



Balloon Folding Fixtures

- Capable of Processing a Wide Range of Product Sizes
- Temperature Controlled Blades
- Accommodates Balloons from 1cm to 14cm long.
- Balloons can be Folded into 3, 4, 5, 6, or 8 Flutes
- Cost Effective
- Compact and Easy to Use

BALLOON FOLDING PARAMETERS

- Balloon inflated diameter
- Inner lumen diameter
- Folding blade temperature
- Heat setting dwell
- Inflation pressure
- Vacuum level



GENERAL INFORMATION

Interface Associates' **Balloon Folding Fixtures** (figure 2) are cost effective tools that are specifically developed for manufacturers of balloon catheters. These fixtures substantially speed-up, simplify and improve the balloon folding and wrapping process. In less than five seconds the balloon can be folded with high consistency and uniformity. Depending on the model selected, the balloon can be folded into three, four (figure 3),

five, six or eight flutes. Fixtures can be ordered with different lengths of folding blades that accommodate balloons from 1cm to 14cm long. The standard design folding blades can handle balloon sizes from Ø1.5mm to Ø20mm. All models are equipped with heated folding blades. The blade tips are shaped into a unique interlocking profile (figure 1) that imparts a "fan wheel" shape to the balloon folds. The fully folded balloon is then heat-set and a vacuum is applied to lock the folds in place. The folded balloon is then removed from the fixture and inserted into the cavity of the Balloon Wrapping Fixture, Model W8FH. The wrapper utilizes a principle of a variable cavity to tightly and uniformly wrap the balloon flutes around the catheter shaft. The balloon folding parameters as well as balloon inflation pressure/vacuum are selected by the operator on the front panel of a control unit (figure 4) that comes with each fixture. Customized versions are available to handle other balloon sizes.

OPERATION

The catheter is connected via a luer fitting to the front panel of the control unit. The machine cycle is started by depression of a foot switch, which causes air pressure to be applied to the shaft mounted balloon. The inflated balloon is then inserted into a cavity formed by the folding blades. To facilitate an easy and accurate insertion of the balloon, a guiding "v"-block is situated in front of the cavity. The block travels on a ball bearing slide and guides the catheter tip into the cavity. Precision X-Y stage with micrometer dials allows for alignment of the catheter centerline with the centerline of the cavity. The operator then depresses a foot switch again to activate the motion of the folding blades. The balloon walls remain under slight pressure to ensure the uniformity of folding. The blades continue moving radially towards the center of the catheter shaft. After the balloon is completely collapsed, vacuum is applied and the balloon walls fold into multiple wings or flutes. The number of flutes may vary from three to eight, depending on the type of fixture selected. Balloon size, material and wall thickness generally determine the suitable number of flutes. The hot folding blades stay stationary for the duration of selected dwell time in order to heat set the balloon material and impart it with shape memory. The vacuum remains on to lock the flutes firmly in place. Next, the folding blades move out and the folded balloon can be now transferred into the wrapping fixture. See the Balloon Wrapping Fixture, Model W8FH brochure for additional details about the process.

Balloon Folding Fixtures



CONSTRUCTION

The fixture is constructed from precision machined aluminum parts. All machined components are hard anodized to enhance surface hardness, corrosion resistance and appearance. It employs a set of radially arranged blades (3 to 8 blades). Precision stepper motor driven ball screws control the motion and position of the blades with 0.001" (.025mm) resolution. The folding blades are attached to miniature ball bearing slides, providing precision guidance. The tips of the blades are shaped in such a way that they form a complex cavity resembling a miniature "fan wheel" with curved spokes. As the blades move inward, the wrapping cavity becomes progressively smaller. Small blade tolerances guarantee a smooth motion and an interlocking fit in the fully closed position. The blades are machined from heat treated beryllium copper, using a wire EDM process. This material offers an excellent combination of hardness and thermal conductivity. Each blade has a built-in electric heater and thermocouple, with a multi-station temperature controller, accurately maintaining the blade temperature at the set value. The range of adjustment is from ambient temperature to 125 °C (257 °F). Several different sizes of blades are available both in terms of length, number of flutes and the catheter shaft diameter. The photographs (figure 1 and 5) show the detail of the five flute fixture with the blades in both closed and opened positions. For safety reasons, all moving parts of the fixture are covered by a clear polycarbonate safety shield.

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
- g. Balloon inflation pressure
- h. Balloon folding pressure
- i. Balloon vacuum

The magnitudes of individual parameters are displayed on two digital readouts and 3 dial gauges. Additional LED control lights indicate the part of the cycle the machine is currently executing and which blade temperature is displayed at that particular moment.

SPECIFICATIONS

Balloon Sizes: Up to 20mm x 120mm Long

Number Blades: 3, 4, 5, 6 or 8

Heat Setting Temperature Range: from ambient to 125 °C (257 °F)

Size - Fluting Fixture: 12.50 W x 13.50 H x 13.75 D (318mm x 343mm x 349mm)

Size - Control Unit: 10.13 W x 8.50 H x 8.00 D (257mm x 216mm x 203mm)

Weight - Fluting Fixture: 9.0 to 18 lbs (4.0 to 8.2 kg)

Weight - Control Unit: 8.0 lbs (3.6 kg)

Power Requirements: 95 to 240 VAC, 50 to 60 Hz, 60W



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