MASTEL

Use and Care Instructions **Thornton Fixation Rings**



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About:

The Mastel traditional Thornton-type fixation ring is available as an open or closed ring with a swivel or fixed configuration. (See Page 3)

All rings feature highly detailed fixation teeth, providing superior fixation, as well as a high degree of safety.

All rings allow the choice of either the Bores or the more traditional Thornton style handle.



Product Application:

Fixates the globe for phaco incisions and astigmatic keratotomies

Fine-Thornton rings are designed primarily for use in forming well-controlled phaco incisions through the cut out portion of the ring. These can also be used for AK's or LRI's, using the ten degree increments machined on the faces along with blackened cardinal references for orientation to meridia. As the rings are non-numerical, this feature allows them to be finer and less bulky than numbered Mendez rings.

The complete circle Thornton rings are for astigmatism management only.

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Additional Product Information:

The open-ended or Fine Thornton model is adjustable, allowing incisions to be made in the open area of the ring.



13.00 mm 14.00 mm 14.75 mm

The teeth are engineered to fixate with minimal epithelial scratching or hymphema.

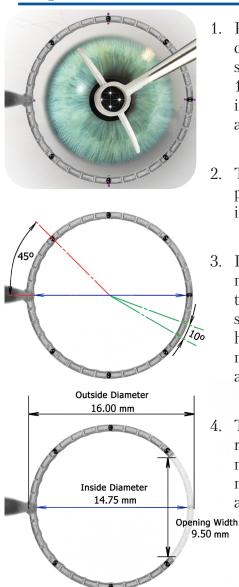
> Swivel Ring Sizes Inside Diameter

> > 13.00 mm 14.00 mm



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Surgical Use:



- Place the ring directly on the cornea. The ring's 36 teeth stabilize the eye, providing 10 degree reference points in addition to fixation and alignment.
- 2. The ring's diameter allows easy positioning of a two ray for intra-operative marking.
 - If using a fixation ring for marking: Align the ring using the cardinal references [as shown with blue line] to horizontal premarks. The steep meridian is then marked as well as the extents of the LRI's.
- 4. The opening in Fine Thornton rings is convenient for maintaining fixation when making free hand phaco or arcuate incisions.

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Use And Care:

After use, adequate cleaning and disinfection are required to maintain the marker's continued proper function.

Instruments should be sterilized between cases.

- Optimally, Mastel markers are stored and sterilized in their designated tray. Their tray may be run along with other surgical instruments in the autoclave. Standard facility cleaning procedures apply.
- When cleaning and disinfecting manually, avoid use of metal brushes, scouring agents or other aggressive methods. Ultrasonic cleaning may also be used if desired.
- The use of distilled or deionized water for all reprocessing cycles (including precleaning) is recommended.



- Products must be stored appropriately during sterilization, i.e. not on top of one another, and fixed in place with sterilization strips or plates.
- Sterilized products should be stored in a dry environment.

Sterilization:

The times and temperatures specified are minimum requirements. If, for procedural reasons, the values have to be lowered, the user must validate these. It is possible to exceed the time and temperature specifications. However, longer sterilization times and higher temperatures stress the materials, causing them to age prematurely.

Only products that have been cleaned and disinfected can be sterilized.

General sterilization criteria are listed below. Download complete *"Packaging and Sterilizing Instructions"* from the link on the following page.

Prevacuum high temperature steam sterilizer

- Four minutes at 132°C/134°C (270°F/273°F), or
- Twenty minutes at 121°C (250°F) wrapped

Gravity displacement autoclave

- Five minutes at 132°C / 134°C (270°F / 273°F), or
- Twenty minutes at 121°C (250°F) unwrapped
- Thirty minutes at 121°C (250°F) wrapped

Statim® steam sterilizer with radiant heat drying

- Three and one half minutes at 135°C (275°F) for unwrapped, or
- Ten minutes at 135°C (275°F) wrapped

Sterilization Continued:



The use of gravity displacement process must be approved by means of additional validation (longer sterilization times may be necessary).



A steam sterilizer in accordance with DIN EN 13060 and DIN EN 285 and validated in accordance with ISO 17665 (valid selection and product-specific performance qualification)



Maximum sterilization temperature 137°C (279°F) (plus tolerance range in accordance with ISO 17665)



Drying times as recommended by the sterilizer manufacturer

The manufacturer will accept no liability for other sterilization processes (e.g., hot-air, ethylene oxide, formaldehyde, radiation or low temperature plasma sterilization).

Should these be selected, validate them in accordance with the applicable standards DIN EN ISO 14937/ANSI AAMI ISO 14937 and/or process-specific standards, taking into account the specific geometry of the product, and be able to provide proof of the suitability and effectiveness of the process (including analysis of the sterilizing agent residue if applicable).

Please Visit: <u>www.mastel.com/faq/uci/</u>

To download relevant PDF's including **Validation Documents!**

These files contain complete information on **packaging**, **sterilizing**, and **preserving** the life of your instrument.

Product Numbers:

Fixed Rings		Swivel Rings	
Closed	Open	Closed	Open
25.255.1201	25.257.1201	25.266.1301	25.268.1301
25.255.1202 25.255.1301	25.257.1202 25.257.1301	25.266.1302 25.266.1401	25.268.1302 25.268.1401
25.255.1301	25.257.1301	25.266.1401	25.268.1401
25.255.1401	25.257.1401		
25.255.1402	25.257.1402		
25.255.1471 25.255.1472	25.257.1471 25.257.1472		Handles end with 1 Handles end with 2



and its team of craftsmen, engineers and service representatives strive to provide you with the very best in ophthalmic surgical instruments. Our products are delivered to you with pride.

If, for any reason, you need further assistance, please call one of our service representatives. They will provide the help you seek.

Thank You!

Certifications & Licenses:

Mastel is FDA registered.

Certifications:

• ISO 13485:2016 (MDSAP)

Licenses:

• Health Canada

Product numbers were updated 3/1/2022. For more information: please visit mastel.com/sku-update/





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