PRESCRIPTION DEVICES

Caution: This product is for sale by or on the order of a physician only.

DESCRIPTION

Vivinex Impress™ is a foldable posterior chamber intraocular lens (IOL) (Fig.1) pre-loaded in a single use injector (Fig.2) that automatically folds the lens prior to injecting the IOL into the eye. After injection the IOL gently unfolds to allow placement in the capsular bag. The lens is made from an ultraviolet-absorbing high-refractive index hydrophobic soft acrylic polymer.

IOL CHARACTERISTICS:

	Model XY1-EM*
Optic Configuration	Biconvex aspheric
IOL Material and Composition	100% Soft acrylic (UV-absorbing acrylic polymer)
IOL Color	Yellow
UV Cutoff at 10%T	416 nm (+20.00 D)
Refractive Index	1.548 (23°C)
IOL Power (Spherical Equivalent)	+6.00 to 30.00 D in steps of 0.50 D
Haptic Configuration	Modified-C loop

**This model may not be commercially available in your country.*

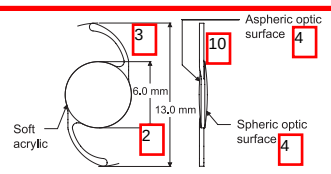

Fig.1: Lens

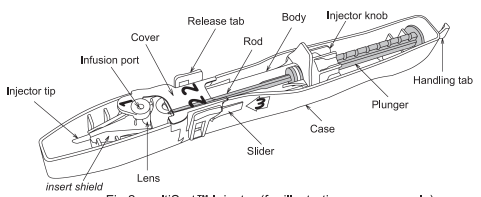

Fig.2: multiSert™ Injector (for illustrative purposes only)

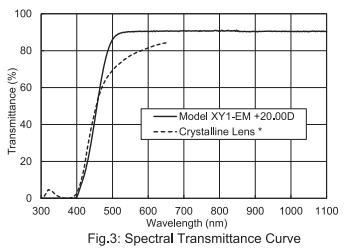

Fig.3: Spectral Transmittance Curve

This graph shows the spectral transmittance curve for the Vivinex Impress™ IOL at +20.00 D. It also shows the spectral transmittance curve* for a phakic eye of a 53-year-old person (Boettner, E.A. and Wolter, J.R., "Transmission of the Ocular Media," *Investigative Ophthalmology*, Vol. 1, 776-783, 1962).

INTENDED PURPOSE

The Vivinex Impress™ IOL is intended to be placed into the capsular bag of the eye after extracapsular cataract removal, functioning as a refractive medium to replace the natural crystalline lens.

INDICATIONS

The Vivinex Impress™ IOL is indicated for the visual correction of aphakia after implantation in the capsular bag in adult patients.

WARNINGS

1. There are no known contraindications for adults to the implantation of monofocal aspheric intraocular lenses into the capsular bag after extracapsular cataract removal. However, for patients suffering from certain medical conditions or combinations of conditions below, the surgeon should carefully evaluate the pre-operative situation and make sound clinical judgment on the risk/benefit of the implantation.
   - Amblyopia
   - Atopic disease
   - Congenital ocular anomalies, e.g. Marfan Syndrome, macular dystrophies
   - Corneal endothelial pathologies, e.g. corneal dystrophy
   - Corneal scars impeding visualization
   - Diabetic maculopathy or retinopathy
   - Glaucoma, especially with optic nerve atrophy
   - Inadequate medical mydriasis
   - Intraoperative choroidal haemorrhage
   - Macular degeneration
   - Microphthalmos
   - Optic nerve atrophy of other forms
   - Patient who is judged to be unsuitable by a surgeon for reasons such as accompanying systemic or ophthalmic disease
   - Peripheral retinal degenerations predisposing to retinal detachment
   - Pre-existent traumatic or intraoperative zonular rupture and lens (sub-)luxation
   - Previous corneal transplant
   - Pseudoexfoliation syndrome and other diseases associated with zonular weakness
   - Retinal detachment
   - Rubeosis iridis
   - Serious intraoperative complications
   - Shallow anterior chamber
   - Uveitis/Iritis, especially when active
2. The following adverse events related to IOL implantation may occur:
   - Conjunctival hyperemia
   - Acute corneal decompensation
   - Corneal endothelial damage or stomal edema
   - Dry eyes syndrome
   - Striae in Descemet's membrane
   - Wound leak
   - Abnormal pupil shape or size (e.g. block, capture, dyscoria, fixed mydriasis)
   - Bleeding (e.g. subconjunctival hemorrhage, hyphema)
   - Infection or inflammatory reactions (e.g. uveitis/iritis, endophthalmitis, TASS, keratitis, conjunctivitis, hypopyon, hyalitis)
   - Iris damage, adhesion or prolapse
   - Adhesion of cells or foreign bodies onto the lens surface
   - Capsular or zonular dehiscence
   - Cyclitic membrane
   - Opacification of posterior or anterior capsule
   - Striae in posterior capsule
   - Choroidal detachment
   - Cystoid macular edema
   - Macular degeneration
   - Posterior hyaloid detachment with floaters
   - Retinal detachment
   - Transient or persistent changes of intraocular pressure (hyper-, hypotony)
   - Vitreous hemorrhage / opacification
   - Vitreous prolapse
   - Chromatopsia
   - Foreign body sensation
   - Impaired visual function (e.g. suboptimal visual acuity, reduced contrast sensitivity, dysphotopsia, induced astigmatism, monocular diplopia)
   - Lens explantation
   - Secondary surgical intervention
3. The following malfunctions related to the IOL or the injector system may occur:
   - Haptic damage
   - Haptic folds incorrectly
   - Haptic-to-optic sticking
   - Injector malfunction
   - Injector tip crack
   - Lens decentration or tilt
   - Lens discoloration
   - Lens dislocation
   - Lens luxation
   - Optic damage
   - Optic glistening
   - Optic opacification
   - Optic surface reflection
4. If any of the following conditions occurs during surgery, the surgeon should consider alternative methods of correcting aphakia and consider implantation of this IOL only if alternatives are deemed unsatisfactory to meet the needs of the patient.
   - Mechanical or surgical manipulation to enlarge the pupil
   - Posterior capsule tears resulting in vitreous loss or loss of integrity of the capsular bag necessitating implantation of an IOL in the ciliary sulcus or anterior chamber or when IOL stability could be compromised
   - Significant anterior chamber bleeding
   - Uncontrollable intraocular pressure

   Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
5. Patients with preoperative problems such as corneal endothelial disease, abnormal cornea, macular degeneration, retinal degeneration, glaucoma, and chronic drug miosis may not achieve the visual acuity of patients without such problems. The surgeon must determine the potential risk/benefit ratio to be derived from IOL implantation when such conditions exist.

LENS POWER CALCULATION

The A-constant is presented as a starting point for the lens power calculation. When calculating the exact lens power, it is recommended that calculations be performed individually, based on the equipment used and operating surgeon's own experience. Methods for calculating lens power are described in the literature cited below.

Sanders, D.R., Retzlaff, J., and Kraff, M.C., "Comparison of the SRKII formula and other second generation formulas", *Journal of Cataract and Refractive Surgery*, Vol. 14, pp. 136-141, 1988.

Retzlaff, J.A., Sanders, D.R., and Kraff, M.C., "Development of the SRK/T intraocular lens implant power calculation formula", *Journal of Cataract and Refractive Surgery*, Vol. 16, pp 333-340, 1990; ERRATA, Vol. 16, pp 528, 1990.

PRECAUTIONS

1. The Vivinex Impress™ IOL has been validated with sodium hyaluronate Ophthalmic Viscosurgical Devices (OVDs); the use of other OVDs and lubricants may cause damage to the lens and potential complications during implantation.
2. Special attention must be paid while inserting the lens in the eye to assure the optic is positioned with the proper side up (as shown in Fig.4). In vivo studies in rabbits indicated that a reversed position would increase the rate of complications such as capsular bag distention syndrome and PCO. Read and follow all "INSTRUCTIONS FOR USE" before use. If the lens is implanted in the reversed postition, the surgeon may consider further surgical treatment options including inverting the lens in a safe manner, explantation / re-implantation or posterior capsulotomy.

Fig.4: Correct IOL haptic-optic shape in the capsular bag (surgical view)

3. Before surgery, the surgeon should consider the following;
   - Inform patients of the potential risk/benefit associated with this product.
   - Leave the device for at least 30 minutes at a temperature of 18 to 25 °C to achieve optimal lens conditions for folding.
   - Handle the device with care to prevent haptic damage due to excessive twisting, strong impact, or excessive pressure.
   - Avoid attempting to insert the lens forcibly through a too small incision; this may result in a torn incision and lead to possible complications. The outer diameter of the front of the injector tip is 1.70 mm.
   - Allow the OVD to attain a temperature of 18 to 25 °C prior to use (for details, consult the instructions for use attached to the OVD).
4. As a high level of surgical skill is required for IOL implantation, the surgeon should have observed and/or assisted in numerous cataract surgeries, IOL implantations, and surgical intervention techniques before attempting to implant an IOL.
5. The supplied device has to be used in a sterile environment in an operating room in a hospital or in private ophthalmology clinics.
6. **Do not resterilize or reuse either the injector or intraocular lens**. Reuse or resterilization may compromise the structural integrity of the devices and/or lead to device failure which, in turn, may result in patient injury or illness. Reuse or resterilization may also create a risk of contamination of the devices and/or cause patient infection or cross-infection, including but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the devices may lead to injury or illness of the patient.
7. Care should be taken to remove the OVD from the eye at the end of surgery.
8. After use, discard the injector as medical waste per your local country regulations.

INSTRUCTIONS FOR USE

PRELIMINARY STEPS

1. Confirm the expiration date, the dioptric power and the model of the lens. The model of the lens and the dioptric power are printed on the outer box label and the injector label.
2. Inspect the sterilization pouch carefully. DO NOT use the injector or lens if their sterility seems to be compromised due to the rupture in the pouch, etc.
3. Open the seal of the sterilization pouch. Pull the injector out of the pouch by holding the handling tab. Handle the device aseptically after opening the pouch.
4. Confirm that the injector and lens are not damaged and there are no visible foreign bodies adhering to the lens surface.

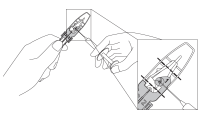

Fig.5: Step 1 - Infuse OVD

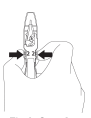

Fig.6: Step 2 - Remove cover

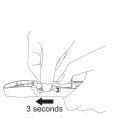

Fig. 7: Step 3 - Push slider slowly

INJECTOR PREPARATION STEPS

1. Infuse the sodium hyaluronate OVD into the injector through the infusion port (Fig.5). Fill up the area indicated by the dotted lines in Fig.5 with the OVD, and confirm the OVD has reached the entire optic.
2. Press the release tabs, lift up and remove the cover from the injector case (Fig.6).
3. Hold injector body with thumb and slowly push the slider forward in an even manner for about 3 seconds, without applying upward or downward pressure, until it stops (Fig.7). Verify the slider stops at the injector case (as indicated in Fig. 8, by the arrow). DO NOT pull the slider back. After slider advancement, implant the IOL within 3 minutes.
4. Remove the injector from its case (Fig.9). Go immediately to Step 5 once removed.
5. Gently advance the plunger forward in one smooth, continuous motion until haptic tucking state reaches the specific position as illustrated in figure (Fig.10). This plunger advancement should require about 5 seconds.
   DO NOT pull the plunger back AT ANY TIME.

   Pay special attention that the trailing haptic is tucked correctly as the rod advances to the back edge of the optic. As the lens advances further confirm that the leading and trailing haptic are tucked correctly, and that the rod tip pushes the edge of the optic in the center (Fig. 10). If no issues are observed, go immediately to Step 6. If the *insert shield* is not used, go to Step 6A. If the *insert shield* is used, go to Step 6B.

   DO NOT proceed if the leading and / or trailing haptics are not in correct position, or the rod tip does not push the edge of the optic in the center (Fig.11).

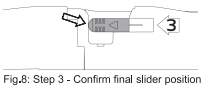

Fig.8: Step 3 - Confirm final slider position

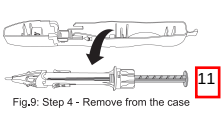

Fig.9: Step 4 - Remove from the case

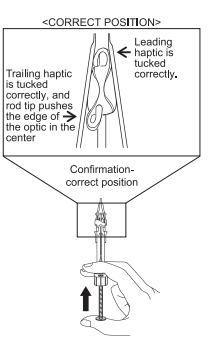

Fig.10: Step 5 - Push plunger and verify haptic positioning

<WRONG POSITION>

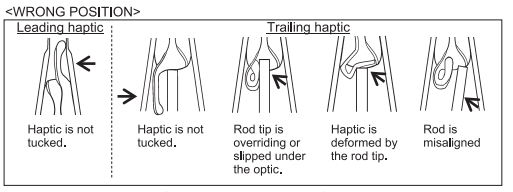

Fig.11: Step 5 - Do not proceed in case of wrong position

6. Insertion Depth Options of the Injector Tip

   6A. *insert shield* Option A: Delivery into the Capsular Bag
   Use the injector without moving the *insert shield* from its default position. Go immediately to IMPLANTATION steps 1 through 4.

   NOTE: The *insert shield* is pre-attached to the injector and CANNOT be removed.

   6B. *insert shield* Option B: Delivery through the Incision Wound Tunnel
   Hold the injector body and slide the *insert shield* gently forward until it stops with a click at the final position (Fig.12). DO NOT pull the *insert shield* back. Go immediately to IMPLANTATION steps 1 through 4.

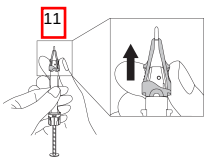

Fig.12: Step 6B - Advance *insert shield*

IMPLANTATION STEPS

1. Insertion of the Injector Tip
   1A. *insert shield* Option A: Delivery into the Capsular Bag
   Place the slit of the injector tip in a downward position before inserting through the incision of eye. This is to ensure the correct IOL orientation.

   1B. *insert shield* Option B: Delivery through the Incision Wound Tunnel
   Place the slit of the injector tip in a downward position before inserting through the incision of eye. This is to ensure the correct IOL orientation. Insert up to the *insert shield*.
2. IOL Injection Options
   2A. Injection Option A: Injector Knob Rotation
   Slowly rotate the injector knob clockwise to insert the lens into the capsular bag. DO NOT turn the knob in reverse direction during advancement. Rotation of the injector is NOT required.

   2B. Injection Option B: Push Plunger
   Slowly push the plunger forward to insert the lens into the capsular bag. Do NOT pull the plunger back during advancement. Rotation of the injector is NOT required.
3. Ensure the trailing haptic is released completely from the tip before pulling out the injector from the incision.
4. Adjust the position of the lens, using a hook or other instrument.

RETURN GOODS POLICY

Regarding lens return or exchange, please contact your local distributor.

PATIENT IMPLANT CARD AND SELF-ADHESIVE LABELS

The Patient Implant Card is included in the package to record all implant information. The card should be given to the patient and shown when seeking eye care in the future. The self-adhesive labels are provided for inclusion in patient records to ensure traceability of the products.

HOW SUPPLIED

The Vivinex Impress™ IOL is supplied sterile in a sterilization pouch for single use only. Both the lens and injector have been sterilized using ethylene oxide.

STORAGE CONDITIONS

Do not store the product in direct sunlight, high humidity, or at temperatures below 5 °C or above 30 °C.

EXPIRATION DATE

The expiration date printed on the outer box label is expressed as four digits for the year, two digits for the month, and two digits for the day. This product must not be implanted after the indicated expiration date.

SYMBOLS

Symbols	Description	Symbols	Description
STERILE EO	Sterilized using ethylene oxide	D	Diopter
	Do not reuse	MD	Medical Device
	Do not resterilize	EC REP	Authorized representative in the European Community
	Consult instructions for use		Use by (YYYY-MM-DD : year-month-day)
5°C 30°C	Do not store below 5 °C or above 30 °C		Date of manufacture (YYYY-MM: year-month)
	Manufacturer	SN	Serial number
	Keep away from sunlight	$\varnothing_T$	Overall diameter
	Do not use if package is damaged	$\varnothing_B$	Optic diameter (Body diameter)

Manufacturer:
HOYA Medical Singapore Pte. Ltd.
455A Jalan Ahmad Ibrahim,
Singapore 639939

CE 0123

EC REP **EC Rep address:**
HOYA Surgical Optics GmbH
De-Saint-Exupéry-Strasse 10, 60549 Frankfurt am Main, Germany
Tel: +49-(0)69-664-268-0

Manufacturing Site:
HOYA Lamphun Ltd.
75/2 Moo 4, Tambol Banklang,
Amphur Muang, Lamphun, 51000 Thailand