DK7797-2 INSTRUCTIONS FOR USE

PLEASE READ ENCLOSED INSTRUCTIONS BEFORE USING THIS DEVICE

Duckworth & Kent
Ophthalmic Titanium Surgical Instruments

CE

DK7797-2

Injector

1. Introduction

Indication For Use: The DK7797-2 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
DK7797-2 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 Injector (DK7797-2) comprises one main component, as shown in figure 1.

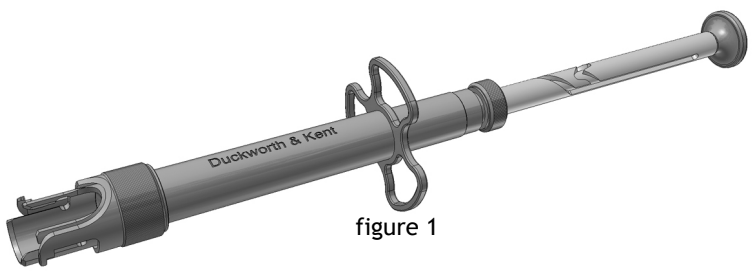

figure 1

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 Injector is in good working condition.

- Advance the tip until the plunger stops in the 'pre-load' position (figure 2). Release plunger and ensure plunger holds at 'pre-load position. Fully advance the tip out of injector body (figure 3). Slowly release plunger and ensure tip returns into body after being fully advanced. Ensure there is no resistance throughout the plunger movement.
- Visually inspect the tip end and plunger 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.

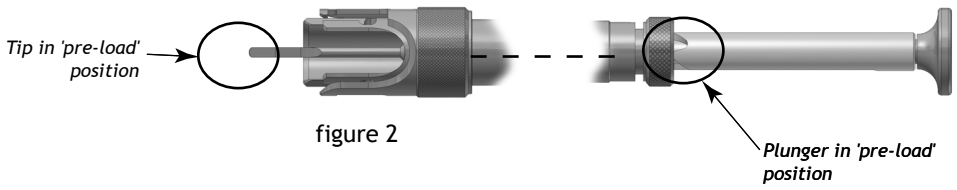

figure 2

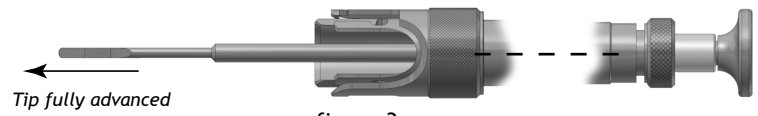

figure 3

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.

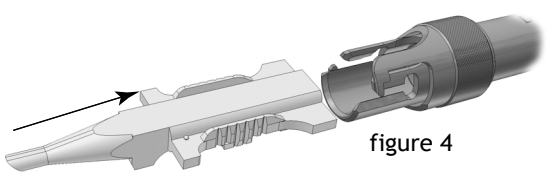

figure 4

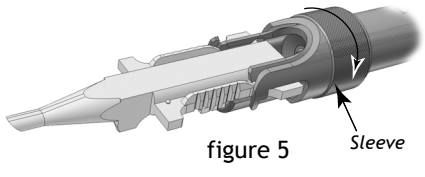

figure 5

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

Pre-Delivery
To advance the plunger, apply pressure to the thumb pad at the end of the plunger. The plunger tip should make initial contact with the cartridge ramp. Advance the plunger forward until the plunger physically stops. Release the plunger and the tip and plunger will hold in the 'pre-load' position, as shown in figure 2.

! **With the IOL in the right location (refer to section loading cartridge), when advancing the plunger to pre-load position the tip will make initial contact with the IOL and move it forward 2-3mm. The plunger will then physically stop and not continue any further. Releasing the plunger brings the tip back 3-4mm from the IOL before holding at the 'pre-load' position.** ***It is essential that the plunger is pushed all the way until it physically stops to ensure the correct engagement of the 'pre-load' position.***

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.**

Place the cartridge tip to the incision and slowly advance the plunger forward from the 'pre-load' position, which in turn moves the IOL forward through the cartridge. Advance the plunger so that the lens is implanted into the eye.

Once the delivery is completed, slowly release plunger so tip retracts back into Injector.

! **Do not *release* or *fully retract* plunger until the IOL has been delivered. Doing so may require the plunger to go to the 'pre-load' position before advancing further.**

5. Cleaning and Sterilization

These are only instructions for Injector (DK7797-2). 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 Injector comprises two components (figure 6), the "main body" and the "plunger and tip". It is recommended that the Injector is cleaned and sterilized separated, as shown in figure 6. To separate plunger and tip from main body, grip the knurled ring 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.

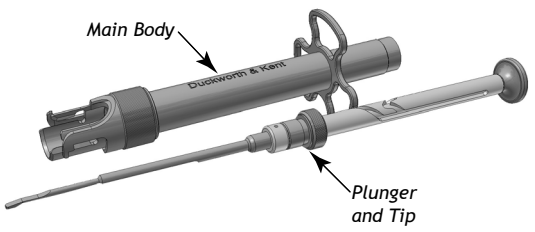

Figure 6

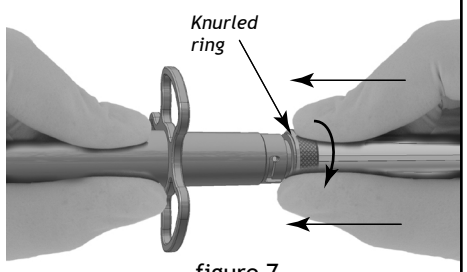

figure 7

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 the 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 surface. 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, rise 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 injector secure to reduce damage during cleaning and sterilizing. Never stack other instruments on top of the injector.**

General Care
- Do not allow blood, tissue, saline or viscoelastic to dry on the injector.
- Never use saline or balanced salt solution for rinsing the 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 injector, hold main body of device behind the flange 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.

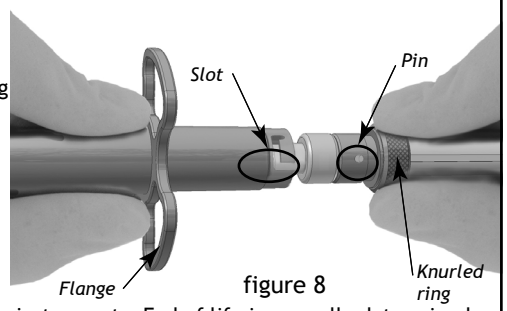

figure 8

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

Duckworth & Kent Ltd.
Terence House
7 Marquis Business Centre
Royston Road, Baldock,
Hertfordshire SG7 6XL
ENGLAND

EC REP Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

8. Symbol Information

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

Manufactured in accordance with Medical Directive 93/42/EEC

S-0314-7, DCP 6429, Printed March 2020