

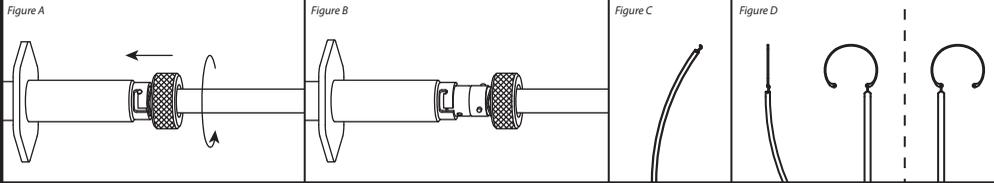


# Duckworth & Kent

ophthalmic titanium surgical instruments

7-812

## Capsule Tension Ring Inserter



### Description:

The 7-812 Capsule Tension Ring Inserter is a reusable medical device, designed to insert Bio Vision Capsule Tension Rings.

### Indication for use:

The 7-812 Capsule Tension Ring Inserter is used to deliver the Bio Vision Models CTR-11W, CTR-11B / CTR-12W, CTR-12B and CTR-13W, CTR-13B Capsule Tension Rings into the capsular bag.

### First use:

The 7-812 Inserter is supplied "Non-sterile" and must be cleaned and sterilised before first use.

### Cleaning & Disinfection:

The Capsule Tension Ring Inserter is comprised of 2 components that come apart for cleaning. By pushing and rotating the knurled ring, the body and plunger are separated. (fig A)

### Manual Cleaning:

Rinse excess soil from the device.  
Fully immerse device into detergent solution not exceeding 30°C.  
It is recommended that the device 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 device is left to soak for 30 minutes in the detergent solution.  
Using a brush, vigorously wash and scrub, applying detergent solution to all surfaces.  
It is important to ensure that no air is trapped inside the device and that the detergent covers all surfaces.  
After manual cleaning, rinse the device in clean water for a minimum of three times.

### Disinfection:

Disinfectant solution may be used in accordance with label instructions of the disinfectant manufacturer.  
After manual disinfection, rinse the device with the freshly distilled or deionised water for a minimum of 3 times. Ensure that running water passes through the device.

### Automated cleaning:

Place the 2 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 2 components.  
Avoid the use of acid based products when cleaning the device and always follow the guidelines set by the detergent and mechanical cleaner manufacturer.  
If possible, sterilising trays should be used to hold the device in a secure position during cleaning and storage to prevent damage. Store device in a dry area.  
The above instructions have been validated.

### Sterilisation:

Moist heat (steam) in autoclavable bags is the preferred method of sterilisation. Only products that have been cleaned and disinfected can be sterilised.  
Use either CE marked or validated vacuum autoclave, always following the instructions of the machine manufacturer. When sterilising multiple devices in one autoclave cycle, ensure that the steriliser's maximum load is not exceeded.  
Ensure devices are dry before sterilisation.  
A sterilisation cycle of 134°C with a holding time of 3 minutes has been validated.

### Reprocessing validation:

All cleaning and sterilisation processes require validation at point of use.

### Re-assembly of the device:

To re-assemble the Inserter, gently push the plunger into the main body and align the pin with the slot in the main body. Engage the pin in the slot and rotate the plunger clockwise until the pin locks into place. (fig B)

### Operating Instructions:

Carefully read all instructions before loading and using the Capsule Tension Ring Inserter to implant Bio Vision Capsule Tension Rings.

The Capsule Tension Ring Inserter has been designed for clockwise or anticlockwise implantation of the Bio Vision Capsule Tension Rings (CTR).

Check the Inserter is working correctly by fully depressing the Inserter plunger to expose the hook on the end of the centre rod, make sure the hook is not damaged and is free from debris. (fig C)

After unpacking the Capsule Tension Ring (CTR) in accordance with the manufacturer's instructions, the CTR can be loaded into the Inserter. Depress the plunger to expose the hook at the tip. (fig D) Carefully insert the hook into either eyelet at the end of the CTR, then slowly release the plunger to draw the CTR into the barrel of the inserter, when the plunger is fully retracted the CTR is ready for implantation.

### Implantation of the CTR:

See the Instructions for use of the Capsule Tension Ring.

### Warnings or Precautions:

When loading the CTR into the barrel of the inserter, Do not rapidly release the plunger as the CTR may be damaged.  
The CTR should be implanted within 3 minutes of loading into the inserter.  
It is important that the Inserter is cleaned directly after implantation of the CTR, because intraocular fluids, irrigating solutions or viscoelastic may have been drawn into the Inserter and should be removed as soon as possible.



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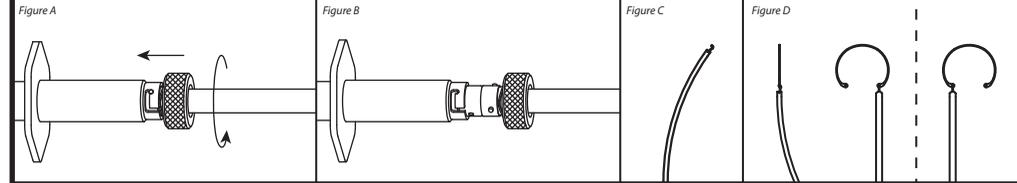


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### Implantation of the CTR:

See the Instructions for use of the Capsule Tension Ring.

### Warnings or Precautions:

When loading the CTR into the barrel of the inserter, Do not rapidly release the plunger as the CTR may be damaged.  
The CTR should be implanted within 3 minutes of loading into the inserter.  
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