Xpand^{NT} Single Use Iris Expansion System - Instructions For Use – English

For all Xpand^{NT} product reference numbers beginning with "34"

1.0 Intended Use:

The Xpand^{NT} Iris Speculum is a device for the mechanical dilation of the pupil during cataract surgery. It is generally used when the pupil will not dilate via normal means due to chronic parasympathomimetic drug use, scarring or trauma, or if the patient has an unusually small pupil.

2.0 Precautions:

- Use of the device is restricted to qualified physicians and should only be used by those physicians familiar with techniques employed during
 ophthalmic surgical procedures. As with all medical devices, sound professional judgment must always be used in determining if a device is fit
 for surgical use and the physician has the sole responsibility in making that determination.
- All persons using this device should be knowledgeable in the use and handling of surgical instruments, accessories and related equipment.
- Do not use if damaged (broken, misshaped, etc) and do not attempt to repair any damage yourself.

3.0 Device Description:

The Xpand^{NT} is made from a medical implant-grade titanium alloy and the carrier is a medical implant-grade polystyrene. The single-use device is packaged sterile, inside a Tyvek[®] pouch.

4.0 Instructions for Use:

Note: The Xpand^{NT} Speculum is pre-packed inside a specially made, rectangular carrier. The carrier is the vessel for storage of the device prior to use. The device is intended to be used with the Xpand^{NT} Injector (item 52660, not included).

Videos showing the surgical procedure can be found online at www.diamatrix.com

Once the Xpand^{NT} Speculum and carrier have been removed from the Tyvek[®] pouch:

- 4.1 Loading the Xpand^{NT} Into the Injector:
 - 4.1.1 With the injector actuator button all the way forward and the groove of the carrier facing up, lay the injector into the groove of the carrier and slide the injector along the groove until the neck of the injector is flush with the carrier. Ensure the injector lumen is oriented properly to the carrier by confirming the lip of the lumen is flat against the bottom of the carrier.
 - 4.1.2 Engage the proximal foot of the device with the horizontal hook of the injector tip.
 - 4.1.3 Draw the device back into the injector lumen by sliding the actuator button to the rear. Ensure the device is fully inside the injector lumen.
- 4.2 Inserting the Xpand^{NT}:
 - 4.2.1 Introduce Ophthalmic Viscosurgical Device (OVD) into the anterior chamber (AC) and under the iris rim.
 - 4.2.2 Slide the injector cannula into the AC via the primary incision and position the lumen to approximately mid-pupil.
 - 4.2.3 Advance the injector plunger so the distal foot of the Xpand engages the distal iris rim.
 - 4.2.4 Continuing to inject, allow the two lateral feet to emerge from the lumen and engage the iris rim while the proximal foot rests on the anterior iris.
 - 4.2.5 Using the Williamson manipulator (item no.24277) or similar device, engage the proximal foot and place it on the proximal iris rim.

Note: If the proximal and distal feet are aligned with the primary incision the Xpand^{NT} is in the proper position.

- 4.3 Removing the Xpand^{NT} from the AC:
 - 4.3.1 Following lens implantation and prior to removal of the OVD, using a push/pull type manipulator, such as the Williamson Xpand Manipulator (item 24277), disengage all four feet.
 - 4.3.2 Reintroduce the injector through the primary incision and place the proximal foot of the Xpand^{NT} on the footplate of the injector lumen.
 - 4.3.3 Engage the device with the horizontal hook of the injector tip.
 - 4.3.4 Drawing the actuator button to the rear of the injector, allow the device to fully enter the lumen of the injector cannula. Remove the injector through the primary incision.
 - 4.3.5 Remove Xpand^{NT} from the injector by advancing the actuator button. Dispose of the Xpand^{NT} and its carrier.

5.0 Contents:

- Five (5) Xpand^{NT} Devices
- One (1) Instructions for Use

444	Diamatrix Ltd, 210 Nursery Road, The Woodlands, Texas 77380 USA www.diamatrix.com
(The second s	Do Not Re-Sterilize
R_XOnly	Available By Prescription Only
Ĩ	Consult These Directions for Use Prior to Using This Device
8	Single Use Only
\odot	Do Not Use if Packaging is Damaged
STERILE R	Sterilized via Irradiation

Xpand NT Injector Directions for Use

The Xpand NT Injector (REF 52660) is designed to deliver the Xpand through a 2.4mm incision or greater.

When using with Xpand NT item 146701 (Multi-Use) After following the directions for use for cleaning the Xpand NT (DFU140000A), proceed with the steps below.

When using with Xpand NT item 346701 (Single-Use) Proceed immediately to the steps below after removing the Xpand NT device from the sterile pouch.





After following the directions for cleaning and sterilization, (TF 60006) advance the actuator button all the way forward, exposing the tip of the actuator.



Insertion



Slide the injector tube along the groove to the internal stop. Engage the Xpand NT, drawing it into the tube.



Insert the injector tube into the AC. Advance the actuator button and engage the distal foot of the Xpand NT with the iris rim.



Slowly advance the Xpand NT engaging the two lateral feet while withdrawing the injector and placing the proximal foot on the iris surface.



Engage the proximal foot with the manipulator and place on iris rim.



Center the Xpand NT as needed.



Disengage all four feet.





Engage small proximal foot with the actuator.



Draw the Xpand NT into the injector tube.



Clean and sterilize using manufacturers directions for use.

Doc No. DFU140003A Rev B

This document acts as a supplement to DFU140000A or DFU340000A, not as a replacement. DFU140000A or DFU340000A must still be followed.



Diamatrix Hand-Held Reusable Instruments Care and Cleaning Supplement to TF 60005 for Item 52660

This document is a supplement to Document No. TF 60005, Hand Held Instrument Care, Cleaning and Sterilization Instructions. The instructions below should be performed prior to step 3a of Document No. TF 60005.

1) <u>Cleaning:</u> a) Thoro

- Thoroughly clean the device prior to each use:
- i) Rinse the exterior surfaces of the injector with distilled water to remove all surface contaminants/residues and wipe it with a lint-free cloth.
- ii) Position the injector button actuator to the open position and attach tubing* by sliding it over the injector tube as seen below.
- iii) Fill a 10 ml syringe with distilled water.
- iv) Flush the distilled water from the syringe through the injector tube and out the actuator slot.
- v) Repeat steps iii and iv three more times.
- vi) Proceed with step 3a of TF 60005



*Tubing and Luer-Lock supplied with Item 52660

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Diamatrix Hand-Held Reusable Instruments Care, Cleaning and Sterilization Instructions

Proper cleaning, rinsing and drying will contribute significantly to the useful lifespan of your instruments.

- 1) <u>Cleaning</u>
 - a) Immediately after surgery, rinse the instrument with distilled water. Never let foreign materials, such as BSS or proteins, dry on the instrument.
 - b) Clean the instrument with a mild soap solution and gently scrub stubborn stains with a soft toothbrush as needed, paying particular attention to joints and serrations, which are primary locations for foreign particles to accumulate. Do not use metal brushes, steel wool or abrasive powders that will seriously damage the surface finish of instruments.
 - c) Completely rinse the instrument with distilled water, followed by air drying, before returning them to the instrument tray for storage. Instruments may also be dried using a lint-free cloth or a hot-air blower.
- 2) Lubrication
 - a) Most instruments should not require lubricating baths, but it is recommended that an instrument with joints and moving parts be lubricated after cleaning. Treat such parts with a steam-permeable, water soluble, instrument lubricant following each cleaning and prior to sterilization.
- 3) <u>Ultrasonic Cleaning</u>
 - a) The best method for cleaning the instrument is to use an ultrasonic cleaner. Ultrasonic cleaning is recommended for all instruments at the end of each surgical day or after a number of surgical procedures as indicated by the appearance of the instrument.
 - b) Follow the instructions as supplied by the manufacturer of your ultrasonic cleaner. Always use distilled water for ultrasonic cleaning or a cleaning agent specifically recommended for surgical instruments.
 - c) Water temperature of approximately 150°F (65°C) is ideal for this purpose and will produce the best cleaning results. Many ultrasonic cleaners come with built-in heaters, but if your unit does not have one, you may use an immersion heater or heat the water in a separate stainless steel container.
 - d) The instrument(s) should be placed in a wire or perforated plastic basket and suspended in the cleaning solution to avoid damaging delicate tips. Instruments must be totally submerged in the solution but should not be in contact with each other. If you use ultrasonic cleaning regularly, a cleaning cycle of approximately 5 minutes should be adequate, but some debris may require additional time.
 - e) After the ultrasonic cycle, thoroughly rinse the instrument under running water and then follow with a final rinse in a clean bath of distilled water. Cleaning and rinsing solutions should be replaced frequently.
 - f) Air-dry the instrument or dry with a hot-air blower or a lint-free cloth before returning it to storage.
- 4) Inspection and Storage
 - a) All microsurgical instruments should be inspected under magnification at the end of each surgical day by qualified personnel to ensure they're in proper working condition. Damaged instruments should be removed from circulation and immediately repaired or replaced.
 - b) Instruments with delicate tips should be stored using a protecting cover.
 - c) The instrument should be stored in the same container in which it will be sterilized. If multiple instruments are in the same tray, they should not be touching.
- 5) Sterilization
 - a) Instruments should be sterilized in the open or unlocked position, if applicable.
 - b) Instruments made of different alloys should be cleaned and sterilized separately.
 - c) Steam autoclave sterilization is recommended. Standard autoclave cycle:
 - i) Steam sterilize at 270°F (132°C) for 5 minutes.
 - Other time and temperature cycles may be used but the user must validate any deviation from the recommended time and temperature. Refer to the manufacturer of your autoclave to confirm appropriate cycle settings. Autoclave temperatures should not exceed 280°F (137°C) to avoid damage to any non-metallic parts.

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