

**From:** Smith, Charles  
**Sent:** 10/25/2011 10:51:24 AM  
**To:** Riek, Nichole; Goddard, James  
**Subject:** FW: Bio assessment for China lot of Marlex : no certification available.

**Importance:** High

FYI

**From:** Smith, Charles  
**Sent:** Tuesday, October 25, 2011 10:41 AM  
**To:** Batty, Jessica; Beckord, Hollie  
**Cc:** Hood, Alan M.; Burrill, Dan; Heroux, Adam  
**Subject:** RE: Bio assessment for China lot of Marlex : no certification available.

Jessica

Thks

Hollie

Feel free to call Dan or myself as needed.

thks

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**From:** Batty, Jessica

**Sent:** Tuesday, October 25, 2011 10:21 AM

**To:** Beckord, Hollie

**Cc:** Smith, Charles; Hood, Alan M.; Burrill, Dan; Heroux, Adam

**Subject:** FW: Bio assessment for China lot of Marlex : no certification available.

**Importance:** High

Hi Hollie!

The team that is working on the mesh PFR and sling products has encountered a new challenge that we need your help with. A new lot of Marlex material has been discovered in a warehouse in China that the team has been working to qualify for use. There is no certification available for the lot, but the engineering group has conducted testing to verify the identity of the material and they are now comfortable saying that the lot is Marlex and is suitable for use. During the testing, however, some small differences were discovered between the existing Marlex material and this new lot. We would like your help in determining whether these differences are significant to the composition of the material and therefore to biocompatibility.

Dan Burrill (cc'd) is leading the engineering side of the effort and he will have the best understanding of the testing was performed and the concerns that exist with the materials. If you could take a look at their data (attached in the email below) and provide your feedback/recommendations on the situation that would be very helpful. Please note that this is a pressing situation and we would really appreciate your consideration as soon as possible. If you have any questions please feel free to give me a call!

Thank you!

Jess

**Jessica Batty**

**Boston Scientific Corporation**

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**From:** Smith, Charles

**Sent:** Tuesday, October 25, 2011 9:58 AM

**To:** Batty, Jessica

**Cc:** Heroux, Adam; Goddard, James; Burrill, Dan; Riek, Nichole

**Subject:** Bio assessment for China lot of Marlex : no certification available.

**Importance:** High

Jessica

Here is information to pass along to Hollie for review. Dan is leading the report effort of the material testing we just completed:

1. Raw data on from test house. PDF

2. Equivalency testing Protocol as approved in PDM.

<http://pdmprd.bsci.com/Windchill/servlet/WindchillAuthGW/wt.enterprise.URLProcessor/URLTemplateAction?action=ObjProps&oid=VR%3Aext.bsc.doc.BSCDocument%3A2515852803>

3. Summary slide deck of our internal review, Dan can provide latest copy of this, as needed

4. We are currently working on report as discussed.

We are available as needed to discuss with Hollie. I can set-up meeting, let me know.

Thks

Charlie