



**ASPIRA-aXA**

XL OPTIC - VISION WITHOUT LIMITS

NEW: ASPIRA-aXA

TRIPLE TECHNOLOGY IN A SINGLE IOL

The innovative XL optic of the ASPIRA-aXA combines the advantages of a 7.0 mm optic with the stability of the innovative cut-out haptic design, conveniently provided in the preloaded SAFELOADER® implantation system.

ASPIRA-aXA

VERSATILE IN APPLICATION

ASPIRA-aXA provides a tailor-made solution for a diverse range of needs. Possible applications range from standard cataract and refractive surgeries to combined retinal surgery interventions.

XL SECURITY

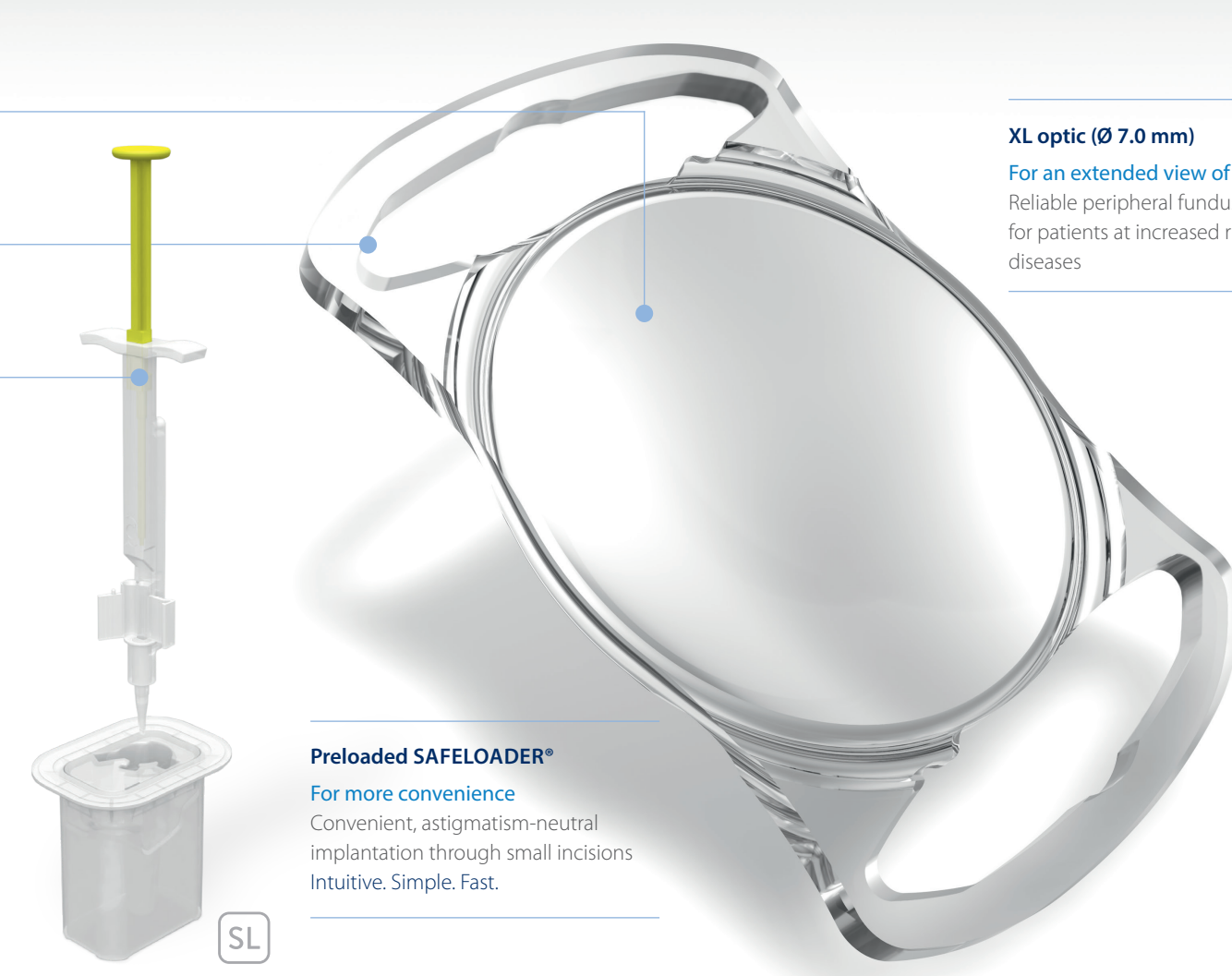
XL OPTIC

XL STABILITY

CUT-OUT HAPTICS

XL COMFORT

PRELOADED SAFELOADER®



The diagram illustrates the ASPIRA-aXA IOL and its implantation system. On the left, a vertical view shows the Preloaded SAFELOADER (SL) with a yellow handle and a clear capsule containing the IOL. On the right, a perspective view shows the IOL with its large circular optic and two haptic arms. Blue lines connect the text boxes to specific parts of the IOL and the SAFELOADER.

XL optic (Ø 7.0 mm)

For an extended view of the fundus

Reliable peripheral fundus view, ideal for patients at increased risk of retinal diseases

XL optic (Ø 7.0 mm)

For large pupils

Avoidance of interfering optical phenomena, especially in patients with large pupils

Cut-out haptics

For more stability

Added stabilization for reliable refractive results

HIGHEST PRECISION

FOR THE BEST POSSIBLE

PATIENT CARE

SNR TECHNOLOGY

Premium optic quality

For brilliant, clear, and sharp images

ASPHERICAL OPTIC DESIGN

Aberration-free

Suitable for all patients, regardless of corneal spherical aberrations

To preserve depth of field\* and enhance contrast sensitivity\*\*

EXCELLENT IOL MATERIAL

Inspired by nature

Glistening-free with excellent uveal biocompatibility

360° LEC BARRIER

To prevent PCO

XL OPTIC

Ø 7.0 mm

Preloaded SAFELOADER®

For more convenience

Convenient, astigmatism-neutral implantation through small incisions

Intuitive. Simple. Fast.

SL

“The new ASPIRA-aXA combines an excellent, stable optic with easy in-the-bag implantation through a 2.4 mm incision. The patient response has been overwhelmingly positive.”<sup>1</sup>

(Prof. G. Duncker, Halle)

“The large ASPIRA-aXA optic has proven itself in phaco-vitrectomies because it allows an edge-free view into the outer retinal periphery.”<sup>2</sup>

(Prof. W. Sekundo, Marburg)

“The ASPIRA-aXA with its enlarged XL optic represents a promising approach to minimize dysphotopsia.”<sup>3</sup>

(Dr. Piskula/Dr. Becker, Oranienburg)

“The creation of a larger capsulorhexis with implantation of a 7.0 mm optic IOL contributed to a larger anterior capsule opening after cataract surgery in patients with DM [diabetes mellitus].”<sup>44</sup>

\* Compared to aberration-correcting IOLs.

\*\* Compared to spherical IOLs.

“The new ASPIRA-aXA combines an excellent, stable optic with easy in-the-bag implantation through a 2.4 mm incision. The patient response has been overwhelmingly positive.”<sup>1</sup> (Prof. G. Duncker, Halle)

“The large ASPIRA-aXA optic has proven itself in phaco-vitrectomies because it allows an edge-free view into the outer retinal periphery.”<sup>2</sup> (Prof. W. Sekundo, Marburg)

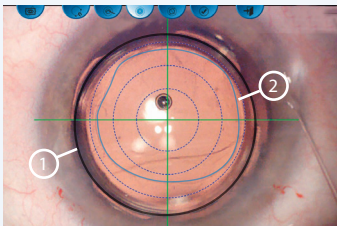
“The ASPIRA-aXA with its enlarged XL optic represents a promising approach to minimize dysphotopsia.”<sup>3</sup> (Dr. Piskula/Dr. Becker, Oranienburg)

“The creation of a larger capsulorhexis with implantation of a 7.0 mm optic IOL contributed to a larger anterior capsule opening after cataract surgery in patients with DM [diabetes mellitus].”<sup>44</sup>

WWW.HUMANOPTICS.COM

XL OPTIC

EXTENDED FUNDUS VIEW



Intraoperative image (using Verion) with implanted ASPIRA-aXA.  
(1) Edge of the XL optic.  
(2) Rhexis: diameter 6.0 mm.

APPROX. 20% – DIABETES TYPE 2<sup>5</sup>

In the age group of the average cataract patient<sup>6</sup>

OVER 80% – OVERWEIGHT<sup>7</sup>

In the age group of the average male cataract patient

MORE THAN 2/3 – HYPERTENSION<sup>8</sup>

Within the over-65 population

- Opening of the anterior capsule with a rhexis diameter of up to 6.5 mm
- Extended fundus view for convenient assessment of the posterior segment of the eye
- Facilitated implementation of therapeutic measures for peripheral retinal diseases

ASPIRA-aXA offers patients with an increased risk of ocular diseases an advantage for long-term, successful pseudophakic treatment.

LARGE PUPILS

APPROX. 20% – SCOTOPIC PUPIL DIAMETER<sup>9</sup>

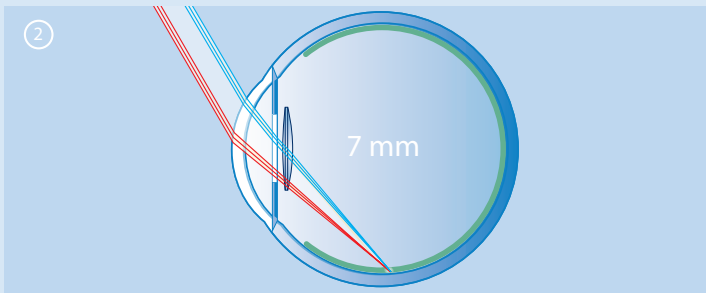
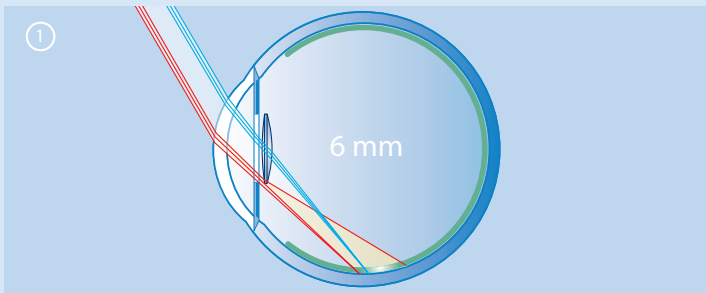
20% of cataract patients have a scotopic pupil diameter of ≥6 mm.

APPROX. 10% – MESOPIC PUPIL DIAMETER<sup>9</sup>

In 10% of patients, even the mesopic pupil is ≥6 mm.

- The pupil overlaps with the IOL optic, even with large pupil diameters
- Incident light safely passes through the XL optic
- Reduced interfering edge effects and avoidance of direct light passing the IOL and striking the retina directly

The ASPIRA-aXA with its XL optic is an ideal treatment option for large pupils.



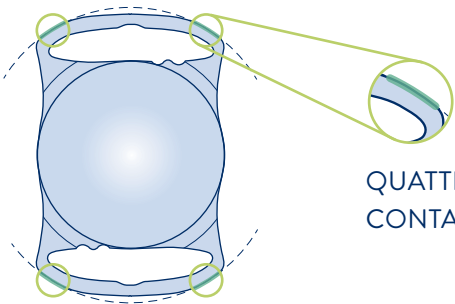
Simulated beam guidance (temporal), based on a simulation using Zemax, OpticStudio 16.5 with a 6 mm optic (1) and a 7 mm optic (2); pupil size 4 mm each.

CUT-OUT HAPTICS

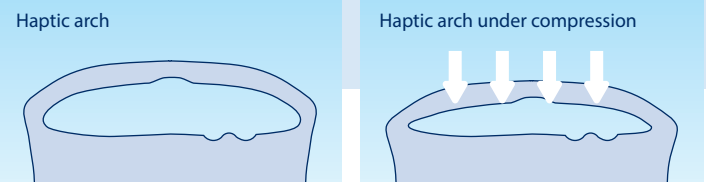
ADDITIVE STABILIZATION

Combining the benefits of C-loop haptics and conventional plate haptics for added stabilization

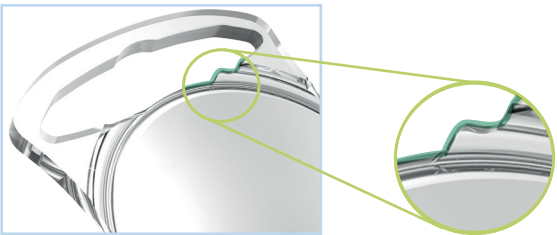
- The haptics are designed as absorption elements to absorb the energy of external forces without transmitting them to the IOL optic
- Quattro point design for stable placement in the capsular bag



QUATTRO POINT CONTACT ZONE



Schematic drawing: when force is applied, the cut-out haptics prove to be stable elements for positioning the IOL.<sup>10</sup>



POSITION MARKING  
For doubled security  
Secure, correct placement

7.0 MM OPTIC IN THE SAFELOADER®

Precise and reliable supply of the ASPIRA-aXA in the unique Autoloading SAFELOADER® system

- **Easy to use – for more convenience**  
Intuitive, easy handling replaces manual cartridge loading
- **Separate components – for maximum safety**  
With its separate components, the preloaded implantation system offers the highest level of safety: both the IOL and the injector undergo separate sterilization processes
- **Contactless one-way system**  
The separate storage of the IOL ensures that it only comes into contact with the coating additives of the cartridge immediately prior to the surgery



Optional combination with the Medice Accuject™ injector; recommended application: in-the-bag

2.0

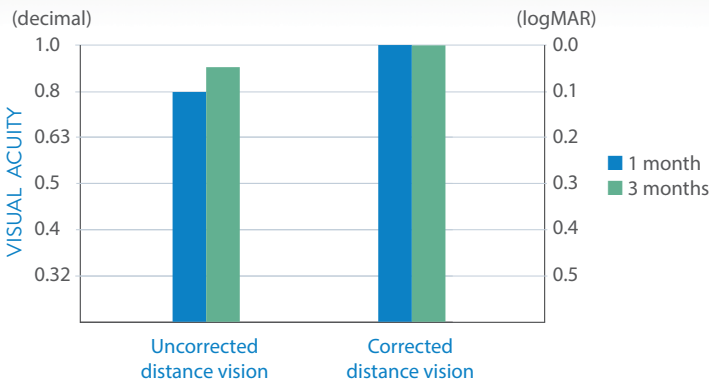
2.2

ONE DESIGN, TRIPLE EFFECTIVENESS

The ASPIRA-aXA has proven its excellent clinical properties.<sup>11</sup>

EXCELLENT VISUAL PERFORMANCE

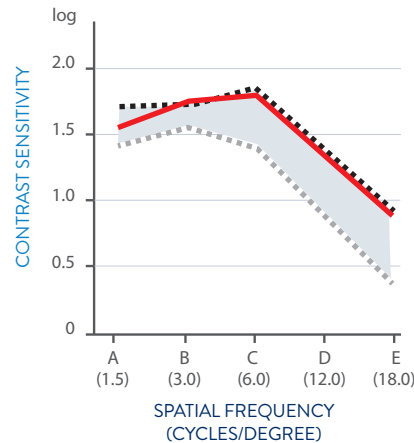
Patients treated with ASPIRA-aXA showed good uncorrected monocular distance visual acuity (UDVA) one month and three months postoperatively (n = 58). Corrected distance visual acuity (CDVA) was 0.00 logMAR (median) at both follow-ups with 93% of eyes achieving 0.10 logMAR or better.



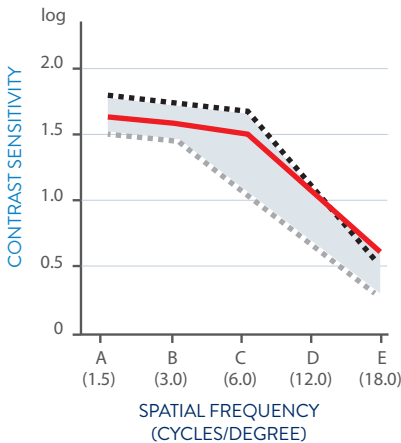
EXCELLENT CONTRAST SENSITIVITY

After implantation with ASPIRA-aXA, patients achieved better contrast vision under both photopic and mesopic conditions, compared to non-operated persons of the same age group.

PHOTOPIC



MESOPIC



Contrast sensitivity of ASPIRA-aXA without glare (median)

Contrast sensitivity of persons over 60 years of age who did not undergo surgery<sup>12</sup>

Upper and lower limit of the 95% confidence interval

RESULTS

The ASPIRA-aXA achieves very good clinical results in terms of visual performance, contrast sensitivity and patient satisfaction. The IOL demonstrates stable centration during the study. Nd:YAG capsulotomy was unnecessary in all cases. The ASPIRA-aXA is a safe and effective intraocular lens for the treatment of cataract patients.

100% PATIENT SATISFACTION

A patient survey indicated that all patients were either satisfied or very satisfied with the ASPIRA-aXA. Furthermore, 3-months postoperatively, 100% of the patients stated that they rarely or never noticed photic phenomena.



REFERENCE

<sup>1</sup> Duncker, G. (2018). Personal Statement, Institute for Ophthalmology Halle.

<sup>2</sup> Sekundo, W. (2018). Personal Statement, University Hospital Giessen and Marburg.

<sup>3</sup> Piskula, M. Becker, E. (2018). Reduzierte pseudophake Dysphotopsien durch vergrößerte IOL-Optik. Presentation DGI (Deutschsprachige Gesellschaft für Intraokularlinsen-Implantation), interventionelle und refraktive Chirurgie (2018).

<sup>4</sup> Takamura, Y. et al. Large capsulorhexis with implantation of a 7.0 mm optic lens during cataract surgery in patients with diabetes mellitus. J Catract Refract Surg 2014; 40(11):1850-1856.

<sup>5</sup> Deutscher Gesundheitsbericht Diabetes 2016 (2016 ). Publisher: diabetesDE – Deutsche Diabetes-Hilfe und Deutsche Diabetes Gesellschaft (DDG).

<sup>6</sup> BVMed website <http://cms.augeninfo.de/nc/hauptmenu/presse/statistiken/statsitik-katerakt.html>. Last accessed on May 29, 2018.

<sup>7</sup> Mensink, G. et al. (2016 DEGS). Studie zur Gesundheit Erwachsener in Deutschland. Übergewicht und Adipositas in Deutschland: Werden wir immer dicker? Robert Koch Institute.

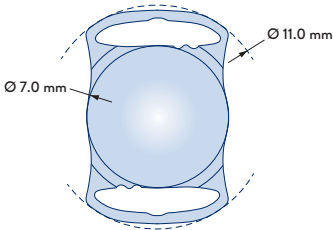
<sup>8</sup> Neuhauser, H., Kuhnert, R., Born, S. (2017). Journal of Health Monitoring 2017 2(1) DOI 10.17886/RKI-GBE-2017-007. Robert Koch Institute.

<sup>9</sup> Becker, E. (2017). ASPIRA-aXA. Die Antwort auf pseudophake Dysphotopsien? Presentation DOC 2017. At the Meet-the-Expert event, HumanOptics booth.

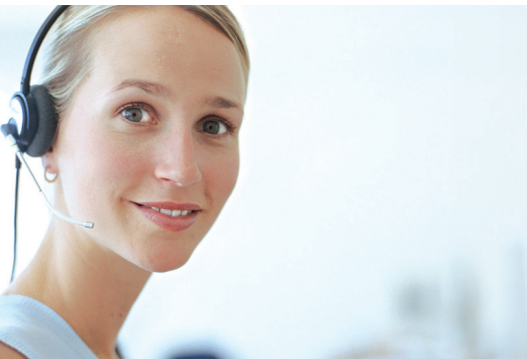
<sup>10</sup> HumanOptics AG (2017). In vitro simulation, data on file.

<sup>11</sup> HumanOptics AG (2018). Interim study analysis, data on file.

<sup>12</sup> Hohberger, B. et al. (2007). Measuring contrast sensitivity in normal subjects with OPTEC 6500: influence of age and glare. Graefes Arch Clin Exp Ophthalmol, 245, 1805-14.

| ASPIRA-aXA                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                    |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|
| <div><ul style="list-style-type: none"><li>• XL optic</li><li>• Cut-out haptic</li><li>• Sub-nano resolution technology</li></ul><div><div><br/>SNR<br/>TECHNOLOGY</div><div><br/>MADE IN<br/>GERMANY<br/>PREMIUM<br/>QUALITY</div></div></div> |  |
| Type                                                                                                                                                                                                                                                                                                                                                                                                              | Foldable 1-piece posterior chamber lens                                            |
| Material                                                                                                                                                                                                                                                                                                                                                                                                          | Glistening-free, hydrophilic acrylic, UV blocker                                   |
| Water content                                                                                                                                                                                                                                                                                                                                                                                                     | 26% at 35°C                                                                        |
| Optic design                                                                                                                                                                                                                                                                                                                                                                                                      | Aspherical anterior surface, aberration-free*                                      |
| Optic diameter                                                                                                                                                                                                                                                                                                                                                                                                    | 7.0 mm                                                                             |
| Total diameter                                                                                                                                                                                                                                                                                                                                                                                                    | 11.0 mm                                                                            |
| Haptic design                                                                                                                                                                                                                                                                                                                                                                                                     | Cut-out haptic                                                                     |
| Diopter range                                                                                                                                                                                                                                                                                                                                                                                                     | 10.0 to 30.0 D in 0.5 D steps                                                      |
| Preloaded                                                                                                                                                                                                                                                                                                                                                                                                         | SAFELOADER®                                                                        |
| Optical A constant (estimated)                                                                                                                                                                                                                                                                                                                                                                                    | 118.3                                                                              |

\* The term "aberration" is used in this document in the sense of "spherical aberration."



DISTRIBUTED BY