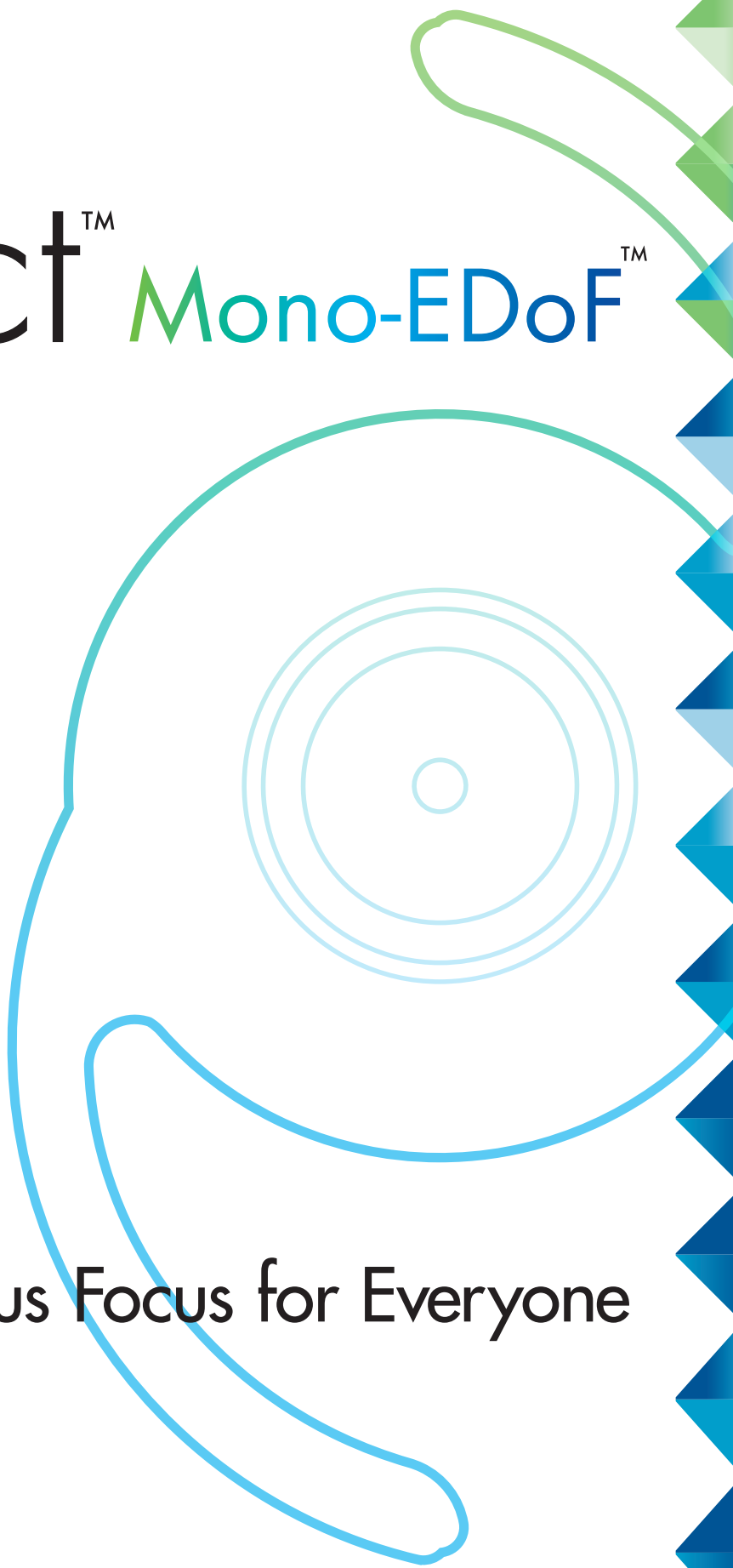


Santen

A Clear Vision For Life™

xact™ Mono-EDoF™

Continuous Focus for Everyone



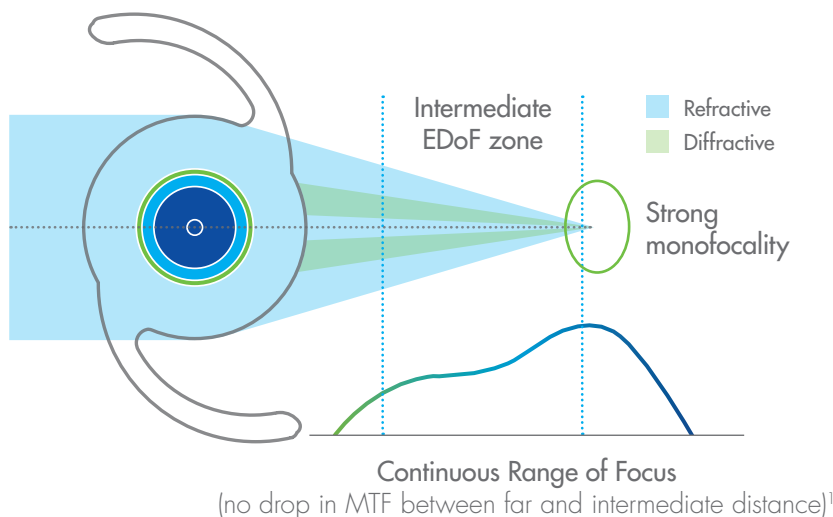
What is **Mono-EDoF**[™]?

- ◆ CE Mark approved as a monofocal IOL
- ◆ Offers continuous focus with high quality vision from distance to intermediate¹⁻⁴
- ◆ Minimal level of halo and glare, equivalent to monofocal IOLs³

Extended depth of focus with **one elongated peak**

Distinctive optical design

Specifically designed to provide excellent image quality for an extended depth of vision

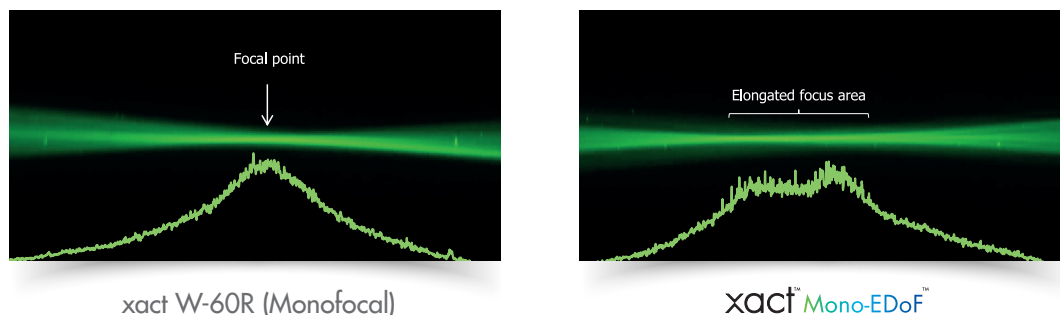


Pupil-size independence

All 4 diffractive rings fall within a **3.2 mm diameter**, allowing for less sensitivity to pupil size and for maximum refractive monofocal optic

Ray-propagation visualisation¹

Light-pathways visualisation and the light intensity profile (solid line)





xact Mono-EDoF[™] IOLs create an extended field of focus (seen in green laser light propagation and light intensity profiles) unlike monofocal IOLs that have one focus that corresponds to the nominal lens power¹

Clinical confidence

The **xact™ Mono-EDoF™** IOL has demonstrated outstanding visual acuity combined with high image contrast, bringing your patients' lives back into focus

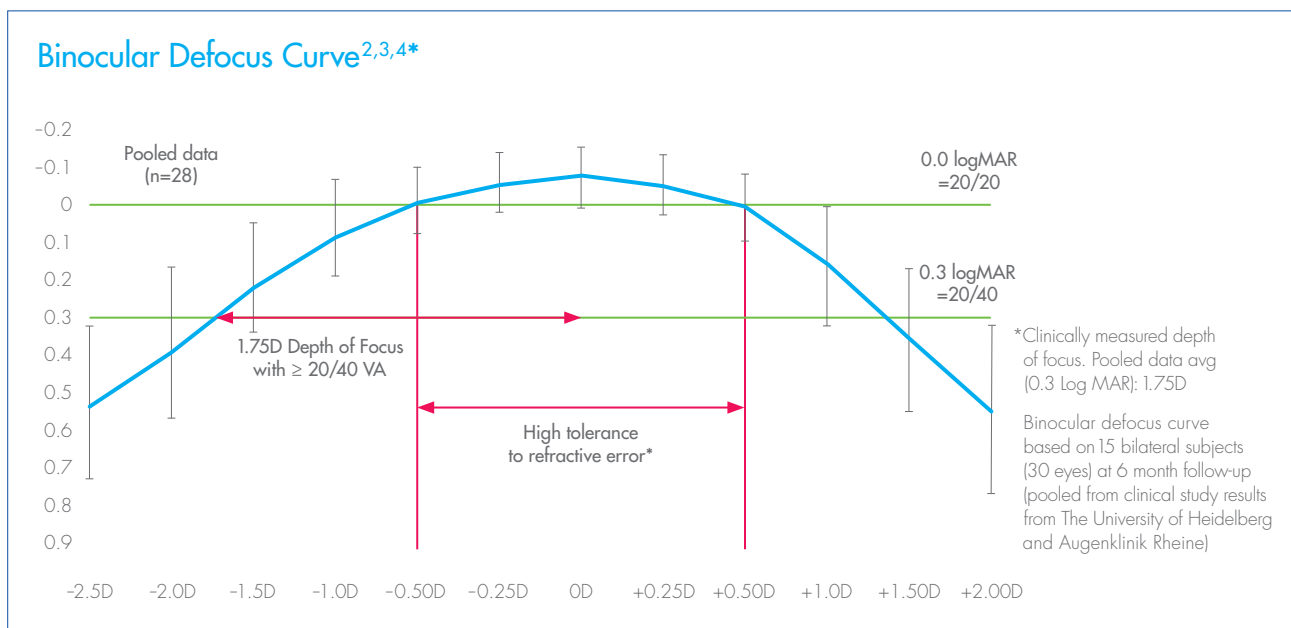
Outstanding visual acuity

Clinical results show outstanding post-operative visual acuity – both for distance and intermediate vision³

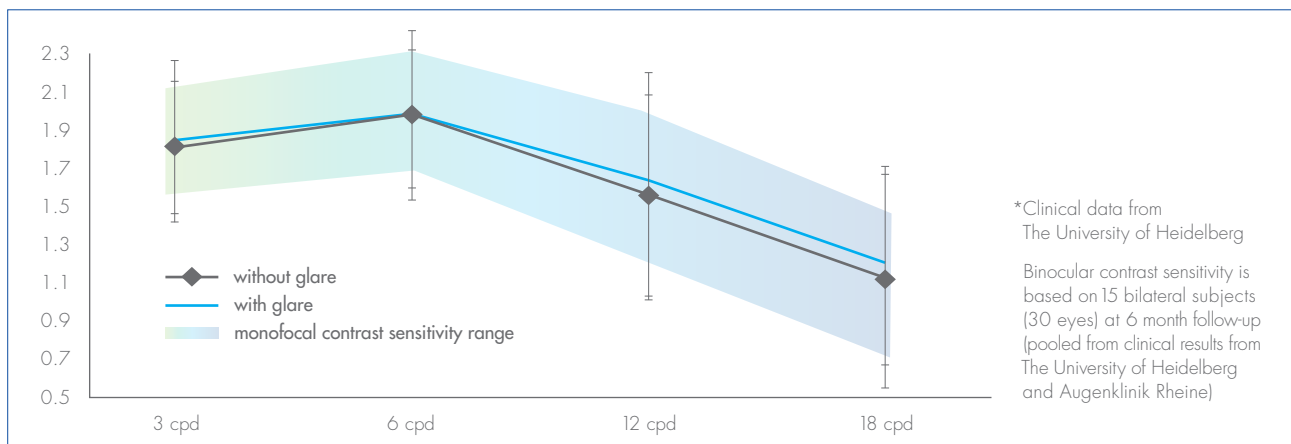
	Intermediate		Distance
	60 cm	70 cm	4 m
 Uncorrected	0.19 (20/30)	0.10 (20/25)	0.04 (20/21)
 Distance corrected	0.23 (20/33)	0.16 (20/28)	-0.02 (20/19)

Based on 15 bilateral subjects (30 eyes) at 3 month follow-up in a clinical study by The University of Heidelberg

High tolerance for refractive error



Photopic contrast sensitivity^{2,3,4}



- ◆ Provides high image contrast comparable to a monofocal IOL
- ◆ Demonstrates no significant difference between the contrast sensitivity measured with and without the glare source

Delivering vision for living

Minimal halo and glare

xact™ Mono-EDoF™ is associated with less frequent, and lower intensity halo and glare than a typical multifocal IOL³

Multifocal IOL



Simulated image typical of a multifocal IOL with halo rating of 5

xact™ Mono-EDoF™



Simulated image with xact™ Mono-EDoF™ based on clinical study conducted by The University of Heidelberg

Percentage of patients reporting little or no difficulty with:^{2,3,4}



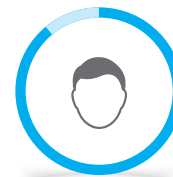
100%
driving
in the day



89%
reading a newspaper or
a book, even without glasses



89%
watching
television



89%
recognising people
when they are close



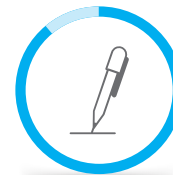
86%
driving
at night



88%
cooking



88%
games such as bingo,
dominos, card games



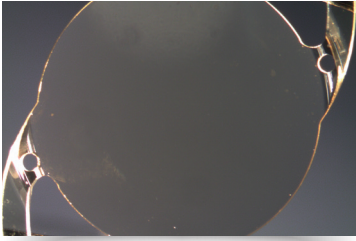
89%
writing checks or
filling out forms

*The questionnaire was a patient satisfaction (VF14), patients rated difficulty on a scale of 0–4; 4 being no difficulty and 0 being unable to do

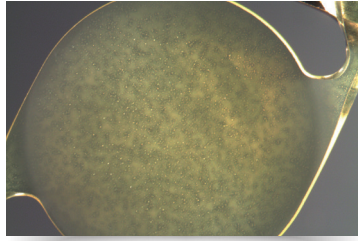
VF14 data is based on 18 bilateral subjects (36 eyes) at 6 month follow-up (pooled from clinical results from The University of Heidelberg and Augenklinik Rheine)

IOL = Intraocular lens

xact™ Mono-EDoF™ IOLs are made using a unique glistening-free hydrophobic material

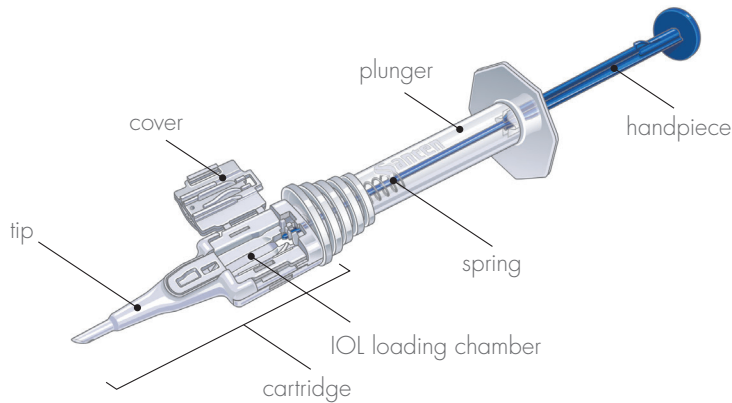


xact™



Hydrophobic IOL with glistening²

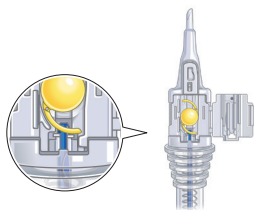
Injector guide



Directions For Use

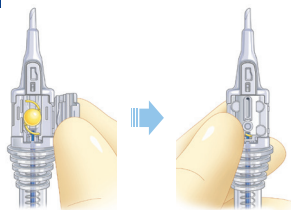
For details, please refer to Instructions For Use

1



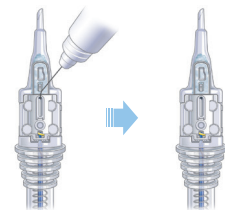
Set the IOL in the loading chamber. Ensure that trailing haptic sits on the tip of the plunger

2



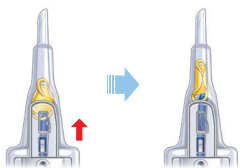
Close and lock the cap

3



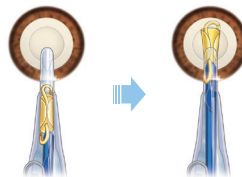
Insert the cannula into the OVD loading point

4



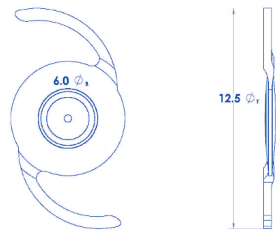
Point the plunger forward and press slowly to advance the IOL inside the nozzle of the injector

5



Approach the incision with the nozzle bevel down and insert the IOL into the eye. Slowly push the plunger and the IOL will be unfolded in the bag

Technical specification

Technical Name	Monofocal Extended Depth of Focus IOL
Model Number	ME4
Optical Characteristics	
Diopter Range	+10.0D to +30.0D in 0.5D increments
Material	Hydrophobic Acrylic Blue-Light Absorbing
Overall Diameter	12.5 mm
Optic Diameter	6.0 mm
Optic Configuration	Bi-convex, aspheric EDoF diffractive
Index of Refraction	1.540 @ 35°C
Haptic Angulation	0°
IOL image	
Optical Biometry	
Suggested A-Constant	
SRK/T	119.5
SRK II	119.5
Holladay 1 SF	2.07
Hoffer Q pACD	5.84
Haigis a0	1.64
a1	0.40
a2	0.10
Recommended Injectors	Santen SWJ-60R Medicel Accuject 2.2 BL
Target Incision Size	≥ 2.2 mm
Square Edge	360°

Indication:

Mono-EDoF™ Foldable Hydrophobic Acrylic Ultraviolet-Absorbing and Blue-Light Absorbing Posterior Chamber Intraocular Lens is indicated for the visual correction of aphakia in adult patients in whom the cataractous lens has been removed by an extracapsular cataract extraction method. The lens is intended for placement in the capsular bag. For optimal performance of the Mono-EDoF™, it is suggested that this IOL is implanted in patients with pre operative corneal astigmatism of ≤ 1.0D and care should be exercised not to increase the post operative astigmatism because of surgically induced astigmatism.

References:

1. Data on File, David J Apple Laboratory. Santen Pharmaceutical Co., Ltd. 2019. 2. Data on File, Combined Clinical Data Analysis of CP7801 and CP7882 [ESR 7959]. 2019. 3. Data on File, The University of Heidelberg [AVS CP7882]. 2019. 4. Data on File, Augenklinik Rheine [AVS CP7801]. 2019.