

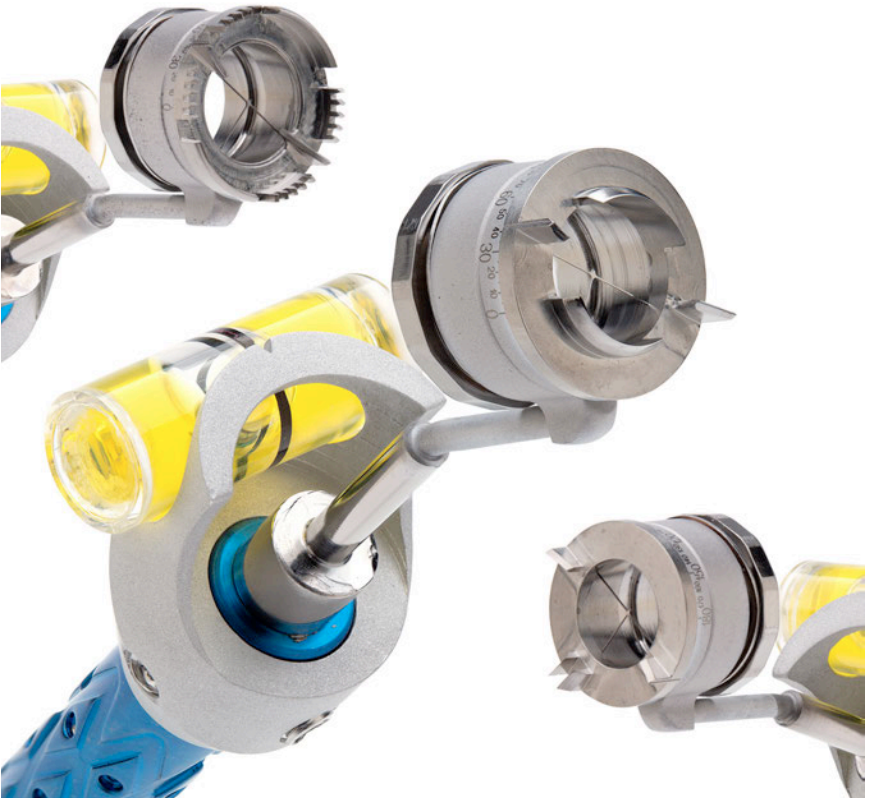


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# Use and Care Instructions

## Ambati OneStep Levels™

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## About:

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The Ambati OneStep Level™ Marker is designed to provide accurate astigmatic alignment pre-marking. The levelable handle combines with a rotating head to dial-in the desired steep corneal meridian. This eliminates the secondary step of moving from classic cardinal pre-marks to the primary meridian using a Mendez ring.

## Product Application:

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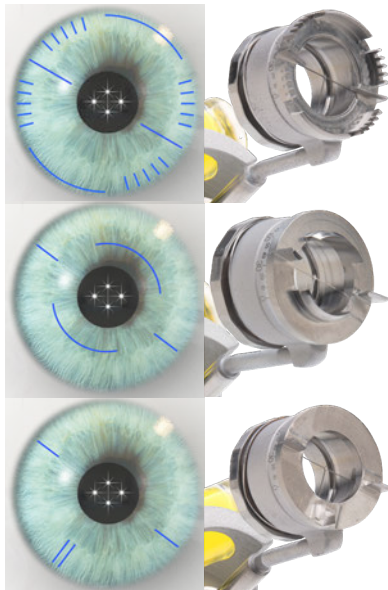
Used to pre-mark steep meridian for: AK, LRI, and Toric IOL procedures.

## Three Models:

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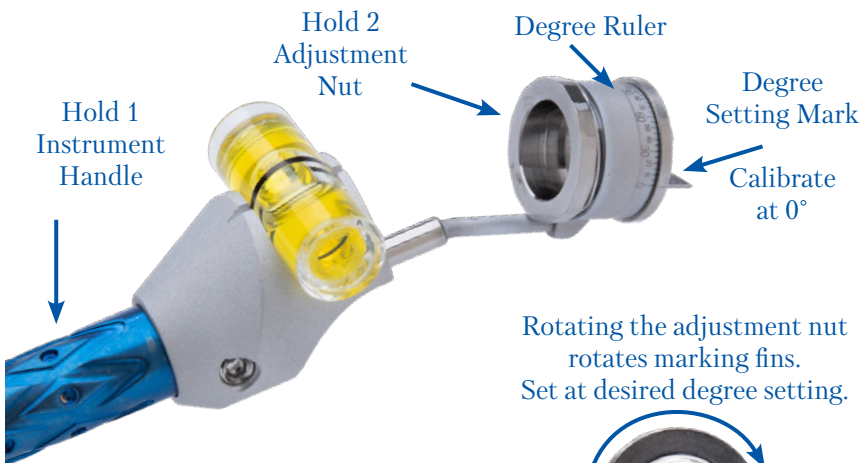
The basic function of all three models are similar. Each model marks the steep meridian.

1. The Ahmed adds in arcs at a 9.5 mm optical zone. Provides paired arc lengths of 30°, 45°, 60°, 75°, and 90°.
2. The Arc version features the steep meridian line as well as a partial capsulorhexis 5.75 mm optical zone mark.
3. The Steep/Flat (Fin) model marks three quadrants. Two form the steep meridian. The third quadrant (flat) is straddled by a pair of short fins to avoid any confusion between steep and flat.



\*Marking fins are highly tuned to facilitate inkless pre-marking.\*

# Setting The Steep Maridian:



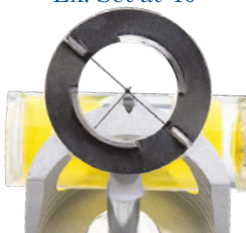
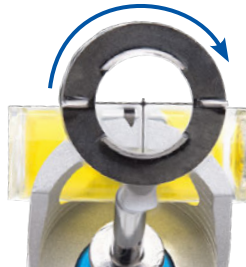
1. Hold the instrument handle in one hand and the adjustment nut in the other.

**Calibration note:** When the degree setting is 0° the crosshairs should be aligned with the top of the bubble level. Verify that the bubble is completely seated in the channel when calibrating.

2. Rotate the adjustment nut until the degree setting mark aligns with the appropriate degree setting on the degree ruler.

**Magnification Recommended:** Using a magnification device to see the degree ruler is recommended.

3. Verify setting



## Preoperative Use:

The OneStep Levels™ may be used either inside the operating room or in the pre-operative area.

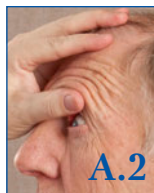


1. Remove sterile marker from its dedicated case.
2. Using a magnifying lens, rotate the meridian marks to the appropriate angle.
3. Seat the patient upright, facing you squarely.
4. Have the patient fixate on your eye to align with the visual axis.

Note: Try to bring the marker in from the side or below.

5. Common hand positions: Hold the OneStep Level™ in your dominant hand.

**A.** Use your free hand to cover the patient's fellow eye (A.1) and retract the upper lid using the thumb (A.2). Use fourth finger and pinky of marking hand to stabilize and retract patient's lower lid (A.3).



## Preoperative Use Continued:

**B.** Use your free hand to spread the patient's eyelids. It may help to have an assistant cover the patient's fellow eye. Stabilize marking hand by placing outside fingers on patient's nose or cheek.

6. Once close to the cornea, level the bubble and align the marking fins.

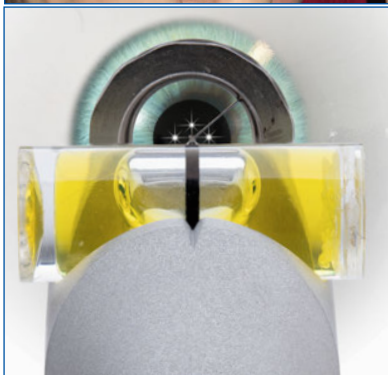
7. Keep the patient focused on a distant point, centration light or your eye.

8. Place the marks oriented to the visual axis.

9. Apply gentle pressure and hold for several seconds to ensure marking.

Note: Ink may be used on the fins if desired.

10. Remove the marker from the eye by pulling straight away from the patient.



## With or Without Ink:

- Designed for use without ink.
- Ink can be used for enhanced visibility if desired.

- Inkless corneal marks are still visible up to an hour later. Drying the eye can improve mark visualization.

## Pre-Operative Use Continued:

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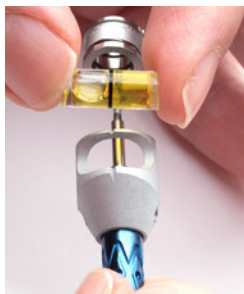
11. Remove level and return the marker to its dedicated case for cleaning, disinfection, and sterilization.



## Level Care:

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Mastel's Levels are engineered to meet sterilization needs with bubble levels that are simple to remove, clean, and replace.



Plastic levels will not survive the autoclave.

**Please remove the level from the marker prior to placing the instrument in your autoclave.**

After the level is removed it should be cleaned and disinfected prior to reuse. Levels can be wiped with or soaked in alcohol or other approved disinfectant.

A level may be reused as many times as it holds securely in its channel. If the level fits loosely it should be replaced.

Each new marker is sold with three replacement levels for your needs. [Replacement bubble levels](#) are available at Mastel (Product #: [22.102.9964](#)).

\*Please allow 3 to 5 business days to receive replacement levels.\*



## Product Features Continued:

### Bubble Removal

Hold the instrument firmly with one hand. Gently apply a tilting pressure on the ends of the level with your forefinger and thumb.

The level should come free with slight, but firm pressure.



Regular twisting of the level could bend the bracket.

Avoid touching the marker fins with your hands when removing the bubble.



### Bubble Installation



Align the level using the two alignment notches in the ridge of the saddle and the level's stripe.



A misaligned level may appear skewed during marking.

### Position Matters!

Once the level is properly centered, apply steady, firm pressure to seat the level in the bottom of the channel.

Inspect final alignment. Verify that the level is seated flat in the channel, with even space between level and channel on both sides.



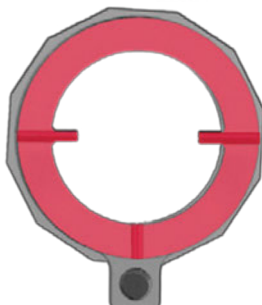
If alignment is off remove and realign the level.

## Use And Care:

After use, cleaning and disinfection are required to maintain the marker's continued proper function. Wiping the patient contact areas of the marker with an alcohol swab for 5-10 seconds is recommended prior to sterilization.

OneStep™ markers should be sterilized before each use. Mastel recommends sterilizing and storing the marker in a dedicated tray apart from other instruments.

Verify that the Level has been removed before sterilization see pages 6 & 7 for level removal and care.

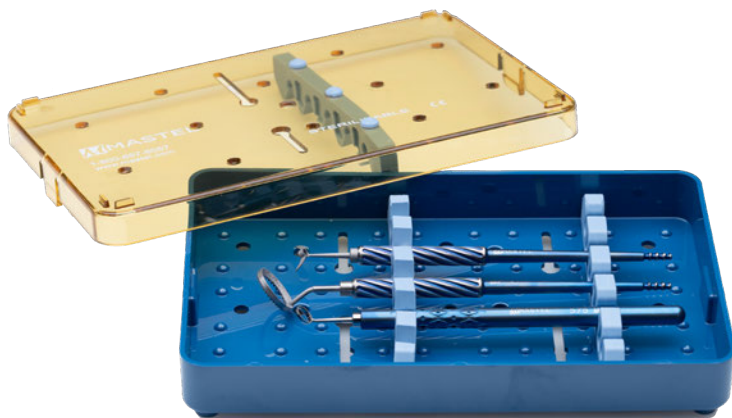




## Additional Care and Sterilization Notes:

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- Optimally, Mastel markers are sterilized in their designated tray. They may be run along with other surgical instruments in the autoclave. Standard facility cleaning procedures apply.
- Sterilized products should be stored in a dry environment.
- When cleaning and disinfecting manually, avoid use of metal brushes, scouring agents or other aggressive methods. Ultrasonic cleaning may also be used if desired.
- Products must be stored appropriately during sterilization, i.e. not on top of one another, and fixed in place with sterilization strips or plates.
- The use of distilled or deionized water for all reprocessing cycles (including pre-cleaning) is recommended.



## Sterilization:

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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:

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-  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: [www.mastel.com/faq/uci/](http://www.mastel.com/faq/uci/)**

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:

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23.114.6020	Ambati OneStep Level™ Arc
23.114.6025	Ambati OneStep Level™ Steep/Flat
23.114.6030	Ambati OneStep Level™ Ahmed

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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



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