

а версия. Да не се използва.  
ze. Ne používat.  
n. Må ikke anvendes.  
icht verwenden.  
e kasutage.  
ησιμότητα.

# rezūm®

Instructions for Use  
Rezūm® Delivery Device Kit for BPH  
Model D2201



Остаряла версия. Да не се използва.  
Zastaralá verze. Nepoužívat.  
Forældet version. Må ikke anvendes.  
Version überholt. Nicht kasutage.  
Αεγονυδ versioon. Άργε kasutage.  
Παλιά έκδοση. Μην την χρησιμοποιείτε.  
Outdated version. Do not use.  
Versión obsoleta. No utilizar.  
Version périmée. Ne pas utiliser.  
Zastarjela verzija. Nemojte upotrebljavati.  
Úrelyt útgáfa. Notið ekki.  
Versione obsoleta. Non utilizzate.  
Pasenusi verzija. Neizmantot.  
Elavult verzió. Ne használja!  
Dit is een verouderde versie. Niet gebruiken.  
Utdatert versjon. Skal ikke brukes.  
Wersja przeterminowana. Nie używać.  
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Güncel olmayan sürüm. Kullanmayın.

**IMPORTANT: Carefully read and understand all instructions, indications, warnings and precautions and directions for use prior to using any Rezūm® System component or the generator. Failure to do so could result in compromised patient safety, patient complications and/or insufficient treatment.**

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# rezūm®

## Trademarks and Copyright

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Richard-Wolf® is a registered trademark of Richard Wolf GmbH.

Tyvek® is a registered trademark of DuPont.

## Manufacturer

The Rezūm® System for BPH is manufactured by:

NxThera, Inc.

7351 Kirkwood Lane

Suite 138

Maple Grove, MN 55369

USA

Internet: [www.nxthera.com](http://www.nxthera.com)

Phone: +1-763-515-0404

Toll free: +1-888-319-9691

[bscemailorders@bsci.com](mailto:bscemailorders@bsci.com)

Emergo Europe 

Princessegracht 20

2514 AP The Hague

The Netherlands






[www.emergogroup.com](http://www.emergogroup.com)

 0413

# Symbols on Package Labeling

## 1 Symbols on Package Labeling

The following symbols may appear in this manual, on the Delivery Device and on Generator labeling and/or packaging. Some of the symbols represent standards and compliances associated with the Delivery Device, Generator and their use.

	Caution: Contains parts and assemblies susceptible to damage by electrostatic discharge (ESD)		Consult Instructions for Use
	Warning		Prescription device. Sold to or on the order of a medical professional only.
	EU Authorized Representative		This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.
	Date of Manufacture		Keep away from water
	Type BF Applied Part		Model Number
	Catalogue Number		Not made with natural rubber latex
	Manufacturer		Non-ionizing electromagnetic radiation
	Protection against Ingress of Solids and Liquids		Universal Serial Bus (USB) port connector
	Protective earth (ground)		Caution
	Alternating Current		Sterilized using Ethylene Oxide
	Serial Number		Single Use
	Expiration Date		Lot Number
	Do Not Resterilize		Manufacturer Part Number
	Pack Lot Number		Do not use if package is damaged
	Fragile, Handle with care		
	Quantity		



## 2 Safety

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



**WARNING!** This alert identifies hazards that may cause serious personal injury or death.



**CAUTION:** This alert identifies hazards that may cause minor personal injury, product damage, or property damage.

### 2.1 Warnings

**TRAINING:** NxThera requires physician training specific to the Rezūm System procedure prior to use. Please contact NxThera 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 1cm from the partially treated site, and repeat needle deployment steps.

**NEEDLE RETRACTION:** 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 Section 9. 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 delivery device while in use with a patient.

# System Overview

## 2.2 Cautions

**ACTIVE URINARY TRACT INFECTION:** Patients with an active urinary tract infection should have their infection treated and resolved before being treated with the Rezūm System.

**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.

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

## 2.3 Precautions

**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 IFU.

**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 4mm, 30 degree, 30cm 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.

### 3 Indications for Use

The Rezūm System is intended to relieve symptoms, obstructions, and reduce prostate tissue associated with 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.

### 4 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

### 5 The Rezūm System Overview

The Rezūm System is designed to treat patients with bothersome urinary symptoms associated with benign prostatic hyperplasia (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.

#### The Rezūm System includes the following major components:

- Rezūm Generator (reusable)
- Rezūm Delivery Device Kit and Accessory (disposable)

#### 5.1 Rezūm Generator

The portable Rezūm Generator is provided with the following reusable components (Fig. 1):

- Generator
- One Power Cord



(Fig. 1) Rezūm Generator.



# System Overview

## 5.2 Rezüm Delivery Device Kit and Accessory

- The Rezüm 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

## 5.3 Rezüm Delivery Device Component Functions and Specifications (Fig. 2)



(Fig. 2) Delivery Device Components.

# System Overview

**Table 2 Functional Description of the Delivery Device**

Description	Function	Specification
<b>A. Shaft</b>	Provides enclosed channel for needle, vapor tubing, rigid scope lens and flush irrigation	Shaft length = 8.6 inches Needle exit point = 8.3 inches Shaft diameter = 20Fr (0.264 inch diameter)
<b>B. Tip</b>	Guides shaft into treatment area and houses needle	1 inch (26mm)
<b>C. Needle</b>	Inserted into the targeted prostate tissue to deliver vapor treatment	Needle length = 10.25mm Needle diameter = 0.05 inches Needle angle = 90°
<b>D. RF Cable</b>	The RF cable is the energy line and connections for the switches and thermocouples	RF cable length = 95 inches
<b>E. Saline Flush Line</b>	Provides saline flush for irrigation through the Delivery Device	Saline flush line length = 162 inches
<b>F. Water Line</b>	Line to move water into the Delivery Device	Water line length = 106 inches
<b>G. Drain Line</b>	Line to allow urine to be drained from the bladder	Drain line length = 48 inches
<b>H. Rigid Cystoscope Lens Port</b>	Provides secure connection of rigid cystoscope lens in Delivery Device	Standard 4mm, 30 degree, 30cm Storz® or Richard-Wolf® rigid cystoscope lens
<b>I. Flush Activation Button</b>	Provides saline flush (normal, high)	Top, front button (white)
<b>J. Needle Deployment Button</b>	Located behind the flush button, deploys the needle into the prostate tissue	Top, back button (grey)
<b>K. Vapor Activation Button</b>	Activates vapor after needle has been deployed	Bottom button (blue)
<b>L. Needle Retraction Button</b>	Retracts needle back into Delivery Device shaft	Grey button located on the underside of the nose cone
<b>M. Nose Cone Release Pin</b>	Detaches shaft from Delivery Device to allow the safe manual retraction of needle into shaft if Needle Retraction Button fails	Clip located between nose cone and base of shaft

## 6 The Rezüm Procedure

### 6.1 User Supplied Materials

Other materials that are typically required for the Rezüm System procedure include, but are not limited to, the following items:

- Cart or sturdy surface for the Rezüm 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 (1L, 2L, 3L, 4L, 5L or 500ml)
- IV pole for Saline supply
- 4mm, 30 degree, 30cm Storz or Richard-Wolf rigid cystoscope lens
- Light source and cord
- Video camera and display; recorder optional
- Drain bucket
- Hemostat

### 6.2 Preparing the Patient

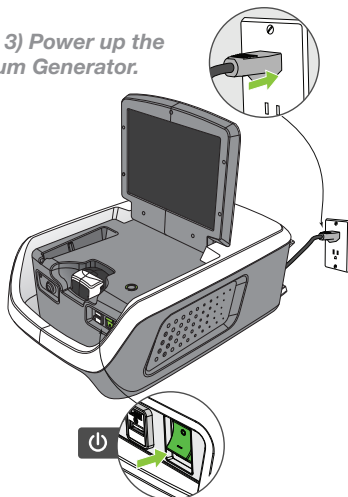
1. Prior to the procedure, administer physician-preferred pain and/or anti-anxiety medication. If using oral medications, allow sufficient time for the medications to reach peak levels.
2. Instruct patient to completely void bladder prior to procedure.



**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.

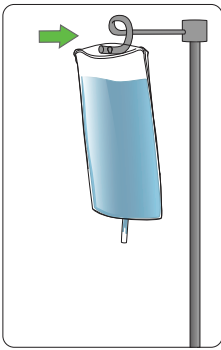
(Fig. 3) Power up the Rezüm Generator.



### 6.3 Power up the Rezüm Generator

1. Place Generator within reach of patient and an electrical outlet.
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. (Fig. 3)
5. Turn on the Generator.
6. The Generator is in an inactive state until a valid Delivery Device is connected.

# Preparing the Syringe



(Fig. 4) Hang the saline bag on IV pole.

## 6.4 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 Rezüm Generator.

2. Hang bag on an IV pole. (Fig.4)

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

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

## 6.5 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.

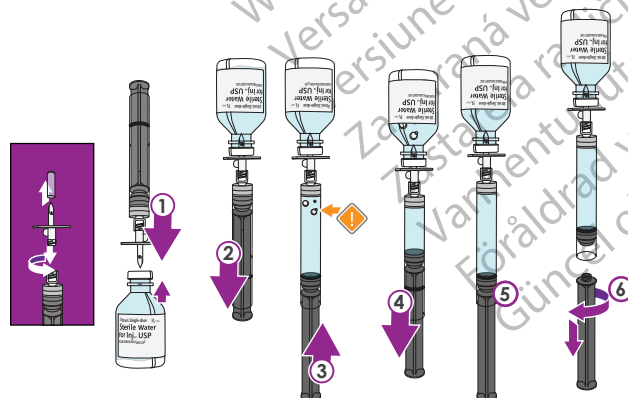
1. Prior to opening, inspect the integrity of the outside and inside packaging to ensure sterility. Do not use if the packaging is damaged.
2. Lay out sterile field and place some lubricating gel.
3. Remove the Sterile Water Vial from the corner of the box. Remove the cover from the water vial and wipe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

## 6.6 Prepare the Syringe

1. With clean hands, 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. (Fig. 5) Remove plunger shaft once Syringe is filled.

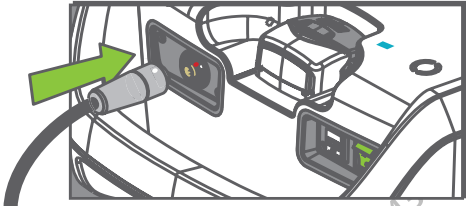
**PRECAUTION:** Ensure air bubbles are removed from the syringe. If bubbles are trapped in the line, an insufficient treatment may result.

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

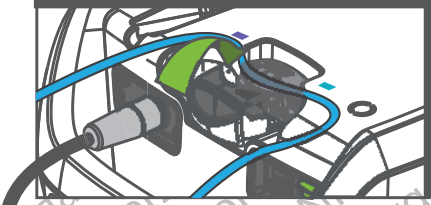


(Fig. 5) Filling the syringe.

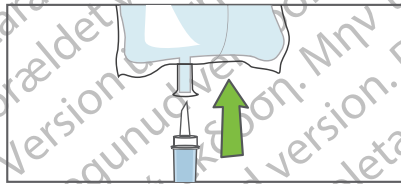
# Setting Up Rezüm Delivery Device



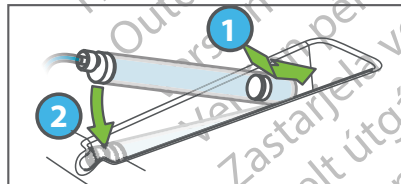
(Fig. 6) Connecting cable into Generator.



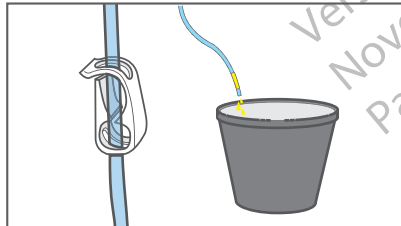
(Fig. 7) Loading Saline Flush Line into Saline Pump.



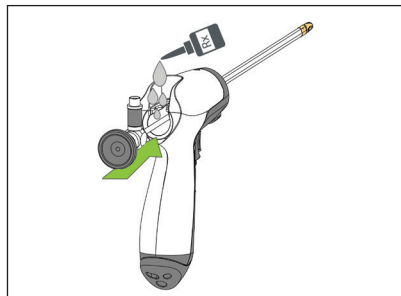
(Fig. 8) Connecting Saline Flush Line to Saline Bag.



(Fig. 9) Loading Syringe.



(Fig. 10) Closing clamp on Drain Line.



(Fig. 11) Insert Rigid Cystoscope Lens.

## 6.7 Set Up the Rezüm Delivery Device

1. Remove the Delivery Device RF cable and plug into generator, ensuring white dot is aligned with red dot (Fig. 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. Use the color indicators on the Generator and Saline Flush Line to guide placement (Fig. 7).



**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 (Fig. 8). Ensure clamp on Saline Flush Line and vent on Drip Chamber are open.
7. Remove Spike Adaptor and Sterile Water Vial from Syringe.
8. Load the filled Syringe into the Syringe cradle (Fig. 9).

**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 (Fig. 10).
11. Using sterile technique, remove delivery device from packaging tray.



# Priming the Delivery Device

## 6.8 Insert the Rigid Cystoscope Lens

The Delivery Device is compatible with a 4mm, 30 degree, 30cm length Storz 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.

**PRECAUTION: The Delivery Device is compatible with a 4mm, 30 degree, 30cm Storz 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. (Fig. 11)
3. Gently insert the lens into the lens port and advance into position until it snaps into place.

## 6.9 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 (Fig. 12):
  - 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.

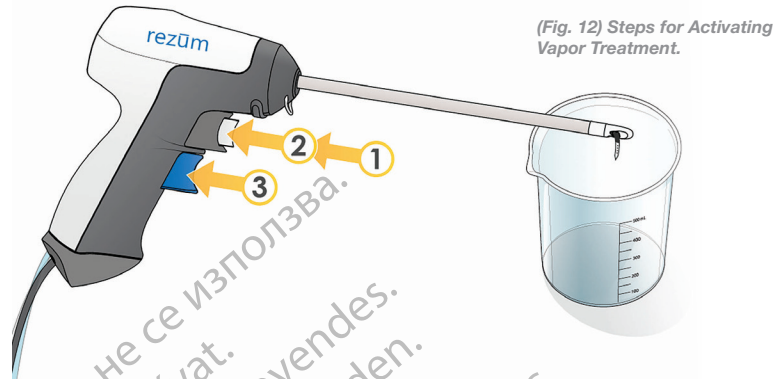
**PRECAUTION: If finger is released from Vapor Activation Button before the priming cycle is complete, vapor will automatically stop and the priming steps will have to be repeated.**

- f. If the Vapor Activation Button is released before the end of the priming cycle, repeat the priming cycle (steps a to c).
- g. If priming cycle is not successfully completed, repeat steps a to c or replace Delivery Device.

## 6.10 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 (Fig. 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.

# Perform Rezüm Vapor Treatment



(Fig. 12) Steps for Activating Vapor Treatment.

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

## 6.11 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. Point tip of Delivery Device upward to help remove any remaining bubbles in line.
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:** 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 (Fig. 13).
8. Based on the length of the vapor treatment zone, determine the number of treatments per lobe (Table 3). A treatment consists of a single 9-second delivery of vapor.
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  $\geq 35$  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.

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

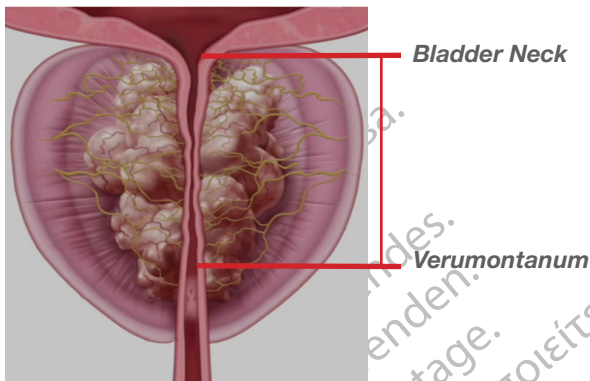
Table 3 Guidelines for determining the number of treatments (lateral lobe)

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

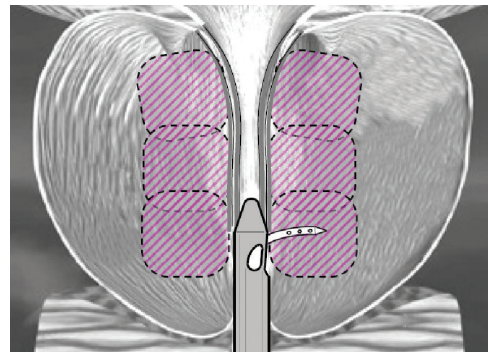
**NOTE:** A maximum number of 15 full treatments can be delivered with each Delivery Device.

# Perform Rezūm Vapor Treatment

(Fig. 13) Prostatic Treatment Length.



(Fig. 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 ceiling, 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 1cm 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.



## Post Procedure

**NOTE:** When the vapor treatment begins, the Rezūm 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.

**PRECAUTION:** 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 both Flush Activation and Vapor Activation buttons 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.
21. 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.

22. 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.
23. Repeat steps 10 through 20 until second lobe is fully treated.
24. 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.

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

### 6.12 Post Procedure

1. Remove the Delivery Device from the urethra.
2. Remove the cystoscopic lens for cleaning and reprocessing

## Additional Procedural Instructions

3. Transfer procedure summary information to a portable USB memory device (Optional).
4. Disconnect the Delivery Device electrical cable from the Generator.
5. Open roller pump door and remove Saline Flush Line from pump.
6. Remove Syringe and Water Line from syringe cradle.
7. Dispose of Delivery Device and Syringe.

**PRECAUTION: 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.**

8. Turn the Generator off.
9. Disconnect the Generator from the electrical outlet.

### 7 Method for Draining the Bladder

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

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

### 8 Method for Clearing Visual Field and/or Removing a Clot

1. 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.
2. When visualization is cleared, release Flush Activation Button. Flush will run at normal rate the next time the Flush Activation Button is engaged.

### 9 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. (Fig. 15)
3. Hold the shaft firmly in position and withdraw the handle just sufficiently to draw the needle into the shaft tip (1 inch minimum). (Fig. 16)

**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.
6. Report all incidences of manual needle retraction to NxThera Customer Service. Clean device and return to NxThera.

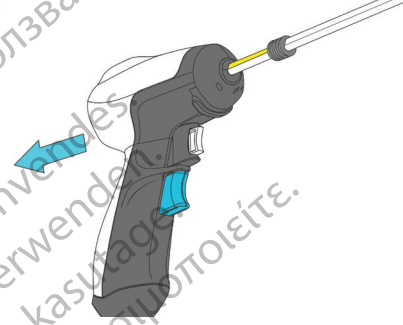


# Storage and Handling

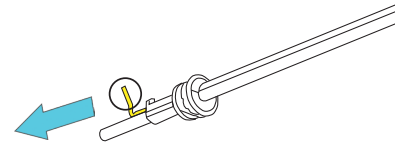
**! WARNING:** Do not remove device from the patient if the needle is not fully retracted. In case of incomplete needle retraction, manually retract needle before removing the device from the patient. Do not attempt to reassemble device for reuse after manual needle retraction.



(Fig. 15) Pulling Down Release Pin.



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



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

## 10 Storage and Handling

### 10.1 Rigid Cystoscope Lens

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

### 10.2 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. Protect from freezing.

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.

### 10.3 Rezüm Generator

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

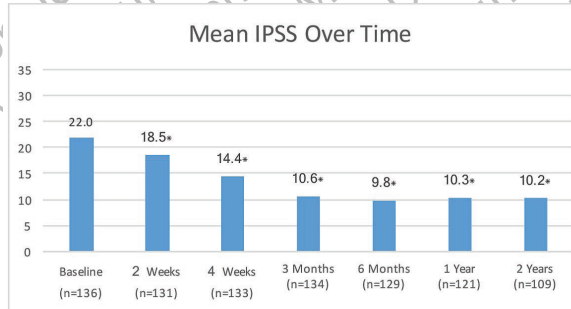
## 11 Pivotal Clinical Study Summary

### 11.1 Efficacy

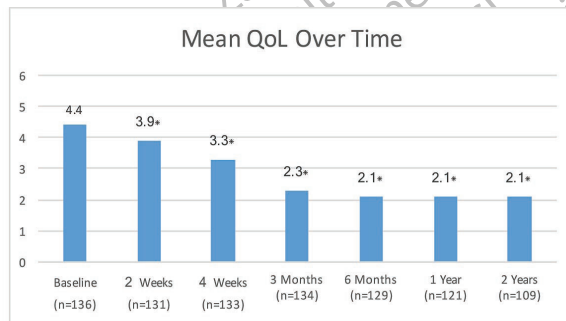
The Rezūm II Study was a multicenter, randomized, controlled, double-blinded study comparing the improvement in BPH symptoms at baseline and at 3 months post-procedure, as measured by IPSS, for subjects in the Treatment Arm as compared to subjects in the Control Arm. The Treatment Arm consisted of subjects 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 2 years for IPSS, Qmax, and Quality of Life. A post hoc analysis on IPSS severity at baseline identified a clinically significant improvement in both the moderate and severe groups. The study was not powered to demonstrate statistical significance in this sub-group. The stratification graphs below summarize the results through 2 years for IPSS, Qmax, and Quality of Life, when IPSS is stratified by moderate and severe at baseline.

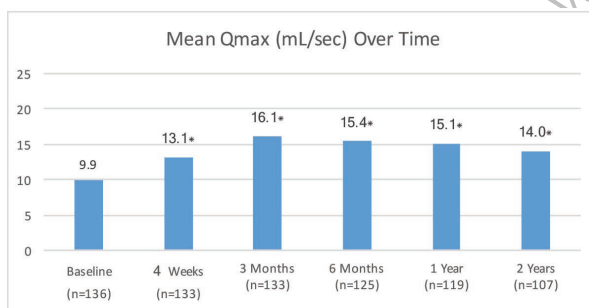
**Graph 1. Mean IPSS Over Time (Treatment Arm - All)**



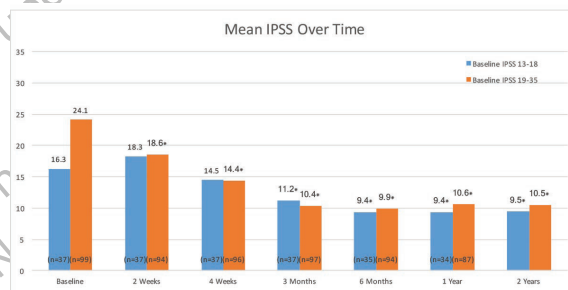
**Graph 2. Mean Qmax Over Time (Treatment Arm - All)**



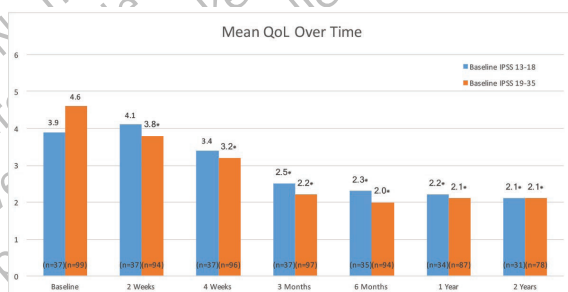
**Graph 3. Mean QoL Over Time (Treatment Arm - All)**



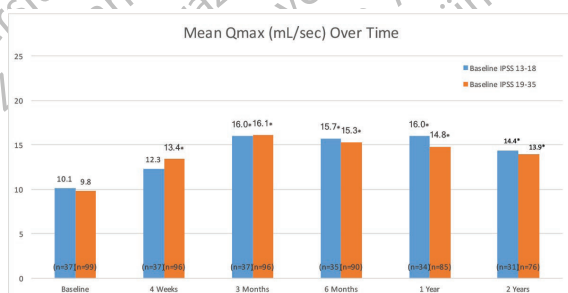
**Graph 4. Mean IPSS Over Time (Treatment Arm - Stratified by Moderate and Severe IPSS at Baseline)**



**Graph 5. Mean Qmax Over Time (Treatment Arm - Stratified by Moderate and Severe IPSS at Baseline)**



**Graph 6. Mean QoL Over Time (Treatment Arm - Stratified by Moderate and Severe IPSS at Baseline)**



## 11.2 Reported Adverse Events

A summary of the adverse events reported and adjudicated in the Rezüm II Pivotal study at treatment out through report date of August 25, 2016 is presented in the table below. 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 were 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 August 25, 2016, 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 4. Adjudicated Procedure and/or Device Related Adverse Events**

All Adjudicated Procedure and/or Device AEs for Treatment and Crossover Subjects					
Adverse Event	Percentage of Subjects				
	Procedure or Device Related AEs	Severity			Resolved AEs
		Mild	Moderate	Severe	
Dysuria	18%	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%
Urinary Retention	5%	<1%	4%	<1%	100%
UTI, Suspected	5%	4%	1%	0%	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%
Pain/Discomfort, Pelvic	2%	1%	<1%	<1%	100%

Prostatitis	2%	1%	1%	0%	100%
Urethral Stricture	2%	0%	2%	0%	100%
Gross Hematuria with Clots	2%	1%	<1%	0%	100%
Pain/Discomfort with Ejaculation	2%	0%	2%	0%	100%
Pain/Discomfort, Penile	2%	2%	0%	0%	100%
Poor Stream	2%	2%	0%	0%	100%
Splayed Stream	2%	<1%	1%	0%	100%
Gross Hematuria with retention	1%	0%	1%	0%	100%
Hematuria, Intermittent uncomplicated	1%	1%	0%	0%	100%
Hematuria, Micro	1%	1%	0%	0%	100%
Incomplete Voiding	1%	<1%	<1%	0%	100%
Urinary Incontinence, Urge	1%	<1%	<1%	0%	100%
Urinary Tract Infection (UTI)	1%	1%	0%	0%	100%

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.

### 11.3 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.

### 11.4 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 5. 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%

## 11.5 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 6. Catheterization**

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

## 11.6 Subsequent Treatments

Out of 188 subjects treated in the Treatment Arm, and Crossover group 9 subjects (5%) sought alternative treatment options within 2 years post initial Rezum treatment.

### First year

- One subject had large intravesical prostatic protrusions that were not identified and treated. The subject remained symptomatic and had a prostatectomy.
- Two subjects went on to TURP/Laser.
- One subject restarted BPH medications.

### Second year

- Two subjects went on to a TURP/Laser.
- Three subjects restarted BPH medications.



Остаряла версия. Да не се използва.  
Zastaralá verze. Nepoužívat.  
Forældet version. Må ikke anvendes.  
Version überholt. Nicht kasutage.  
Αεγονυδ versioon. Άρεγε kasutage.  
Παλιά έκδοση. Μην την χρησιμοποιείτε.  
Outdated version. Do not use.  
Versión obsoleta. No utilizar.  
Version périmée. Ne pas utiliser.  
Zastarjela verzija. Nemojte upotrebljavati.  
Úrelt útgáfa. Notið ekki.  
Versione obsoleta. Non utilizzate.  
Novecojsi versija. Neizmantot.  
Zastarjela verzija. Neizmantot.  
Úrelt útgáfa. Notið ekki.  
Versione obsoleta. Non utilizzare.  
Pasenusi versija. Nenaudokite.  
Elavult verzió. Ne használja!  
Dit is een verouderde versie. Niet gebruiken.  
Utdatert versjon. Skal ikke brukes.  
Wersja przeterminowana. Nie używać.  
Versão obsoleta. Não utilize.  
Zastarela različica. Ne uporabite.  
Vanhentunut versio. Älä käytä.  
Föråldrad version. Använd ej.  
Güncel olmayan sürüm. Kullanmayın.