

ROTATIONAL STABILITY
MAKES THE DIFFERENCE

3! FLEX



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EYE SURGERY ESSENTIALS.

MEDI  NTUR



3! FLEX T

ROTATIONAL STABILITY
MAKES THE DIFFERENCE

Bi-Flex Platform – the Proven Platform of Excellence

01

Proven Stability – less than
2 degrees long-term rotation

02

Optimal biomaterials

03

Posterior Toric Lens surface with marks
indicating the flat axis of the lens

04

Unique Bitoric Concave-Convex
technology

05

Improved PCO prevention –
360° sharp edge

06

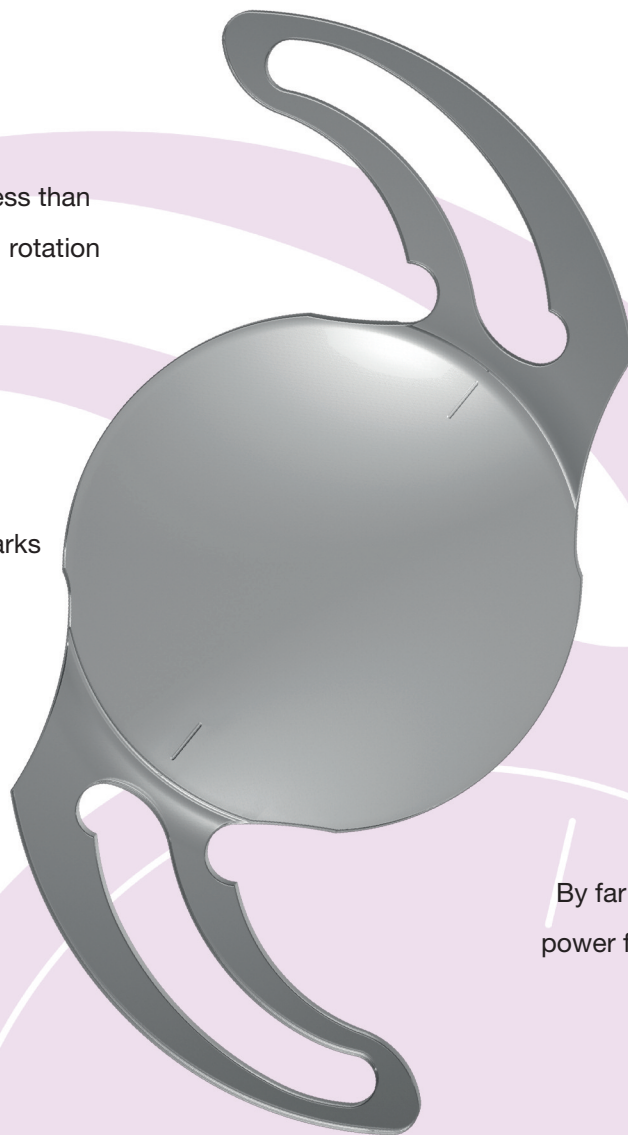
By far the widest range of cylindrical
power for extremely astigmatic patients

07

Aspheric optic with neutral
approach

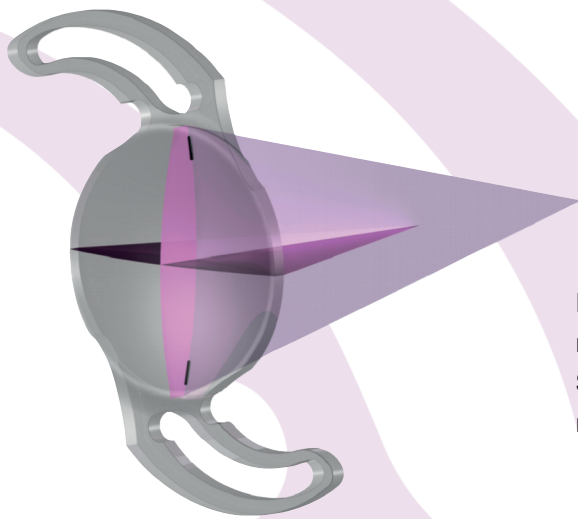
08

Very low chromatic aberration
(Abbe number 58)



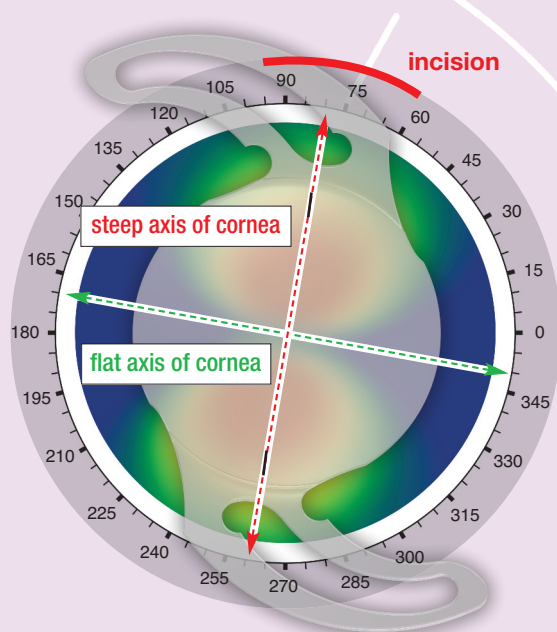


Marks Indicate Flat Axis



Flat axis at biggest radius = small curvature =
min. power (D): marked
Steep axis at smallest radius = big or hard curvature =
max. power (D): perpendicular to marked axis

Flat axis of the toric IOL should be aligned with the steep axis of cornea



Steep axis of cornea should be aligned with
flat axis of the IOL indicated by marks



Unique Bitoric Concave-Convex Technology

- By far the widest range of options for patients with astigmatism
- Significant reduction of the IOL thickness
- Easy folding and injection even with extremely high cylinders
- Allows manufacturing of high cylindrical powers even for highly myopic patients (IOLs with negative SEQ)
- Protection against capsule shrinkage through adequate compression force
- **Optimized shoulder-shaped haptic** with a wide loop connection and special double joints at the haptics base
- **Sharp square edge all over 360°** even at the optic-haptic junction zone.

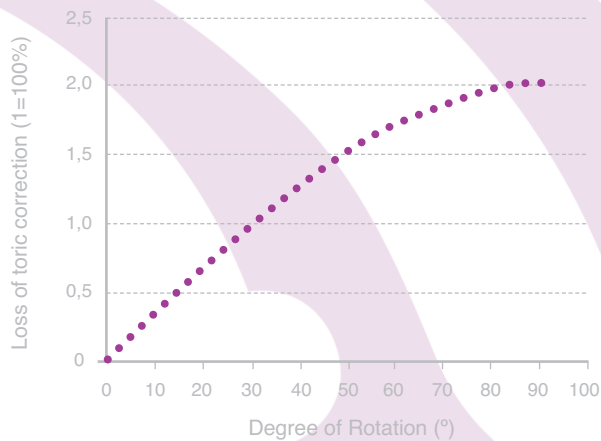




Rotational Stability – Key Factor for a Toric IOL

Rotational stability, accuracy in marking procedures and precise calculation are essential.^{[1] [2]}

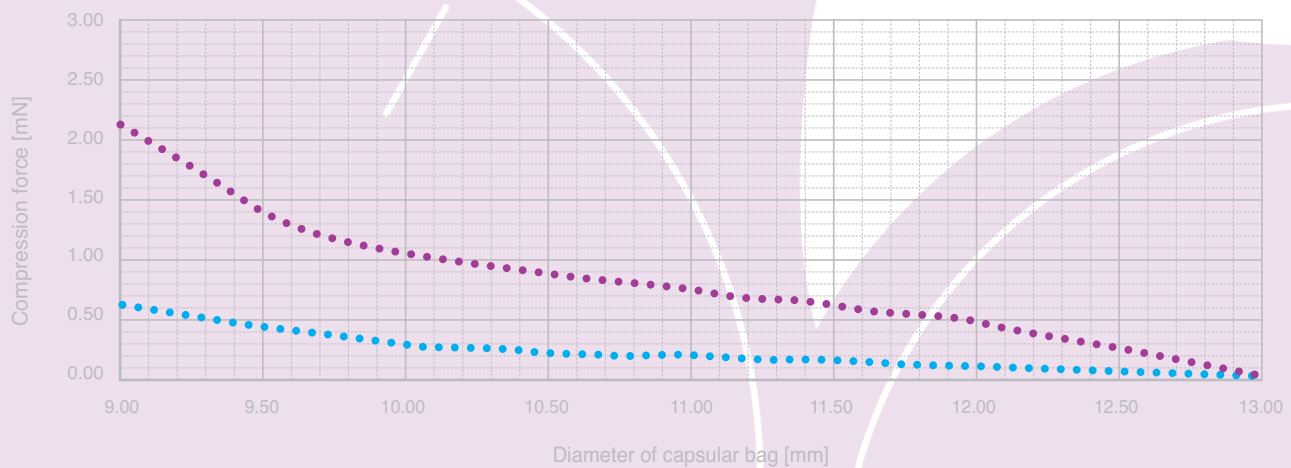
The loss of the cylindrical power in relation to the rotation of the toric IOL



- Each degree of off-axis rotation results in 3.3% loss of lens astigmatic power
- A deviation of 10 degrees decreases the potential correction by 35%
- At 30 degrees of rotation, the cylindrical power is down to 0.

Comparison of the haptic compression force of a “shoulder-shaped” Bi-Flex haptic and of a “stableforce” haptic

Graph shows superior ability of Bi-Flex T in preventing capsular shrinking throughout all capsular diameters



- “shoulder-shaped” haptic
- “stableforce” haptic

[1] Viestenz A, Seitz B, Langenbucher A. Evaluating the eye's rotational stability during standard photography; effect of determining the axial orientation of toric intraocular lenses. J Cataract Refract Surg 2005; 31:557-561; [2] Weinand F, Jung A, Stein A, et al. Rotational stability of a single-piece hydrophobic acrylic intraocular lens: new method for high-precision rotation control. J Cataract Refract Surg 2007; 33: 800-803

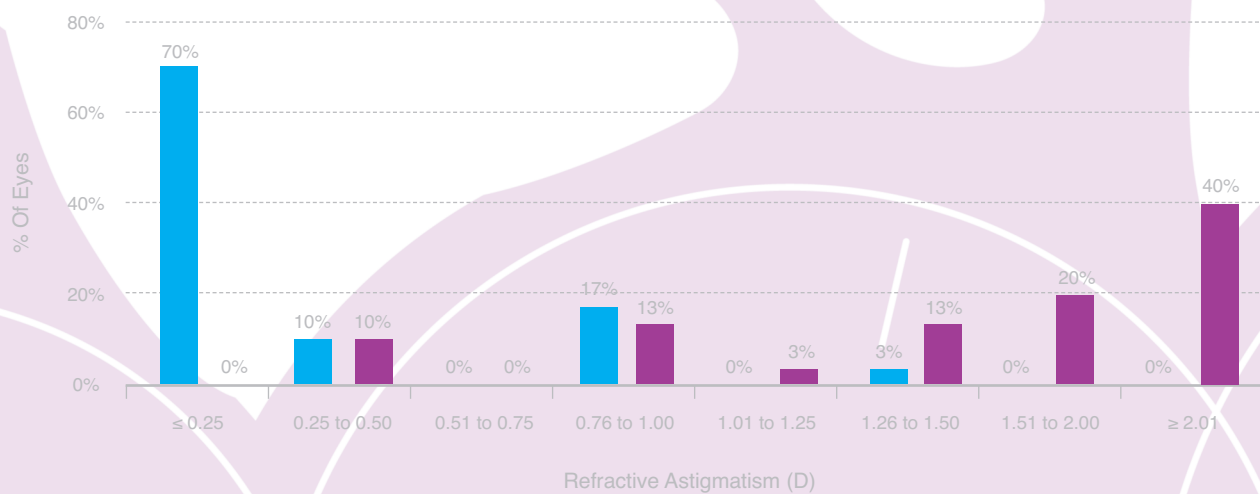


Superior Rotational Stability of Bi-Flex T

The study^[3] confirmed:

- 93% of patients achieved 20/32 or better UCVA
- 100% of patients achieved 20/25 or better CDVA
- 97% of patients achieved ≤ 1.00 D of residual refractive cylinder
- **The median IOL rotation between 1 day and 3 months was 0 degree.**
No IOL rotated more than 2 degrees within this time period
- 100% of implanted patients were highly satisfied and they would choose the toric Medicontur IOL Bi-Flex T again
- This prospective study was conducted at the Department of Ophthalmology, Paracelsus Medical University, Salzburg, Austria. 30 eyes of 20 consecutive patients were enrolled in the study.

Postoperative Refractive Astigmatism



30 eyes, 3 months postop • ≤ 0.50 D: 80% ≤ 1.00 D: 97%

■ Postop ■ Preop

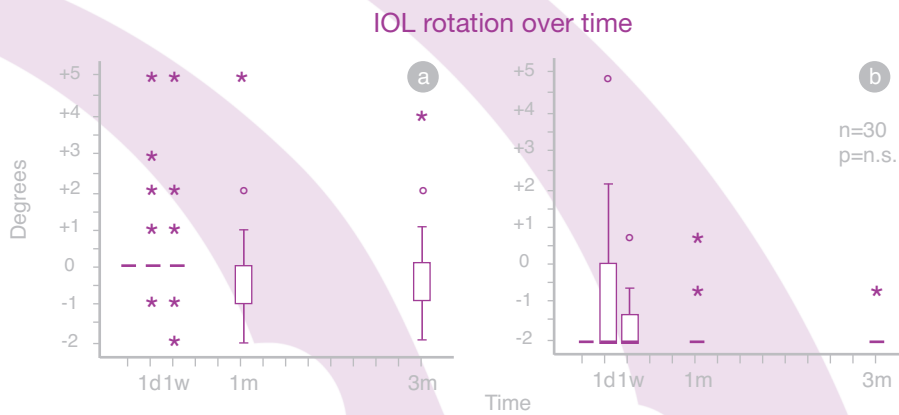
"Most IOL rotation was seen within the first 24 hours after implantation, and we believe this misalignment may have been the result of inadequate clearing of the OVD trapped behind the IOL, causing minor IOL instability." [3]

[3] Bachernegg A, Rückl T, Riha W, Grabner G, Dexl A: Rotational stability and visual outcome after implantation of a new toric intraocular lens for the correction of corneal astigmatism during cataract surgery. J Cataract Refract Surg 2013; 39:1390-1398.



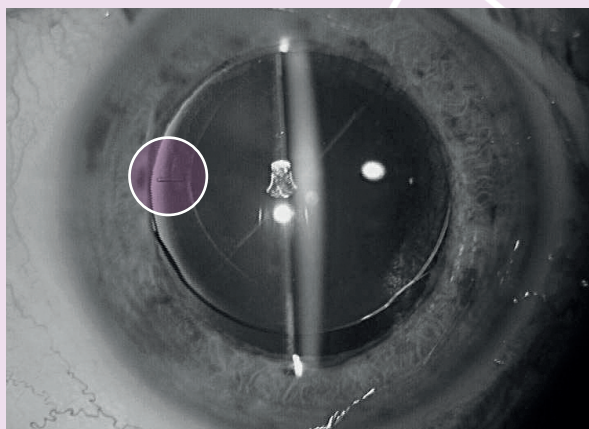
Superior Rotational Stability of Bi-Flex T

The success of a toric IOL can be judged by its ability to reduce refractive astigmatism immediately after surgery as well as its ability to maintain a stable position in the capsular bag over the long term.

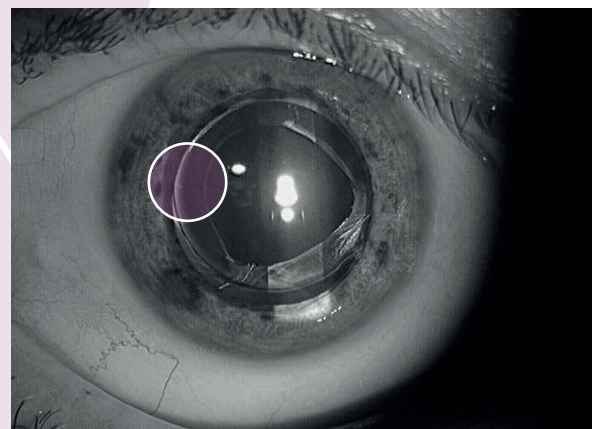


Rotation between different follow-up visits. The median IOL rotation between placement at the time of surgery and 1 day was 0 degree (range 0 to +5 degree). The median IOL rotation between 1 day and 3 months was also 0 degree. No IOL rotated more than 2 degrees.^[3]

Clinical outcome of a patient implanted with Bi-Flex T: the picture shows the rotational stability of Bi-Flex T within the follow-up period (flat axis indicated with marks on the posterior side of the optic); rotation = 0 degree



1 day after Bi-Flex T implantation



3 months after Bi-Flex T implantation. Marks on the posterior side of Bi-Flex T indicate outstanding rotational stability of the lens – during period 1 day-3 months axis change = 0°



BI FLEX T

ROTATIONAL STABILITY
MAKES THE DIFFERENCE

Medicontur IOL Optimizer Fast, Precise and Predictable results

Easy Input

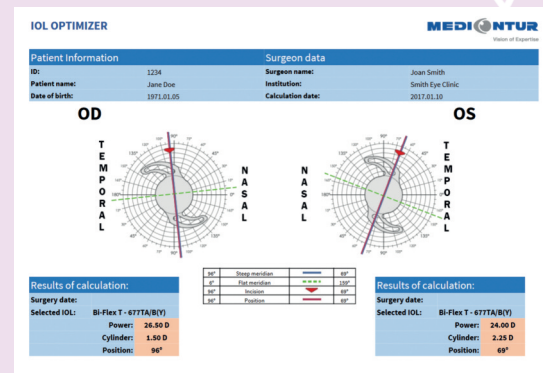
- Patient data
- Choice of keratometer index for all different values used worldwide
- Expected surgically induced astigmatism
- Keratometry in millimeters for higher precision, independent from Javal/Zeiss indices
- Incision location according to the surgeon's preference (Medicontur highly recommends to set the incision on the steep or flat axis for most precise and predictable outcomes.)

Precise Output

- Recommendation of an IOL model with SEQ and cylindrical power
- Axis placement
- Anticipated residual astigmatism
- Patient and surgeon data documentation
- Schematic drawing indicating the position of the toric IOL and incision site
- Print and e-mail option
- Surgery Aid in landscape format, both eyes on one page

toriccalculator.net

The screenshot shows the Medicontur IOL Optimizer software interface. It includes sections for General Data (Patient name, Surgeon name, ID No., Date of birth, Date of examination, Institution, Measurement, K index (p)), Right Eye (OD) and Left Eye (OS) Biometry (Axial length, ACD, Steep/Flat meridians), Selected IOL (IOL Type, Surgery date, Target refraction), Formula (HAGG, SRK, Hoffer Q, Holladay 1), IOL Constants (A, pACD, SF), Pre-OP Corneal Astigmatism (Corneal plane, Induced astigmatism), Incision (Induced astigmatism, Steep/Flat/Custom meridians), and Results of Calculation (Refraction, Selected power).





Bi-Flex Platform · Design Makes the Difference

A unique & patented design for ultimate centration & long-term stability

Only a specific design offering a large contact angle and adequate haptics resistance can provide long-term centration and stability.

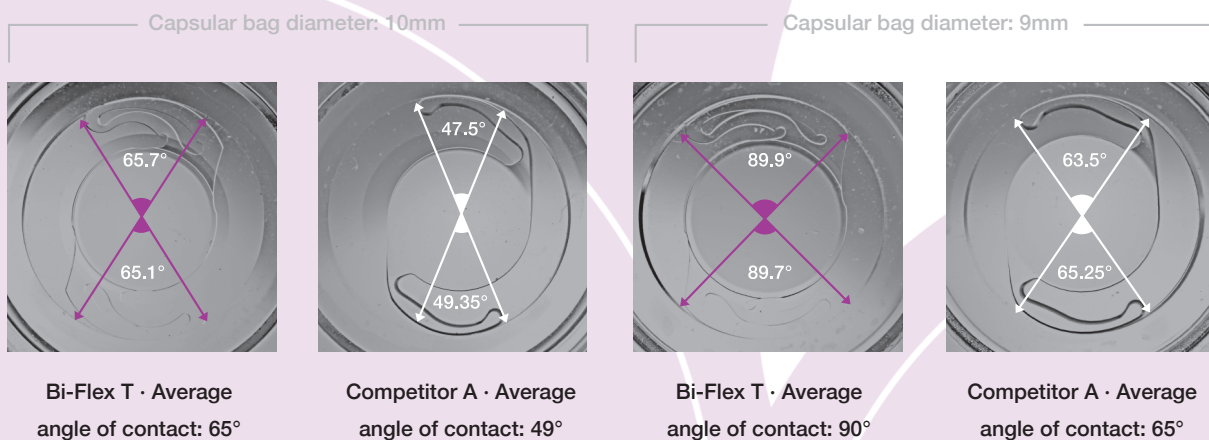
Bi-Flex T benefits from all assets of the Bi-Flex platform design characteristics

- for reproducible centration of the IOL
- for axial, radial and rotational stability.

These unique characteristics are

- the largest contact angle between haptics and capsular bag equator among all IOLs
 $2 \times 90^\circ = \text{Total } 180^\circ \text{ contact angle}$
- the Dolphin zone & the specific double haptics design
 - for immediate and symmetric unfolding
 - for optimized compressibility & resistance against capsular bag compression force.

Experimental simulation of different capsular bag diameters



Bi-Flex T angle of contact with the capsular bag equator is by far larger.



Real 360° Square Edge

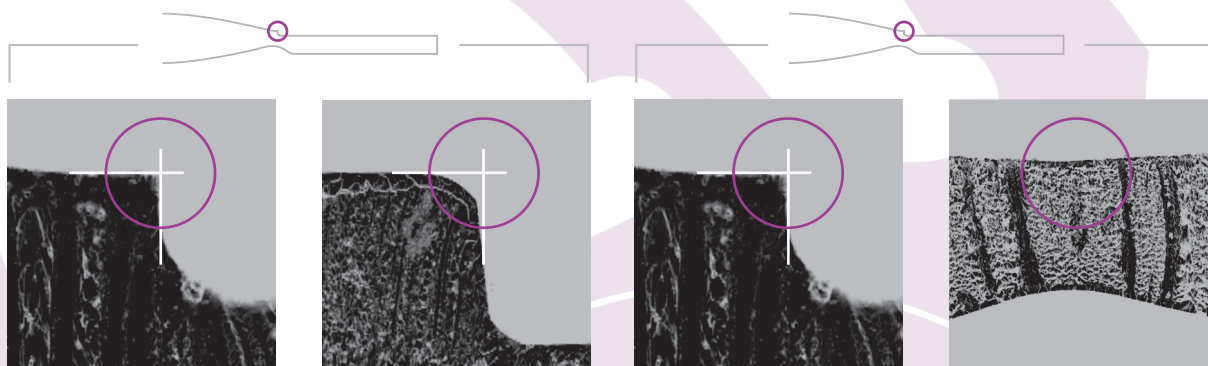
Only a real square edge can stop cell migration.

Studies [4] [5] have highlighted the essential role of the optic's profile design – especially the existence of a square edge all around the optic – to control cell migration.

Patented design characterizes all Bi-Flex IOLs with a sharp square edge all over 360° including the optic-haptic junction zone.

A highly protective “edge effect” against crystalline lens epithelial cell migration.

Comparative scanned images of IOLs marketed as having a “sharp edge” at the optic-haptic junction



Medicontur Bi-Flex:
Real square edge

Competitor A:
No real square edge

Medicontur Bi-Flex:
Real square edge over 360°

Competitor B:
No square edge over 360°

Medicontur Bi-Flex T is the only lens which has a real square edge over 360° even at the optic-haptic junction.

[4] Werner L, Mamalis N, Pandey SK, et al. Posterior capsule opacification in rabbit eyes implanted with hydrophilic acrylic intraocular lens with enhanced square edge. · J Cataract Refract Surg 2004; 30:2403-2409 · [5] Tetz M., Wildeck A. Evaluating and defining the sharpness of intraocular lenses. Part 1: Influence of optic design on the growth of the lens epithelial cells in vitro. · J Cataract Refract Surg 2005; 31:2172-2179



Low PCO Rate

Prospective comparative study with hydrophobic IOLs conducted between 2009–2012

70 eyes, 35 patients · G. Scharioth, MD, PhD, Recklinghausen, Germany

	Alcon AcrySof	Medicentur hydrophobic
PCO inside optic		
• 12 months	8	0
• 24 months	16	16
YAG capsulotomy		
• 12 months	1	0
• 24 months	5 (14%)	3 (8%)

By courtesy of G. Scharioth, MD (ESCRS 2012)

Cumulative capsulotomy rate of Medicentur hydrophilic IOLs over a 5-year period

176 eyes, 156 patients with age related cataract surgery · P. Vámosi, MD, Budapest, Hungary (2004)



By courtesy of P. Vámosi, MD



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Vision of expertise

An independent European company, ever growing and evolving for almost 30 years.

Consistent high quality with more than 4 million intraocular implants manufactured and implanted.

The most diverse portfolio of Intraocular Lenses, both hydrophilic and hydrophobic, all premium categories, state of the art preloaded systems.

A team of more than 250 dedicated professionals constantly pushing the limits of quality.

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Distribution in more than 60 countries with a growing share worldwide.

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