



MSI's Solution to pleating and folding long length balloon catheters

Problem:

Creating an accurate and repeatable process for pleating and folding long length balloon catheters (up to 250 mm) with the smallest possible profile.

Solution:

Machine Solutions Inc. (MSI) is the industry standard for pleating and folding PTCA and PTA balloon catheters. The patented, original Wavepleat™ technology has been successfully pleating and folding balloon catheters for years and is now available in lengths up to 250mm.

A common challenge facing many PTA device manufacturers is creating a repeatable process for pleating and folding longer length balloon catheters with the lowest possible profile. Many companies currently hand-fold their long length balloon catheters, which can be a time consuming, operator dependant process. The balloon profile, deployment characteristics and ability to re-fold upon deflation may differ greatly from unit to unit.

The MSI FFS875S and WS1275 equipment have been fitted with pleat and fold heads in 250mm lengths to address these issues. The pleat heads are manufactured in 2 to 6 pleat configurations and are made to customer specifications including: inflated balloon diameter, double wall thickness, distal seal and marker band diameters. MSI does not believe in a one size fits all approach to pleating and folding balloon catheters. Custom sizing the pleat head to the product specifications creates optimized folded balloons with the smallest profile with good deployment and re-fold characteristics of certain balloon materials.

MSI FFS Equipment Features

Eliminate operator variance

The MSI FFS equipment provides a single station design incorporating both the pleat and fold processes onto one machine base. The pleat and fold heads are made to customer specifications so that they function the same regardless of the operator. This leads to uniform processing results across all manufacturing lines and shifts.

Pleat & Fold Head Operation

As the pleat head is closing the inflated balloon is centered inside of the elements designed for this balloons dimension. Once the pleat head has come to a full close vacuum is applied and the heated (up to 120°C) elements fit tightly around the circumference of the catheter shaft they were sized to fit. The balloon material fits snugly into the wing gaps creating each identically spaced and sized Wavepleat™.

The root of each pleat originates from the closest point to the catheter shaft as possible with a definitive apex created by the elements closing to the balloon double wall thickness specification they were built for. The product then goes into the fold head, which can be heated to 120°C, while vacuum is being applied the pleats are folded from the root so that the wrap tightly around the catheter creating the lowest possible profile.

Repeatability

Our FFS pleat heads are built to extremely tight tolerances, ensuring optimized repeatable operation and process results cycle after cycle. Coupled with our precision pleat heads is our full featured servo motor operated, PLC/PC controlled machine bases which provide accurate control over all process parameters including but not limited to: diameter, temperature, balloon pressure/vacuum and delay/dwell times. Having the ability to easily and accurately control these process parameters further increases the machines repeatability.

Decreased Cycle times

The MSI FFS machines have the ability to produce equal pleats simultaneously in a single quick motion and then fold these pleats into a finished product much quicker than possible when trying to replicate this quality by hand folding or other 2 step processes.

Output

Decreased cycle time coupled with decreased rejection rates may greatly increase output.

Product Profile

The fact that our pleat heads are manufactured per customer specification to tight tolerances allows for optimized pleat creation which is then folded to the lowest possible profile utilizing our proprietary segmental compression technology.

Deployment & Re-fold

When deploying the balloon processed with the MSI FFS equipment, each pleat is identical allowing for a uniform expansion. Once deflation is initiated the pleats that were imparted in the balloon material may provide re-fold characteristics (dependant on materials) which allow the balloon to fold at the locations previously imparted in the material allowing for a low extraction profile.