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CASE NUMBER: 15-2-05472-4 SEA

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Honorable Steve Rosen

IN THE SUPERIOR COURT OF THE STATE OF WASHINGTON
IN AND FOR THE COUNTY OF KING

THERESA BIGLER, individually and as
Personal Representative of the Estate of
RICHARD BIGLER,

Plaintiff,

v.

OLYMPUS AMERICA, INC., a foreign
corporation, OLYMPUS CORPORATION OF
THE AMERICAS, a foreign corporation;
OLYMPUS MEDICAL SYSTEMS CORP., a
foreign corporation; and VIRGINIA MASON
MEDICAL CENTER,

Defendants.

NO. 15-2-05472-4 SEA

DECLARATION OF KARIN J.
MITCHELL IN SUPPORT OF
VIRGINIA MASON'S
SUPPLEMENTAL BRIEFING ON
FAILURE TO MITIGATE

I, Karin J. Mitchell, hereby declare as follows:

1. I am over the age of 18 years and one of the attorneys representing Defendant Virginia Mason Medical Center. I submit this declaration upon personal knowledge and in support of Defendant Virginia Mason Medical Center's Supplemental Briefing on Failure to Mitigate

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2. Attached as **Exhibit A** hereto and incorporated herein is a true and correct copy of email correspondence dated February 28, 2008, between Mr. Kitano and Mr. Higashimoto.
3. Attached as **Exhibit B** hereto and incorporated herein is a true and correct copy of email correspondence dated April 15, 2008 to April 18, 2008, between Mr. Otawara, Mr. Higashimoto, and Mr. Shimada.
4. Attached as **Exhibit C** hereto and incorporated herein is a true and correct copy of email correspondence dated May 27, 2009 to June 3, 2009, between Mr. Otawara, Mr. Minasawa and Mr. Shinji.

I DECLARE UNDER PENALTY OF PERJURY UNDER THE LAWS OF THE STATE OF WASHINGTON, THAT THE FOREGOING IS TRUE AND CORRECT.

DATED this 4th day of December, 2017, at Seattle, Washington.

JOHNSON, GRAFFE, KEAY, MONIZ & WICK, LLP

s/Karin J. Mitchell
Karin J. Mitchell, WSBA #44101

From: Seiji_Kitano/jp/olympus
To: <Masakazu_Higashimoto/Endo/OE/Olympus-EU%OLYMPUS-EUROPA%G__OLYMPUS>
Sent: 2/28/2008 11:10:05 PM
Subject: Re: Sealed tip dummy
Attachments: pic00245.gif

This is Kitano.

Yes, there's definitely a possibility that that would open a can of worms.
Please consult with Miyamoto-san.

It may not be necessary to say this, but:

- CDS properties have been confirmed in in-house tests.
- The durability of the O-ring, arm, etc. has also been confirmed in in-house tests.

That's all. Thank you in advance for your support.

 Masakazu Higashimoto/Endo/OE/Olympus-EU@OLYMPUS-EUROPA

	To
Masakazu Higashimoto/Endo /OE/Olympus-EU@OLYMPUS- EUROPA	Seiji Kitano/jp/olympus@OLYMPUS@G__OLYMPUS
	cc
2008/02/28 22:05	Subject
	Re: Sealed tip dummy <u>Seiji Kitano</u>

With regard to the following, I think it would be better not to show the customer the transparent dummy product.


I consulted with Kaneko-san about whether to take the transparent dummy product this time. With the brush with the scope enclosed, it is not possible to do good brushing inside the tip cover, and contrary to what we want, it would become completely obvious that the brush does not come into contact with the bottom part of the raising-up stand, so in the worst case scenario, it would open a can of worms, and therefore I had him agree not to take it.

I think it would be better to show it to them after it becomes possible to use the special brush.

I will talk to Miyamoto and confirm the situation before thinking about how to respond.

That's all. Thank you in advance for your support.

.....
Masakazu Higashimoto
R&D Liaison
OLYMPUS MEDICAL SYSTEMS EUROPA GMBH
Wendenstr. 14-18 D-20097 Hamburg
Phone: +49-40-23773-3227 Fax: -656
e-mail: masakazu.higashimoto@olympus-europa.com
.....

 Seiji Kitano/jp/olympus@OLYMPUS

Seiji Kitano/jp/olympus@OLYMPUS	To
2008/02/28 12:09	Masakazu Higashimoto/Endo/OE/Olympus-EU@Olympus-Europa
	cc

CONFIDENTIAL

OLY-Young 0279930

EXHIBIT A

Subject

Sealed tip dummy

This is Kitano from Scope 1G.

Did [I] hand [you] the sealed tip dummy?

Liaison Miyamoto contacted me.

- During a visit to Prof. Aabakken's facility, a nurse asked questions about the sealed CDS.
- Tried to explain the sealed structure, but memory was not clear so a complete explanation could not be given.

I am thinking of sending a 3D-CAD illustration to Liaison Miyamoto and having him/her explain it to the nurse. I also thought another option would be to show the actual product and recover it on the spot, so that's why I'm sending this inquiry.

I don't really want to show the user the actual product, but I thought I would like to use that as a last resort. If you have it, please hand it to Liaison Miyamoto.

Thank you in advance for your support.

CONFIDENTIAL

OLY-Young 0279931

City of New York, State of New York, County of New York

I, Aurora Landman, hereby certify that the document “Oly-Young 279930-31” is, to the best of my knowledge and belief, a true and accurate translation from Japanese into English.



Aurora Landman

Sworn to before me this
August 15, 2017



Signature, Notary Public



Stamp, Notary Public

From: Naoya_Shimada/jp/olympus
To: <Masakazu_Higashimoto/Endo/OE/Olympus-EU%OLYMPUS-EUROPA%G_OLYMPUS>
CC: <Seiji_Kitano/jp/olympus%olympus>; <Takayasu_Miyagi/jp/olympus%olympus>; <Takashi_Otawara/jp/olympus%olympus>
Sent: 4/18/2008 1:32:04 AM
Subject: Re: TJF-Q180V brush
Attachments: pic14304.gif; pic24100.gif

This is Shimada.
Thank you for your assistance.

It is a great honor to become a brush representative, the same as you.
I ask for your assistance moving forward.

I was somewhat relieved to read your opinion in the email below.
I sense that the conclusions both of us are aiming for are not so far apart.
I will state my opinion at the current stage.
(Please read this as no more than the personal opinion of a representative at this point since things are not yet coordinated with GI Marketing, let alone Development. I'm sorry.)

First, as an assumption, I believe the advantage of the R-type is not its "high level of cleanliness" (though cleanliness might inevitably be better, it is not as if there is a problem with cleanliness for the F-type), but the fact that "you can confirm that the washing was performed properly." Therefore, I see the new brush not as "a brush that allows for a higher level of cleanliness," but "a tool for confirming that the washing was done properly."

In the bacteria tests being conducted currently by Kitano, it looks as though good results can be obtained even when the MH-507 is not used (without inserting the brush into the raising base), so after declaring that "there is no problem with CDS," I believe the stance should be "if you wish to confirm that the washing was done properly, please use this brush."

Based on the above, I would like to propose the following.

- ① Make the brush an unsterilized disposable product (like the BW-201 T and others)
- ② Make it a brush that is similar to a small writing brush instead of a twist brush (similar to the brush that comes with the dummy)
- ③ (At least for the time being) Make it a promotional item, not a product (don't include it in the packaging)

⊕ and ⊖ are the same opinions as yours, so I won't touch on them here, but I would like to add notes in regards to ⊕.

There are three major reasons I would like to "Make it a promotional item, not a product":

I. I don't want to actively market it since it makes it harder to make an appeal based on the high level of cleanliness and ease of cleaning.

Even if we are able to obtain good results in the bacteria validation, I feel as though we may unnecessarily give a false impression to users by going out of our way to provide them a new brush as a product (they might think they can't wash properly without the new brush, etc.).

Also, since "cleanliness improved due to the sealing" as well as "washing became easier with the F-type. See, the results from the bacteria test also showed that there are no problems" can be used as marketing claims. However, I don't know what we would be implying by saying "we have a new brush for you. Please use it."

II. It could affect the schedule for the TJF main unit.

I believe that there will be man-hours for the scope side in terms of manual development, product standards and regulations (filings), etc. when the brush is commercialized. I don't want to have the risk of delaying the scope due to problems with the brush or a need to revise the specs

III. There is a good chance that if it is commercialized, we won't be able to synchronize it with the start up of production for the TJF.

In my current estimate, the shortest timing for commercialization would be sometime between the beginning and end of November.

This timing assumes that it would be commercialized by re-using a marketed item, priority is placed on the brush itself and its relationship to other operations is ignored, and that no problems occur in the examination. There is a very good chance it would actually go later than that (about 1-2 months?).


However, if we were to handle it as a promotional item, we can synchronize test manufacturing with TJJ, and would be able to have it meet the timing of the TJJ trial manufacture even if there are slight problems during the examination of the prototype and the need to revise specs.

However, I would also like to proceed with preparations for commercialization so this could be done quickly should there be demand from users for commercialization after the TJJ is introduced to the market.

Those are my personal opinions.

Could you please let me know your opinion of making it a promotional item as proposed in ☺?

Thank you.

 Masakazu Higashimoto/Endo/OE/Olympus-EU@OLYMPUS-EUROPA

Masakazu Higashimoto/Endo
/OE/Olympus-EU@OLYMPUS-
EUROPA

4/16/2008 9:31 PM

To

Takashi Otawara/jp/olympus@OLYMPUS@G_OLYMPUS

cc

Naoya Shimada/jp/olympus@olympus, Seiji Kitano/jp/olympus@olympus, Takayasu
Wiyagi/jp/olympus@olympus

Subject

Re: TJJ-Q180V brush; Naoya Shimada

This is Higashimoto.

While those are most certainly the brush proposals, I think they are impossible this time since, just as we thought, there is no time. Even so, at least they are convinced. I would appreciate it if you could keep these in mind as a reference.

I have jotted down thoughts that came to mind in blue, and ask that you please use them as a reference.

- There is no technology for making a brush that goes through the gap behind the forceps base. (It is definitely impossible if we manufacture it internally.)
 - I bought an interdental brush and tried to pass it through the gap between the raising base revolving axis and the C main unit, and it was impossible. However, the brush attached to the dummy could be inserted from the back of the raising base up to where it hit the C main unit, and that brush can at least be explained logically. That convinces me. So that brush would be fine.
- Is it possible to make an entry in the manual unnecessary when including it in the packaging? (Would bacteria validation be necessary if writing about it in the manual?)
 - This would certainly be difficult. Since bacteria validation hasn't been done yet, can't something be done if it were inserted into the protocol in the future? For instance, make the protocol so that the brush is used in the place of the MH-507, which barely enters the back of the raising base. I am sure this would no doubt increase cleanliness.
- Packaging format (necessity of sterile packaging)
 - Definitely so. I think BW-201T and MAJ-1339 will serve as reference. Do they have sterile packaging? It won't be used in the test itself, so don't think it needs to be sterile.

In conclusion, consciousness towards CDS is very high here. (So much so that OMSE ET Marketing is worried about whether CDS is a problem.)

That is why they are requesting a transparent dummy.

Even if it is difficult to include it in the packaging, I feel that it is headed in a direction where commercialization cannot be avoided...

If it isn't included in the packaging or commercialized, the transparent dummy requested separately is useless.

I hope to find a good conclusion while thinking of several possibilities.

I apologize for the bother, but thank you.

Masakazu Higashimoto

R&D Liaison
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e-mail: masakazu.higashimoto@olympus-europa.com

.....
Takashi Otawara/jp/olympus@OLYMPUS

Takashi Otawara/jp/olympus@OLYMPUS
4/16/2008 11:42 AM

To
Masakazu Higashimoto/Endo/OE/Olympus-EU@OLYMPUS-EUROPA@G_OLYMPUS

cc
Naoya Shimada/jp/olympus@olympus, Seiji Kitano/jp/olympus@olympus, Takayasu
Miyagi/jp/olympus@olympus

Subject
Re: TJF-Q180V brush; Masakazu Higashimoto

This is Otawara.

Thank you for the detailed answers and information.
I came to a very good understanding of the views of OMSE in the email below.

Honestly, I am surprised that you are thinking of including it with the scope.
I'm glad I learned about the gap in our thinking this early.

I am currently having Shimada calculate the advantages and disadvantages of making the TJF brush into a product.
I will send you the information once that is put together.

I think there will be substantial obstacles should it be commercialized, and more so if it is included in the product packaging.

- There is no technology for making a brush that goes through the gap behind the forceps base. (It is definitely impossible if we manufacture it internally.)
- Is it possible to make an entry in the manual unnecessary when including it in the packaging? (Would bacteria validation be necessary if writing about it in the manual?)
- Packaging format (necessity of sterile packaging)
As well as others.

Though the investigation is still insufficient, we will put everything together.
Please hold for now.

*The idea of attaching it to the opposite end of the MH-507 is interesting.

Masakazu Higashimoto/Endo/OE/Olympus-EU@OLYMPUS-EUROPA

Masakazu Higashimoto/Endo
/OE/Olympus-EU@OLYMPUS-
EUROPA

2008/04/15 04:04
4/15/2008 4:04 AM

To
Takashi Otawara/jp/olympus@OLYMPUS@G_OLYMPUS

cc
Naoya Shimada/jp/olympus@olympus, Seiji Kitano/jp/olympus@olympus

Subject
Re: TJF-Q180V brush; Takashi Otawara

This is Higashimoto at OMSE.
It has been a while.

I spoke about the matter with the product manager.

⊕ How much need is there for a brush in the first place?

First, it is thought that this brush is desired as a standard accessory.

I asked if that explanation worked even though the TJF-145, which is also a fixed-type, does not have one, he said it would not be a problem.

The biggest concerns are the customers who currently use the R, and it is thought that the message communicated to them will be **⊕ simplification of the tip shape + ⊕ ability to provide the same level of CDS as the current removable type by adding a new brush.**

The advantage of a removable type is thought to be that you can visually confirm whether or not the device was properly cleaned, and in order to confirm the same for a fixed-type, ⊕ and ⊕ above are essential. (Only with the new brush can we say “the brush enters this gap, allowing dirt to go out the hole on the opposite side, and allowing you to confirm that there is no dirt = removable-type,” which is why the new brush carries so much weight.)

He said it would be fine to explain to TJF-145 users that the brush is included to make washing easier.

Therefore, it will not be “something that can be presented immediately to users who doubt whether cleaning is being done properly after changing to an F-type by saying if you feel that uneasy, then use this brush,” but the understanding is that it will be essential as a standard accessory in order to make a logical explanation that does not contradict the promotional line used for past R-types in which we said “you can confirm that it has been properly cleaned by removing the tip cover.”

Actually, he commented that there are customers in places like Italy where they are not that concerned, and they tried asking them how important it would be if it were actually sold. The thought was, conversely, that it is necessary to properly educate about the importance of CDS to customers who are not that concerned about it. (Which is obvious if you think about it.)

Thus, the need for this brush is thought to be around the level of “we would like it as a standard accessory,” and thus we think it should make it something that they feel “we would like it as a standard accessory.”

Personally, I feel that ultimately normal people use a toothbrush, and those who are more concerned use an interdental brush, but since this case is more like washing dentures that were previously removed to be washed without removing them, when you consider the process leading up to the final state, I think it will be fine if we are able to come up with a situation where we are able to explain to those who are concerned that the dentures can actually be washed without taking them out (situation where we can reply that the new brush is included as a standard accessory so it can be used that day). (It is not that much of a problem for it to be there for those people who are not concerned, but if it is not there, it is a problem for those people who are concerned.)

This talk ignores the situations in other areas and the fact that we don't know actual costs, etc.

When L Kaneko and L Miyamoto of ET had the TJF prototype the other day, they were unable to convince a nurse who had asked about the ease of CDS for the prototype, so I went to provide an answer.

Using the transparent tip dummy to explain, I was ultimately able to convince her by saying that we had conducted bacteria tests and confirmed that the ease of CDS was equivalent to the current TJF, but then the nurse said that a report in English certifying the ease of CDS would be necessary when it was marketed, and asked, “You do want to sell these, right?”

I sensed that even if, for example, we are able to persuade people, if we don't convince them, they won't buy the product.

I also felt as though it will actually be more important for people in Sales to have a higher level of knowledge than that of L Kaneko and L Miyamoto.

That is why I am in the camp that feels as though, if there are no problems, it should be included in the packaging.

I may be veering off topic, but I would like to first discuss whether it should be included in the packaging.

It would be helpful if Development could provide a little more detailed input on their opinions on the matter.

I will take those opinions and discuss the matter again with the section manager.

⊕ When is it assumed that the brush will be used?

We are assuming use after every case.

⊕ Should the prototype be for something that is to be commercialized or a promotional item (like the clear cap for the H260AZ)?

Since it assumed to be disposable and used after every case, commercializing it would be better.

4 Other

MH-507 and BW-20T are reused. This new brush will be disposable, so it would be ideal to, for example, make the MH-507 disposable, attach the new brush to the opposite end, have it play both roles, and then throw it away after use.

I apologize for the bother, but thank you for your assistance.

.....
Masakazu Higashimoto
R&D Liaison
OLYMPUS MEDICAL SYSTEMS EUROPA GMBH
Wendenstr. 14-18 D-20097 Hamburg
Phone: +49-40-23773-3227 Fax: -656
e-mail: masakazu.higashimoto@olympus-europa.com
.....

.....
Takashi Otawara/jp/olympus@OLYMPUS
.....

Takashi Otawara/jp/olympus@OLYMPUS

4/11/2008 10:52 AM

To

Masakazu Higashimoto/Endo/OE/Olympus-EU@Olympus-Europa

cc

Naoya Shimada/jp/olympus@olympus, Seiji Kitano/jp/olympus@olympus

Subject

TJF-Q180V brush

This is Otawara from Scope Group I.
It has been a long time.

It has been decided that my team will be in charge of the theme in the subject for this period (with Shimada as the lead, and Kitano in charge of Q180V as has been the case up until now).
Thank you for your assistance.

In regards to the brush, we have started to break down current issues so it can be introduced as simultaneously as possible with the TJF-Q180V.
There are many points that are unclear, and I am sure the questions will keep coming as we move forward, but I would like to ask for your help.

First, I please let me know some of the basics.

1 How much need is there for a brush in the first place?

It is my understanding that it is "something that can be presented immediately to users who doubt whether cleaning is being done properly after changing to an F-type by saying if you feel that uneasy, then use this brush."
What percentage of TJF-Q180V users are you predicting will voice the dissatisfaction above?

2 When is it assumed that the brush will be used?

Should it be used after each case, or will it be fine to use the brush at the end of the day?

3 Should the prototype be for something that is to be commercialized or a promotional item (like the clear cap for the H260AZ).

Do you want it to be something users purchase?
I am not very clear on the level of consciousness of CDS in OMSE.
Do you have a desire for which is better?

We would like to gradually decide on the specs from the outline based on this information.

- Made in-house or purchased?
- Disposable or reusable?

- Manufactured in house or purchased from a vendor?
- Exterior shape
- Packaging method

As well as others.

I apologize for the bother, but I await your answers.



TRANSPERFECT

City of New York, State of New York, County of New York

I, Aurora Landman, hereby certify that the document "OLY-BIGLER 0176748" is, to the best of my knowledge and belief, a true and accurate translation from Japanese into English.

Aurora Landman

Sworn to before me this
September 14, 2017

Signature, Notary Public



Stamp, Notary Public

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
From: Shinji1_lwata/jp/olympus
To: <Takashi_Otawara/jp/olympus%olympus>
Sent: 6/3/2009 8:16:02 PM
Subject: Re: TJJ brush: Request to investigate the advisability of introduction in OAI/NFM
Attachments: pic21813.gif; pic22195.gif

TL Otawara,

Thank you for your reply.
Understood.

I will consider proceeding with absolutely not including the brush in the package, but making it possible to introduce it separately after introducing the scope when there is the strong desire to do so.

That is all.
Thank you.
Iwata

 Takashi Otawara/jp/olympus

Takashi Otawara/jp/olympus
6/3/2009 6:32 PM

To: Shinji1_lwata/jp/olympus@olympus
cc
Subject: Re: TJJ brush: Request to investigate the advisability of introduction in OAI/NFM; [Shinji Iwata](#)

Iwata,


Thank you for your hard work today.

Though we would like to tell NFM as well that we would like to avoid including in the packaging by all means, Development has no problem in particular with the introduction.

If there were, the worry is that “would orders exceed the capacity of the vendor currently doing the manufacturing if orders increased?,” but since they are not predicted to increase as much OMSE thinks, it is thought that there is no need to worry so much and there will be no problems.

I believe the effort necessary during sales promotions that you already gave as an example will be a major disadvantage.

Otawara

 Shinji1 Iwata/jp/olympus

Shinji1 Iwata/jp/olympus
6/2/2009 3:44 PM

To: Takashi Otawara/jp/olympus@olympus
cc
Subject: Re: TJJ brush: Request to investigate the advisability of introduction in OAI/NFM; [Takashi Otawara](#)

TL Otawara,

Thank you for your hard work.

As communicated to you yesterday in the CC, I sent an email about the brush to BC and received the following questions from NFM. I would like to consult with you on how to answer.

- Is it really that difficult to add NFM as a destination since it has been decided to introduce the brush for OMSE?

Though they are thinking of a way to convince NFM to not introduce the brush, OMSC is saying that the reasoning for not introducing it is a little weak, and would like to strengthen that reason.

The announcement contains the nuance that it would require development man-hours and costs, and that it would hinder the start up of production of the TJF-Q180V, but those were reasons for when it was included in the packaging... I would like to prepare a response in case they request that the brush be introduced even if it is not at the same time as the scope, and even if they say that the brushes can be made slowly.

From a sales perspective, as stated below, there are few advantages, but several disadvantages, to introducing the brush, and I would like to include these in the response.

- Can we give a good explanation for why the brush was introduced even though we have already obtained validation? (It will cause doubts among customers.)
- There will be increased support for something that is unnecessary, and it will be time consuming.
- Care will become complicated if there are different methods for introduction for each region.

I'm sorry for the bother, but if you could please answer.

Iwata

Takashi Otawara/jp/olympus

Takashi Otawara/jp/olympus
6/1/2009 8:55 AM

To: Hitoshi Minasawa/jp/olympus@olympus

cc: Masanobu Koitabashi/jp/olympus@olympus, Masayuki Yamaguchi/jp/olympus@olympus, Naoya Shimada/jp/olympus@olympus, Seiji Kitano/jp/olympus@olympus, Shinji Iwata/jp/olympus@olympus, Takayasu Miyagi/jp/olympus@olympus, Tomomichi Onoe/jp/olympus@olympus

Subject: Re: TJF brush: Request to investigate the advisability of introduction in OAI/NFM; Shinji Iwata

GL Minasawa,

Thank you for examining the matter.
Understood.
Thank you.

Otawara

Hitoshi Minasawa/jp/olympus

Hitoshi Minasawa/jp/olympus
5/31/2009 7:30 PM

To: Takashi Otawara/jp/olympus@olympus

cc: Masanobu Koitabashi/jp/olympus@olympus, Masayuki Yamaguchi/jp/olympus@olympus, Naoya Shimada/jp/olympus@olympus, Seiji Kitano/jp/olympus@olympus, Shinji Iwata/jp/olympus@olympus, Takayasu Miyagi/jp/olympus@olympus, Tomomichi Onoe/jp/olympus@olympus

TL Otawara:

Thank you for your assistance. This is Minasawa in GI Marketing.

Thank you for your email.


I consulted with Iwata on Friday, and we decided to negotiate with BC so the response will be on time for the FDR on June 11.

While we are thinking of giving BC a deadline of the 8th for their response, we will proceed so that it is on time for FDR even if the submission is late.

I apologize for the bother, but thank you for your assistance.

Minasawa

Hitoshi Minasawa
GI Marketing Group
GI & Respiratory Marketing Department
Phone: +81-3-6901-3948
FAX : +81-3-6901-3959
E-mail: hitoshi_minasawa@ot.olympus.co.jp

 Takashi Otawara/jp/olympus

Takashi Otawara/jp/olympus
5/28/2009 3:11 PM

To
Hitoshi Minasawa/jp/olympus@olympus

cc
Masanobu Koitabashi/jp/olympus@olympus, Masayuki Yamaguchi/jp/olympus@olympus, Naoya Shimada/jp/olympus@olympus, Seiji Kitano/jp/olympus@olympus, Shinji Iwata/jp/olympus@olympus, Takayasu Myagi/jp/olympus@olympus, Tomomichi Onoe/jp/olympus@olympus

Subject
Re: TIF brush: Request to investigate the advisability of introduction in OAI/NFM; Hitoshi Minasawa

GL Minasawa,


Thank you for examining the matter.
Understood.

I apologize for returning a question with a question, but when can we expect a response?

Our limit is 6/10 (the day before FDR-1 on 6/11), but since there will be major revisions should the response be "introduction and including in the packaging are essential," we would like it as quickly as possible.

I apologize for the bother, but thank you for your consideration.

Otawara

 Hitoshi Minasawa/jp/olympus

Hitoshi Minasawa/jp/olympus
5/27/2009 10:03 PM

To
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cc

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Subject

Re: TJF brush: Request to investigate the advisability of introduction in OAI/NFM, Takashi Otawara

TL Otawara:

Thank you for your assistance. This is Minasawa in GI Marketing.

Sorry to break into the conversation.

I was wondering if you would allow us a little more time for your request.


I asked Iwata to do the investigation the other day, and though it is his intention to take action, DDW just happens to be held from the end of this week through the beginning of next week in the United States, bringing OAI marketing functions to a complete halt, and I don't think we can have them make a decision until June 3. (While it may be possible to ask NFM in advance of that, I think the deadline of June 3 will be difficult for OKM as well.)

I apologize that there are areas of our handling that have fallen behind, but I hope that you will understand in light of the situation above.

Thank you.

Minasawa

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 Takashi Otawara/jp/olympus

Takashi Otawara/jp/olympus

5/27/2009 3:23 PM

To

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Subject

TJF brush: Request to investigate the advisability of introduction in OAI/NFM

Iwata,

This is Otawara from Scope Group 1.
Thank you for your assistance.

I am writing with requests regarding the subject.
I apologize for the long email.

[Requests]

Please confirm the following with OAI and NFM, which are regions where the TJF-Q180V will be introduced (not necessary for OMSE).

- ◊ Necessity of introducing a cleaning brush for the rear of the raising base axis (tentative name: JTF Brush)
- ◊ Supposing the response is that ◊ is necessary, is it necessary to include it in the scope packaging?

[Requested deadline for your response]

Sometime during normal work hours on June 3, 2009 (I apologize for the rush. We are synchronizing this with the submission date for the TJF-Q180V FDR-1 materials.)

[Circumstances behind commercializing the TJF brush]

There are plans to make the tip structure of the TJF-Q180V, which had both R-type and F-type up through the 160 series, just an F-type.

There are three main reasons for this.

- 1) Due to the increase in the CCD size for the PF-2 ERCP scope, the outer diameter is wider than the TJF-Q180VR, and it was discovered that the commercial prospects were not satisfactory.
- 2) Since the TJF-Q180VR is wider than the TJF-160VR, it is necessary to start production of a new tip cover. If you take the IPF-2 generation into consideration, there are four tip covers (1 for JF, 3 for TJF), and it was determined that this is certain to cause confusion in the market, such as the cap falling off due to attaching the incorrect one.
- 3) There will be an even greater burden on man-hours and it will be more difficult to secure the schedule for a simultaneous start up of production with the TJF-Q180VR.

Based on these, when I checked with OMSE and NFM, who have introduced the R-type:

OMSE → Approved conditional on starting production on a brush that can wash around the axis behind the raising base.

NFM → Introduction is unnecessary.

The confirmations above were made in the fall of 2007, and since a year and a half has passed since then, I would like to check with OMSE and NFM once more through an official route, and to check the necessity of introducing the brush in the OAI region, which has not been confirmed.

I am already coordinating separately with OMSE, and would like you to investigate the wishes of OAI and NFM.

[Main specs]

Image (Top is the current TJF brush, bottom is MH-507)

<<Attachment deleted by Otawara>>

- Bristles are nylon
- Unsterilized, disposable
- Brush to be manufactured by an outsource vendor

[Schedule]

Mid July 2009: Product Planning Meeting
End of November – End of December 2009: Trial Manufacture Meeting

[Additional notes]

Though it would be ideal to introduce the brush at the same time as the TJF-Q180V Trial Manufacture Meeting, the final shape is not fixed, and doing at simultaneously is seen as being difficult. OMSE has already accepted this, and replied earlier that it is fine as long as there is a stable supply.

However, OMSE is very particular that it be included in the scope packaging. Packaging it along with the scope will have an impact on feasibility at the TJF-Q180V Product Planning Meeting, so we have started coordinating so that it can somehow be commercialized without including it in the packaging since, in the worst case, it would lead to a delay in the TJF-Q180V schedule.

OMSE is a little difficult, so please allow me to carry out the investigation with them in a different way.

So, my view is that the following response would be ideal:

“The introduction is solely for OMSE, and OAI and NFM don’t need it. OMSE, the only one to introduce it, sees not including it in the packaging as being fine.”

That is the situation under which the investigation will be done.

Since the contents may be insufficient to communicate the matter, I will call you with additional notes if anything is unclear.

I have consulted with GL Minasawa on how to release information on the product, and it was determined that the same route for releasing information used for TJF-Q180V would be optimal, and though I am sorry to trouble you, that is why I am making the request to you.

I apologize for the bother, but thank you for your assistance.

End



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I, Aurora Landman, hereby certify that the document “OLY-BIGLER 0194722” is, to the best of my knowledge and belief, a true and accurate translation from Japanese into English.

Aurora Landman

Sworn to before me this
September 14, 2017

Signature, Notary Public



Stamp, Notary Public

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