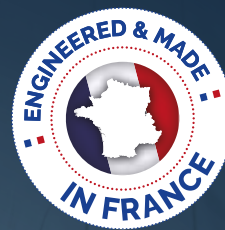




CUTTING EDGE
sense of innovation



Synthesis[®] (+) Toric
EDOF Toric Implant

Toric

EDOF

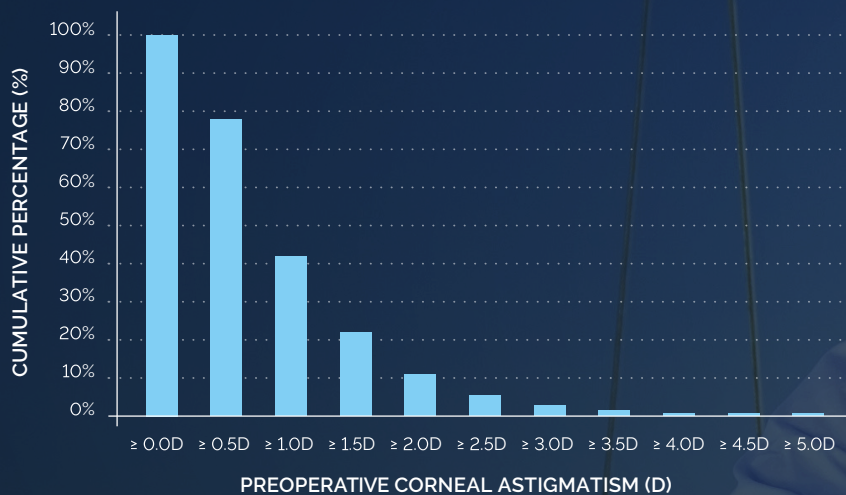


TECHNICAL BROCHURE

ASTIMAGTISM PATIENT CARE

- **Astigmatism needs to be treated**
to reduce the dependency on glasses for distance vision. ⁽¹⁾
- **78 % of the cataract patient population present with corneal astigmatism $\geq 0,5$ D.** ⁽²⁾

Distribution of preoperative astigmatism
in patients undergoing cataract surgery (N=110,468) ⁽²⁾



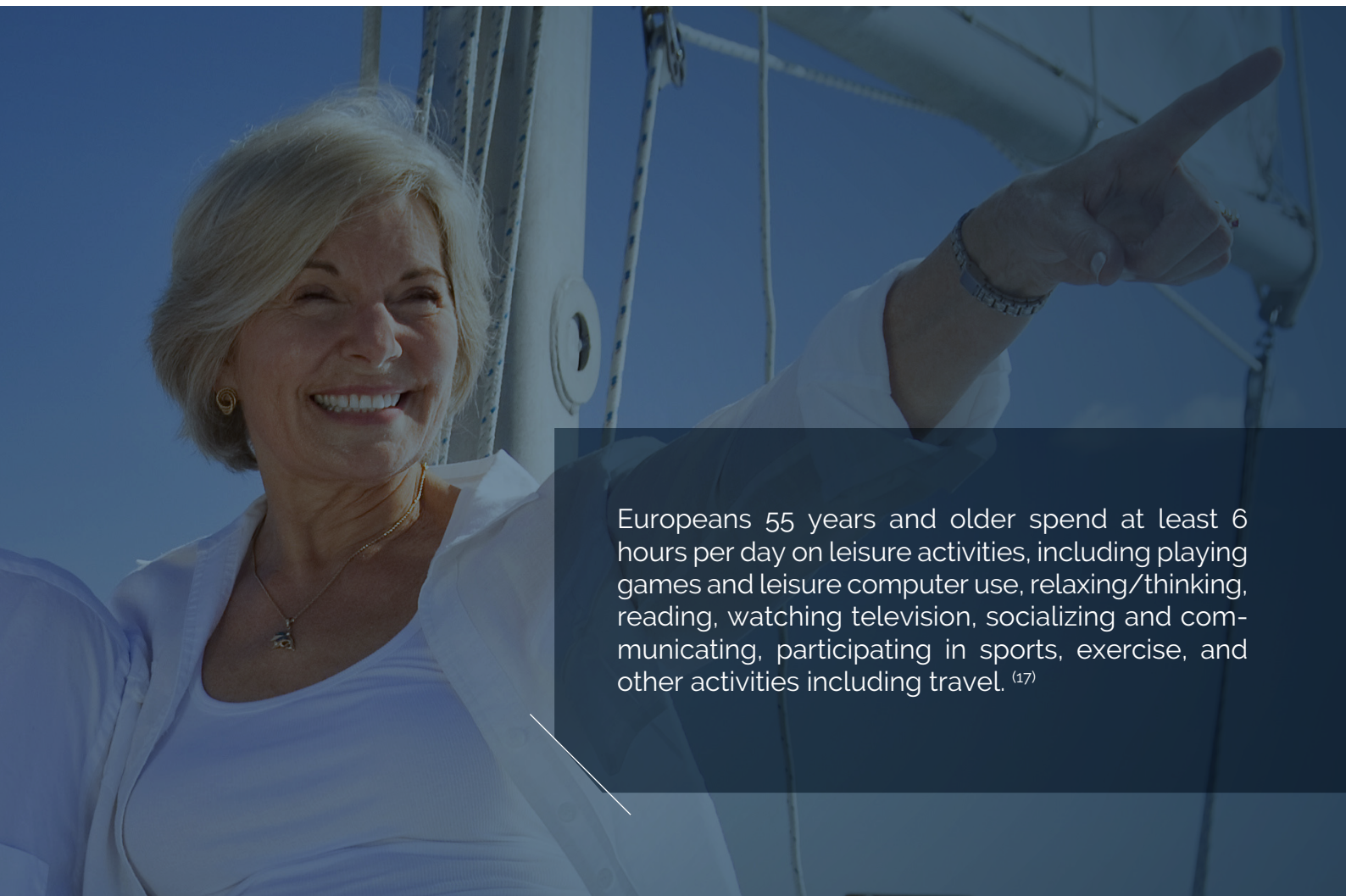
TORIC IOLS CAN OFFER AN EFFECTIVE SOLUTION ⁽³⁾

THE ADOPTION AND USAGE OF TORIC IOLS REMAIN RELATIVELY LOW DEPENDING
ON THE COUNTRY, RANGING FROM (4 to 9%) ⁽⁴⁾

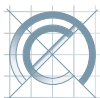
ENHANCING THE SOCIAL VISION OF YOUR PATIENT

Daily activities

- Intermediate vision
- Far vision
- Improved near vision ⁽¹⁸⁾



Europeans 55 years and older spend at least 6 hours per day on leisure activities, including playing games and leisure computer use, relaxing/thinking, reading, watching television, socializing and communicating, participating in sports, exercise, and other activities including travel. ⁽¹⁷⁾



CUTTING EDGE

MANAGING ASTIGMATISM TORIC

Takes into consideration
all sources of astigmatism ⁽⁵⁾



Latest generation
Calculator



MICS
Minimizes induced astigmatism ⁽¹⁵⁾



Large combination
of Sphere / Cylinder



Can treat corneal astigmatism
from 0.5D

Clinically proven
rotational stability ⁽⁶⁾



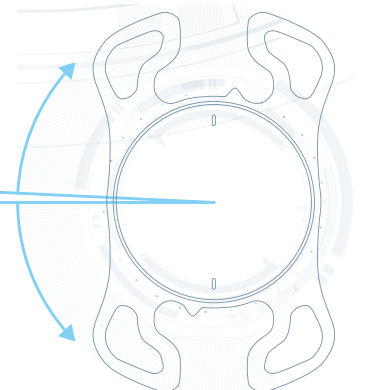
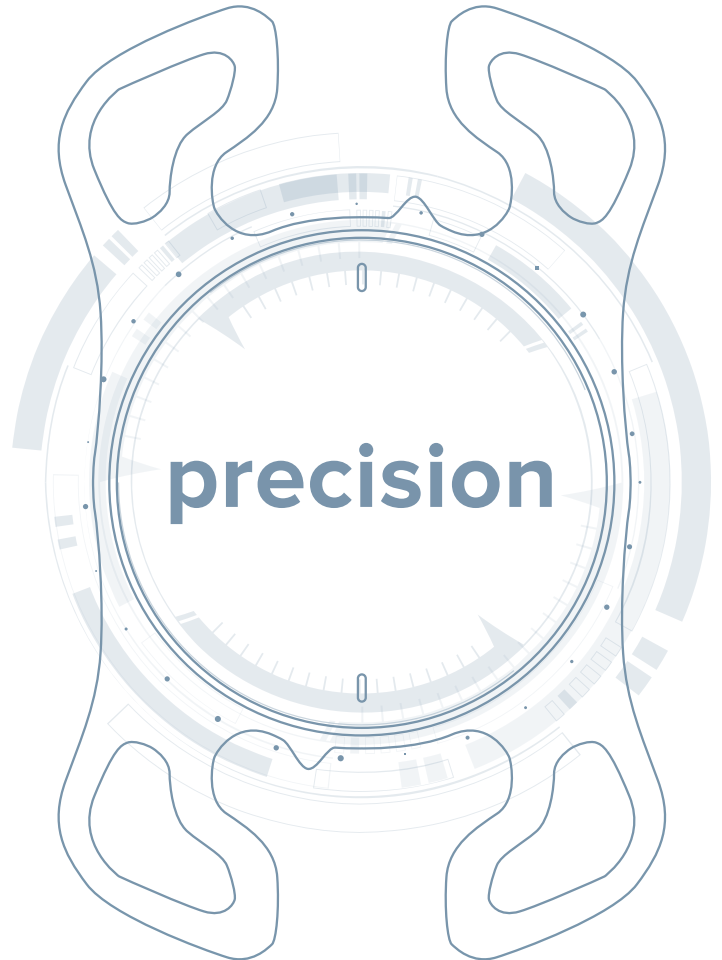
93% of patients with less than 5° rotation from
surgery day (D0) over a 4 month follow-up period.

Surgical maneuverability

Easy clockwise and anticlockwise positioning



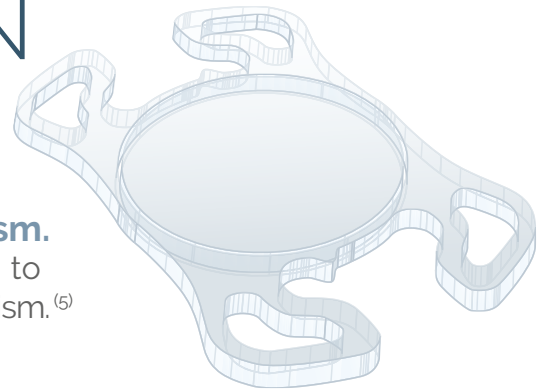
2,93°+ to -1,99°
Average rotation
between D0 and 4 months



NEXT GENERATION ONLINE CALCULATOR

- **Takes into account posterior corneal astigmatism.**

Ignoring posterior corneal astigmatism may lead to the incorrect estimation of the total corneal astigmatism.⁽⁵⁾



CUTTING EDGE CUTTING EDGE Toric Calculator English Sign in

Information

Surgeon's name* DUPONT Patient's ID* XZZ123 Date of birth dd/MM/yyyy Gender ☒ M ☐ F Date of surgery dd/MM/yyyy

IOL Model* Synthesis Plus Toric Eye* ☒ OD ☐ OS Include posterior astigmatism* ☒ Yes ☐ No

Flat K* 40.0 D Axis* 180 K Index* 1.3375

Steep K* 42.0 D Axis* 90

BIA* 0.1 Incision* 90

AL* 23.0 mm ACD 0.0 mm

A-constant* 118.66 Refractive target* 0.0 D

Ensure that the data entered are correct. Cutting-Edge does not send or save information for patient identification. By clicking on the "Accept and calculate" button, you agree to the **TERMS AND CONDITION OF USE**.

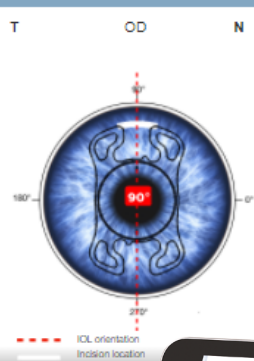
Expected Results

Cylinder 1.0 D **Cylinder 1.5 D** Cylinder 2.25 D

IOL power (SE) (D)	SRK/T	IOL orientation	Residual astigmatism
+24.25	0,55	90°	0,25D @ 90°
+24.75	0,18	90°	0,25D @ 90°
+25.25	-0,19	90°	0,25D @ 90°

Recommended IOL:
Cylinder: 1.5 (Ideal Cyl: 1,84)
IOL power (SE): 24.75 (IOL emme.: 25,00)
Residual astigmatism: 0,25D @ 90°

Selected IOL: PPLU 8T150+24.00
Cylinder: 1,5
IOL power (SE): 24.75
IOL spherical power: 24,0
Residual astigmatism: 0,25D @ 90°



Linear correlation coefficient of Cutting Edge Toric calculator compared to Kane's formula: (19, 20)

$$\text{SE: } r^2 = 0.99$$

$$\text{CYL: } r^2 = 0.98$$

$$\text{axis: } r^2 = 0.99$$

toriccalc.cutting-edge.fr



CUTTING EDGE



EDOF A NEW FRONTIER

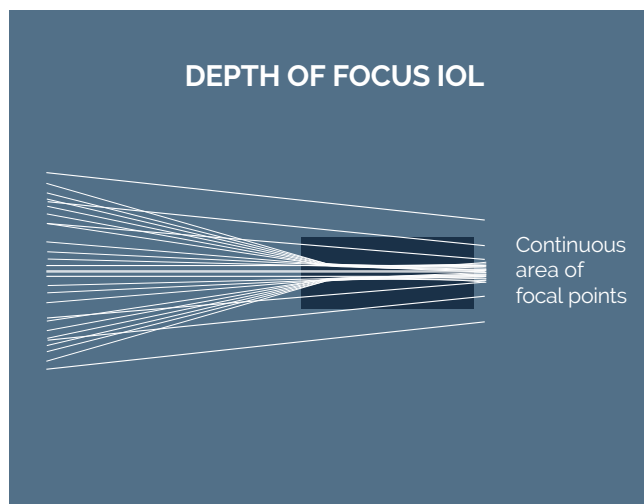
Lens with extended depth of field by pure refractive technology with quality far vision and improved intermediate vision.⁽¹⁸⁾

ADVANTAGES⁽⁷⁾

- Greater contrast sensitivity
- Lower incidence of dysphotopsia

DISADVANTAGES⁽⁷⁾

- Less strong near vision



RANGE OF VISION

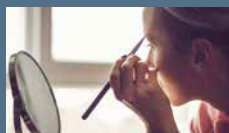


Near Vision



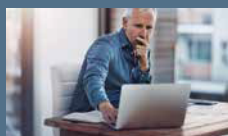
Distance Vision

ZONE 1
30-50 cm



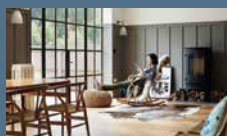
Near vision

ZONE 2
50-90 cm



Near intermediate vision

ZONE 3
90cm - 2m



Intermediate vision indoor activities

ZONE 4
Beyond 2m



Outdoor vision

ZONE 5
Dim condition vision



Night vision

(21, 22, 23, 24)

BIFOCAL IOL



TRIFOCAL IOL



Hybrid EDOF multifocal diffractive IOL



Refractive EDOF IOL



continuous social vision

OPTICAL QUALITY

AN INNOVATIVE OPTICAL DESIGN

Continuous area with an EDOF central zone, a transition zone and monofocal optical periphery.

4th and 6th spherical aberrations of opposite signs permits depth of field increase^(8, 9).

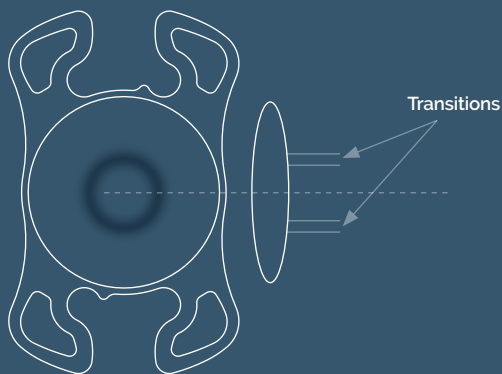


Patented transition zone

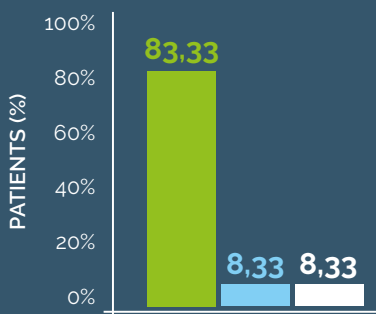
SYNTHESIS® (+) RAY TRACING⁽¹⁰⁾

EDOF Zone

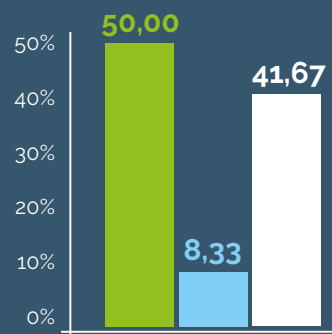
(10)



DISTANCE VISION⁽¹²⁾
spectacle independence



NEAR VISION*⁽¹²⁾
spectacle independence



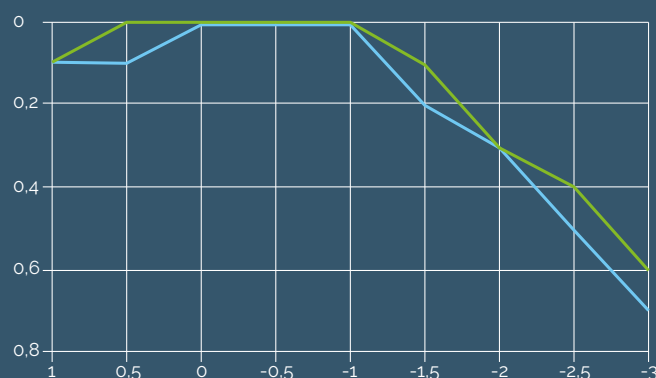
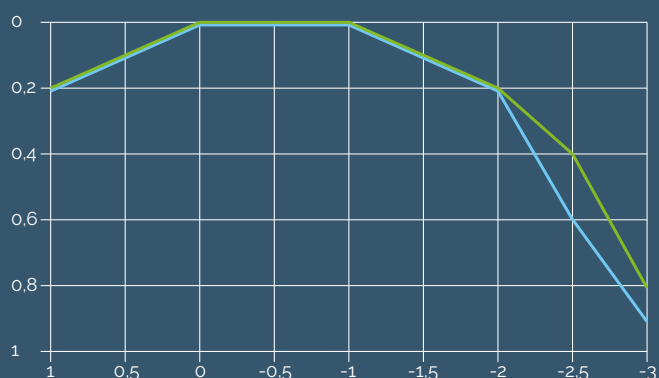
GLASSES : ■ Do not need ■ Sometimes need ■ Always need

*Prospective data on 12 patients (24 eyes) at 3 months after surgery, without correction with a residual mean spherical equivalent of $-0.29 \pm 0.32D$ with Synthesis Plus

DEFOCUS CURVE⁽¹¹⁾

Examples of patients operated bilaterally with Synthesis Plus

— Monocular — Binocular



SYNTHESIS PLUS TORIC

Innovative lens design empowering social vision
EDOF & TORIC !

Spectacle independence ⁽¹²⁾

50% of people with total independence from glasses

Patented transition zone
minimising photic phenomena ⁽⁷⁾

Surgical maneuverability

clockwise and anticlockwise

Contrast preservation ⁽⁷⁾

Cylinder range

to suit most corneal astigmatism

Clinically proven
rotational stability

MICS

Minimises surgically induced astigmatism ⁽¹⁵⁾

Pre-loaded injection system

Robust to tilt and decentration ⁽¹⁴⁾
for **potential tolerance to high kappa angles**

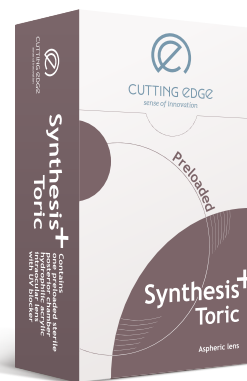
Clear material for the preservation of the **melanopsin regulation** ⁽¹³⁾

OPTIMISATION

TECHNICAL SHEET



Synthesis[®]+ Toric
EDOF Toric Implant



INTRAOCULAR EDOF TORIC LENS
CLEAR PRELOADED
Incision MiCs 1,6 mm

REFERENCES

Clear implant

PRELOADED

PPLUST

DESIGNATIONS	SPECIFICATIONS
Optic diameter	6 mm across the power range
Total diameter	11 mm across the power range
Design	4 point-fixation, C-Edge+ ≤ 5 microns
Optical	Aspheric and toric
Angulation	0°, posterior-shift feature
Dioptric power (Sphere)	1.0D increment between +5.00D to +10.00D 0.5D increment between +10.50D to +30.00D 1.0D increment between +31.00D to +32.00D
Dioptric power (Cylinder)	0,75D/1,0D/1,5D/2,25D/3,0D/3,75D/4,5D/5,25D/6,0D
Biometry available on the IOLcon website https://iolcon.org	Optical biometry : SRK/T : A = 118,66 Haigis : a0 = 1,107 (with a1 = 0,4 et a2 = 0,1) Hoffer-Q : pACD = 5,336 Holladay 1 : SF = 1,59
Sterilisation	Steam
Packaging	Single pack
Class	IIIb
CLADIMED	S50BIO3
Incision size	From 1,6 mm
Calculator	toriccalc.cutting-edge.fr

This product is guaranteed latex free and phthalates free.

	Brand	Medicel, Accuject TM PRO 1.6	
	References	LP604550P (box of 10)	
	Wound-assisted recommended incision	1.6 mm	
	In-the wound recommended incision	1.8 mm	
	In-the-bag recommended incision	2.0 mm	



Synthesis[®]

Hydrophilic monofocal



Synthesis[®] ⊕

EDOF



Synthesis[®]  Toric
EDOF Toric Implant



Synthesis[®]  Toric
Toric Implant

BEYOND EXPECTATIONS



CUTTING EDGE
sense of innovation

CUTTING EDGE SAS

770 rue Alfred Nobel
Immeuble le Nobel
34000 Montpellier - France

Tel. : +33 (0)5 62 24 65 03
Fax : +33 (0)5 62 24 65 05

www.cutting-edge.eu

KESTREL OPHTHALMICS LTD

Unit 9 Cabot Business Village
Holyrood Close, Poole
Dorset, BH17 7BA
United Kingdom

Tel. : +44 (0) 1202 69 69 63

info@cutting-edge.eu

CUTTING EDGE SURGICAL

70 izq Local Avinguda
Manuel Girona
08860 Casteldefels
España

Tel. : +34 658 208 691



Bibliography:

- (1) Wilkins M, Allan B, Rubin G. Spectacle use after routine cataract surgery. Br J Ophthalmol 2009;93:1307-1312
- (2) Day AC, Dhariwal M, Keith MS, et al. Distribution of preoperative and postoperative astigmatism in a large population of patients undergoing cataract surgery in the UK. Brithish Journal of Ophthalmology. Published Online First: 06 Septembre 2018. doi: 10.1136/bjophthalmol-2018-312025
- (3) Kessel L, Andresen J, Tendal B et al. Toric Intraocular Lenses in the Correction of Astigmatism During Cataract Surgery. ASysmatic Review and Meta-analysis. Ophthalmology. 2016. 123(2):275-86
- (4) Freeman B, Market Scope, 2016 IOL Report: A Global Market Analysis for 2015 to 2021.
- (5) Koch D, Ali S, Weiker M et al. Contribution of posterior corneal astigmatism to total corneal astigmatism. J Cataract Refract Surg 2012; 38:2080-2087
- (6) Evaluation de la stabilité rotatoire de l'implant monofocal SISA® (Cutting Edge) après chirurgie de la cataracte - Etude prospective non contrôlée en ouvert. ID-RCB number: 2017-A00924-49. Data on file.
- (7) Breyer DRH, Kaymak H, Ax T et al. Multifocal Intraocular Lenses and Extended Depth of Focus Intraocular Lenses. Asia Pac J Ophthalmol (Phila). 2017. 6(4):339-349
- (8) Benard Y, Lopez-Gil N, Legras R. Subjective depth of field in presence of 4th-order and 6th-order Zernike spherical aberration using adaptative optics thechnology. J Cataract Refract Surg. 2010. 36(12):2129-38
- (9) Benard Y, Lopez-Gil N, Legras R. Optimizing the subjective deth-of-focus with combinations of fourth- and sixth-order spherical aberration. Vision Res.2011. 51-23-24):2471-7
- (10) Internal report 180810. Lightfield report. Institute of Experimental Ophtalmology - Saarland University | 66421 Homburg/Saar | Germany
- (11) Outcomes provided as courtesy from Dr BOUCHUT -Safir_e-symposium mai 2021. implants monofocaux EDOF.
- (12) Moser C. Visual performance of a new extended depth of focus (EDOF) intraocular lens - early experience. ePoster ESCRS 2019.
- (13) Mendoza-Mendieta ME, Lorenzo-Mejia AA. Associated depression in pseudophakic patients with intraocular lens with and without chromophore. Clin Ophthalmol. 2016 Mar 31;10:577-81
- (14) Chellappa SL, Bromundt V, Frey S, Steinemann With Circadian Rythms, Cognitive Function, and Sleep in Order Adults. JAMA Ophtalmol. 2019 May 23;137(8):878-85
- (15) Optical and Image quality simulation after IOL tilt and decentrations, For Cutting-Edge, 07/07/07 Norberto López-Gil
- (16) Tetikoglu M, Yeter C, Helvacioğlu F et al. Effect of Corneal Incision Enlargement on Surgically Induced Astigmatism in Biaxial Microincision Cataract Surgery. Turk J Ophthalmol 2016, 46; 3: 99-103
- (17) Ribeiro F, Cochener B, Kohnen TM. Definition and clinical relevance of the concept of functional vision in cataract surgery ESCRS Position Statement on Intermediate Vision: ESCRS Functional Vision Working Group. J Cataract Refract Surg2020; 46:S1-S3
- (18) Lesieur G. Preliminary outcome analysis and comparison of two new extended depth of focus (EDOF) lenses. ePoster ESCRS 2020
- (19) Kane JX, Chang DF. Intraocular Lens Power Formulas, Biometry, and Intraoperative Aberrometry: A Review. Ophthalmology. 2020 Aug 13;S0161-6420(20)30789-2.)
- (20) Cutting Edge Calculator Technical File
- (21) Rampat R, Gatinel D. Multifocal and Extended Depth-of-Focus Intraocular Lenses in 2020. Ophthalmology. 2021 Nov;128(11):e164-e185.
- (22) Gatinel D, Houbrechts Y. Comparison of bifocal and trifocal diffractive and refractive intraocular lenses using an optical bench. J Cataract Refract Surg. 2013 Jul;39(7):1093-9.
- (23) Gatinel D. EDOF IOLs. electronic congress SAFIR 2021
- (24) Zapata-Diaz JF, Rodriguez-Izquierdo MA, Ould-Amer N,Lajara-Blesa J, López-Gil N. Total Depth of Focus of Five Premium Multifocal Intraocular Lenses. J Refract Surg. 2020 Sep 1;36(9):578-584.

The Synthesis Plus Toric intraocular lens is an implantable Medical Device manufactured and distributed by CUTTING EDGE SAS. This Class IIb Medical Device is a regulated health product that bears the CE mark n° 0197. Synthesis Plus Toric is a monobloc posterior chamber implant in preloaded copolymer, reserved for the use of ophthalmic surgeons for the replacement of the lens in the surgical correction of aphakia. Read the instructions for the device carefully before use. This medical device is covered by public health insurance bodies for its inclusion in the financing of homogeneous groups of patients and stays relating to intraocular interventions on the lens (cataract).

Class IIb and class IIa medical devices - Read the instructions for use carefully.

