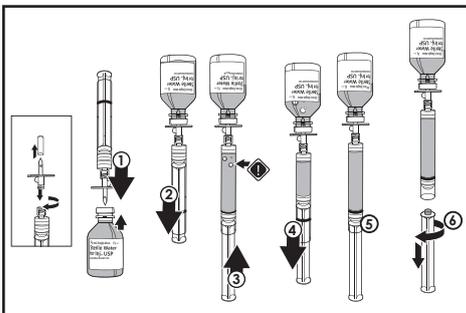


Figure 5. Filling the syringe.

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

5. Keeping the Syringe connected to the Spike Adaptor and Sterile Water Vial, set aside outside the sterile field.

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).

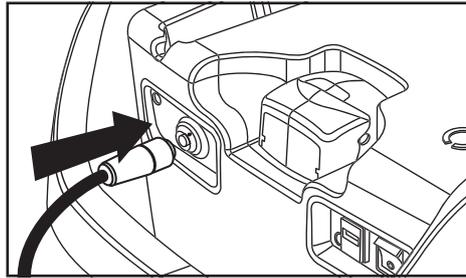


Figure 6. Connecting cable into Generator.

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).

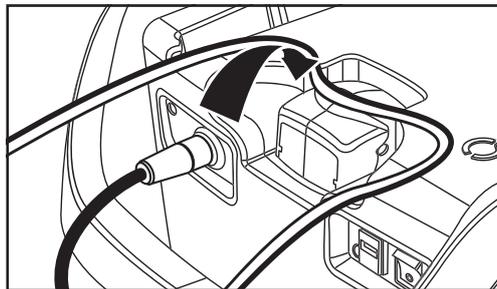


Figure 7. Loading Saline Flush Line into Saline Pump.

Caution: Use 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.

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

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.

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.

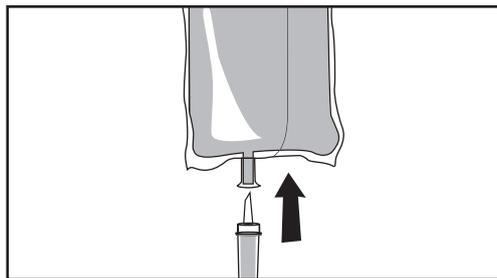


Figure 8. Connecting Saline Flush Line to Saline Bag.

7. Remove Spike Adaptor and Sterile Water Vial from Syringe.
8. Load the filled Syringe into the Syringe cradle (Figure 9).

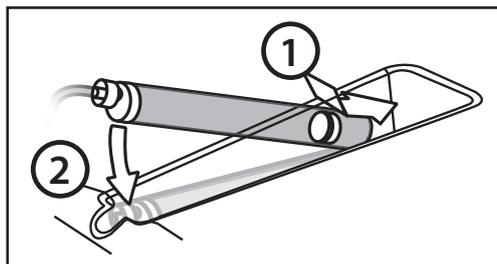


Figure 9. Loading Syringe.

Note: Syringe luer should be positioned on top of the Syringe to push fluid out of the Syringe.

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).

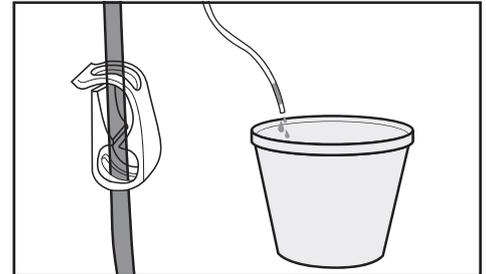


Figure 10. Closing clamp on Drain Line.

11. Using sterile technique, remove Delivery Device from packaging tray.

Insert the Rigid Cystoscope Lens

The Delivery Device is compatible with a 4 mm, 30 degree, 30 cm length Storz®, InnoView® or Richard-Wolf® rigid cystoscope lens. The lens provides direct or video display visualization to help the physician position the Delivery Device needle within the prostatic urethra.

Caution: 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.

1. Inspect and ensure lens is cleaned and prepared per manufacturer's instructions prior to use.
2. Coat lens shaft near lens tip with lidocaine gel anesthetic or water soluble lubrication to ensure smooth insertion into Delivery Device. Do not coat the lens itself, as this may impede visualization (Figure 11).

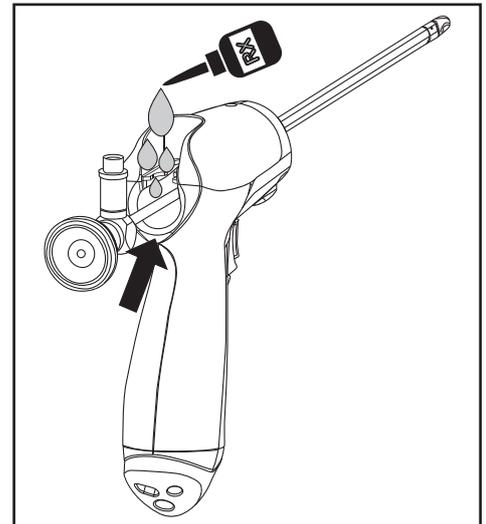


Figure 11. Insert Rigid Cystoscope Lens.

3. Gently insert the lens into the lens port and advance into position until it snaps into place.

Priming the Delivery Device

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.

1. Prime the Delivery Device using the following steps (Figure 12):

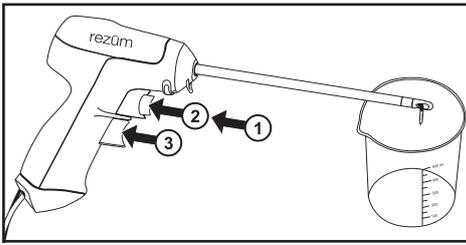


Figure 12. Steps for Activating Vapor Treatment.

A. Hold tip of Delivery Device over a liquid waste container.

Note: Ensure tip remains sterile.

- B. 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 Rezüm™ 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).

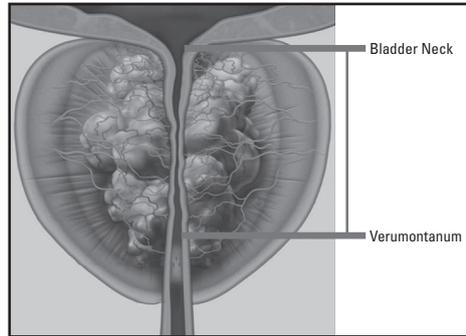


Figure 13. Prostatic Treatment Length.

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).

Distance from Bladder Neck to Veru	Estimated Number of Treatments per Lobe
< 2.0 cm	1-2
2.0 – 3.0 cm	2-3
> 3.0 cm	3-4

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: 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.

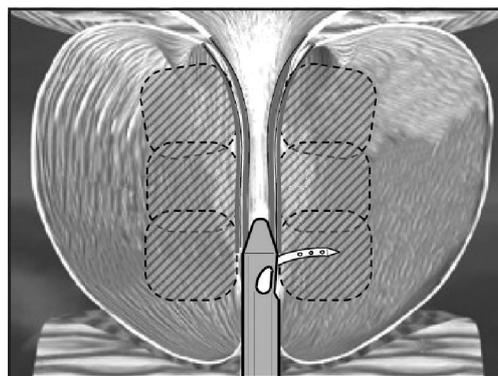


Figure 14. Illustrative example of 6 Vapor Treatments.

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

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 that 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 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.

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 Rezüm 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.

- Complete steps 10-20 until all treatments in the first lateral lobe are complete. The final treatment location within each lobe should be on the proximal side of the verumontanum.

Warning: 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.

- Return Delivery Device to the start position at the bladder neck for treatments in the contralateral lobe. Rotate the Delivery Device 90 degrees to enable needle insertion at desired location on opposite lobe.
- Repeat steps 10 through 20 until second lobe is fully treated.
- For intravesical prostatic protrusions of either the lateral or median lobes, position Delivery Device 1 cm from the proximal edge of the protrusion and deliver the vapor treatment with the needle positioned approximately 45 degrees toward the midline. One treatment for a small median lobe (< 2 cm) and two or more treatments for a larger median lobe (> 2 cm). For an enlarged central zone, deliver treatments 1 cm from the bladder neck with the needle positioned at 45 degrees toward the midline of the tissue. Do not treat on the floor of the urethra within at least 1 cm of the verumontanum.

Caution: Care should be taken during procedure to monitor remaining saline level. If saline source is empty, patient could experience urethral discomfort due to no flush flow.

- With lens in place, visually inspect the urethra and bladder at the end of the treatment and withdraw the Delivery Device from the urethra.
- To conclude procedure, select Remove Device on Generator screen and follow instructions.

Post Procedure

- Remove the Delivery Device from the urethra.
- Remove the cystoscopic lens for cleaning and reprocessing.
- Transfer procedure summary information to a portable USB memory device (Optional).
- Disconnect the Delivery Device electrical cable from the Generator.
- Open roller pump door and remove Saline Flush Line from pump.
- Remove Syringe and Water Line from syringe cradle.
- Dispose of Delivery Device and Syringe.

Caution: After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices and applicable local, state, and federal guidelines.

- Turn the Generator off.
- Disconnect the Generator from the electrical outlet.

METHOD FOR DRAINING THE BLADDER

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

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

METHOD FOR CLEARING VISUAL FIELD AND/OR REMOVING A CLOT

- To clear bubbles from the field of vision and/or to remove a clot, activate the Turbo Flush feature by double tapping and holding the Flush Activation Button.
- When visualization is cleared, release Flush Activation Button. Flush will run at normal rate the next time the Flush Activation Button is engaged.

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.

- Disconnect Delivery Device Electrical Cable from the Generator.
- 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).

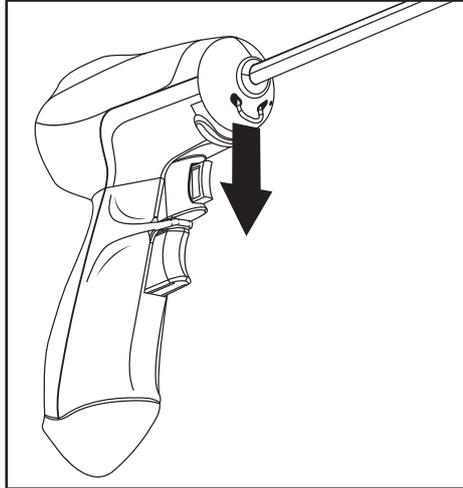


Figure 15. Pulling Down Release Pin.

- Hold the shaft firmly in position and withdraw the handle just sufficiently to draw the needle into the shaft tip (1 inch minimum) (Figure 16).

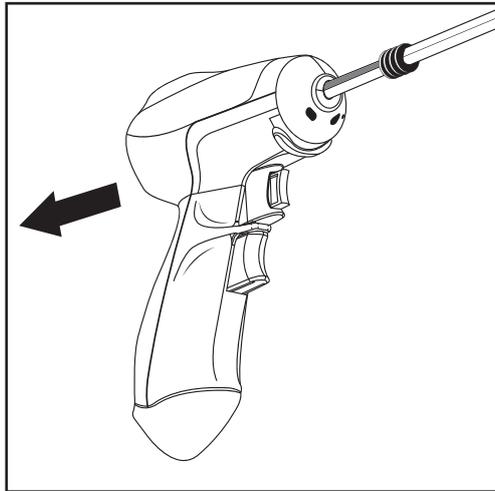


Figure 16. Holding Shaft Steady in Patient, Withdraw the Handle Just Sufficiently to Draw the Needle into the Shaft Tip (1 inch minimum).

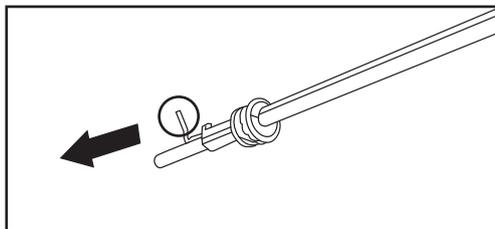


Figure 17. Holding Shaft Steady in Patient, Pull Needle Driver Out of Shaft to Retract Needle Into Tip.

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).

- While maintaining the needle tip within the shaft, remove Delivery Device from patient.
- If treatment is incomplete, re-start procedure with new Delivery Device and complete procedure.
- Report all incidences of manual needle retraction to Boston Scientific Customer Service. Clean device and return to Boston Scientific.

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.

STORAGE, HANDLING, AND DISPOSAL

Rigid Cystoscope Lens

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

Rezüm™ 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.

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.

Rezūm Generator

1. Unplug the power cord and store the cord with the Generator.
2. Clean the Generator as per the instructions found in the Rezūm Operator's Manual.
3. Close the display screen to protect it from damage.
4. Store the Rezūm Generator in a safe, clean and dry location.
5. To transport the Rezūm Generator, use handle to carry.

Disposal of the Product, Accessories and Packing Materials

Dispose of all products, accessories and packaging materials in accordance with hospital, administrative and/or local government policy.

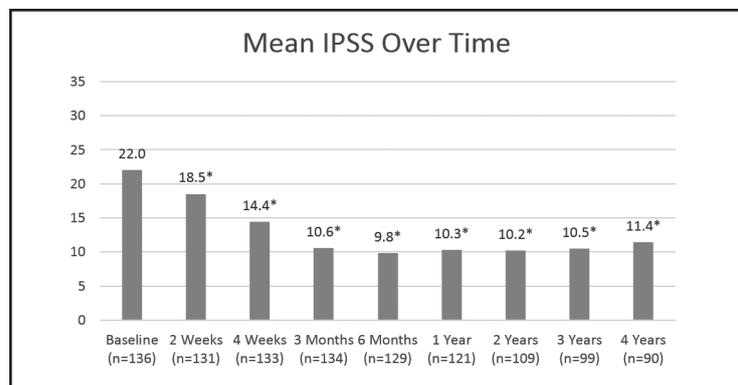
PIVOTAL CLINICAL STUDY SUMMARY

Efficacy

The Rezūm 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 ($p < 0.0001$).

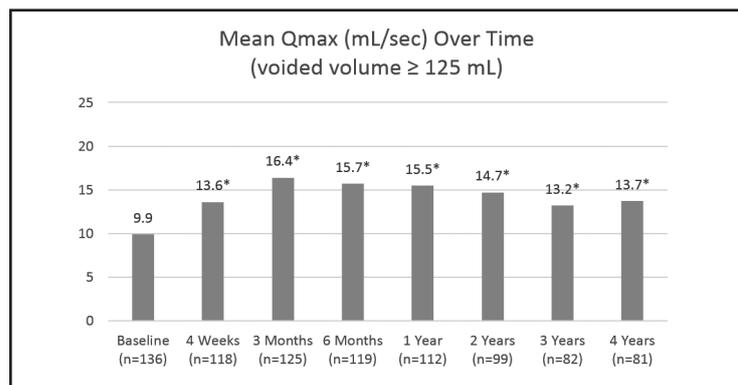
The graphs below summarize the Treatment Arm outcomes through 4 years for IPSS, Qmax, and Quality of Life.

Graph 1. Mean IPSS Over Time.



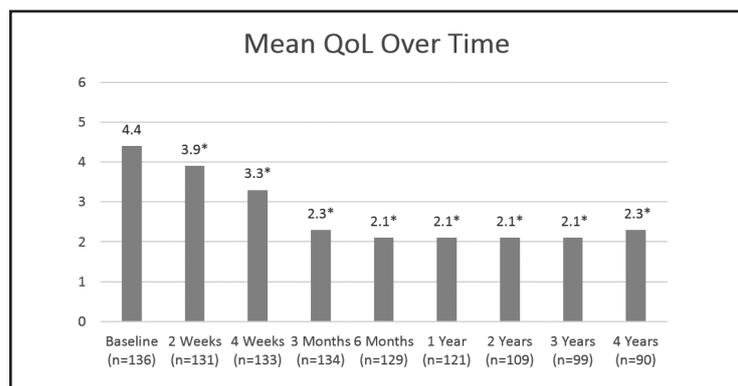
*Changes relative to baseline are significant, $p < 0.001$.

Graph 2. Mean Qmax Over Time.



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

Graph 3. Mean QoL Over Time.



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

REPORTED ADVERSE EVENTS

A summary of the adverse events reported and adjudicated in the Rezūm™ 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 AEs. 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, 89% 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 3. All Adjudicated Procedure and/or Device Related AEs for Treatment and Crossover Subjects Through 4 Year Follow-up.

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

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.

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.

Types of Medication	# of Subjects (N=196)	Percentage of Subjects
Oral Pain Medication	135	69%
Prostate Block	41	21%
IV Sedation	20	10%

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.

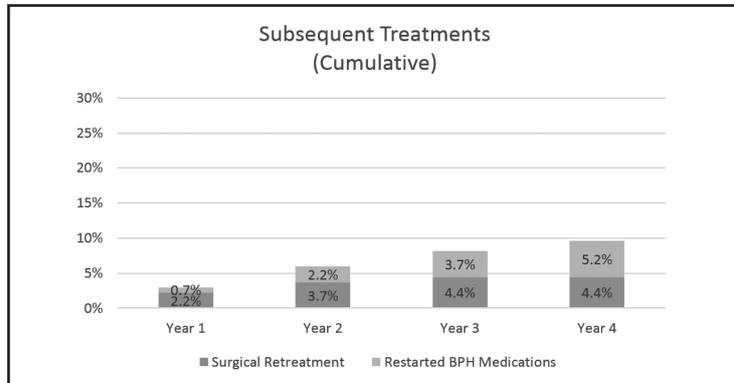
Subjects with catheterization performed	Treatment (N=135)	Control (N=61)
	90.4% (122/135)	19.7% (12/61)
Duration of catheterization, days		
Mean ± Std (N)	3.4 ± 3.2 (123)	0.9 ± 0.8 (12)
Median [Min - Max]	2.9 (0.0 - 30.9)	0.9 (0.0 - 2.0)

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 Retirements (Cumulative).



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Supplier's Declaration of Conformity 47 CFR § 2.1077 Compliance Information	
Unique Identifier:	Rezūm M006D2201-003 GTIN 0871472992547 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.	

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