From: Arnaud, Axel [ETHFR]

Sent: Tue, 31 Jan 2006 14:46:42 GMT

To: Kammerer, Gene [ETHUS] <GKAMMERE@ETHUS.JNJ.COM>

Subject: RE: TVT - TVT-O Specifications

Dear Gene,

Thanks a lot for your mail.

We had a TVM Group meeting last week in presence of many people from Gynecare US. The Group, when asked for its feedback regarding the Prolift, sent the clear message to Bob Roda that all efforts regarding potential improvements of the product should be focused on preventing mesh shrinkage.

Please let me know about any progress.

I have heard about the major changes in R&D and I cross my finger you will get an interesting position. Best regards

Axel

> -----Message d'origine---->De : Kammerer, Gene [ETHUS]
>Envoyé : lundi 30 janvier 2006 17:51
>À : Arnaud, Axel [ETHFR]
>Objet : RE: TVT - TVT-O Specifications

>thanks. I see the PROFIX device has just been launched about a week ago. We had a launch party, about 50 people here in the Cafateria. I had a chance to speak to the group and told them of the work you did for Prolift and Profix and how it came about that we launched both a needle passage technique and a fixation technique. People change positions here so fast that many of them do not know the history of the products. Anyway, I was able to tie the two products together in my talk and maybe explain some things.

>

>I am still working on the tissue engineering project, and we have some new constructions with collagen and polymer foams. We are putting them on both the Gynemesh and the Ultrapro. I am trying to identify a tissue structure in the pig which is similar to the endopelvic fascia in humans. We will start a SKID mouse study in a few weeks to see if these new constructs impact scar formation and we want to use the best tissue we can.

>Many changes in the R&D organization are happening. I will know in a week or so how it will impact me.

>Talk to you later. Maybe I can plan a trip to Paris.

>

>Gene

>

> -----Original Message-----

> From: Arnaud, Axel [ETHFR]

> Sent: Monday, January 30, 2006 11:37 AM

- > To: Kammerer, Gene [ETHUS]
- > Subject: TR: TVT TVT-O Specifications
- >
- >
- >



> ----- Message d'origine-----

- > De : Kammerer, Gene [ETHUS]
- > Envoyé : vendredi 20 janvier 2006 15:19

> À : Rha, Sungyoon [ETHUS]; Gorky, Traci [ETHUS]; Arnaud, Axel [ETHFR]

> Cc : Flatow, Jacqueline [ETHUS]; St. Hilaire, Price [ETHUS]

> Objet : RE: TVT - TVT-O Specifications

>

> Axel,

> It has been a long time, and it is good to hear from you my friend. I think this may help you.

><< File: Pore size.ppt >>

> There are two distinct pore sizes in the PROLENE 6 mil mesh (TVT). The major pore in about 1176 um. It is the large tetrahedral shaped opening. The minor pore is about 295 um. It is a tear drop shaped opening which is formed by the loop of the filaments. These pores are relatively consistent, but as you know the mesh is created in a very wide sheet, pulled under tension and such and there is a range which these pores can be.

>

- > If you need anything else, please let me know.
- > Best regards,
- > Gene
- > Gene W. Kammerer
- > Engineering Fellow
- > Ethicon R&D
- > Procedural Implants
- > phone 908-218-3067
- > fax 908-218-3000
- > gkammere@ethus.jnj.com

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- >
- > ----- Original Message-----
- > From: Rha, Sungyoon [ETHUS]
- > Sent: Thursday, January 19, 2006 2:15 PM
- > To: Gorky, Traci [ETHUS]
- > Cc: Kammerer, Gene [ETHUS]; Flatow, Jacqueline [ETHUS]; St. Hilaire, Price [ETHUS]
- > Subject: RE: TVT TVT-O Specifications
- >
- > Traci:
- >

> No, I do not have information on the pore size.

>

> Our current MS-0000108 does not indicate the pore size, but refer to courses (cross direction - stitches run in the width direction) and wales (machine direction - stitches run in lengthwise direction) per inch. For our TVT products, we use RMC 050166 which has the following spec requirement:

> courses/inch: 26 +/- 2

- > wales/inch: 11 +/-2
- >

> << File: MS-0000108v2 Material Specification for TVT PROLENE Polypropylene Mesh Roll Stock.doc >>

HIGHLY CONFIDENTIAL SUBJECT TO STIPULATION AND ORDER OF CONFIDENTIALITY << File: MS-0000108 APP II for TVT PROLENE Mesh Roll Stock.doc >>

> I suppose we (R&D) can measure them, but we need to be clear where we take the measurement from the courses/wales direction.

>

- > Best Regards,
- > Sunny Rha
- > OPERATIONS INTEGRATIONS
- > A Division of ETHICON, INC.,
- > A Johnson & Johnson Company
- > US ROUTE 22 WEST, P.O. BOX 151,
- > SOMERVILLE, NJ 08876-0151>
- > Office \* (908) 218-2860
- > Fax \* (908) 218-3515
- > Email \* srha@ethus.jnj.com
- >

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- > -----Original Message-----
- > From: Gorky, Traci [ETHUS]
- > Sent: Thursday, January 19, 2006 1:46 PM
- > To: Rha, Sungyoon [ETHUS]
- > Subject: FW: TVT TVT-O Specifications
- > Importance: High

>

> Sunny,

>

> Do you know if the mesh specification includes any reference to pore size?

>

- > Traci Gorky
- > Platform Manager, Tissue Reinforcement
- > ETHICON
- > a Johnson & Johnson company
- > P. O. Box 151, Somerville, N.J. 08876-0151
- > \* (908) 218-2878
- >FAX (908) 218-5433
- > \* tgorky@ethus.jnj.com
- >
- >

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> ----- Original Message-----

PX288.3

> From: London Brown, Allison [ETHUS] > Sent: Thursday, January 19, 2006 1:16 PM > To: Amin, Dharini [ETH]; St. Hilaire, Price [ETHUS]; Leclair, Nancy [ETHUS]; Gorky, Traci [ETHUS]; Manley, Quentin [ETHUS]; Kammerer, Gene [ETHUS] > Subject: FW: TVT - TVT-O Specifications > Importance: High >> do one of you have this information? perhaps we have used it in a technical/claims document? >> ----- Original Message-----> From: Roda, Bob [ETHUS] > > Sent: Thursday, January 19, 2006 11:58 AM > To: London Brown, Allison [ETHUS] > Subject: FW: TVT - TVT-O Specifications > Importance: High >> >> Bob Roda > Group Marketing Director, WW > Urology, Pelvic Floor and Incontinence > office 908-218-2808 > fax 908-218-3663 > broda2@ethus.jnj.com >

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> ----- Original Message-----

> From: Arnaud, Axel [ETHFR]

> Sent: Wednesday, January 18, 2006 12:26 PM

- > To: Roda, Bob [ETHUS]
- > Subject: TVT TVT-O Specifications
- > Importance: High

>

> Dera Bob,

>

> I have an urgent request from Italy. They need to know the pore size expressed in  $\mu$ m of the TVT and TVT-O mesh.

> I have the number of 1640 X 960 for TVT but I am not 100% sure of the source. The information is for an answer to a tender in the hospital of W. Artibani and it is very important.

- > Regards
- > Axel
- >
- >

PX288.4