

DATE: August 07 2012  
 FROM: Charlie Smith  
 SUBJECT: Mesh Resin Core Team Meeting Minutes. PDM# (90726533)

Note: Bold denotes attendance; see last page.

Meeting Attendance: **REQUIRED by all core team members.** Core team members should make every effort to attend each meeting. In the event that this is not possible, one of the following alternatives can be pursued: (1) send a qualified representative that is prepared to represent your function, (2) arrange to call into the meeting, or (3) forward a copy of your input to the Project Manager prior to the meeting.

**NEXT CORE TEAM MEETING:**

Tuesday AUG 21, 2012 @ 8:30am  
 MAR ConRm 200-3-Uro/WH R&D 1

- AT&T Conference Call:** Dial in Number: 877-663-6338  
 Participant Code: 6329059
- Project Number PDM:** U0311 for technical reports currently; will be extended to family product folders as needed once material release is determined.
- Project Objective:** Release Marlex resin lot (Missing vendor certification) to produce mesh products.
- Executive Summary:** SIX major work streams in process gating material release (critical path/critical chain in red). First shipment from China arrived in states, in route to Gould. Last two reports in process. Delays due to Atlas team focus on DV priorities and vacation time:

1. Material equivalency: **DONE.**
2. Mechanical testing (PFR): **DONE.**
3. Biocompatibility testing: **DONE.**
4. Mechanical testing (slings): **DONE.**
5. Mechanical testing (Atlas): Fiber specification approved in CR# 1136111 on August 3<sup>rd</sup>. Atlas report is in CR review.
6. Mechanical testing (Y-Mesh): Draft reviewed, CR collaboration being prepared.

Current Project Phase	Next PIB Review	Target Completion	Target Completion (Per Dynamic Timeline)
N/A (Material Testing) PFR	Update given @ May 17 <sup>th</sup> opening.	Q1/2012	Q1/2012 –DONE MAR 8th.
N/A (Material testing) Slings	Update given @ May 17 <sup>th</sup> opening.	Q2/2012	Q2/2012 –DONE MAY 23.
N/A (Material testing) Atlas	Update given @ May 17 <sup>th</sup> opening.	Q2/2012	AUG/2012 –see attached.
N/A (Material testing) Y Mesh	Update given @ May 17 <sup>th</sup> opening.	Q2/2012	AUG/2012 –see attached.
N/A Release Material for use.	Update given @ May 17 <sup>th</sup> opening.	JULY/2012	<del>SEP</del> /2012 –see attached
<b>Key Accomplishments</b> <ul style="list-style-type: none"> <li>Last container of resin shipped from China port.</li> <li>BSC Change request # 1136111 for fiber specification for Atlas clarifications completed.</li> </ul>			
<b>Upcoming Key Deliverables</b> <ul style="list-style-type: none"> <li>CR for sling and PFK fibers update for clarification to match Proxy update.</li> <li>CR 1133644; approval of Atlas report.</li> </ul>			
<b>Risks to Timeline:</b> Additional tasks for Y-Mesh/Atlas: <u>Additional delays for focus on key Atlas priorities/vacations have moved Material release into SEP.</u> Timeline updated to reflect actuals.			

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**Project Scope:** To complete activities needed to release Marlex lot without certification from manufacturer.



Action Items:

Task	Responsibility	Due	Status/details
Finalize movement of resin (10k lbs.) Second shipment from distributor location to Gould.	George	JUL 11	Quote completed, prepared by Mike with vendor in China to initiate preparation. PO # 6346670 in place. Container shipped from China port on JUL 11 <sup>th</sup> . Arrived AUG 7 <sup>th</sup> in US port. To arrive at Gould on AUG 17.
Finalize movement of resin (10k lbs.) Third and final shipment from distributor location to Gould.	George	JUL 31	Quote completed, prepared by Mike with vendor in China to initiate preparation. PO # 6346670 in place. Packaging completed. Left Hong Kong harbor JUL 31; due in US port on AUG 24.
Update BSC Atlas fiber specification	Ken	AUG 3 <del>DONE</del>	In collaboration in ECN# 1136111 as of July 20 <sup>th</sup> . Completed AUG 3 <sup>rd</sup> .
Approve report (Atlas Mechanical)	Team	AUG 17	Eric is drafting section on fiber based upon change to fiber specification. Will be ready for pre CR review on Jul 31. Delays due to collaboration time, new target assigned based upon vacation times and Atlas project priorities.
Draft Report for Y-Mesh report	Eric/Charlie	AUG 21	Date changed due to priority on the Atlas report and update on Pinnacle report.
Update BSC fiber specification for other families	Eric	AUG 20	Eric will initiate when receive Proxy updates late next week. Not on critical path, clean-up activity to align all non-Atlas fiber specifications. Proxy updates approved, Eric drafting CR. Drafts to be sent out to team by end of week. Delay due to priority on Atlas report. Date adjusted.
REVIEW MEETING	Charlie	AUG	Will set-up once DRAFT report completed for Y-Mesh and Atlas Report sign off completed.
Release Material in WIP	Chris	AUG 31	
Move resin from Marlboro to Gould	Damian	AUG	Gould asked to prepare quote for additional storage.
Release resin	Chris	SEP	Date revised based upon delays in two final report per timeline review.
Close Quality plan	Charlie	SEP	
Revise Pinnacle report Draft	Charlie/Dean	AUG 7 <sup>th</sup>	Reviewed wording at team meeting on the 7 <sup>th</sup> . Agreement reached on format for report, to submit to collaboration.

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**Core Team Members**

Name	Team Function	Location
<b>Charlie Smith</b>	Core Team Leader	Marlborough
<b>Carolina Villarreal</b>	R&D Eng II	Marlborough
<b>Janice Courtois</b>	Sr. Quality Engineer	Marlborough
<b>Nichole Riek</b>	Regulatory Affairs – Manager II	Marlborough
Dan Burrill	R&D Principal Engineer	Marlborough
Adrienne Podmore	Supply Chain	Marlborough
Eric Hubbard	R&D Engineer I	Marlborough

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Name	Team Function	Location
Chris Cuddy	DQA Manager	Marlborough
Paul Keady	Prin. Quality Engineer	Marlborough
George Vialle	Director Supply Chain	Marlborough
Jessica Batty	Biocompatibility – Scientist I	Natick
<b>Dean King</b>	Proxy; Mesh forming manufacturer	Ireland
Mike Slawter	MedVenture: Final assembly Manufacturer	Indiana
Thierry Beyltiens	Luxilon: Mesh extruder	Belgium
<b>Damian Kieran</b>	Manager Supply chain	Marlborough
Missy Kahan	Quality Engineer II	Marlborough
Ken Flynn	SR R&D Engineer	Marlborough
Seamus O'Connor	Proxy: Quality	Proxy

**Management/ Support Team**

Name	Team Function	Location
Brent Palmisano	Marketing Director	Marlborough
John Sherry	R&D Director	Marlborough
Donna Gardner	Regulatory Director	Marlborough
Al Intocchia	VP R&D	Marlborough
Mitch Wheeler	Director DA	Marlborough
Kevin Newell	R&D Manager	Marlborough
Jim Goddard	R&D Sr. Manager	Marlborough