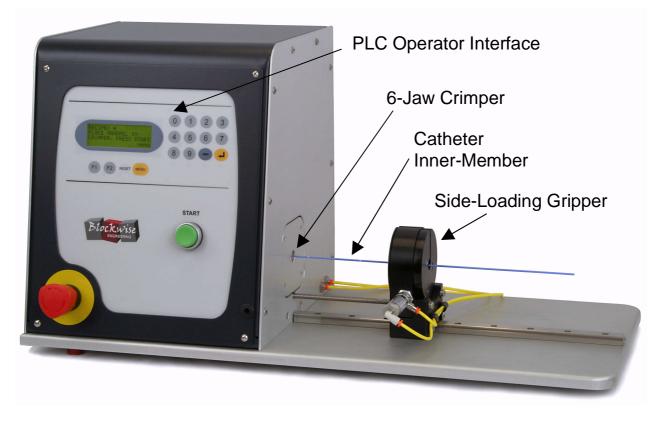
Marker Band Positioner / Precrimper Model PMC



Blockwise Engineering, LLC <u>http://www.blockwise.com</u>

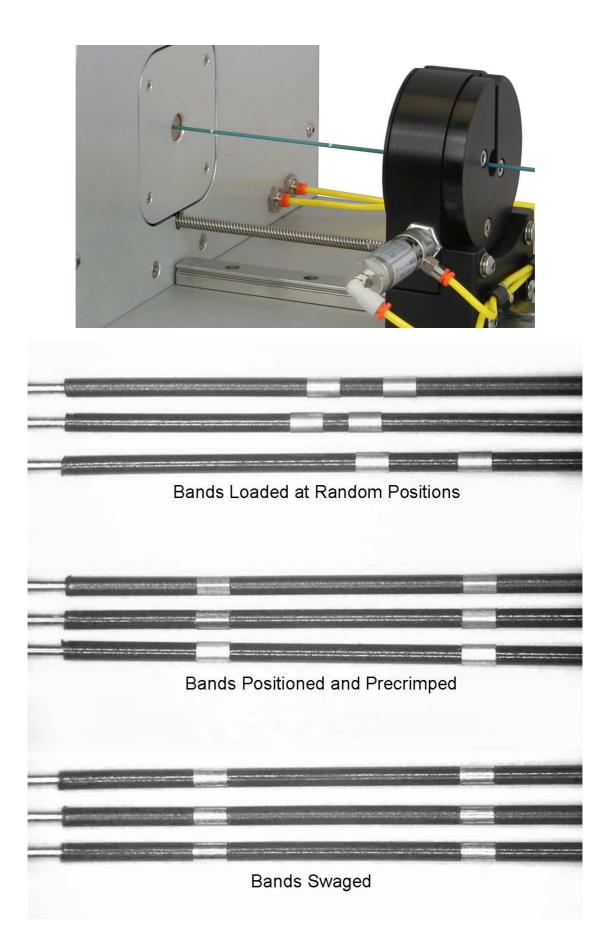
The **Blockwise marker band positioner / precrimper model PMC** is a tabletop machine that slides bands along a catheter inner member or other substrate to position them, then lightly precrimps the bands into a hexagonal shape to hold them in position prior to swaging.



The band positioner / precrimper model PMC uses a simple, reliable, mechanical approach to positioning bands, with no optical sensors or vision systems. The PLC control software can be set up by a novice in just a few minutes.

In a typical application, the product consists of an "inner member" (plastic tube) slipped over a mandrel, with two bands placed on the mandrel.

In a **typical operating sequence** (after setting up a recipe in the PLC) the operator places the catheter inner member with bands into the side-loading gripper, the mandrel into the crimper, and then presses the START button. The crimper closes, and the operator touches the tip of the inner member against the face of the crimper dies (providing a position reference for the machine), then presses the START button again. The machine then uses the crimper, with almost zero closing force, to gently slide the bands, as a group, along the inner member to a known position. Then, one-by-one, the crimper is used to grab the outside of each band to move it away from the group, then push the band into position using the face of the crimper dies, then precrimp the band into a hexagonal shape.



Cycle time depends on the process settings; typical cycle time for PTCA-type catheters is about 28 seconds.

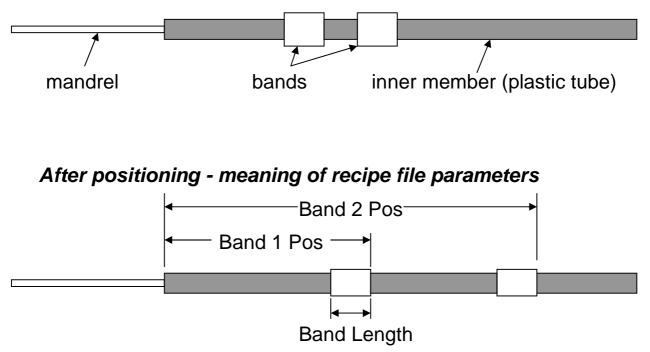
The 6-jaw crimper has 3 crimp-force settings that are used and commanded by the PLC: 1) a high crimp force (diameter-limited) for precrimping the bands into a hexagonal shape, 2) a low crimp force for grabbing the outside of a band that's adjacent to another band without deforming the band, 3) a very low (almost zero) force used when sliding the bands along the catheter by pushing them with the face of the dies. The inner member is not harmed by the dies when sliding the bands.

When precrimping the bands, the crimper diameter can be limited by a mechanical stop set by a fine-pitch adjusting screw.

The **PLC software** provides up to 100 user-changeable "recipes" that contain:

- 1) The number of bands to be positioned and precrimped (1 to 25).
- The length of the bands (Band Length in the drawing below).
 The desired positions of each band from the tip of the inner member to the right side of the band (Band 1 Pos and Band 2 Pos in the drawing below).

Prior to positioning – randomly-positioned bands



After positioning each band, the machine uses Blockwise's 6-jaw precrimper to form the band into a hexagonal shape that holds it firmly in position for swaging.



The model PMC band positioner / precrimper provides **very accurate results**. The standard deviation of band-to-band position is normally about 0.025 mm. The subsequent swaging step will slightly elongate the bands and the plastic tube beneath the bands, so the band-to-band and tip-to-band distance changes measurably. Those changes can be measured and compensated for when setting up a recipe for the model PMC machine, so that the average post-swage positions match the desired values. Besides shifting the average positions, the swaging process also adds its own position variability; in fact the additional variability from the swaging process is usually more significant than that from the model PMC positioning process.

In an experiment with 22 typical PTCA-sized catheters (44 bands), the following results were measured:

After position and precrimp - band-band distance standard deviation was 0.025 mm, tip-band distance standard deviation was 0.061 mm.

After swaging - band-band distance standard deviation was 0.051 mm, tip-band distance standard deviation was 0.069 mm.

In another experiment with 71 typical PTCA-sized catheters (142 bands) (a different catheter design from the above experiment), the following results were measured:

After position and precrimp - band-band distance standard deviation was 0.021 mm, tip-band distance standard deviation was 0.087 mm.

In yet another experiment with 20 typical PTCA-sized catheters (40 bands) (another catheter design different from either of the above experiments), the following results were measured:

After swaging - band-band distance standard deviation was 0.045 mm, tip-band distance standard deviation was 0.106 mm.

Finally, in an experiment with 12 catheters of 0.065 inch diameter and 19 bands per catheter (228 bands), the following results were measured:

After position and precrimp - overall pooled standard deviation of band position relative to a reference feature on the catheter was 0.028 mm

Measured band position results ← Tip-Band → ← Band-Band →

Specifications:

Typical Cycle Time 2 bands PTCA-type Catheter	28 seconds
Standard Deviation Band to Band Distance	0.028mm
Allowable Number of Bands:	1 to 25
Band Diameter Range:	0.25 to 4.7 mm
Maximum Tip-to-Band Distance Setting:	290 mm
Side-Loading Gripper Die Material:	Acetal Copolymer Plastic
6-Jaw Crimper Die Material:	Hardened Stainless Steel
Control System:	PLC with LCD Operator Interface Screen and Keypad
Machine Dimensions:	26 inches wide x 12 inches deep x 14 inches tall
Sequence Control:	Programmable Relay
Service Connections	AC Power 120 V or 240 V, 2A
	Compressed Air 6.9 to 8.3 bar