



Clinique **St Luc** Bouge



Traitement ambulatoire de l'hypertrophie bénigne de la prostate: la technique Rezūm™

Dr Luc de Visscher
Service d'Urologie

Clinique Saint-Luc
Bouge



35^{ème} Congrès de l'AFISO

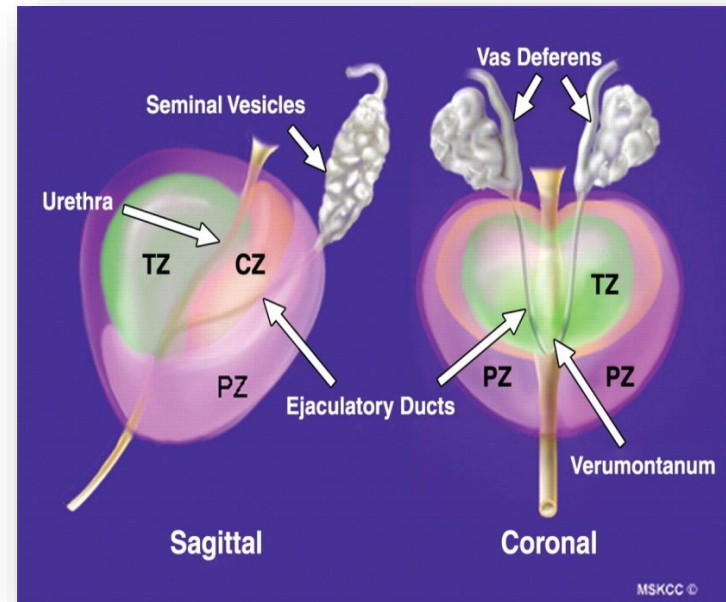
Samedi 26 mars 2022

Plan

- Prostate : rappel anatomique et SBAU**
- Traitements SBAU de type Obstructive**
- Technique Rezūm™**
 - Indications**
 - Contre indications**
 - Technique**
 - Résultats à 5 ans**
 - Coût du Rezūm™**
- Take Home Message**

Prostate

Anatomie chirurgicale



Symptomatologie Obstructive du Bas Appareil Urinaire

Latence pré-mictionnelle

Faiblesse du jet urinaire

Vidange vésicale incomplète

Gouttes retardataires

Pollakiurie diurne/nocturne



Traitements SBAU de type Obstructif

Médicamenteux

Phytothérapie

Alpha-bloquants

tolérance

éjaculation rétrograde

Inhibiteurs 5-alpha-réductase

perte libido

Non-médicamenteux

Résection endoscopique de la prostate (Gold Standard)

Adénomectomie chirurgicale (Millin/Hryntschak)

HoLEP (Holmium Laser Enucleation of Prostate)

Green Light™ (Pulvérisation Laser)

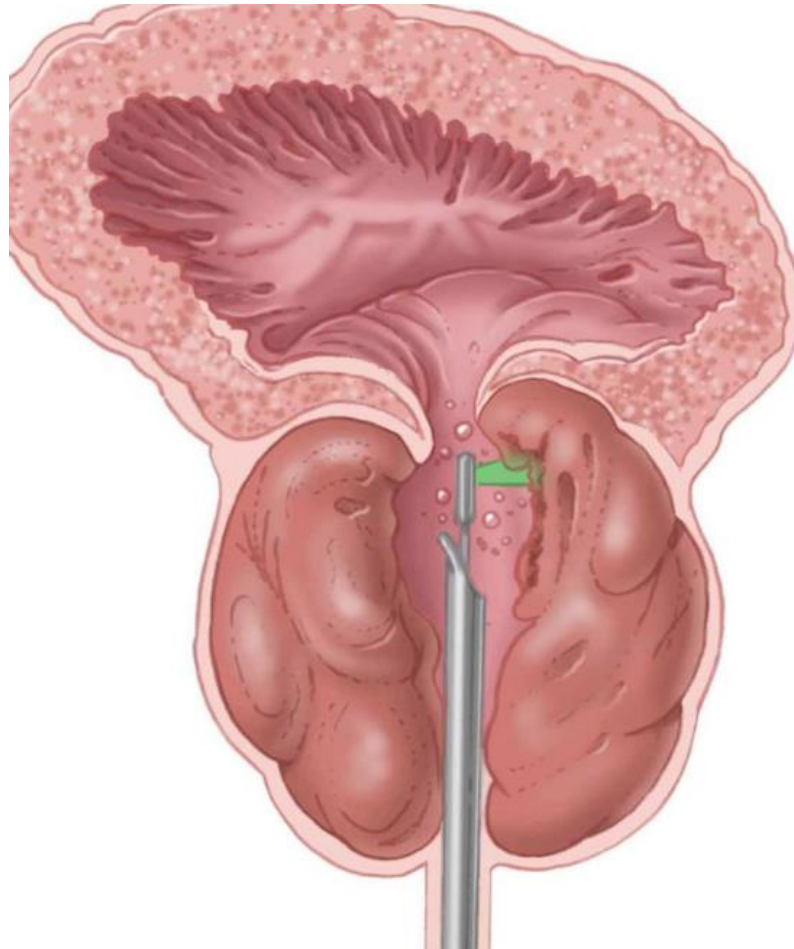
UroLift™

Rezūm™

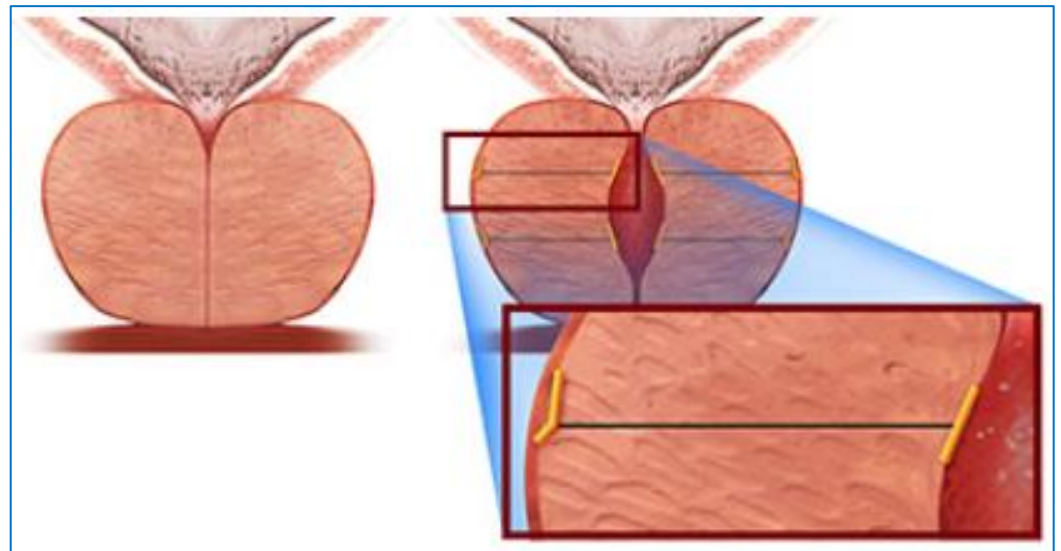
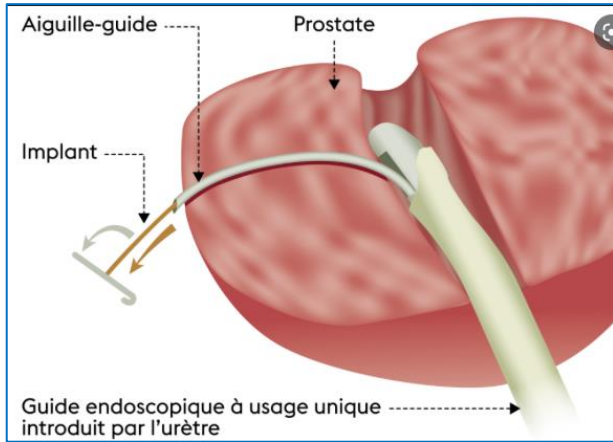
HoLEP (Holmium Laser Enucleation of Prostate)



Green Light™ (Pulvérisation Laser)



UroLift™



Technique Rezūm™

Indications

Prostate de 30cc à 60cc (80cc)

Hypertrophie zone centrale ou petit lobe médian

Souhait préservation éjaculation

Rétention urinaire aiguë

Contre indications

Sténose de l'urèthre

Cancer de la prostate

Infection urinaire en cours

Gros lobe médian

Calcul vésical

Prise Combodart® au préalable

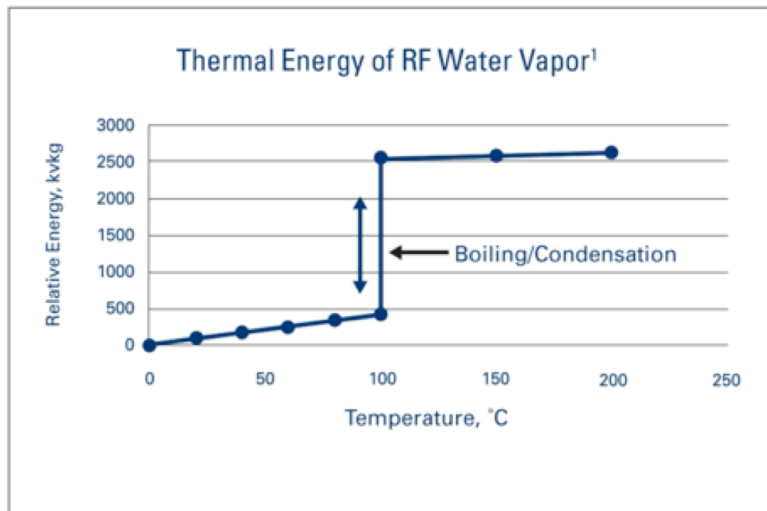
Technique Rezūm™



Technique Rezūm™

The Science Behind Rezūm™ Water Vapour Therapy: The Power of Steam

**Boston
Scientific**
Advancing science for life™



Relative Energy of Water

When water turns to steam, 540 calories/ml are stored in wet thermal energy ⁵

103°C water vapour is delivered to the prostate tissue in 9-second treatments.

The vapor is convectively dispersed throughout the tissue, releasing thermal energy and resulting in instantaneous cell death ⁵

Technique Rezūm™

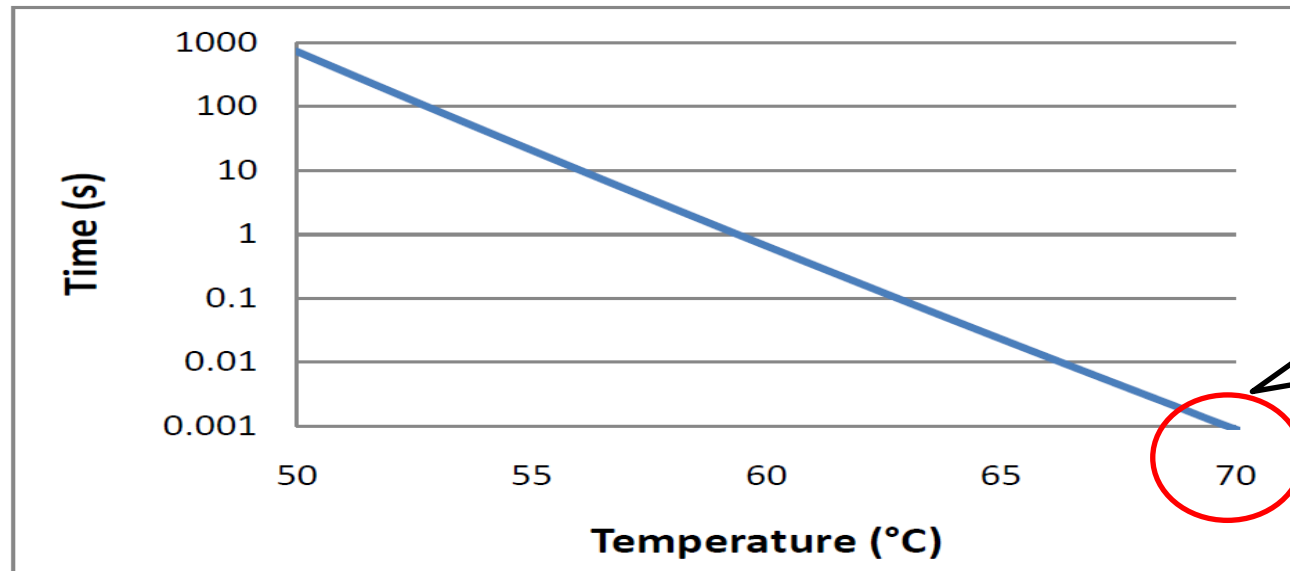


Figure 3. Graph of temperature vs. the time needed to cause tissue ablation (necrosis).

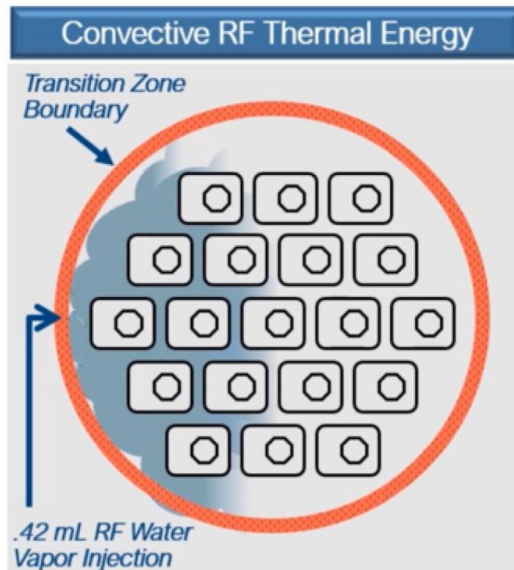
At >70°C cell death is immediate and irreversible

During a Rezūm™ treatment, 103°C water vapor is convectively delivered into 37°C prostate tissue, increasing the temperature of tissue within each treatment area to approximately 70°C+ over the course of each 9 second treatment, resulting in instantaneous cell death².

Technique Rezūm™

The Science Behind Rezūm™ Water Vapour Therapy: The Benefit of Convection^{1,6}

**Boston
Scientific**
Advancing science for life™



Convective RF Thermal Energy

0.42ml RF vapour convectively dispersed through interstices

Condensation uniformly releases 208 cal stored thermal energy

Cell membranes gently denatured causing cell death

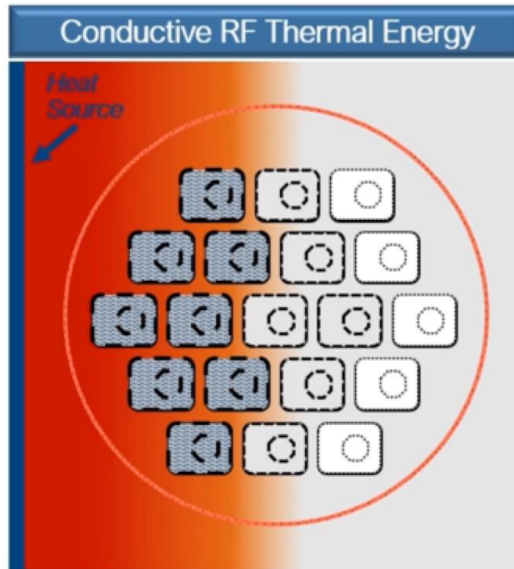
Convection denatures tissue to be reabsorbed by the body

Conduction causes unpredictable impacts to cell causing encapsulation and volume reduction

Technique Rezūm™

The Science Behind Rezūm™ Water Vapour Therapy: The Benefit of Convection^{1,7}

**Boston
Scientific**
Advancing science for life™



Conductive RF Thermal Energy

Conductive heat transfer cell to cell

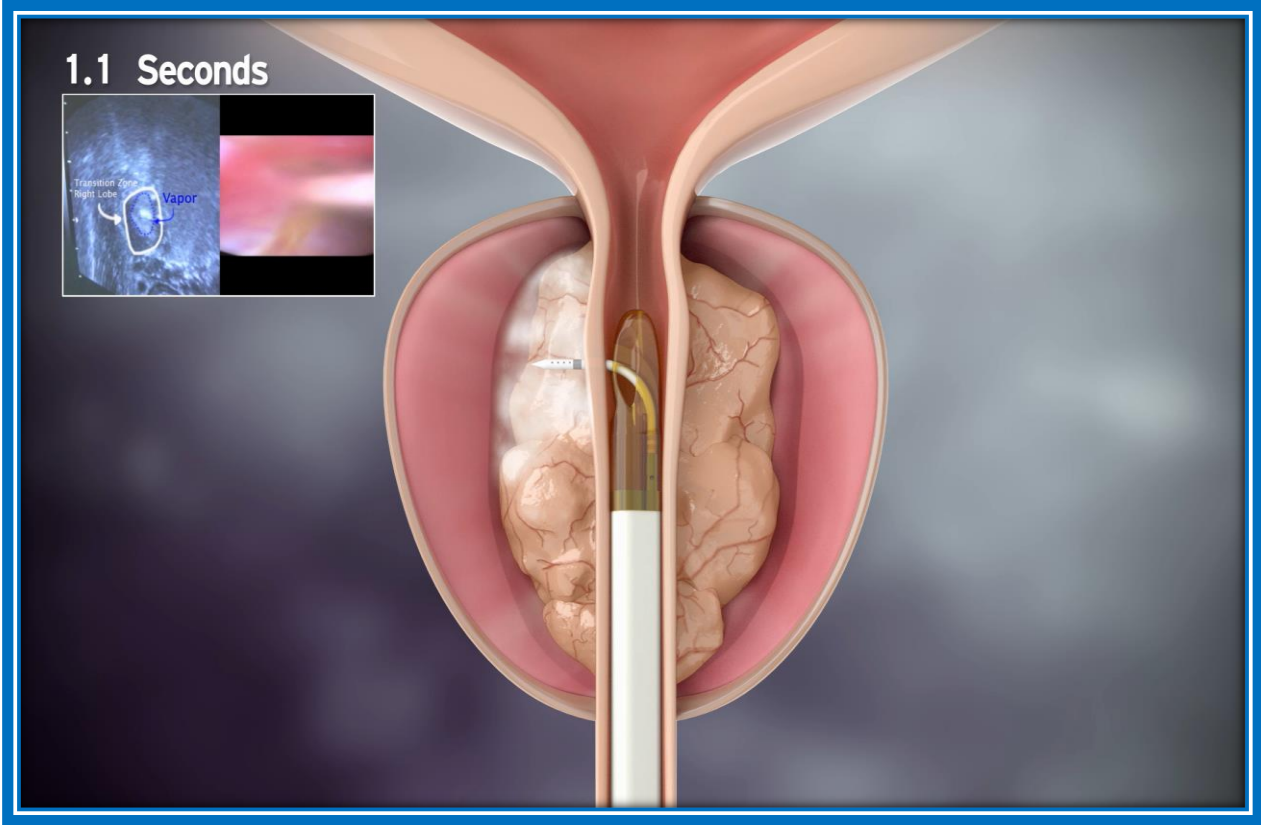
Non-uniform heat gradient results in cells near source being heated substantially more than those far away

Conductive heating of prostate capsule may occur

Convection denatures tissue to be reabsorbed by the body

Conduction causes unpredictable impacts to cell causing encapsulation and volume reduction

Technique Rezūm™



Technique Rezūm™

Procedural Times¹

Boston
Scientific

The average procedure time for subjects in the treatment-arm was
(initial insertion of device until complete removal)

5.3 minutes \pm 3.5

and

4.4 minutes \pm 1.7

in the crossover-arm

The mean number of vapor injections per subject was

4.5 \pm 1.8 (135)

and

5.1 \pm 1.9 (53)

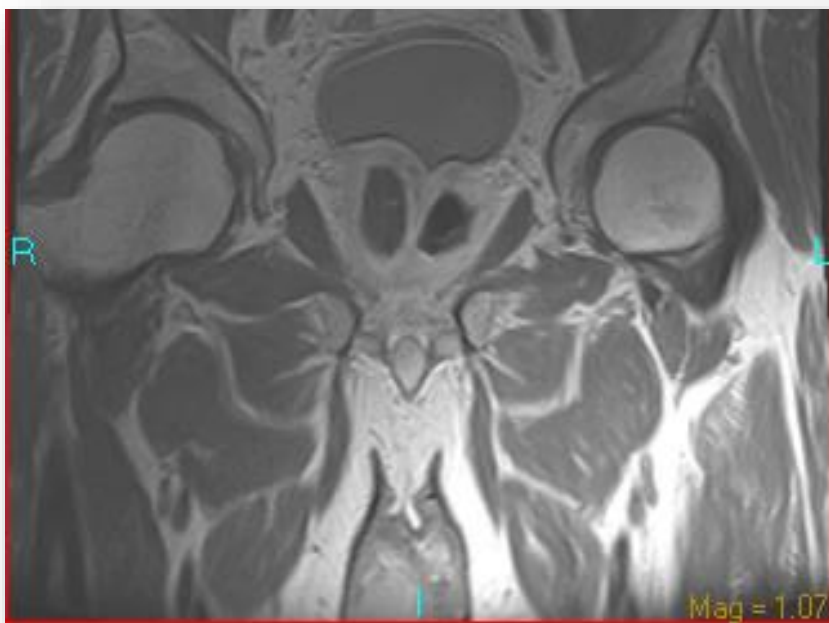
across the treatment and crossover groups, respectively

Middle lobe was noted and treated in 58 of 188 subjects (30.9%). These subjects received an additional mean 1.6 injections \pm 0.7 to the median tissue.

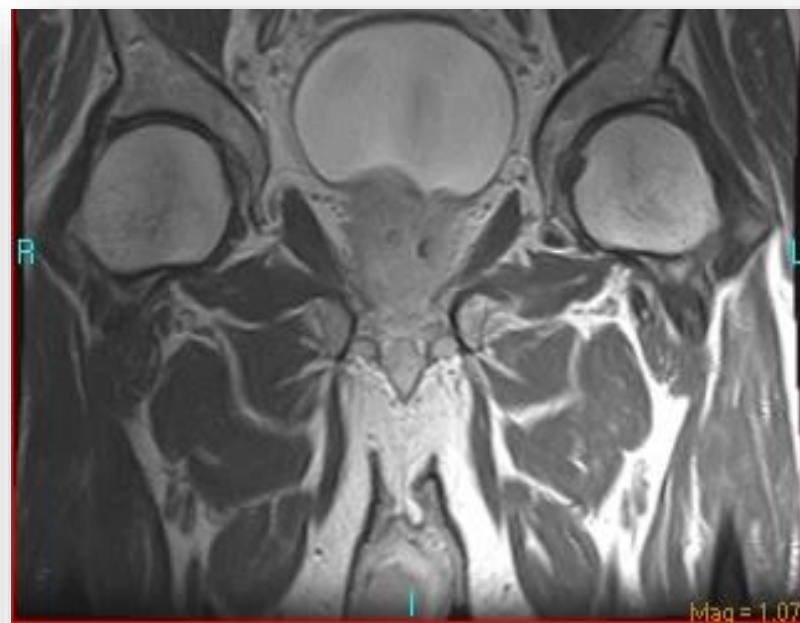
EDUCARE

Technique Rezūm™

1 semaine



3 mois



Technique Rezūm™

Sous anesthésie générale / Rachis + sédation

Stop anticoagulants

ABprophylaxie

Chirurgie ambulatoire

Sondage vésical pour une durée de 3 à 7 jours

Reprise anticoagulants le lendemain

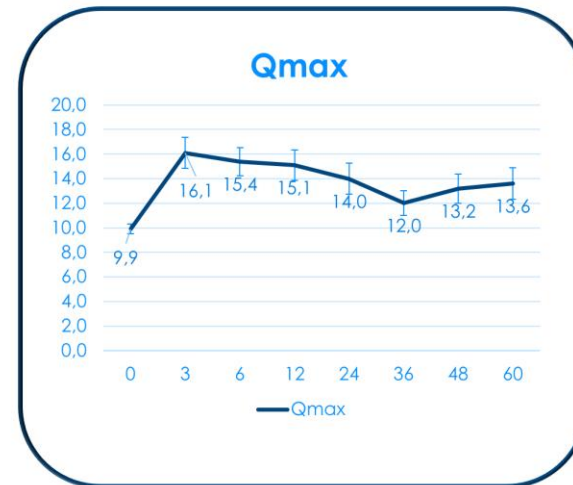
Amélioration symptômes entre 1 et 3 mois

Résultats Rezūm™

IPSS and Qmax^{1,2}

Significant improvement from baseline through 5 years

Boston
Scientific



mean values shown

EDUCARE

Résultats Rezūm™

Middle Lobe-Treated Subjects Through 12 Months²

Boston
Scientific

Median lobe treated in ~31% of Rezūm™ patients in study (58/188)³



EDUCARE

■ LL and ML Treated (n=58)
■ LL Treated, ML Identified but Not Treated (n=12)

Résultats Rezūm™

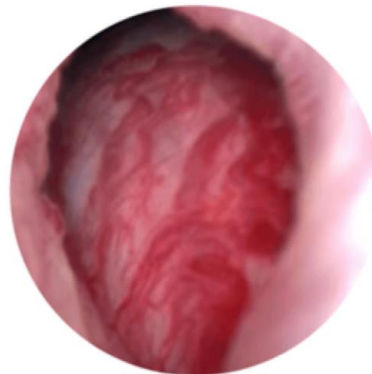
Median Lobe Efficacy

**Boston
Scientific**
Advancing science for life™

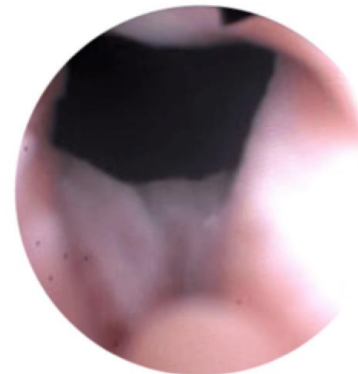
“Rezūm™ is the best choice for a minimally invasive procedure when treating an enlarged central zone. This convective vapor treatment markedly reduces the obstruction from an enlarged central zone, with minimal patient discomfort and in the office setting.”

Dr. Beahrs, Metro Urology

Post-treatment results on the prostate from the pivotal study¹



Pre-treatment
52 cm² prostate

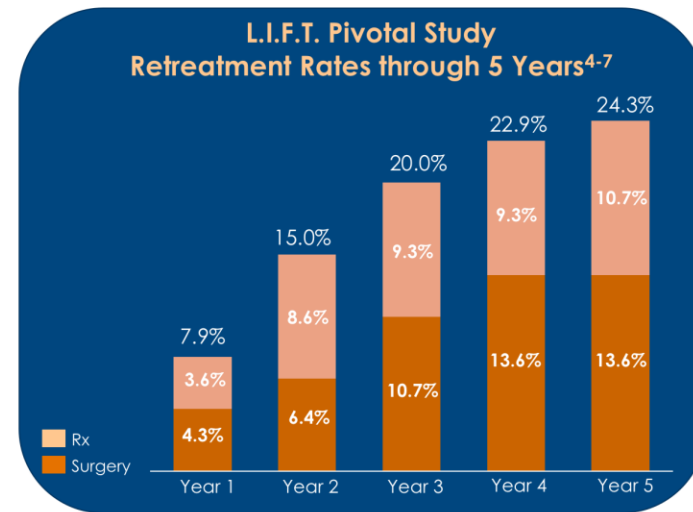
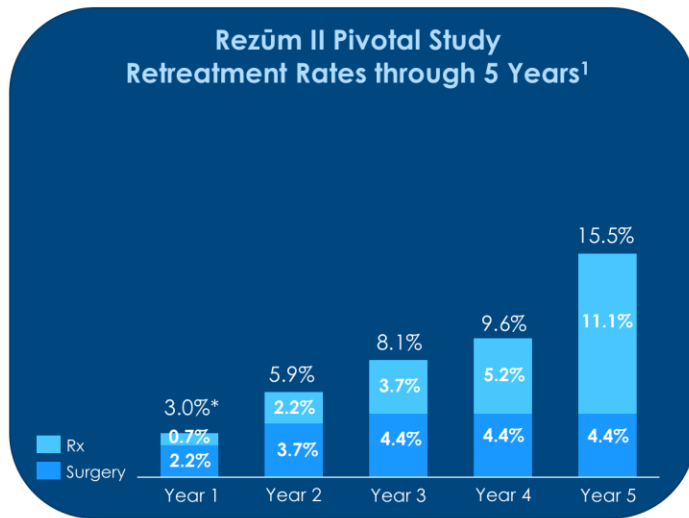


Post-treatment
3Tx/RLL; 4Tx/LLL; 2 Tx/ML

Résultats Rezūm™

Retreatment Rates: Rezūm™ and UroLift™ Pivotal Studies

Boston
Scientific



*Due to rounding.

Because data from the Rezūm System and UroLift System studies were not collected in a head-to-head study, direct comparisons between the Rezūm System and the UroLift System cannot be made. Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.

EDUCARE

Effets secondaires Rezūm™

Most Common Device and/or Procedure Related Adverse Events	Treatment and Crossover Subjects (N=188) Number of Events (% Occurrence)	Resolved
Dysuria	34 (18.1%)	33
Hematuria, Gross	22 (11.7%)	22
Hematospermia	12 (6.4%)	12
Urinary Frequency	11 (5.9%)	9
Urinary Retention	11 (5.9%)	11
Urinary Urgency	9 (4.8%)	7
Total – All study reported device and/or procedure AEs	Number of Events (Number of Patients, %)	Resolved
	209 (81, 42.9%)	185

Coûts du Rezūm™ pour l'institution

1800€ tvac pour le matériel

Remboursement INAMI de 1100€ si One Day

Forfait 150€ AG One Day

Prélèvement code chirurgical K225

Perte forfait hospitalier pour adénomectomie

**Mais: gain durée opératoire / séjour hospitalier
satisfaction patient**

Take Home Message Rezūm™

Traitement chirurgical ambulatoire de l'adénome prostatique symptomatique (30-80cc + petit LM) par injection de vapeur d'eau

Sondage vésical de maximum 1 semaine

Amélioration lente mais stable des symptômes

Préservation de l'éjaculation, réversibilité

Merci pour votre attention



Références

1. Michael Hoey, PhD “Water Vapor for Tissue Ablation”. NxThera Inc, 2009.
2. Dixon, C et al. “Transurethral convective water vapor as a treatment for lower urinary tract symptomatology due to benign prostatic hyperplasia using the Rezum® system: evaluation of acute ablative capabilities in the human prostate. *Research and Reports in Urology* 2015;7 13–18 <http://dx.doi.org/10.2147/RRU.S74040>
3. Dixon, C et al. “Efficacy and Safety of Rezum System Water Vapor Treatment for lower urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia”. *Urology* 86 (5), 2015, pg 1044.
4. Jennifer M. Burr et al. Hot and cold technologies for tissue ablation in urology. 2006 University of Aberdeen. *Journal Compilation* © 2006 BJU International 98, 1149-1153
5. McNeal, John E. The Zonal Anatomy of the Prostate. *The Prostate* 2:35-49 (1981)
6. Dixon CM, Cedano ER, Mynderse LA, Larson TR. Transurethral convective water vapor as a treatment for lower urinary tract symptomatology due to benign prostatic hyperplasia using the Rezum® system: evaluation of acute ablative capabilities in the human prostate. *Res Rep Urol.* 2015;7:13-18. <https://doi.org/10.2147/RRU.S74040>
7. Mynderse LA, Hanson D, Robb R, Pacik D, Vit V, Varga G, Wagrell L, Tornblom M, Rido, Cedano E, Woodrum D, Dixon CM, Larson TR. Rezum System Water Vapor Treatment for Lower Urinary Tract Symptoms/Benign Prostatic Hyperplasia: Validation of Convective Thermal Energy Transfer and Characterization with Magnetic Resonance Imaging and 3D Rendering. *UROLOGY.* 2015;86:122-127. <https://doi.org/10.1016/j.urology.2015.03.021>
8. 3032-004 Rezum Instructions For Use rev H (EU)
9. McVary K, Rogers T, Roehrborn C. Rezum water vapor thermal therapy for lower urinary tract symptoms associated with benign prostatic hyperplasia: 4-year results from randomized controlled study. *Urology.* 2018. *In Press.*
10. Kevin T. McVary,* Steven N. Gange,† Marc C. Gittelman et al. Minimally Invasive Prostate Convective Water Vapor Energy Ablation: A Multicenter, Randomized, Controlled Study for the Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia. *Journal of Urology* <http://dx.doi.org/10.1016/j.juro.2015.10.181> Vol. 195, 1529-1538, May 2016
11. McVary KT, Roehrborn CG: Three-year outcomes of the prospective, randomized controlled Rezum System study: convective radiofrequency thermal therapy for treatment of lower urinary tract symptoms due to benign prostatic hyperplasia. *Urology* 2018;111:1-9. <https://doi.org/10.1016/j.urology.2017.10.023>
12. Data on File Boston Scientific
13. Marberger, M. The MTOPS Study: New Findings, New Insights, and Clinical Implications for the Management of BPH. *European Urology Supplements* 5 (2006) 628–633
14. Gupta N, Rogers T, Holland B, et al. Three-Year Treatment Outcomes of Water Vapor Thermal Therapy Compared to Doxazosin, Finasteride and Combination Drug Therapy in Men with Benign Prostatic Hyperplasia: Cohort Data from the MTOPS Trial. *J Urol.* 2018 Aug;200(2):405-413.
15. McVary KT, Rogers T, Mahon J, Gupta NK. Is Sexual Function Better Preserved After Water Vapor Thermal Therapy or Medical Therapy for Lower Urinary Tract Symptoms due to Benign Prostatic Hyperplasia? *J Sex Med.* 2018 Dec;15(12):1728-1738
16. Data on file with Boston Scientific. Sources include 2013 Dymedex Market research report and BSC BPH market model.
17. Roehrborn CG, Gange SN, Gittelman MC, et al. Convective Thermal Therapy: Durable 2-Year Results of Randomized Controlled and Prospective Crossover Studies for Treatment of Lower Urinary Tract Symptoms Due to Benign Prostatic Hyperplasia. *J Urol.* 2017 Jun;197(6):1507-1516