TITLE	Marlex® HGX-030-01 Mechanical Testing Protocol - Slings
DOCUMENT NUMBER	90740928
PROJECT NAME AND NUMBER	Uro/Gyn Sustaining / U0311
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APPROVALS	Approvals and approval dates are captured through electronic signature within the PDM system.

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1.0 BACKGROUND

Phillips Sumika has discontinued production of Marlex® HGX-030-01, a Polypropylene Homopolymer grade. Therefore, Boston Scientific (BSC) obtained the same polymer from a second source (material distributor). While the material has been supplied in the correct Phillips Sumika bags with an identifiable lot number, there was no CoA supplied with this lot, and the distributor is not able to reproduce the CoA. The second lot of material was obtained from the material distributor Emai Plastic Raw Material (Dongguan) Inc
This document outlines the strategy for the mechanical testing that BSC will conducted to ensure the new lot of Marlex® HGX-030-01, received from Emai Plastic Raw Material, is equivalent to the existing lot of Marlex received from Channel Prime Alliance through the current manufacturing process.

2.0 PURPOSE

The purpose of this document is to outline the testing strategy and acceptance criteria that will be used for the lot 6120105 base resin, Marlex® HGX-030-01, to determine lot equivalence when evaluated with the current manufacturing processes at Luxilon, Proxy, AIM and MedVenture Technology Corporation (MTC) to be used in the urethral slings family products.

3.0 SCOPE

The scope of this protocol is to outline the functional material testing that will be conducted for the base resin Marlex® HGX-030-01 received from Emai Plastic Raw Material (Dongguan) Inc at Luxilon, Proxy, AIM, MTC and BSC. The material information is listed in Table 1:

Table 1. Base resin - Material information

MATERIAL NUMBER	DESCRIPTION	LOT NUMBER	QUANTITY (KG)
90207538-01	Polypropylene Resin (Marlex® HGX-030-01)	6120105	Natural: 25kg

All product produced during this build, will be considered non-saleable until final acceptance is documented.

Testing will apply in the representative products for the nominal conditions detailed in Table 2.

Table 2. List of the Representative Product Family

PROXY / LUXILON / AIM COMPONENT INFORMATION		
BSC NUMBER	**PART NUMBER**	**DESCRIPTION**
34106700	PPS50046	Polypropylene Monofilament Yarn - 6 mil (Nat)
34114200-02	400010008 ES012 - 002	Advantage Mesh Sheet
90409292-01	90409292	Carrier Base
90409293-01	90409293	Carrier cover
MEDVENTURE PRODUCT INFORMATION		
CATALOG NUMBER	**UPN PRODUCT NUMBER**	**DESCRIPTION**
850200	M0068502000	Advantage™ System
85020005	M006850200051	Advantage™ System, Box 5
850211	M0068502110	Advantage Fit™ System
850211	M0068502111	Advantage Fit™ System, Box 5
68504000	M0068504000	Obtryx™ System – Curved - Single
68504001	M0068504001	Obtryx™ System- Curved - 5-Pack
68505000	M0068505000	Obtryx ™ System – Halo -Single
68505001	M0068505001	Obtryx™ System – Halo - 5-Pack
850-700	M0068507000	Solyx™ SIS System – Single
850-700	M0068507001	Solyx™ SIS System – 5 Pack
68503000	M0068503000	Lynx Suprapubic Sling System
68503001	M0068503001	Lynx System 5-Pack
68506000	M0068506000	Pre-pubic Sling - Single
68506001	M0068506001	Pre-pubic Sling - 5-Pack

Since all base resin Marlex® HGX-030-01 extrusion parameters will remain the same, no worst case has been selected at Luxilon.

4.0 REFERENCE DOCUMENTS

Document Number	Description
90036920	Corporate SOP Capability of Variable Data
90030419	Corp SOP Design Verification Sampling/ Process Validation Sampling Plans
S842767-00	Corp SOP Risk Analysis
S842769-00	CORP SOP DESIGN VERIFICATION
90356869	Solyx Risk Analysis Report
90301643	Solyx Product Specification
90082464	Lynx Risk Analysis Workbook
90078003	Lynx System Product Specification
90055034	Advantage Product Specification

Document Number	Description
90055035	Advantage Risk Analysis Workbook
90106687	Obtryx Risk Analysis Workbook
90104642	TTFS Product Specification
90141370	PPS Product Specification
90141908	Pre-Pubic Risk Analysis Workbook
90732450	BCA - Marlex HGX-030-01 Mesh

5.0 BUILD CONDITIONS

Boston Scientific (BSC)

BSC will supply the base resin Marlex® HGX-030-01 to Luxilon and AIM to manufacture the components needed, to perform this protocol.

Luxilon Industries NV (Luxilon)

Luxilon will extrude the base resin Marlex® HGX-030-01 utilizing current approved manufacturing process standards as per their Quality System. Luxilon will then ship the fiber to Proxy for the Mesh processing.

For the purpose of this protocol, a copy of the results obtained will be sent to BSC and the Certificate of Compliance will be sent to Proxy.

PPS50046 - Polypropylene Monofilament Yarn - 6 mil (Nat)

Characteristic	Unit	Value	Tolerance	Measurement Standard	Key Performance / Process Characteristic
Denier (Weight in grams per 9,000 meters)	Den	152	± 10	Spool Average	**Key Performance**
Dtex (Weight in grams per 10,000 meters)	Dtex	170	± 11	Spool Average	**Key Performance**
Outer Diameter	µm	152	± 16	WIQA Spool Average	**Key Performance**
Tensile Strength	N	9.6	Min	Spool Average	**Key Performance**
Elongation At Break	%	22	± 7	WIQA Spool Average	**Process Characteristic**
Knot Strength[1]	N	7	± 1	WIQA Batch Average	**Process Characteristic**
Shrinkage[1]	%	8	± 3	Shrinkage will be measured using a hot air oven at 132°C (270°F) for 10 minutes. Batch Average	**Process Characteristic**
GDP[1] (Gram Denier Point)	%	3	± 1	WIQA Batch Average	**Process Characteristic**

[1] These are specific process characteristics that are evaluated at Luxilon per their Quality System

Proxy BioMedical (Proxy)

Proxy will receive the fiber from Luxilon, weave and knit the mesh and build the mesh sheets. The mesh sheet (34114200-02/AG) will be produced in accordance with the current manufacturing process standards as per their current Quality System. Traceability will be maintained through lot number assignment and recorded for all components.

All testing will be performed as per test specimen requirement detailed in the applicable test method listed in the table below and mesh sheets will be shipped directly to MTC.

ES012 – 02 Engineering Design Specification Proxy Biomedical Knit-BSC Advantage Mesh

Test	Min Performance Required	Sample Size & Acceptance Criteria	Specification	Test Method
Thickness[1]	95%/ 95%	n = 30, Ppk ≥ 0.75, Pp ≥ 0.82	0.0026" ± 0.006"	MPS012
Courses per inch (CPI)[2]	95%/ 95%	n = 30, Ppk ≥ 1.21, Pp ≥ 1.24	25 -26	QAP068
Wales per inch (WPI)[2]	95%/ 95%	n = 30, Ppk ≥ 1.21, Pp ≥ 1.24	12 ± 1	QAP068
Aerial Density[3]	95%/ 95%	n = 30, Ppk ≥ 0.75, Pp ≥ 0.82	100 g/m^2 ± 38%	QAP047
Tensile Strength Machine Direction[3]	95%/ 95%	n = 30,Ppk ≥ 0.74	≥37 (lbf)	QAP059
Elongation Test Machine Direction[3]	95%/ 95%	n = 30,Ppk ≥ 0.74	4.1%-14.7%.	QAP060
Device Stiffness[3]	95%/ 95%	n = 30, Ppk ≥ 0.74	≤ 10 (bending length in cm; average face and back) @ 1.1cm width	QAP061
Burst Strength[3]	95%/ 95%	n = 30, Ppk ≥ 0.74	≥ 66 (psi)	QAP062

[1] n=30, Ppk ≥ 0.75, Pp ≥ 0.82 per BSC's internal requirements of 95% confidence of 95% reliability (LTPD 5%) for a risk level I characteristic (2-sided spec.) per Corp SOP Design Verification/Process Validation Sampling Plans 90030419.

[2] n=30 Ppk ≥ 1.21, Pp ≥ 1.24 per BSC's internal requirements of 95% confidence of 95% reliability (LTPD 0.3%) for a risk level II characteristic (2-sided spec.) per Corp SOP Design Verification/Process Validation Sampling Plans 90030419.

[3] n=30, Ppk ≥0.74 is BSC's internal requirements of 95% confidence of 95% reliability (LTPD 5%) for a risk level I characteristic (1-sided spec.) per Boston Scientific Corp SOP Design Verification/Process Validation Sampling Plans 90030419 & Boston Scientific Corp SOP Design Verification S842769-00. Some of these characteristics may not be RI=I in BSC's dFMEAs listed in section 4.0, but will be tested to those requirements for this protocol.

For the purpose of this protocol, a copy of the results obtained will be sent to BSC and the Certificate of Compliance will be sent to MTC.

AIM Plastics (AIM)

Base resin Marlex® HGX-030-01 will be injected in the mold at AIM during 2 hours, utilizing current approved manufacturing process standards as per their Quality System. Carrier base (90409292-01) and carrier cover (90409293-01) will then be shipped to MTC for processing. Samples will be randomly pulled from the production run from each cavity to perform the following measurements:

CARRIER BASE (90409292-01)

Characteristic	Min Performance Required	Sample Size & Acceptance Criteria	Specification	Measurement standard
Critical dimension Q1	95%/ 95%	n = 30, Ppk ≥ 0.75, Pp ≥ 0.82	.040 ± .003	Vision system
Critical dimension Q2	95%/ 95%	n = 30, Ppk ≥ 0.75, Pp ≥ 0.82	.043 ± .003	Vision system
Critical dimension Q3	95%/ 95%	n = 30, Ppk ≥ 0.75, Pp ≥ 0.82	.047 ± .002	Vision system
Critical dimension Q4	95%/ 95%	n = 30, Ppk ≥ 0.75, Pp ≥ 0.82	2 X .051 ± .005	Vision system
Critical dimension Q5	95%/ 95%	n = 30, Ppk ≥ 0.75, Pp ≥ 0.82	2 X .058 ± .005	Vision system
Critical dimension Q6	95%/ 95%	n = 30, Ppk ≥ 0.75, Pp ≥ 0.82	.125 ± .005	Vision system
Critical dimension Q7	95%/ 95%	n = 30, Ppk ≥ 0.75, Pp ≥ 0.82	4 X .030 ± .003	Vision system

n=30, Ppk ≥ 0.75, Pp ≥ 0.82 per BSC's internal requirements of 95% confidence of 95% reliability (LTPD 5%) for a risk level I characteristic (2-sided spec.) per Corp SOP Design Verification/Process Validation Sampling Plans 90030419.

CARRIER COVER (90409293-01)

Characteristic	Min Performance Required	Sample Size & Acceptance Criteria	Specification	Measurement standard
Critical dimension Q1	95%/ 95%	n = 30, Ppk ≥ 0.75, Pp ≥ 0.82	4 X .034 ± .002	Vision system
Critical dimension Q2	95%/ 95%	n = 30, Ppk ≥ 0.75, Pp ≥ 0.82	.041 ± .003	Vision system
Critical dimension Q3	95%/ 95%	n = 30, Ppk ≥ 0.75, Pp ≥ 0.82	.104 ± .005	Vision system

n=30, Ppk ≥ 0.75, Pp ≥ 0.82 per BSC's internal requirements of 95% confidence of 95% reliability (LTPD 5%) for a risk level I characteristic (2-sided spec.) per Corp SOP Design Verification/Process Validation Sampling Plans 90030419.

For the purpose of this protocol, a copy of the results obtained will be sent to BSC and the Certificate of Compliance will be sent to MTC.

A summary for the general process for the proposed Marlex® HGX-030-01 testing in this protocol is shown in flow chart on Figure 2

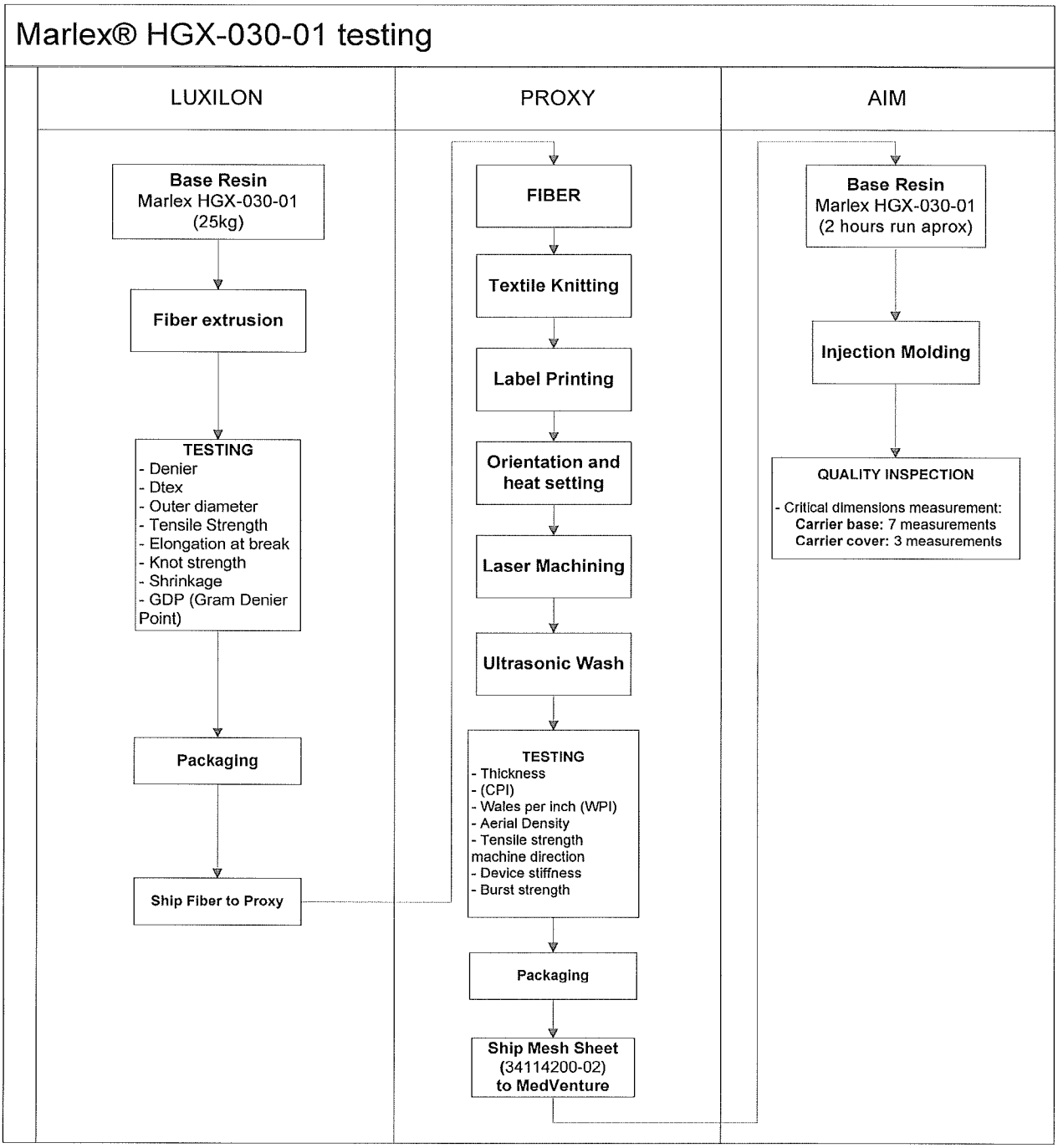

Figure 2. Flowchart for Marlex® HGX-030-01 to be used in the urethral sling family products

6.0 DATA ANALYSIS AND RECORD RETENTION

BSC will review all documentation and data generated from each vendor, compile the information, perform data analysis and update this technical report to include all results obtained.

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APPROVAL FOR OFFICIAL DOCUMENT

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