Corneal Toric Markers - Potential Cause of Errors in IOL insertion.

Problem:

I was given a disposable Malosa 1245 Toric marker in theatre at BWH in May. I noticed that the markings were 90 different to the standard non-disposable marker.

This nearly led to the incorrect position of the toric IOL, but did not.

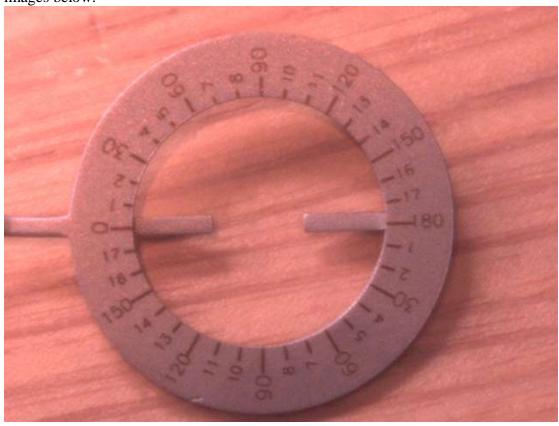
Investigation Report

I collected together information about the Degrees markings/astigmatism and presented to Ali Mearza and Nicholas Heme of Malosa for explanation.

It can be a confusing are, the optical axis can appear very confusing to all staff. Thus clear and simple advice is required.

Malosa Model 1245 - is a secondary Toric Marker, not primary and not to be used to guide the axis in the standard way. It measurers the angles from the 0 and 180

IT does NOT relate to the actual axis of Astigmatism or axis on the cornea as in the images below.



Advice to use this marker is:

Step 1 - Use the Pre-op marker, Slit Lamp etc to find the 0-180 horizontal axis.

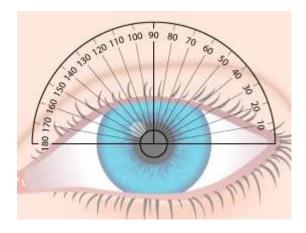
Step 2 - Find the degree on the Toric Marker which you want to mark (30 degrees for example)

Step 3 - Place the required degree (30o) onto the 0-180 axis

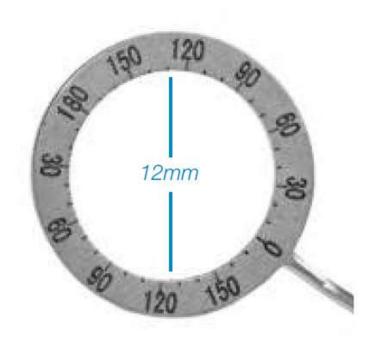
Step 4 - Place enough pressure on to the Toric marker to allow the blades to leave an indentation on the cornea. Ink can be applied to the blades to increase visibility

The blades leave a larger mark on the cornea to help locate the exact location which the Toric IOL should be dialled in at.

Below are the correct markings/axis on the cornea. It is the same for right and left eye.



Malosa 1152 - Mendez style corneal Axis guide Which corresponds to the actual axis degrees as above image.



I spoke with Company representative Nicholas Helmes and he was able to explain the 1245 is a secondary marker

He agrees there could be confusion and that marketing needs to issue a press release and change the packaging to indicate this.

I have asked to know if any have been bought by our hospitals I work in so that I can inform them.

July 15 Nicholas Lee