

# EVA Sprial Tubing Specification

Summary Report: August 22, 2012

## Bio-Compatibility Testing

### Tubing Raw Materials:

#### Natural Tape (Membrane) Wall & Natural Helix Wall

The EVA Resin used to manufacture Natural EVA Spiral Tubing in various diameters and lengths - (Mix #1008) for helix/tape) has been tested and meets the requirements of the following Bio-Compatibility tests:

#### \*L929 - MEM ELUTION TEST - ISO 10993-5 Guidelines

This test was initiated on Jan 18/11 and finalized on Jan 31/11. The results were summarized under clinical report # 11-0119-G1.

#### \*INTRACUTANEOUR INJECTION TEST - ISO - 10993-10 Guidelines

this testing was initiated on Jan 24/11 and finalized on Feb 15/11. The results were summarized under clinical report # 11-0119-G3.

#### \*KLIGMAN MAXIMIZATION TEST - ISO 10993-10 Guidelines

This test was initiated on January 18, 2011 and finalized on March 11, 2011. The results were summarized under clinical report # 11-0119 - G2.

(All three studies were conducted in compliance with the U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.)

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