# MATERIAL SPECIFICATION FOR TVT PROLENE* POLYPROPYLENE MESH ROLL STOCK

## Revision History for MS-0000108

| Revision # | Summary of Change | Change Order # | Originator |
|---|---|---|---|
| 5 | Revised to add FM-0001276 to DMR. Revised to correct Accept/Reject criteria for Mullen Burst test. | CO-0023575 | P. Tilson |
| 4 | Revised to allow test data to be entered into electronic LIMS system. Added reference to form used for recording mullen burst and water extractable results. | CO-0022899 | P. Tilson |
| 3 | Revised Section 1-PURPOSE and Section 2-SCOPE, to include further processing of mesh by ETHICON, Aunea Facility for use in ETHICON Endo-Surgery, Inc. products. Added definition of Old Construction Mesh to Section 3. Revised width requirements for mesh within sections 4.1.1. and 4.1.2. Added Table 1 reference to Section 4.3. Revised Section 4.4.1 for packaging requirements. Removed original section 4.4.2.2. requiring verification of roll labels. Revised Section 5, bullet 3 for the number of samples SECANT Medical is to send for Cornelia for QA testing and how samples are to be pulled. Added bullet 4 under Section 5.2 to include Certificate of Conformance requirement when sending mesh material to Aunea Facility. | CO-0021696 | B. Rickenbaker |

*Trademark
**Original Revisions
//Deletions

Plaintiff's Exhibit
PX 133

## 1 Purpose

Provides requirements for incoming PROLENE* polypropylene mesh roll stock which is knitted, scoured, and heat treated by SECANT Medical; received, tested and released at Cornelia; and further processed at the Neuchâtel facility for TVT or the Aunea facility for use with ETHICON Endo-Surgery, Inc. products.

## 2 Scope

2.1 TVT PROLENE* Mesh roll stock is identified as RMC # 050165 and 050166.

2.2 TVT PROLENE* Mesh is intended for use by the Neuchâtel facility for TVT.

2.3 TVT PROLENE* Mesh is intended for use by the Aunea facility for use with ETHICON Endo-Surgery, Inc. products.

2.3 Applicable to ETHICON, INC. Cornelia facility.

## 3 Definitions

| Term | Description |
|---|---|
| **Wales** | Stitches that run lengthwise in the fabric |
| **Courses** | Stitches that run in the width direction in the fabric |
| **Old Construction PROLENE* Mesh** | Continuous piece of mesh from a knitted roll fabricated from 6 mil (+/- 0.2 mil) clear monofilament or 6 mil dyed monofilament polypropylene extrudate code RMC 047113 and extruded from resin complying with MS455-012 and MS455-013. In the case of this document, old construction PROLENE* Mesh is the same as TVT PROLENE* Mesh. |

## 4 Requirements

The supplier agrees not to change any of the specified materials, process formulations, labeling, packaging, location of manufacture, company name change or any other specified process parameters that could affect Critical to Quality (CTQ) requirements, **without prior written agreement from ETHICON.**

## 4.1 Material Description

4.1.1 PROLENE* mesh roll stock, Fabric RMC# 050165, is a continuous piece of knitted finished fabric. It is fabricated from 6 mil clear monofilament polypropylene extrudate code (Fiber RMC # 047113). Roll width is 15 +/- ½ ". Nominal Roll length is 55 meters. Roll length to be between 30 and 60 meters.

4.1.2 PROLENE* mesh roll stock, Fabric RMC# 050166, is a continuous piece of knitted finished fabric. It is fabricated from 6 mil clear monofilament Monocryl extrudate code (Fiber RMC# 047113) and 6 mil dyed monofilament polypropylene extrudate code (Fiber RMC# 050161). Roll width is 15 +/- ½ ". Nominal Roll length is 55 meters. Roll length to be between 30 and 60 meters.

4.1.3 The construction pattern for the RMCs noted above are as follows:

Back Bar (GB1): 0/2, 4/2

Front Bar (GB3): 2/0, 2/4

## 4.2 Handling and Safety Information (*for ETHICON only*)

**CHEMICAL SAFETY TRAINING IS REQUIRED BEFORE HANDLING CHEMICALS.**

Consult you supervisor for training and read the Material Safety Data Sheet before handling.

### 4.2.1 Information

Safety glasses must be worn while performing Burst test.

## 4.3 Properties and Requirements- See Table 1

### 4.3.1 Properties and Requirements (Test Method) Table

Refer to PR550-010, *Company Procedure for Quality Assurance Acceptance of Incoming Materials.*

**Table 1-**

| Characteristic | Classification Per PR550-010 | Requirements | | | Sample Size | Test Method | Accept/Reject Criteria |
|---|---|---|---|---|---|---|---|
| Identity | CRITICAL | Compares favorably to that of a similarly prepared standard reference spectrum. | | | 1/ Lot | TM403-576 or TM403-257 | 0/1 |
| | | 050165 | Standard Spectrum # P-0153 | | | | |
| | | 050166 | Standard Spectrum # P-0153 and Standard Spectrum # Q-1016 | | | | |
| Mullen Burst (Estimate (with 98% confidence) of the Lower Limit of the Average) | CRITICAL | 050165 | (Avg – (4*STD/ √5)) ≥ 175 psi. | | 5 / Lot | TM406-008 (Note: This test will not be performed by the supplier) | ** 0/1 |
| | | 050166 | (Avg – (4*STD/ √5)) ≥ 175 psi. | | | | |
| Ball Burst (Average) | CRITICAL | 050165 | Avg.>175 lbf. | | 5 / Lot | Supplier Certification (Secant Medical Test Method 8116 Option 1) | Pass / Fail (Per review of SECANT Medical's Certificate of Conformance). |
| | | 050166 | Avg.>175 lbf. | | | | |
| Construction (Stitch Design) | CLASS I | Knitted mesh whose construction meets supplier's internal specifications **OR** Knitted mesh whose 20X magnified construction compares favorably to photograph of acceptable material. *Refer to Appendices.* | | | 1/ Lot | TM403-150 | 0/1 |
| | | Code | Courses/Inch | Wales/Inch | 1/ Lot | TM408-013 | 0/1 |
| | | 050165 | 26 +/- 2 | 11 +/- 2 | | | |
| | | 050166 | 26 +/- 2 | 11 +/- 2 | | | |

| Characteristic | Classification Per PR550-010 | Requirements | | | Sample Size | Test Method | Accept/Reject Criteria |
|---|---|---|---|---|---|---|---|
| Appearance | CLASS III | Supplier shall report all defects. Mesh should be clean with no foreign matter. | | | Per roll | Supplier Certification (SECANT Medical Procedure: FSMK0138 and FSMK0137 apply to RMC 050165 and RMC 050166, respectively) | Pass / Fail (Per review of SECANT Medical's Certificate of Conformance and Defect mapping form) |
| (Mass / Area Density) | CLASS I | 050165 | 3.0 oz. / sq. yd. +/- 0.5 oz. | | Minimum 20 sq. in sample or 130 sq. cm. | Supplier Certification (SECANT Internal Method 8105) | Pass / Fail (Per review of SECANT Medical's Certificate of Conformance) |
| | | 050166 | 3.0 oz. / sq. yd. +/- 0.5 oz. | | | | |
| Thickness (Average of three tests) | CLASS II | 050165 | 27 mils +/- 3.0 mils | (0.686 +/- 0.08 mm) | 3 / Lot | Supplier Certification ASTM D1777-96; Table 1, Option 1 | Pass / Fail (Per review of SECANT Medical's Certificate of Conformance) |
| | | 050166 | 27 mils +/- 3.0 mils | (0.686 +/- 0.08 mm) | | | |
| Extractables | CLASS III | 050165 | 0.60 % w/w maximum-one - 4 x 4 sample | | 1 / Lot | TM403-148 (Note: This test will not be performed by the supplier) | 0/1 |
| | | 050166 | 0.60 % w/w maximum-one - 4 x 4 sample | | | | |
| Elasticity | CRITICAL | 050165 | ≤ 360 mm. | | 13 strips per lot | Supplier Certification (SECANT Internal Method 8118 – 2164) | Pass / Fail (Per review of SECANT Medical's Certificate of Conformance) |
| | | 050166 | ≤ 360 mm. | | | | |

## 4.4 Packaging, Marking, Transportation and Storage

### 4.4.1 Packaging

- Rolls shall be packaged in double plastic bags in cardboard boxes.
- Five (5) rolls per box maximum. Each box shall weigh no more than 15 kg.
- Rolls shall be wound onto a returnable plastic pipe core.

### 4.4.2 Marking

- Requirements

  4.4.2.1. Each incoming box shall be labeled with a barcode that includes the supplier name, ETHICON raw material code (RMC) number, product description, supplier lot number, purchase order number, total roll quantity (yards), and container ID number.

  4.4.2.1.1. All incoming boxes are to be inspected for label requirements.

  4.4.2.2. The packing slip shall contain the supplier name, supplier lot number, purchase order number, product description, roll numbers, length per roll (yards), total quantity in shipment, raw material code (RMC) number, and container ID number (payment trace number).

- Labeling of SQM materials

  Cartons from shipments which have been sampled, tested and accepted will have "Direct Shipment – Supplier Accepted" labels, affixed to identification (stencil/label) side of cartons.

### 4.4.3 Transportation Requirements

Transportation must be by state and federally approved DOT carrier.

### 4.4.4 Storage (For ETHICON Only)

- Storage Requirements

  Store in warehouse conditions using proper methods of segregation.

- Shelf Life and Expiration

  Shelf life is 5 years.

# 5 Special Directions

- Each shipment must be accompanied by the Supplier's Certificate of Conformance that states the material produced meets this material specification's current revision and include test results of those tests performed by the supplier. The Certificate of Conformance shall also include the extrusion lot numbers used to manufacture the batch.
- Supplier shall report all ragged edges, unraveled edges, loosely adherent particles, holes, oil, lubricant, or loose ends (supplier shall provide mapping form with each shipment).
- Each shipment must be accompanied by a minimum of 10 samples per mesh lot for testing by Cornelia QA. (1 - 4"x4" sample for IR, 1- "4x4" sample for Construction or Course/Wales and Extractables; 5 – 4"x4" samples for Mullen Burst; 3 extra samples). Samples are to be pulled by SECANT Medical from each roll and sent to Cornelia QA. Cornelia QA is to, at random, select a minimum of 10 samples from those provided by SECANT Medical, for testing.
- Record mullen burst test data and water extractable weights on FM-0001276. Enter data from this form and all additional test data, (includes testing performed by the supplier) into the electronic data system. FM-0000597 may be used in the event that the electronic system is unavailable. (For ETHICON Only)

**Notes:**

- A shipment can be rejected for non-conformance to the packaging requirements set forth in Section 4.4.

## 5.1 Defect Definitions

Not Applicable.

## 5.2 Disposition of Shipment

- Use the accept/reject criteria in section 4.3 1 for disposition. Record all data on appropriate laboratory records.
- Follow OP611-137 for disposition.
- Cornelia shall provide a Certificate of Conformance for use by Neuchâtel facility.
- Cornelia shall provide a Certificate of Conformance for use by Aunea facility.

## 6 Test Requirements*

**NOTE:** Specific defects are defined in PR550-010, *Company Procedure for Quality Assurance Acceptance of Incoming Materials.*

See Section *4.3.1* Properties and Requirements (Test Method) Table for test requirements.

## 7 Appendices

| Appendix Number | Appendix Title |
|---|---|
| Appendix I | Digital Photograph of 050165 |
| Appendix II | Digital Photograph of 050166 |
| Appendix III | Course and Wale Drawing |

**QUALITY PAGE**
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## APPROVED SUPPLIER

***THIS INFORMATION IS CONSIDERED CONFIDENTIAL.***

| Supplier | Certification Type | Applies to RMC# |
|---|---|---|
| SECANT Medical, LLC<br>700 Park Avenue<br>Perkasie, PA 18944 | Certificate of Conformance<br>(C of C) | 050165<br>050166 |