

MOSES TECHNOLOGY – ELEVATOR PITCH AND Q&A

1. What is the Moses™ technology?

The Moses™ technology was launched by Lumenis in 2017 to address significant challenges in holmium laser treatments for stones and BPH. The technology, which utilizes and leverages the physical “Moses effect”, is a patent-protected (patent no. US-9895196) innovative technology, combining Lumenis holmium laser system and Moses tailored premium fibers. As such, Moses technology allows urologists to take laser lithotripsy techniques (Stone Fragmentation and Stone Dusting) and BPH treatment techniques (HoLEP and Vaporization) to the next level.

Using a unique pulse modulation method and a tailored premium fiber range, the Moses technology optimizes holmium energy delivery within each working distance – hence allowing for effective treatment even when not in full contact. In lithotripsy, it significantly reduces repulsion, stone migration and procedure time^{1,3,4,6}. In BPH, it provides with improved enucleation efficiency (HoLEP), higher vaporization rate of the tissue (Vaporization) and efficient hemostasis⁶.

The Moses pulse modulation, combined with tailored premium quality fibers, is designed to deliver optimal energy transmission, which is optimized per application, working distance and fiber type.

2. How does the Moses technology work?

The Moses technology modulates the laser pulse so that it first separates the water (‘initiation sequence’), and then delivers the remaining energy through the bubble and towards the target (‘treatment sequence’). This way, less energy is lost to the surrounding and energy transmission is optimized to the desired working distance. In addition, the tailored premium quality fiber range of 200, 365 and 550 D/F/L are designed and optimized per application, working distance and fiber type.

3. What applications/procedures is the Moses technology intended for?

The Moses technology is aimed at enhancing holmium lasers lithotripsy and BPH treatments and providing a true step forward to redefine urology care. The Moses technology is applicable for applications such as Ureteroscopy, PCNL, HoLEP and Vaporization, as well as for stone dusting and fragmentation techniques. In addition, Lumenis is continuously evolving the technology and its potential benefits with new optimizations e.g. per stone composition type and new treatment areas, and for other approved indications.

4. What are the key advantages of the Moses technology?

The Moses technology is a game changer in the world of urology care. It is a patent-protected combination of high power laser system and tailored fibers for holmium laser treatments, uniquely optimized per application, working distance and fiber type – with advantages as follows:

LITHOTRIPSY

Moses advantages for stones treatment are clear-cut. Optimized energy transmission, less stone migration and less retropulsion lead to more efficient procedure with proven reduction in procedure time. In double-blinded randomized clinical trial² comparing ‘regular’ and ‘Moses’ modes it was found that Moses technology resulted in 20% less procedure time, 25% less fragmentation time and 60% less retropulsion. In addition, the Moses™ 200 D/F/L fiber flexibility allows surgeons to reach hard-to-access stone locations, and with its ball tip it enables smooth initial fiber insertion through a fully deflected scope.

BPH

Initial clinical experience with the Moses technology showed that in HoLEP procedures it allows the surgeon with a clear incision, effective separation of the adenoma from the capsule and efficient hemostasis during and following the enucleation. In vaporization, Moses technology shows higher vaporization rate (more than 2x) and efficiency⁶, smooth vaporization plane and efficient hemostasis. In addition, the unique combination with the Xpeeda™ D/S/L side-firing fiber demonstrated enhanced fiber control⁵.

5. What clinical evidence supports the benefits of the Moses technology?

The Moses technology was tested in bench testing, pre-clinical testing, clinical evaluation and double-blinded prospective randomized clinical trial (“RCT”) with leading Urologists across the world.

1. Prof. Mostafa Elhilali and Dr. Sero Andonian from McGill University Health Center, Dept. Of Urology, Montreal, Canada have presented their initial clinical work in 19 patients at the EAU 2017 and demonstrating that the Moses technology is associated with significantly less retropulsion¹.
2. Dr. Sero Andonian et al. presented at EAU'18 preliminary results of double-blinded prospective RCT in 66 patients comparing ‘regular’ and ‘Moses’ modes. The results showed 20% less procedure time, 25% less fragmentation time and 60% less retropulsion with Moses compared to regular mode².
3. Further clinical efforts in progress include: a) RCT for BPH comparing high-power HoLEP with regular and Moses modes, b) evaluation of preferred settings and new optimizations for stones and BPH, and c) the effectiveness of holmium laser compared with other lasers.

6. Some competitors claim their laser system can reduce apparent retropulsion using wide pulse length. How does it compare with reducing retropulsion with the Lumenis P120H Moses?

Lumenis has pioneered 'long pulse' into the endourology market several years ago. The invention of the Moses technology is the next step forward in Lumenis' technology leadership for addressing the retropulsion challenge and stone ablation efficiency.

While the use of long pulse may contribute to reducing retropulsion, the Moses technology was proven to simultaneously reduce retropulsion and provide increased ablation rate and optimized energy delivery³. Therefore, the advantages of Moses address the critical factors of efficient holmium laser lithotripsy – resulting in reduced procedure and fragmentation times².

7. How is Lumenis' Moses technology different from Quanta's Vapor Tunnel?

Quanta's Litho 60/100W with Vapor Tunnel mode (also called "virtual basket") is essentially short and long pulses. While the use of long pulse may contribute to reducing retropulsion, the Moses technology was proven to simultaneously reduce retropulsion and provide increased ablation rate and optimized energy delivery³.

The unique capabilities of the Moses technology (optimized energy transmission, better ablation rate and reduced retropulsion) are facilitated due to Moses' Patent-protected pulse delivery mechanism that modulates the Moses bubble into two parts and optimizes the energy transmission to the target.

8. How does the Moses technology result in reduced retropulsion?

The Moses technology results in 60% less retropulsion² due to its optimized Moses bubble characteristics^{3,6}

The unique pulse modulation of the Moses technology creates an optimized 'initiation-treatment sequence', combining the most efficient lithotripsy effect on the stone and minimizing stone motion. The collapse of the Moses bubble, occurring only after the treatment sequence is delivered, stabilizes the stone and minimizes its movement. This balance, coupled with the Moses bubble characteristics and more targeted energy delivery, results in less retropulsion.

9. On which of Lumenis lasers systems and fibers is the Moses technology available?

The Moses technology is a patent protected combination of dedicated systems and fibers. Therefore, we have carefully redesigned the Lumenis Pulse 120H Moses, a powerful all-in-one holmium laser system, in order to integrate the Moses technology. The premium range of Moses fibers are designed for optimal energy transmission and durability and are an integral part of the Moses technology.

10. What is the difference between the Lumenis Pulse 120H and the Lumenis Pulse 120H Moses?

While both systems support a variety of urological treatments (including flexible ureteroscopy, PCNL, HoLEP and Vaporization), the Lumenis Pulse 120H Moses was redesigned to address the new hardware and software requirements of the Moses technology. Only by using the new Lumenis Pulse 120H Moses, together with the premium range of Moses fibers – physicians can enjoy the benefits of innovative Moses technology.

11. What about our existing Pulse 120H customers? Can they enjoy the benefits of Moses as well?

Current Lumenis P120H customers have the opportunity to upgrade their system to Moses. This unique offering will allow the physician to enjoy state-of-the-art technology and perform more efficient and less time-consuming procedures.

The Moses Upgrade Kit is available for ordering by our existing Lumenis P120H system customers. This upgrade kit includes both hardware and software components which are mandatory to utilize the Moses technology. Once ordered, the upgrade will take place on-site by a Lumenis Service Engineer and will take up to a full day to be fully performed.

Attractive offers are available for bundling Moses upgrades with service contract and/or consumables. For more details please refer to the Regional Sales Manager in your region.

12. Which fibers are available for the Moses fiber range?

The Moses fibers are an integral part of the Moses Technology. The tailored premium quality fibers are designed for optimal energy transmission and durability, showing minimal erosion compared to regular fibers⁶.

Moses Single Use end-firing fibers come in the following sizes: Moses 200 D/F/L, Moses 365 D/F/L and Moses 550 D/F/L. In particular, the cutting edge Moses™ 200 D/F/L fibers allow surgeons to reach hard-to-access stone locations and enable smooth fiber insertion through a deflected scope. In addition to Moses Single Use end-firing fibers, Xpeeda™ D/S/L side-firing fiber is used for Vaporization and enables work in full contact mode. Please see below the fibers part numbers for internal reference only:

- Moses™ 200 D/F/L – Flexible with a ball-tip – Max 2J, 80Hz, 60W – P/N AC10030100
- Moses™ 365 D/F/L – Max 6J, 80Hz, 120W – P/N AC10030110
- Moses™ 550 D/F/L – Max 6J, 80Hz, 120W – P/N AC10030120
- Xpeeda™ D/S/L – Max 2J, 60Hz, 120W – P/N AC-1000729

13. Where is the technology currently being used?

Moses technology is currently used in hundreds of sites across the globe. It was evaluated by leading expert urologists in the following locations:

AMERICAS

- Dr. Akhil Das - Jefferson University Hospitals, Philadelphia, PA, USA
- Dr. Amy Krambeck - Indiana University Health, Indianapolis, IN, USA
- Dr. Bodo Knudsen - Ohio State University Wexner Medical Center, Columbus, OH, USA
- Dr. Brian Eisner and Dr. Dianne Sacco - Massachusetts General Hospital, Boston, MA, USA
- Dr. Kerri Barnes - The University of Kansas Physicians, Kansas City, KS, USA
- Dr. Kurshid Ghani - Michigan University, Ann Arbor, MI, USA
- Dr. Manoj Monga - Cleveland Clinic Main Campus, Cleveland, OH, USA
- Dr. Michael Lipkin - Duke University Hospital, Durham, NC, USA
- Dr. Mitchell R. Humphreys - Mayo Clinic, Phoenix, AZ, USA
- Dr. Stephen Nakada - University of Wisconsin Hospitals, Madison, WI, USA
- Dr. Steven Maislos - Urology Institute of Houston, Houston, TX, USA
- Dr. Wilson Molina - Denver Health Medical Center, Denver, CO, USA
- Prof. Mostafa Elhilali and Dr. Sero Andonian - McGill University Health Center, Montreal, Canada

EUROPE

- Dr. Andy Symes - Princess Royal Hospital. NHS, Haywards Heath, UK
- Dr. Herve Baumert - Saint Joseph Hospital, Paris, France
- Dr. Olivier Traxer - Tenon Hospital, Paris, France
- Prof. Amiel, Dr. Badan and Dr. Mullerad - Rambam Health Care Campus, Haifa, Israel
- Prof. Ivano Vavassori - Treviglio-Caravaggio Hospital Treviglio Bergamo, Italy

14. Is the Lumenis P120H Moses FDA Cleared?

Yes, it is covered under K140388 as part of the Lumenis Pulse 120 Holmium System.

15. What marketing and clinical material do we have available?

All marketing and clinical materials are available on partnerzone: <https://partnerzone.lumenis.com/>

STONES

- ✓ 3 Brochures and booklet: Moses for Stones, P120H Moses and Stones booklet
- ✓ P120H 'Moses for Stones' animation video
- ✓ 2 Infographics: Moses evolution and Moses Clinical Trial (presented at EAU'18)
- ✓ 3 procedure videos:
 - Dr. Evangelos Liatsikos (Greece)
 - Dr. Hideyasu Iwamoto (Japan)
 - Dr. Sijo Parekattil (US)
- ✓ RCT²
- ✓ 9 abstracts and posters
- ✓ 2 peer-reviewed articles

BPH

- ✓ 'Moses for BPH' brochure
- ✓ MoLEP video comparing Regular to Moses
- ✓ P120H 'Moses for BPH' animation video
- ✓ Abstract of high-power HoLEP by Dr. Mark Cynk (WCE'16)
- ✓ Randomized Clinical Trial with Prof. Vavassori comparing Moses to Regular mode for HoLEP – in progress

References:

1. Ibrahim A., Carrier S., Andonian S., Elhilali M. Evaluation of the New Moses Technology of Holmium Laser Lithotripsy: Initial Clinical Experience. Abstract presentation at EAU 2017
2. A Ibrahim, N Fahmy, S Carrier, M Elhilali, S Andonian; Double-blinded prospective randomized clinical trial comparing regular and Moses modes of holmium laser lithotripsy: preliminary results presented at EAU 2018
3. Use of the Moses Technology to Improve Holmium Laser Lithotripsy Outcomes: A Preclinical Study, Elhilali et al. J Endourol. 2017 Jun 1; 31(6): 598–604
4. Ahmed Ibrahim, Shadi Badaan, Mostafa M. Elhilali, Sero Andonian, Moses technology in a stone simulator, Can Urol Assoc J. 2018 Apr;12(4):127-130. doi: 10.5489/cuaj.4797. Epub 2017 Dec 22
5. Beaghler M, Leo M, Gass J, March J, Sandoval S, et al. (2017) Initial Experience with New High Powered 120 W Holmium for Vaporization of the Prostate. Urol Nephrol Open Access J 4(2): 00119
6. Bench test results may not necessarily be indicative of clinical performance