

DK7797-3 INSTRUCTIONS FOR USE
PLEASE READ ENCLOSED INSTRUCTIONS BEFORE USING THIS DEVICE



Duckworth & Kent
Ophthalmic Titanium Surgical Instruments



DK7797-3

Screw Thread Injector

1. Introduction

Indication For Use: The DK7797-3 Screw Thread Injector is used in combination with a MONARCH® II B or C cartridge or a MONARCH® III C or D cartridge for implanting Alcon® qualified ACRYSOF® intraocular lenses into the capsular bag.

Description

DK7797-3 Screw Thread Injector is a reusable device designed to be used with the MONARCH® II and MONARCH® III IOL Delivery System.

Production according to EU-Directive

Design and manufacture of this medical product has been carried out in accordance with EU-Directive 93/42/EEC.

Qualified Users

Only suitably qualified trained staff may use this device.

2. Unpacking

Device when sold is supplied fully assembled and in un-sterile packaging.

3. Injector Components

The Screw Thread Injector DK7797-3 comprises one main component, as shown in figure 1.



figure 1

4. Instructions For Use

Prior to Use

Sterilize the device according to the method specified under the section "Cleaning and Sterilization". Sterility assurance is of the user.

Prior to use, perform the following test to ensure that the Screw Thread Injector is in good working condition.

- Advance the tip until it stops in the 'pre-load' position (figure 2). Engage the thread by rotating the knurled knob in a clockwise direction. Continue rotating to fully advance the tip out of body (figure 3). Rotate the knurled knob in an anti-clockwise direction and ensure tip returns into body after being fully advanced. Ensure there is no resistance throughout the tip movement.
- Visually inspect the tip end and thread mechanism to establish there is no damage or mineral deposits. Do not use the device if the tip appears bent or damaged in any way.

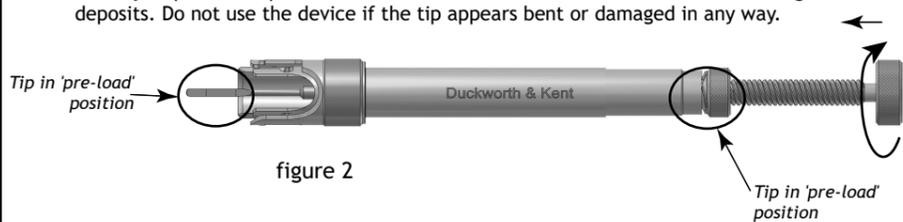


figure 2



figure 3

Loading Cartridge

Always refer to the manufacturers instructions on preparing the MONARCH® II and MONARCH® III sterile single use cartridge and ACRYSOF® lens. To ensure a successful IOL delivery and implantation, correct loading and setting of the IOL into the cartridge is essential. We recommend the Duckworth & Kent Pre-Load forceps (ref: DK7717E) for loading IOL into the correct 'pre-load' position in cartridge.

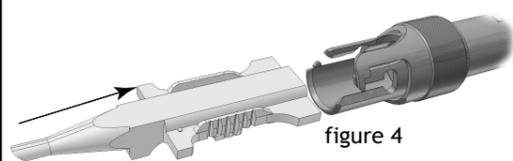


figure 4

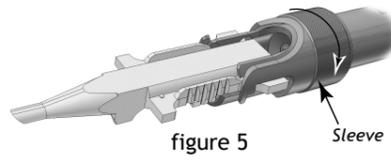


figure 5

Sleeve

As shown in figure 4, insert the cartridge into the Screw Thread Injector from the front. Fully slide the cartridge backwards into the Screw Thread Injector, and rotate sleeve until it stops to lock the cartridge in position, as shown in figure 5.

4. Instructions For Use (continued)

Delivery



Always refer to the manufacturers instructions for details about delivery with the MONARCH® II and MONARCH® III sterile single use cartridge and implantation of the ACRYSOF® lens.

5. Cleaning and Sterilization

These are only instructions for Screw Thread Injector (DK7797-3). For procedure of cleaning and sterilization any part of MONARCH® II and MONARCH® III System, refer to the manufacturers instructions.

First Use

Device is supplied "non-sterile" and must be thoroughly cleaned before first sterilization and first use. The device must also be cleaned and sterilized after each subsequent use.

Disassembly

Remove and dispose of cartridge. The Screw Thread Injector comprises of two components (figure 6), the "main body" and the "plunger and tip". It is recommended that the Screw Thread Injector is cleaned and sterilized separated, as shown in figure 6. To separate plunger and tip from main body, grip the main body of the plunger and tip and push forward into main body (figure 7), then rotate in a counter-clockwise direction. Ensure the tip does not get caught in the spring during retraction from the main body.

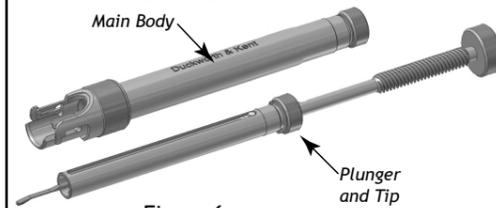


Figure 6

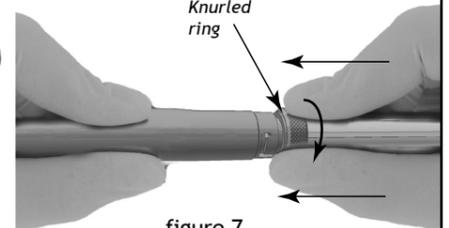


figure 7

Cleaning

It is recommended that a non-ionic detergent suitable for cleaning metallic surgical instruments such as Lancerzyme is used. Fully immerse the two components of the disassembled Screw Thread Injector into a detergent solution not exceeding 30°C. Wash and scrub vigorously the two components with an appropriate brush for at least one minute, applying the detergent solution to all surfaces. It is recommended that the instrument be cleaned as soon after use as possible, however where blood, tissue, saline or viscoelastic has been left to dry it is recommended that the two components are left to soak for 30 minutes in the detergent solution. After manual cleaning, rinse the components in clean water for a minimum of 3 times. Place the two separated components in a suitable container and subject to an automatic dishwasher cycle, consisting of 3 key elements, a 2 minute pre-wash, a 3 minute detergent wash at 93°C and a drying stage sufficient to ensure complete absence of moisture on the two components. Avoid any acid based products when cleaning the instrument and always follow the guidelines set by the detergent manufacturer and mechanical cleaner manufacturer.

Sterilization

Moist heat (steam) in autoclavable bags is the preferred method of sterilization. Please ensure system manufacturers guidelines are followed at all times. A validated sterilization cycle of a maximum temperature of 126°C with a holding time of 26 minutes is recommended. Please reference the ANSI/AAMI Guideline for Good Hospital Practice for Steam Sterilization and Sterility Assurance (ST46 2002) section 5.8.1., "Sterilization Cycle Parameters for Wrapped or Containerized Items."

All cleaning and sterilization processes require validation at the point of use. Their effectiveness will depend on many factors and it is only possible to provide general guidance on proper instrument cleaning and sterilization.



Where possible Sterilizing Trays should be used to hold the Screw Thread Injector secure to reduce damage during cleaning and sterilizing. Never stack other instruments on top of the Screw Thread Injector.

General Care

- Do not allow blood, tissue, saline or viscoelastic to dry on the Screw Thread Injector.
 - Never use saline or balanced salt solution for rinsing the Screw Thread Injector.
- Duckworth & Kent has validated the reprocessing parameters stated above to ensure that they will produce a sterile instrument. The user is responsible for qualifying any method that deviates from Duckworth & Kent's recommended method of cleaning and sterilizing of the injector.

Re-Assembly

To re-assemble Screw Thread Injector, hold main body of device and hold knurled ring of the plunger and tip, as shown in figure 8.

Plunger and tip should be pushed slowly into main body until pin locates into slot. The pin will only enter slot one way. Rotate plunger and tip clockwise until pin locks into position.

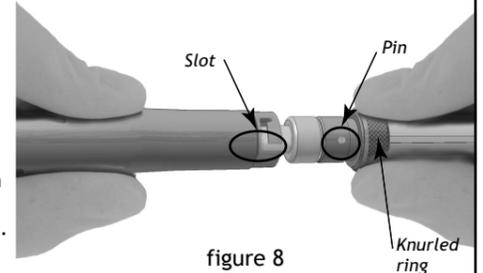


figure 8

Limitations on reprocessing

Repeated processing has minimal effect on the instruments. End of life is normally determined by wear and damage due to use.

6. Warnings

Read the entire instructions before using this device
Never release the plunger part way through the Delivery process and/or until the optic body has been completely released.
Always refer to MONARCH® II and MONARCH® III System manufacturers Instructions for Use with reference to cartridge, IOL and delivery process.
Do not attempt to modify or alter this device as this can significantly affect the function and/or structural integrity of the design.

7. Manufacturer

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8. Symbol Information



Attention, Important note to prevent damage and/or consult accompanying documents



Manufactured in accordance with Medical Directive 93/42/EEC

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