

Jakarta, 02 November 2021
No : SPS/HSO/11/21/0007
Hal : Permohonan Presentasi

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Kepada Yth
Direktur RS Mata Undaan

Kami dari PT Topsindo Megah Utama sebagai distributor tunggal dari produk IOL HOYA, berencana ingin memperkenalkan produk HOYA kepada pihak RS Mata Undaan

- HOYA Hydrophobic Spherical 1-piece IOL iSert 151
- HOYA Hydrophobic Aspherical 1-piece IOL iSert 250
- HOYA Hydrophobic Aspherical 1-piece IOL iSert 251

Besar harapan kami dalam hal ini, kami mohon diperkenankan untuk memperkenalkan produk HOYA dengan cara presentasi kepada pihak RS Mata Undaan
Untuk jadwal presentasi, kami mengikuti sesuai dengan ketersediaan jadwal dari pihak Rumah Sakit yang diberikan kepada kami.

Atas perhatiannya diucapkan terima kasih.

Hormat kami,



Darma Setiawan
Business Manager

iSert[®] 251

ASPHERIC 1-PIECE IOL

Preloaded Injector System | Hydrophobic Acrylic

Simple, fast, predictable^{1,2}

- Physicians find iSert[®] simple to use¹
- Faster average IOL delivery time than manually loaded IOL delivery systems²

Improves efficiency and productivity^{3,4}

- Preloaded features streamline operating procedures and free your staff from time-consuming daily duties

Sharp optic edge⁵

- Designed to reduce posterior capsule opacification (PCO)

Proven hydrophobic IOL material

- Over 10 million IOLs sold worldwide over 15 years⁶



Reference: 1. HOYA post-market clinical follow-up study evaluating safety and performance of HOYA IOLs in routine practice. Data on file, HOYA Medical Singapore Pte. Ltd. 2018. CSR_PMCF-101LONG_6mlr_07092018. 2. Chung B, et al. Preloaded and non-preloaded intraocular lens delivery system and characteristics: human and porcine eyes trial. *Int J Ophthalmol* 2018;11:6-11. 3. HOYA Cartridge IFU. Available at: <http://hoyasurgicaloptics.com/eu/professionals/eifu/>. Accessed on 28 Mar 2019. 4. HOYA iSert[®] 251 IFU. Available at: <http://hoyasurgicaloptics.com/eu/professionals/eifu/>. Accessed on 28 Mar 2019. 5. Werner L, Tetz M. Edge profiles of currently available intraocular lenses and recent improvements. *Eur Ophthalmic Rev* 2009;3:74-76. 6. Data on file, HOYA Medical Singapore Pte. Ltd. 2018.

HOYA
SURGICAL OPTICS

iSert[®] 251

ASPHERIC 1-PIECE IOL

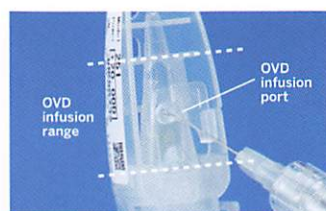
Preloaded Injector System | Hydrophobic Acrylic

Model name	HOYA iSert [®] 251
Specification	UV and blue light filter
Optic material	Hydrophobic acrylic (AF-1)
Optic design	Aspheric lens design, aberration correcting
Manufacturing	Lathe-cut and pad polished
Haptic material	Hydrophobic acrylic with blue PMMA chemically bonded haptic tips
Haptic configuration	Modified C-loop, 5° angulation
Dimension (Optic/OAL)	6.0 mm / 12.5 mm
Power	+6.00 to +30.00 D (in 0.50 D increment)
Nominal A-constant*	118.4
Optimized constants**	Haigis a0 = -0.542 a1 = 0.161 a2 = 0.204 Hoffer Q pACD = 5.30 Holladay 1 sf = 1.52 SRK/T A = 118.5
Front injector tip outer diameter	1.82 mm
Injector	iSert [®] preloaded

*The A-constant mentioned above is presented as a guideline only for lens power calculations. It is recommended that the A-constant measurement be customized based on the surgeon's experience and measuring equipment.

**<https://iolcon.org/lensesTable.php> (Accessed data Mar 15, 2019)

The handling shown below summarizes the product application and does not replace the "Instruction For Use".



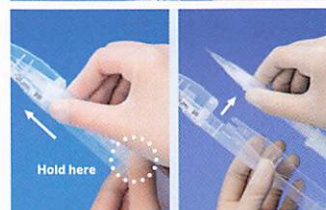
Step A

Infuse the OVD into the injector through the infusion port. Fill up the area indicated by the dotted lines.



Step B

Press the release tabs, lift up and remove the cover from the case.



Step C

Hold body with thumb and push the slider slowly forward until it stops. Remove the injector from the case.



Step D

Push the injector knob forward until it stops. Slowly rotate the knob clockwise. Carefully insert the injector tip into the eye through the incision, keeping the slit of the tip in a downward position to ensure correct IOL orientation. Slowly rotate the injector knob clockwise, to inject the lens into the capsular bag.

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2020-03-31_HSOE_251_DS_EN



iSert® 250

ASPHERIC 1-PIECE IOL

Preloaded Injector System | Hydrophobic Acrylic

Simple, fast, predictable^{1,2}

- Physicians find iSert® simple to use¹
- Faster average IOL delivery time than manually loaded IOL delivery systems²

Improves efficiency and productivity^{3,4}

- Preloaded features streamline operating procedures and free your staff from time-consuming daily duties

Sharp optic edge⁵

- Designed to reduce posterior capsule opacification (PCO)

Proven hydrophobic IOL material

- Over 10 million IOLs sold worldwide over 15 years⁶



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HOYA
SURGICAL OPTICS

iSert[®] 250

ASPHERIC 1-PIECE IOL

Preloaded Injector System | Hydrophobic Acrylic

Model name	HOYA iSert [®] 250
Specification	UV filter
Optic material	Hydrophobic acrylic (AF-1)
Optic design	Aspheric lens design, aberration correcting
Manufacturing	Lathe-cut and pad polished
Haptic material	Hydrophobic acrylic with blue PMMA chemically bonded haptic tips
Haptic configuration	Modified C-loop, 5° angulation
Dimension (Optic/OAL)	6.0 mm / 12.5 mm
Power	+6.00 to +30.00 D (in 0.50 D increment)
Nominal A-constant*	118.4
Optimized constants**	Haigis a0 = -0.542 a1 = 0.161 a2 = 0.204 Hoffer Q pACD = 5.30 Holladay 1 sf = 1.52 SRK/T A = 118.5
Front injector tip outer diameter	1.82 mm
Injector	iSert [®] preloaded

*The A-constant mentioned above is presented as a guideline only for lens power calculations. It is recommended that the A-constant measurement be customized based on the surgeon's experience and measuring equipment.

**<https://iolcon.org/lensesTable.php> (Accessed data Mar 15, 2019)

The handling shown below summarizes the product application and does not replace the "Instruction For Use".

Step A
Infuse the OVD into the injector through the infusion port. Fill up the area indicated by the dotted lines.

Step B
Press the release tabs, lift up and remove the cover from the case.

Step C
Hold body with thumb and push the slider slowly forward until it stops. Remove the injector from the case.

Step D
Push the injector knob forward until it stops. Slowly rotate the knob clockwise. Carefully insert the injector tip into the eye through the incision, keeping the slit of the tip in a downward position to ensure correct IOL orientation. Slowly rotate the injector knob clockwise, to inject the lens into the capsular bag.

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2020-03-31_HSOE_250_DS_EN



iSert® 151

SPHERICAL 1-PIECE IOL

Preloaded Injector System | Hydrophobic Acrylic



Simple, fast, predictable^{1,2}

- Physicians find iSert® simple to use¹
- Faster average IOL delivery time than manually loaded IOL delivery systems²

Improves efficiency and productivity^{3,4}

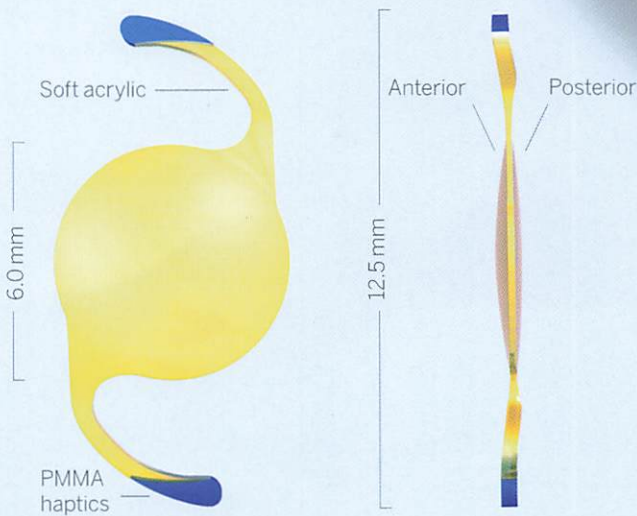
- Preloaded features streamline operating procedures and free your staff from time-consuming daily duties

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iSert® 151

SPHERICAL 1-PIECE IOL

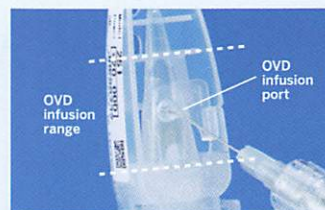
Preloaded Injector System | Hydrophobic Acrylic

Model name	HOYA iSert® 151
Specification	UV and blue light filter
Optic material	Hydrophobic acrylic (AF-1)
Optic design	Spherical lens design
Manufacturing	Lathe-cut and pad polished
Haptic material	Hydrophobic acrylic with blue PMMA chemically bonded haptic tips
Haptic configuration	Modified C-loop, 5° angulation
Dimension (Optic/OAL)	6.0 mm / 12.5 mm
Power	+6.00 to +30.00 D (in 0.50 D increment)
Nominal A-constant*	118.4
Optimized constants**	Haigis a0 = -0.542 a1 = 0.161 a2 = 0.204 Hoffer Q pACD = 5.30 Holladay 1 sf = 1.52 SRK/T A = 118.5
Front injector tip outer diameter	1.93 mm
Injector	iSert® preloaded

*The A-constant mentioned above is presented as a guideline only for lens power calculations. It is recommended that the A-constant measurement be customized based on the surgeon's experience and measuring equipment.

**<https://iolcon.org/lensesTable.php> (Accessed data Mar 15, 2019)

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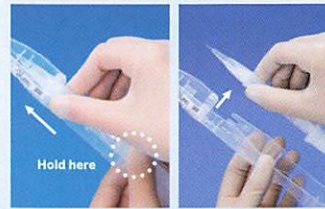
Step A

Infuse the OVD into the injector through the infusion port. Fill up the area indicated by the dotted lines.



Step B

Press the release tabs, lift up and remove the cover from the case.



Step C

Hold body with thumb and push the slider slowly forward until it stops. Remove the injector from the case.



Step D

Push the injector knob forward until it stops. Slowly rotate the knob clockwise. Carefully insert the injector tip into the eye through the incision, keeping the slit of the tip in a downward position to ensure correct IOL orientation. Slowly rotate the injector knob clockwise, to inject the lens into the capsular bag.

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