

B!FLEX

M

PROGRESSIVE VISION WITHIN
FULL ACCOMMODATIVE RANGE

PAD

PROGRESSIVE
APODIZED
DIFFRACTIVE

MEDI  NTUR

Vision of Expertise



Progressive vision within full accomodative range

01

PAD · Progressive-
Apodized-Diffractive

02

Aspheric biconvex
optic with neutral
approach

03

Suitable for
sub 2 mm MICS

04

**Optimized
distribution of light**
for near, intermediate
and far vision

05

Long term axial, radial
and rotational stability

06

Polish free technology
for perfect 360° sharp edge –
improved PCO prevention

07

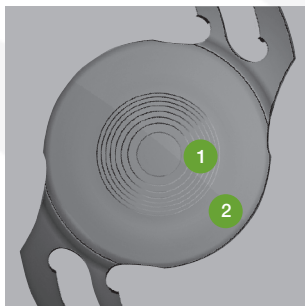
Very low chromatic
aberration (Abbe 58)

08

Quick neural adaption regardless
of patients lifestyle or age



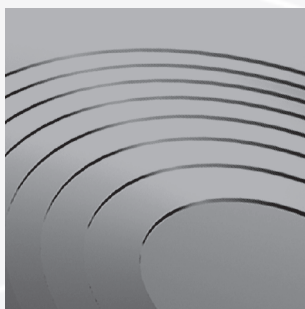
PAD · Progressive Apodized Diffractive



- 1 Central 3.0mm apodized diffractive structure
- 2 Outer refractive zone

Diffractive optical principles

- Diffractive–refractive apodized design to provide improved control of energy distribution whatever the pupil size
- 7 diffractive discontinuities or steps, that have been incorporated in the anterior surface of the acrylic optic to provide the diffractive added power
- Apodized diffractive optic design to minimize visual disturbances
- Highest achievable precision and sharpest edge through polish free lathe milling technology
- Aspheric biconvex optic with neutral approach – to maintain depth of field



The apodization of the Bi-Flex M is defined by an optimized progressive reduction in diffractive step heights from centre to periphery

Progressive Apodized Diffractive – PAD technology

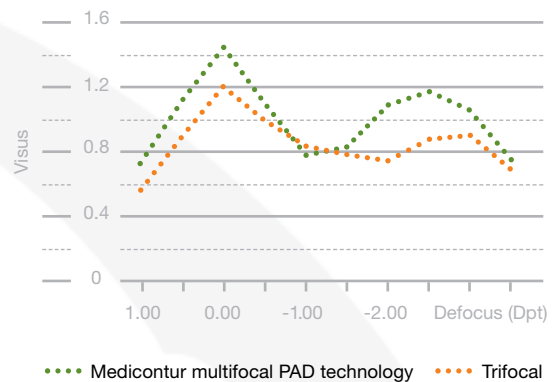
- Improves image quality by optimizing asymmetric light energy delivered to the retina.
- Distributes the appropriate amounts of light to near, intermediate and distant focal points adaptive to any lighting situation.
- Resulting in progressive vision closest to natural accommodative amplitude.



Comparison of a trifocal IOL and the Bi-Flex M progressive IOL

Study conducted in Germany with IOL using Medicontur multifocal (PAD) technology and a trifocal IOL (convolute apodisation technology)

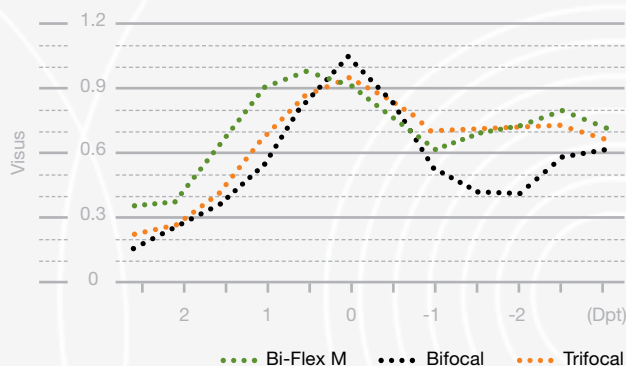
IOL	Bi-Flex M	Trifocal
Eyes	26	44
Age	73 +/- 6 years	70 +/- 7 years
Surgeons	3	3
Post-op	> 2 weeks	2 month



Augenklinik Bellevue, Prof. Dr. D. Uthoff / Dr. D. Holland, Lindenallee 21-23, 24105 Kiel
Praxisklinik I, Bocholt Dr. med. M. Dörner, Königsstr. 32, 46397 Bocholt

Prospective study on multifocal IOLs; bifocal, trifocal and Bi-Flex M (PAD technology)

Each patient has been always implanted with two different IOLs (Mix and Match method), from different manufacturers. The study reveals that Bi-Flex M shows outstanding results on near and far vision with competitive outcome in intermediate vision. The defocus curve of Bi-Flex M shows a progressive vision thanks to the technology based on optimized progressive apodized diffractive (PAD) technology. All patients were highly satisfied regarding the comfort and visual outcome delivered by the Bi-Flex M.



Binocular defocus curve after 1 month follow up

The defocus curve shows a clear advantage of Bi-Flex M for distance and near vision. Intermediate vision shows competitive results (log 0.7) with the trifocal lens.

By courtesy of Michael Assouline, MD (SFO 2013)



Medicontur IOLs known since many years for their low PCO rate

Prospective comparative study with hydrophobic IOLs conducted between 2009-2012

70 eyes, 35 patients · Gábor Scharioth, MD, PhD, Recklinghausen, Germany

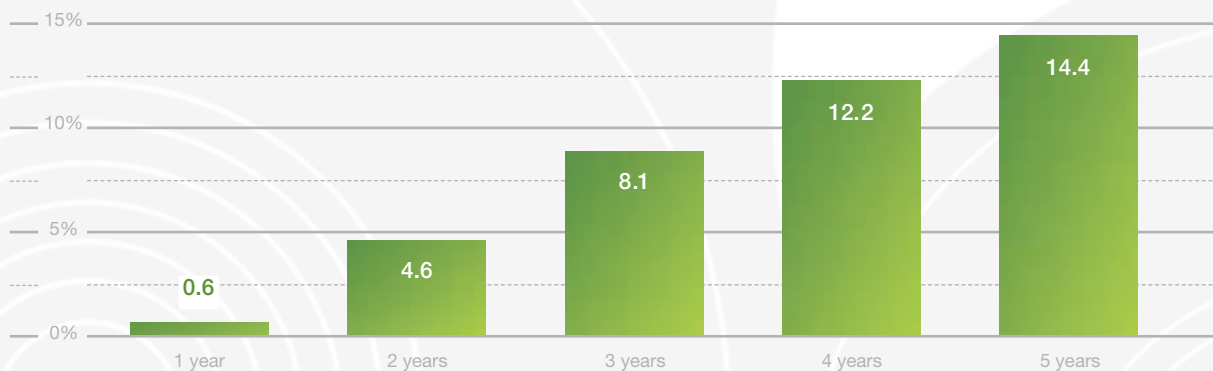
	Alcon AcrySof	Medicontur hydrophobic
PCO inside optic		
• 12 months	8	0
• 24 months	16	16
YAG capsulotomy		
• 12 months	1	0
• 24 months	5 (14%)	3 (8%)

By courtesy of Gábor Scharioth, MD (ESCRS 2012)

Cummulative capsulotomy rate of Medicontur hydrophilic IOLs over a 5 year period

176 eyes, 156 patients with age related cataract surgery ·

Péter Vámosi, MD, Budapest, Hungary (2004)

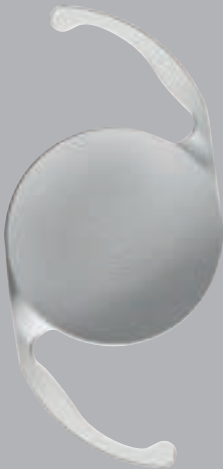


By courtesy of Péter Vámosi, MD



PAD technology Optimized progressive apodization

Here is the new chapter in the evolution of corrected human vision history:
Intraocular Progressive Vision



Competitor A · "Bifocal" IOL

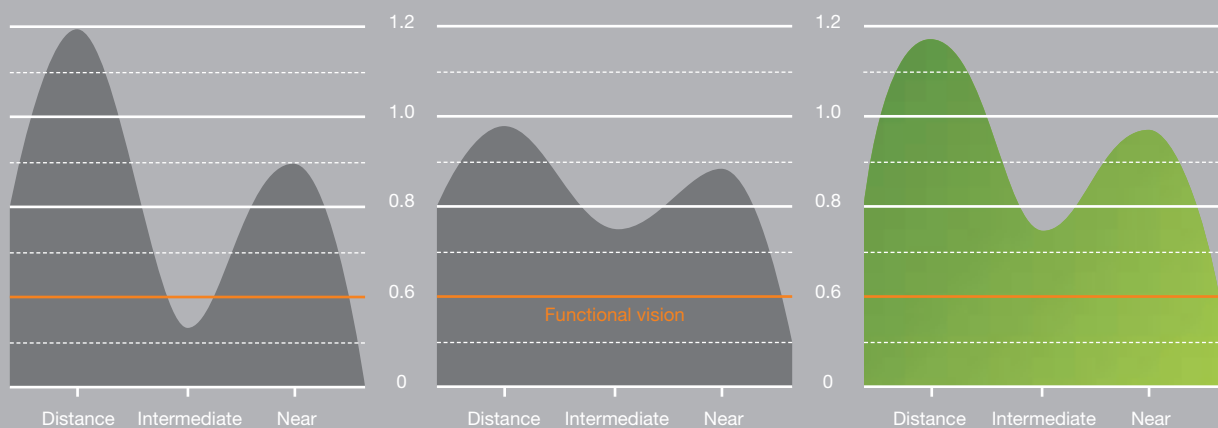


Competitor B · "Trifocal" IOL



Bi-Flex M · "Progressive" IOL

Evolution of functional vision
Distance - Intermediate - Near





Why accept additional loss of minimum 14% of light energy, additional blurs and glares?

No matter what marketing and sales people will tell you about "Trifocal":

A second distinct diffractive array for the intermediate vision has to cause additional loss of light energy, loss of contrast, dispersion, glares, blurs. **This is a physical fact.**

Medicontur PAD technology does not need a second diffractive array to insure intermediate vision.

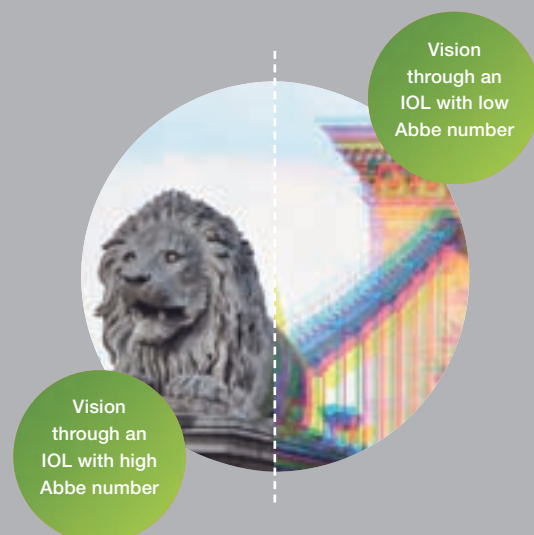
Why accept materials with a low ABBE number?

Bi-Flex M material & the Abbe number

The Abbe number is a measure of a transparent material's dispersion in relation to the refractive index.

The higher the Abbe number
the lower the chromatic aberration.

A major difficulty with diffractive optics is chromatic aberration, which is generally worse than with refractive optics. Chromatic aberration reduces image quality in normal white light because each of its color wavelengths refracts differently.



Excellent optical performance

Bi-Flex M benefits from a very high Abbe number value: 58.



Bi-Flex Platform · Design makes the difference

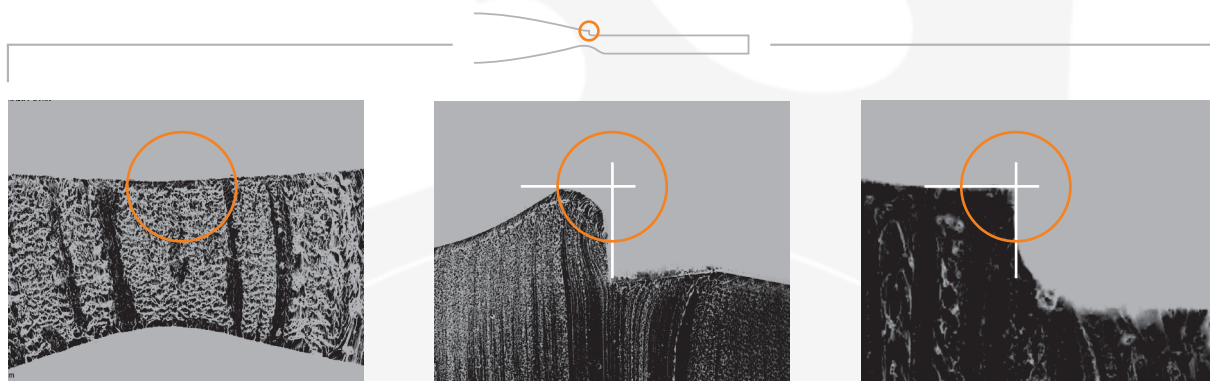
Why accept IOL constructions without a 360° sharpe edge?

Studies^{[1][2]} have highlighted the essential role of the optics profile design – especially the existence of a square edge all around the optic: only a real square edge can stop cells migration.

PCO is limiting factor for the correct function of multifocal IOLs.

PCO rate finally makes a difference in visual outcomes and patient satisfaction.

PCO prevention is more important for patients receiving multifocal IOLs because of their elevated visual demands. Implantation of a multifocal IOL resulted in a greater incidence of posterior capsule opacification than a monofocal lens. The incidence is 3-4 times higher according to literature sources.^[3] "Reasons for this may include increased visual demands of patients receiving presbyopic-correcting IOLs or complex visual phenomena associated with the interaction of multifocal optics and posterior capsule opacification."



Competitor A · "Bifocal" IOL
No square edge at all

Competitor B · "Trifocal" IOL
"Rounded" square edge

Bi-Flex M · "Progressive" IOL
Real square edge over 360°

Specific polish-free process manufacturing and patented design characterize all Bi-Flex IOLs with a sharp square edge all over 360° including the optic-haptic junction zone.

[1] Werner L, Mamalis N, Pandey SK, et al. Posterior capsule opacification in rabbit eyes implanted with hydrophilic acrylic IOLs with enhanced square edge. · J Cataract Refract Surg 2004; 30:2403-2409 · [2] 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 [3] Shah VC, Russo C, Cannon R, Davidson R, Taravella MJ.: Incidence of Nd:YAG capsulotomy after implantation of AcrySof multifocal and monofocal intraocular lenses: a case controlled study. J Refract Surg. 2010 Aug;26(8):565-8. doi: 10.3928/1081597X-20100303-01.



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

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

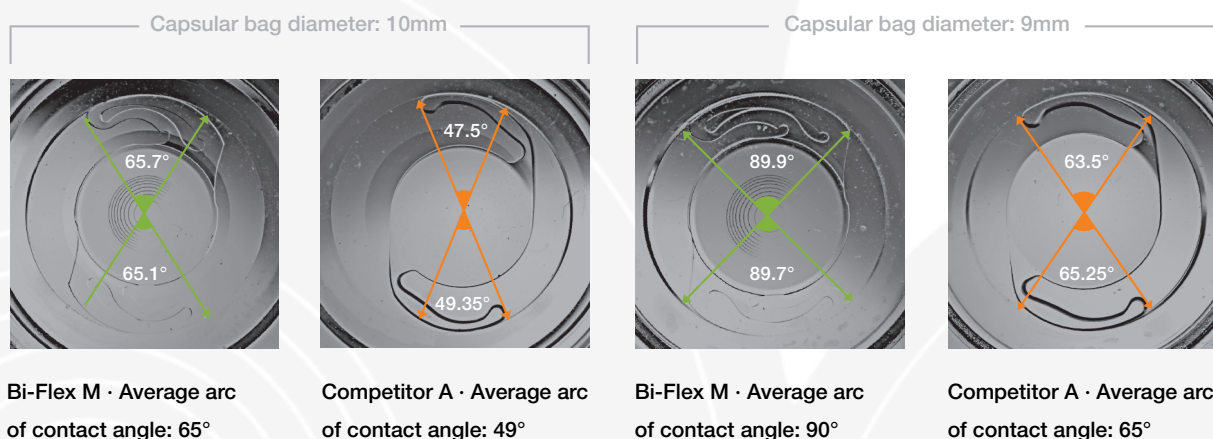
These unique characteristics are

- the largest contact angle between haptics and capsular bag equator among all IOLs

2 x 90° = Total 180° contact angle

- the Dolphin zone & the double haptics specific design
 - for immediate and symmetric unfolding
 - for optimized compressibility & resistance against capsular bag compression force.

Experimental simulator of different capsular bag diameters

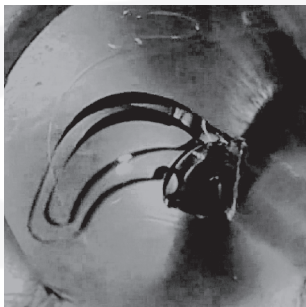


In both cases, Bi-Flex M arc of contact with capsular bag equator is larger.



Bi-Flex Platform · Material makes the difference

Only a material with specific rheological properties is suitable for optimal micro-incision surgery (MICS).



Bi-Flex M is manufactured from a long-time proven 25% water content copolymer material

- optimally combining hydrophilic and hydrophobic monomers
- offering rheological properties required for MICS:
ELASTICITY · SOFTNESS · SHAPE MEMORY
- creating optimal conditions for MICS.

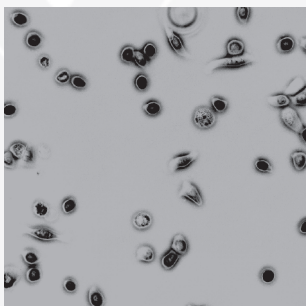
- Smooth continuous gliding of the IOL inside the cartridge, low injection force.
- Immediate, symmetric and atraumatic unfolding inside the capsular bag.

Permanent optic quality & improved safety

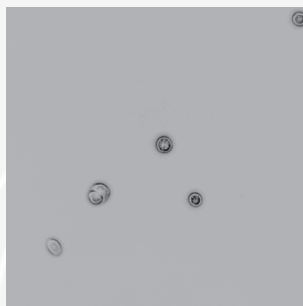
Bi-Flex M material offers permanent optic quality as a result of

- unequaled transparency
- very low chromatic aberration thanks to high Abbe number.

In vitro experiment of cells adhesion



26% Hydrogel · MMA



Bi-Flex M · 25% copolymer

Bi-Flex M material offers improved safety with

- optimized biocompatibility
- low ionicity surface for minimized rates of cells adhesion.



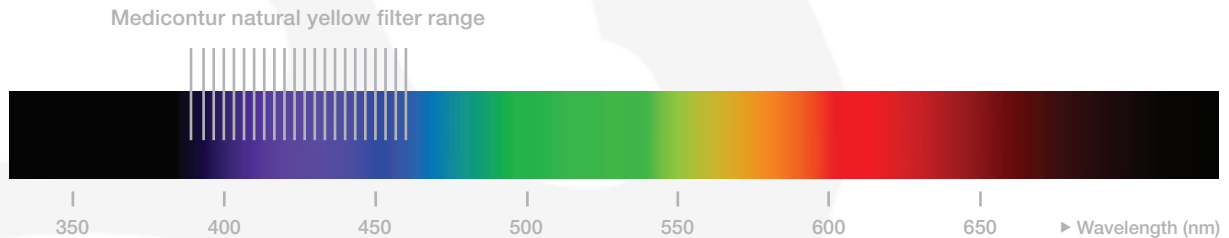
Medicontur Natural Yellow Filter

Only a natural yellow filter can offer the required protection while preserving quality vision.

Violet and blue light corresponds to visible light wavelengths between 390 and 495 nanometers (nm). It is known that short wavelengths are potentially harmful to the macula. On the other hand we know that blue light is important for the scotopic vision (night driving).

Medicontur natural yellow filter cuts from 390 nm to 470 nm

- covering the most critical “high energy” portion of visible light
- preserving the low energy portion of blue light to maintain scotopic vision capacity, colour and contrast sensitivity.



Bi-Flex natural yellow filter



No yellow filter at all

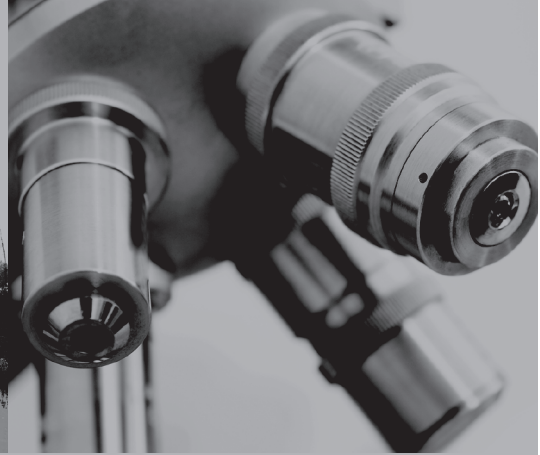


Bi-Flex 1.8 natural yellow filter



Non-natural yellow filter

Bi-Flex natural yellow filter:
Filtering as much as necessary. Preserving as much as possible.



EA-BMCMHLEN 01 2013/09

Vision of expertise

An independent European company in existence for nearly 25 years. High quality with more than 3 million intraocular implants produced and sold.

With its international offices located near Geneva (Switzerland) and at its facilities located near Budapest (Hungary), Medicontur brings together men and women whose skills in the field of copolymer processing serve its demanding policy of continuous innovation.

During the past four years, Medicontur has developed new functional adaptations to the Bi-Flex platform, with several hydrophilic, hydrophobic and premium references.

The products of Medicontur are distributed in more than 60 countries with a growing share worldwide.