Epi-Lasik Surgery

Introducing

Epi-K

powered by Moria

Epi-K

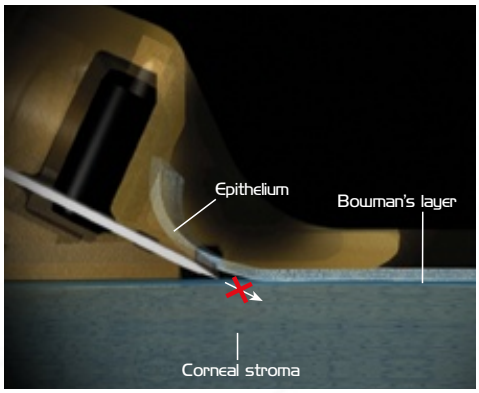
Moria

The Epi-K is a fully automated system with a disposable head and ring that enables surgeons to perform a new refractive procedure. The Epi-K is utilized to mechanically cleave the epithelium from the Bowman's membrane leaving a pristine optical zone for laser ablation.

Epi-LASIK preserves the structural integrity of the stroma and is expected to minimize discomfort, shorten the length of visual recovery, and reduce the incidence of haze associated with other surface ablation procedures, such as PRK and LASEK.

The Evolution of Laser Vision Correction Refractive Surgery

1983-1986	RK - Diamond Knives
1983-1990	ALK - Keratome
1986-1999	PRK - laser only
1991-Present	LASIK - keratectomy & laser
1999-Present	LASEK - with alcohol
2004	Epi - LASIK



Mechanism of action

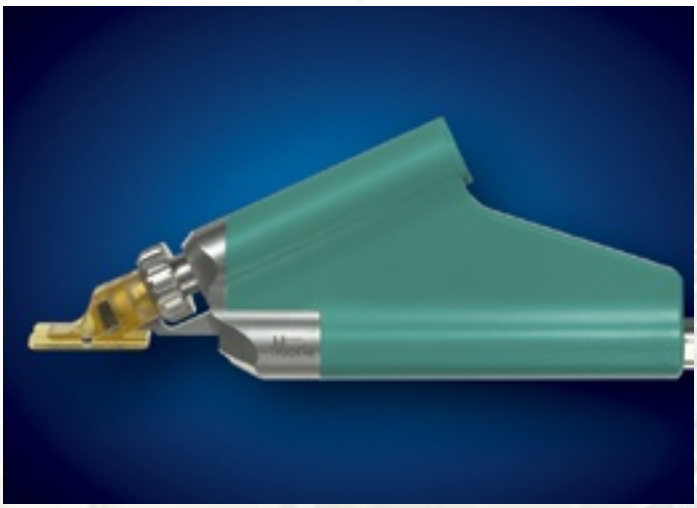
- Precision machining of the metal blade produces uniform, reproducible blunt edge.
- Angle of blade to epithelium allows for cleavage of the epithelial layer instead of cutting.
- Cleavage follows along plane of least resistance by separating and rupturing this plane.
- Cleavage at the level of the basement membrane appears to allow for a viable epithelial layer.
- Presence of an applanation front plate prevents cutting into the stroma.
- Implication of potential better wound healing:
  - less apoptosis (more stable result).
- Possibly less pain.
- Expected more rapid visual recovery.

EPI-K

The Epi-K Handpiece

Moria has built precision, elegance, and practicality into the Epi-K handpiece:

- Advancement, speed specifically calibrated for epithelial separation.
- Safety and reliability of two separate motors:
  - one for head advancement,
  - one for blade oscillation.
- Lightweight, with outstanding ergonomics.



The Epi-K disposable set

Each Epi-K set contains a disposable sterile suction ring, and head with pre-assembled Epi-K non-cutting metal blade.
The disposable system provides unrivalled simplicity, safety, convenience, and ease-of-use :

- Eliminates potential complications from reusable devices that have been improperly cleaned or sterilized.
- Eliminates risks and costs of damaged reusable heads and rings.
- Eliminates blade handling and possible damage.
- Eliminates sterilization and maintenance. Facilitates faster patient turnover, leading to greater profitability.

Evolution³ Control Unit

Moria's computerized console offers a wealth of features to enhance performance, safety, flexibility, and ease-of-use:

- Two high performance pumps rapidly create a stable vacuum.
- Low vacuum option facilitates extremely gentle manipulation of the delicate epithelial flap on the reverse pass and secures globe fixation during laser ablation.
- "Slow vacuum release" option provides gentle onset and release to minimize patient discomfort and potential retinal trauma.
- Runs on wall current, with built-in back up battery for uninterrupted use.
- Continuously monitors all key parameters and confirms status through visual and audible signals.
- Has the flexibility to also operate the new One Use-*Plus*, and M2 LASIK microkeratomes.

Excellent Clinical Results

In clinical trials, the Epi-K consistently produced very high quality epithelial flaps. Post-operative pain and visual recovery compared favorably with other surface ablation procedures.

	Country	Flap diameter Mean ± SD	Zone of ablation Mean ± SD	Hinge length Mean ± SD
Barrie Soloway, MD (16 eyes)	USA	9.2 ± 0.2	8.0 ± 0.4	4.7 ± 1.3
Mark Swanson, MD (32 eyes)	Mexico	9.1 ± 0.6	8.1 ± 0.6	6.1 ± 0.7

	Flap thickness Mean ± SD
Barrie Soloway, MD (16 eyes)	52.3 ± 9.3
Mark Swanson, MD (32 eyes)	46 ± 8.5

	Manifest refraction Mean (Min - Max)		Keratometry Mean (Min - Max)	
	Sph	Cyl	K1	K2
Barrie Soloway, MD (16 eyes)	-4.50 (-9; -0.75)	-0.84 (2.75; 0)	43.75 (40.5 - 45.75)	44.61 (43 - 47)
Mark Swanson, MD (32 eyes)	-3.73 (-9.75; +3.75)	-2.20 (-7.5; 0)	43.50 (41 - 47.4)	45.80 (43.75 - 49.75)

FLAP QUALITY	Dr. Swanson	Dr. Soloway
Edge quality	96%	97.5%
Bed quality	96%	97.5%
Epithelial integrity	100%	100%
Epithelial Stretch	100%	100%
Interface	96%	97.5%

	Post-op Pain Level (0 = none 10 = most) Mean ± SD (Min - Max)
	Dr. Soloway
Evening	3.5 ± 3.8 (0-10)
Day 1	1.0 ± 1.3 (0-4)
Day 2	0.7 ± 1.6 (0-6)
Day 3	0.7 ± 1.6 (0-6)
Day 4	0

Source: Epi-Lasik and lamellar Surgery ESCRS Satellite Symposium (Paris, Sept. 2004)

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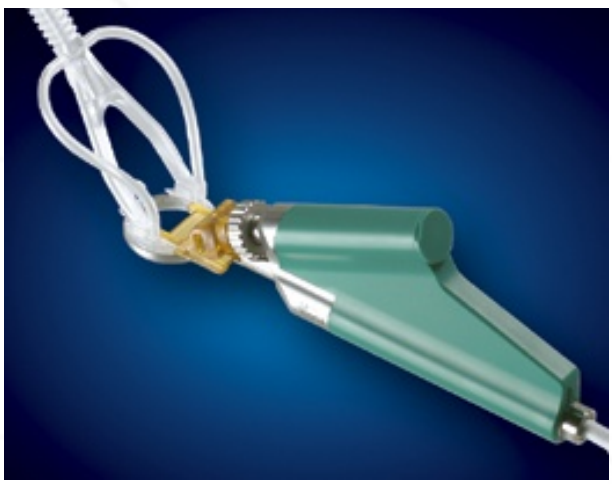

Not yet for sale in the United States
Patent pending