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X1 Ready-Loaded Iris Speculum - Instructions for Use - English

For product reference number: 346722 // UDI: 00813059013927

1.0 Device Description

The Xpand^{NT} X1 Ready-Loaded Iris Speculum is comprised of two functional components:

- Xpand^{NT} Iris Speculum
- X1 Iris Speculum Injector

The Xpand^{NT} Iris Speculum is made from Nitinol. The X1 Iris Speculum Injector is made from white, Polyoxymethylene copolymer (body), titanium (moving parts: plunger with flat jaws and button), and stainless steel (cannula). The Xpand^{NT} Iris Speculum is pre-loaded inside the X1 Iris Speculum Injector. The device is sterilized using Irradiation and is packaged inside a disposable Tyvek® sealed tray. The cannula has an outer diameter less than 1.5 mm. The speculum has an inner diameter of 6.7 mm +/- 10%.

2.0 Intended Use

- The X1 Ready-Loaded Iris Speculum is a medical device used during cataract surgery to mechanically dilate the iris. It is used when the pupil will not dilate via normal means due to chronic parasymphomimetic drug use, scarring or trauma, if the patient has an unusually small pupil, or if the patient exhibits factors that would require a pupil expansion device.
- The device is used to dilate the capsulorhexis or suspend the capsular bag with the iris when additional support is desired. It is used when pupil mydriasis is insufficient or in cases of apparent zonular weakness or loss. The Xpand^{NT} Iris Speculum can be used on the iris, iris-capsule, or capsule alone. This capsular support technique is known to Diamatrix as "capsular expansion" or "iris-capsular capture".
- This X1 Ready-Loaded Iris Speculum and its components are provided sterile and single-use.

3.0 Clinical Benefits

The Xpand^{NT} X1 Ready-Loaded Iris Speculum facilitates ophthalmic surgeries by providing surgeons with easier access to the pupils.

4.0 Device Lifetime

The Xpand^{NT} X1 is single use. If it passes the visual inspection as described in this IFU, it can be expected to perform as intended during the surgical period.

5.0 Precautions / Contraindications

Caution: This Xpand^{NT} Iris Speculum contains nitinol, an alloy of nickel and titanium. Persons with allergic reactions to these metals may suffer an allergic reaction to this device. Prior to use, surgeons should consider a potential for allergy / hypersensitivity to these materials for each patient and assess the risk to the patient with respect to the limited exposure the device contacts ocular tissue when using the device intraoperatively.

- Visually inspect all sterile barrier packaging and product before use. Do not use if any component of the device or its packaging is distorted or broken.
- Sterility is assured only if package is undamaged. Once the seal on the sterile package is broken, the product should not be re-sterilized.
- Do not attempt to repair any damage yourself.
- The width of the incision wound must be greater than 2.4 mm to allow the cannula to enter the anterior chamber (AC).
- Do not use the device for capsular support without a Continuous Curvilinear Capsulorhexis (CCC) that is at least 4.5 mm in diameter.
- Use of the Xpand^{NT} Iris Speculum for capsular support requires an intact anterior capsular edge.
- There is no preparation for use necessary. The device is ready for use.
- Use of the Xpand^{NT} Iris Speculum is restricted to qualified physicians and should only be used by those physicians familiar with techniques employed during ophthalmic surgical procedures. Sound professional judgment must always be used in determining if a medical device is fit for surgical use and the physician has the sole responsibility in making that determination.
- Discard if the device is tangled or fails upon deployment.
- Ensure that other devices do not become ensnared around the ring (e.g. IOL haptics, CTRs, suture, etc.).
- This device is intended for single use and should not be reused or reprocessed. Reuse or reprocessing of single use devices may compromise the device's integrity and result in injury to the patient.
- The Xpand^{NT} is not an implantable device and has not been tested for implantation. Remove the ring from the eye after use.

6.0 Storage

- The Xpand^{NT} X1 Ready-Loaded Iris Speculum should be stored in an area that provides protection from the loss of sterility.

7.0 Handling

- All persons using this device should be knowledgeable in the use and handling of surgical instruments, accessories, and related equipment.
- Improper handling can render the instrument unsuitable for its intended use or even dangerous to the patient or surgical staff.
- All products should be treated with care. Improper use or handling may lead to damage and / or a malfunction of the device.



8.0 Instructions for Use



8.1 Insertion

8.1.1 *Insertion for the Mechanical Dilatation of the Iris*

- 8.1.1.1 Introduce Ophthalmic Viscosurgical Device (OVD) into the AC and under the iris rim.
- 8.1.1.2 Insert the cannulated lumen of the X1 Injector into the AC via an incision large enough to accommodate the cannula's width and position the Injector tip to mid-pupil
- 8.1.1.3 Advance the X1 Injector plunger slowly, allowing only the distal foot of the XpandNT to emerge from the cannulated lumen.
- 8.1.1.4 Engage the distal iris rim with the foot of the Xpand^{NT}.
- 8.1.1.5 Push the X1 Injector plunger toward the Injector tip while slowly withdrawing the Injector from the AC. Allow the two lateral feet of the Xpand^{NT} to emerge from the cannulated lumen.
- 8.1.1.6 Engage the Xpand^{NT}'s lateral feet with the lateral iris rim or allow the ring to rest on top of the iris.
- 8.1.1.7 Continue to push the X1 Injector forward until the Xpand^{NT} and the X1 Injector head to emerge from the cannula. When the plunger exits the cannula, observe that the jaws fully open and the ring disengages from the Injector. With the X1 Injector's jaws fully open, the Xpand^{NT} is no longer held by the Injector.
- 8.1.1.8 Allow the Xpand^{NT} to rest on the proximal iris rim.
- 8.1.1.9 Using an ophthalmic microsurgical manipulator (commonly referred as a push-pull manipulator, manipulating hook, or lens manipulator) or similar device, engage the proximal foot of the Xpand^{NT} and place it on the proximal iris rim.

8.1.2 Insertion for the Capsular Expansion with Iris Expansion

- 8.1.2.1 Follow the steps 8.1.1.1-8.1.1.9 above
- 8.1.2.2 Following the creation of a continuous curvilinear capsulorhexis, using the push / pull manipulator or similar device, disengage one device foot from the iris and engage both the CCC edge and the iris.
- 8.1.2.3 Repeat step 8.1.2.2 for the remaining feet as desired.

8.2 Removal

8.2.1 *Removal using push-pull*

- 8.2.1.1 Following lens implantation and prior to removal of the OVD, using a push / pull type manipulator, disengage all four feet of the Xpand^{NT} from either the pupillary margin or the capsule.
- 8.2.1.2 Using the same or similar push / pull device, engage the proximal foot of the Xpand^{NT} and remove the device from the AC via the primary incision.

8.2.2 *Removal using the X1 Iris Speculum Injector*

- 8.2.2.1 Following lens implantation and prior to removal of the OVD, using a push / pull type manipulator, disengage all four feet of the Xpand^{NT} from either the pupillary margin or the capsule and push the ring away from the primary incision.
- 8.2.2.2 Insert the X1 Injector cannula into the AC in the retracted position.
- 8.2.2.3 Fully advance the X1 Injector to allow its jaws to open.
- 8.2.2.4 Engage the Xpand^{NT} Iris Speculum and slide the X1 Injector button rearward to close the jaws and visualize the ring entering the cannula.
- 8.2.2.5 Retract the Xpand^{NT} Iris Speculum until it is fully within the cannula.
- 8.2.2.6 Remove the X1 Injector with the Xpand^{NT} Iris Speculum inside the cannulated tip.

Note: It may be desirable for the surgeon to use a second instrument to guard the cornea's epithelium while removing the Xpand^{NT} Iris Speculum.

9.0 Disposal

Dispose of the Xpand^{NT} Iris Speculum and the Injector in a proper medical waste container.

10.0 Complaints

For product complaints, contact Diamatrix. Patient's in the European Union experiencing a serious incident in relation to the device should contact Diamatrix and the competent authority of the Member State in which they are established.

11.0 Components

- Four (4) Xpand^{NT} X1 Ready-Loaded Iris Speculum
- One (1) Instructions for Use

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Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner.



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