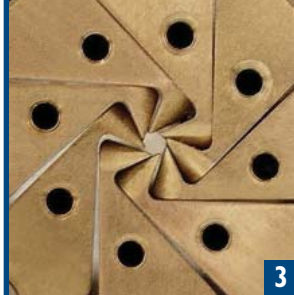
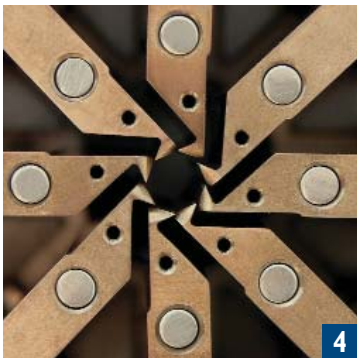




Balloon Wrapping Fixture

Model W8FH

- Cost Effective
- Compact and Easy to Use
- Capable of Processing a Wide Range of Product Sizes
- Temperature Controlled Blades
- Up to 25 lbs. (111.2 N) of Radial Force
- Electronically Adjustable Final Wrapping/Crimping Diameter
- .0005 inch (.0125mm) Radial Positioning Accuracy



GENERAL INFORMATION

Interface Associates' **Balloon Wrapping Fixture** provides controlled means for tight and accurate wrapping of a fluted balloon around the catheter shaft.

Model W8FH is a small, electrically operated tabletop unit. It employs a set of eight radially arranged blades. Precision stepper motor driven ball screws control the motion and position of the blades with 0.0005" (.0125mm) resolution. The tips of the blades are shaped in such a way that they form a cavity of an approximate circular cross section. When the blades move inward towards the center, this cavity becomes progressively smaller and vice versa. Very close tolerances of the blades guarantee a smooth and uninterrupted circumference of the cavity. The blades are machined by a wire EDM process from heat treated beryllium copper. This material offers an excellent combination of hardness and thermal conductivity.

Each blade has a built-in electric heater and a thermocouple. An eight-station temperature controller accurately maintains the blade temperature at the set value. The range of adjustment is from ambient to 125 °C (257 °F). Several different sizes of blades are available both in terms of length and cavity diameters. The detail of the blades shown in their closed position, i.e. minimum cavity diameter, is shown in Figure 3. The tip geometry allows for progressive enlargement of the cavity when the blades start moving radially away from the center of the cavity. The silver colored circles seen in Figure 4 are the tips of the heater cartridges.

To facilitate an easy and accurate insertion of a folded balloon a "V"-block guide is situated in front of the cavity (see Figure 1 & 2). This "V"-block travels on a ball bearing slide and guides the catheter tip into the cavity. A precision X-Y stage with micrometer dials (as shown in Figure 2) allow for alignment of the catheter centerline with the centerline of the cavity. For safety reasons, all moving parts of the fixture are covered by a clear polycarbonate shield.

Balloon Wrapping Fixture

USER INTERFACE:

The system consists of two components linked by signal cables. Shown on the left side in Figure 1 is the wrapping/crimping fixture and next to it is the control unit with LCD displays. The front panel controls allow the operator to set the following parameters:

- a. Speed of the blade travel.
- b. Open cavity diameter in millimeters (maximum 9.5mm on standard models, larger sizes optional).
- c. Closed cavity in millimeters (minimum 0.7mm on standard models, smaller sizes optional).
- d. Blade heating ON-OFF.
- e. Blade temperature, from ambient to 125 °C (257 °F).
- f. Blade dwell time.

Additional LED lights indicate what part of the machine cycle is currently being executed, as well as providing a visual signal of which blade temperature is being monitored at any given moment.



27752 El Lazo Road
Laguna Niguel, CA 92677
Phone: 949.448.7056
Fax: 949.448.7016

www.interfaceusa.com
info@interfaceusa.com

OPERATION

The Balloon Wrapping Fixture works in conjunction with one of several of Interface Associates' Balloon Fluting Fixtures. The balloon folding process itself consists of three distinct steps.

a) Balloon Folding.

During this step the balloon is folded into a multitude of radial flutes. The number of flutes may vary from three to eight, depending on the balloon size, material and balloon wall thickness. The flutes are heat-set by hot folding blades to enhance material shape memory. The radial flutes are held in place by vacuum that is applied to the inside of the balloon. The vacuum stays on for the next two steps of the process. The balloon fluting is performed by a separate device called a Balloon Folding Fixture (Figure 5).

b) Balloon Wrapping.

The tip of the evacuated and fluted balloon is inserted into the cavity of the wrapping fixture that is formed by eight interlocking wrapping blades. The starting diameter of the cavity is electronically adjusted to match the folded balloon envelope. Upon activation of a foot switch, miniature stepper motors start advancing the wrapping blades towards the center. As the octagon shaped cavity becomes progressively smaller, the balloon flutes are forced to curl around the shaft in a symmetrical fashion. In the final part of their travel, the blades compact the balloon with a radial force that can be as high as 25 lbs. (111.2 N). The end of the blade travel is also electronically set according to the catheter shaft diameter. The balloon re-folding characteristic is enhanced by a controlled heat input into the material during the wrapping process. After reaching the end of travel, the blades stay in full contact with the compacted balloon for a period of an adjustable dwell time (typically 10 seconds). At the end of the cycle the blades back off slightly so the wrapped balloon can be easily withdrawn from the cavity.

c) Balloon Sheathing.

The wrapped balloon profile is small and very smooth since there are no secondary creases in addition to the main folds. Furthermore, the wrapped flutes remain straight thus minimizing the possibility of material "bunching" during insertion into the sheath. The sheath can be placed on the balloon from either proximal or distal end by a simple sliding motion. Placement from the proximal end is easier and it can accommodate tighter fitting sheaths. The negative aspect is that this approach must be planned for in the early catheter assembly sequence and the sheath must be placed on the shaft prior to balloon attachment. In a majority of the cases placement of the sheath from the distal tip yields nearly identical results both in terms of balloon profile and ease of installation. As the last step, the catheter luer hub is disconnected from the vacuum source. The total cycle time ranges from 15 to 40 seconds depending on the balloon type, size and heat setting time.

SPECIFICATIONS

Balloon Sizes:	Up to 20mm x 120mm Long
Heat Setting Temperature Range:	from ambient to 125 °C (257 °F).
Size - Wrapping Fixture:	12.50 w x 13.50 h x 13.75 d (318mm x 343mm x 349mm)
Size - Control Unit:	6.0 w x 8.50 h x 8.00 d (152mm x 216mm x 203mm)
Weight - Wrapping Fixture:	9.0 to 18 lbs (4.0 to 8.2 kg)
Weight - Control Unit:	5.5 lbs (2.5 kg)
Power Requirements:	95 to 240 VAC, 50 to 60 Hz, 60W.

Revised 2/06