The TECNIS iTec Preloaded Delivery System
Predictable Delivery in Three Simple Steps

With streamlined preparation, the TECNIS iTec Preloaded Delivery System is designed to improve efficiency in the OR

1. **Ready**
   - Inject HEALON® OVD to completely fill the viewing window with protective cap on (A)
   - Remove protective cap (B)

2. **Set**
   - Advance plunger to the dwell position (hatch mark) (C)
   - Hold for at least 30 seconds, and up to 10 minutes

3. **Go**
   - Depress the plunger past the black band (D) until locked
   - Do not wait more than 1 minute in this position or the device should be discarded
   - Insert the injector tip into the eye
   - Turn plunger clockwise to slowly release the IOL

**Indications:** The TECNIS® 1-Piece Intraocular Lens (IOL) is indicated for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction. This device is intended to be placed in the capsular bag. See Important Safety Information on the back page.
TECNIS iTec Preloaded Delivery System

Predictability ▪ Efficiency ▪ Safety ▪ High-Quality Visual Outcomes

- Preloaded with TECNIS® 1-piece IOL
- 2.2 mm–2.4 mm incision
- Screw-style insertion
- Latex-free

Important Safety Information—TECNIS® 1-Piece IOL with the TECNIS iTec Preloaded Delivery System

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Warnings: Physicians considering lens implantation should weigh the potential risk/benefit ratio for any conditions described in the TECNIS® 1-Piece IOL with the TECNIS iTec Preloaded Delivery System Directions for Use that could increase complications or impact patient outcomes. Do not push the plunger forward to fully advance the lens until ready for lens implantation. Discard the device if the lens has been fully advanced for more than 1 minute. The TECNIS® 1-Piece IOL should not be placed in the ciliary sulcus. Use of methylcellulose viscoelastics is not recommended.

Precautions: The use of viscoelastics is required when using the TECNIS iTec Preloaded Delivery System. Do not use if the TECNIS iTec Preloaded Delivery System has been dropped or if any part was inadvertently struck while outside the shipping case. Do not reuse, resterilize, or autoclave.

Adverse Events: The most frequently reported adverse event that occurred during the clinical trial of the 1-Piece IOL was macular edema, which occurred at a rate of 3.3%. Other reported reactions occurring in less than 1% of patients were secondary surgical intervention (pars plana vitrectomy with membrane peel) and lens exchange (due to torn lens haptic). Caution: Federal law restricts this device to sale by or on the order of a physician. Attention: Reference the Directions for Use labeling for a complete listing of Indications, Warnings and Precautions.

Important Safety Information—Healon® Products

Indications: Healon®, HEALON5®, HEALON GV® and HEALON EndoCoat® OVDs are used to maintain a deep anterior chamber within the eye during ophthalmic surgical procedures to allow efficient manipulation, separation and control of ocular tissues with reduced trauma to the corneal endothelium and other ocular tissues. HEALON® OVD is also used in posterior segment surgery as a surgical aid to separate, maneuver and hold tissues. HEALON EndoCoat® OVD may also be used to coat intraocular lenses and insertion instruments prior to intraocular lens implantation.

Precautions: Remove carefully and completely from the eye by irrigating or aspirating to reduce the risk of early postoperative intraocular pressure (IOP) spikes. Patients with preexisting glaucoma, other causes of compromised outflow, higher preoperative intraocular pressure and surgical complications are more susceptible to postoperative IOP elevation and should be treated with additional care. Carefully monitor intraocular pressure and treat with pressure lowering therapy if required. In posterior segment procedures with HEALON® OVD in aphakic diabetic patients, special care should be exercised to avoid using large amounts of the product. Express a small amount of product prior to use and carefully examine the remainder as it is injected into the eye. Because all HEALON® OVDs contain trace amounts of protein, physicians should be aware of potential allergic risks, such as postoperative inflammation, that may occur with the injection of biological materials. Warnings: The HEALON EndoCoat® OVD delivery system is not designed or intended to be attached to instruments other than the one provided with the product, as it may cause cannula detachment. When using HEALON EndoCoat® OVD for surgery, the eye should not be irrigated with any solution containing benzalkonium chloride, because the mixing of quaternary ammonium salts, such as benzalkonium chloride, with sodium hyaluronate results in the formation of a precipitate. Adverse Events: Increased intraocular pressure has been reported after use of HEALON®, HEALON5®, HEALON GV® and HEALON EndoCoat® OVDs. In rare instances, postoperative inflammatory reactions as well as corneal edema, secondary glaucoma, and corneal decompensation have been reported. Attention: Reference the Directions for Use labeling for a complete listing of Indications, Warnings, and Precautions.