
From: Nathan Moskowitz <nmosk@hotmail.com>
Sent: Wednesday, May 25, 2011 7:27 AM CDT
To: eric sugalski <eric@bostondevice.com>; andy moskowitz <andymoskow@gmail.com>
Subject: RE: Fusion Device

Eric,
I'll talk to you later today. I got caught up until late again.
Nathan

From: eric@bostondevice.com
Date: Wed, 25 May 2011 08:25:21 -0400
Subject: Re: Fusion Device
To: andymoskow@gmail.com
CC: nmosk@hotmail.com

Hi Andy -

The detail that I was trying to point out in the last picture is that the screw you recommended is *significantly* larger both in diameter and in length when compared to the screw that we have been planning on using. We are planning on using a #1 screw, which has a much smaller head diameter and pitch diameter than the one that you proposed which is a #6 screw. Moreover, it has a pan head (yours was a countersink-style flat head), so it ours will rotate much better in the bore that has been designed. These same problems will be encountered with the 90091A112 screw that you sent in your latest email.

Please let me know if you have further questions / comments about this.
Thanks,

Eric

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On Wed, May 25, 2011 at 6:26 AM, Andy Moskowitz <andymoskow@gmail.com> wrote:

Dear Eric,
although it has a funny tip that was the initial screw we used in cadaver testing,
Anything with that core diameter is acceptable- for example
90091A112 would be acceptable. I don't know the core diameter of the current screw you are using the one we
have in the files was modified from this core diameter. If you have the same core diameter there is no need to
change to a different screw.
my father said he will try to call you with the other issues later today.
thanks,
Andy

On Tue, May 24, 2011 at 2:14 PM, Eric Sugalski <eric@bostondevice.com> wrote:

Andy -

Attached is an image of the fusion device with the screw that you specified. I don't think this is the correct screw. Please check on this and provide an alternative part if you would like one implemented.

Eric

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On Tue, May 24, 2011 at 1:44 PM, Andy Moskowitz <andymoskow@gmail.com> wrote:

By "before" I assume you mean the screws that we have in our present design. If you are referring to a different version, please provide details (i.e. screw drawing, part number, etc.)

90330A500 is the mcmaster part in the original or a variation of such.

I still do not understand, Andy. First, are you talking about the "bone screws" or the "drive screw"? Could you *please* provide a sketch / powerpoint file that points to what you are considering the "casing" and the detail that you feel could be eliminated? A simple powerpoint file with arrows pointing to the correct feature would be really valuable here.

The *sheath, covering* around the screw as it goes in the box that acts as a guide in or other boxes we eliminated this feature. Please reference the PDF file. my father will speak to you about it

Also, regarding the "bullet shape," is this different than the "taper"? Please clarify this for me with a dimensioned drawing.

It is different my father will talk to you about it, its teepi shaped more circular at the end like the nose of a jet airplane or the shape of a bullet at the end

My father said he will call you later tonight or tomorrow.

Thanks,

Andy

On Tue, May 24, 2011 at 11:48 AM, Eric Sugalski <eric@bostondevice.com> wrote:

Andy -

Please see my comments below.

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On Tue, May 24, 2011 at 7:51 AM, Andy Moskowitz <andymoskow@gmail.com> wrote:

There were a large number of fusion boxes sent in digital format all having varying geometries. If you would like the side holes implemented, could you please provide specific diameters and distances from 2 labeled datum planes? Please provide this information in a 2D format (i.e. sketch, powerpoint, etc).

with regards to the solidwarks I was specific when I said it should be the 25 degrees boxes with side indentations that are 18 mm long. (enclosed is a PDF file)

Thank you for providing the drawing. We will try to implement the circular holes in the sides of the wedge pieces.

If you (Flexispine) would like to supply us with custom screws, we will integrate them into the assembly. Otherwise, we need to stick with standard screw sizes that can be sourced through supply catalogs (i.e. McMaster-Carr). Please advise.
you should keep with the original mcmasters screws we used before the - diameter need not be reduced.

By "before" I assume you mean the screws that we have in our present design. If you are referring to a different version, please provide details (i.e. screw drawing, part number, etc.)

with regards to the casing I mean there is material around it like a screw guide . In our design (reference the PDF file) we eliminated the need for that we had had a self drill guide so 1)the screws could have a wider diameter and 2) there would be more room for the cavity. this was an important feature of our original design please look more closely at the solid and pdf file to incorporate here

I still do not understand, Andy. First, are you talking about the "bone screws" or the "drive screw"? Could you *please* provide a sketch / powerpoint file that points to what you are considering the "casing" and the detail that you feel could be eliminated? A

simple powerpoint file with arrows pointing to the correct feature would be really valuable here.

Please specify by file name or resend the correct file that illustrates the taper. We reviewed the files and could not identify any of the fixed fusion boxes with the tapered geometry enclosed is a PDF file of what I mean by tapered I am certain that I sent and you received the solidworks of those files a while back. If you examine the PDF file the first part of the box is 10x11 mm the later part where there are no screws is 10x10 which we need for the geometry of the spine. As I stated before if it is 10x13 the later part should be 10x10.

Ok, thank you for this file. We will try to integrate the taper shown here within the context of the current design.

Andy & Nathan - we have already spent much more time on this project than I had anticipated. I am taking a huge loss here. Most of these details that are being requested now were never part of the original proposal request. In not just one but multiple emails before you started work or I signed the contract I stated in emails 1) the dimensions 2) that it should be bullet shaped 3) that it should be tapered 4) side indentations that could be used to reduce the width of box 5) that the outward dimensions with the boreholes should be minimized , These were not just in one email they were in multiple and of course maintain the advantages of the predicate boxes.

Andy - with all due respect, sending me a wish list of design ideas spread between a dozen emails is extremely confusing. From now on, we will require all requirements to be listed in a standard "design inputs requirements table." You can use our format (attached) for compiling these requirements. As expressed in this document, the requirements will need to be clear, quantifiable, and succinct. For instance, "bullet shape PLIF" is extremely ambiguous. It provides no information about the dimensions that need to be applied. Having this table complete in advance of starting any work will enable us to develop products much more quickly for you. Moreover, this is a critical document that is required for regulatory purposes in developing medical devices. If you have any questions about the document or how it should be completed, please let me know.

Also, regarding the "bullet shape," is this different than the "taper"? Please clarify this for me with a dimensioned drawing.

Thanks,

Eric

I think my father will call you later on.

Andy

On Mon, May 23, 2011 at 7:25 PM, Eric Sugalski <eric@bostondevice.com> wrote:

Andy & Nathan -

Please see my embedded responses below (in blue):

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On Mon, May 23, 2011 at 5:27 PM, Andy Moskowitz <andymoskow@gmail.com> wrote:

with regards to cavities there should be holes on the side like the other boxes we sent
my father could answer you more with regards to the cavities

There were a large number of fusion boxes sent in digital format all having varying geometries. If you would like the side holes implemented, could you please provide specific diameters and distances from 2 labeled datum planes? Please provide this information in a 2D format (i.e. sketch, powerpoint, etc).

with the screws you only need to reduce the head diameter not the core diameter. If you cant find good screws with a small enough head and wide diameter you can simply take a custom screw and shave some of the head diameter off. or look at the other designs we have with indentations that look like triangles on the side. this novel and simple concept allows for bigger diameter heads and eliminates the need for a side wall.

If you (Flexispine) would like to supply us with custom screws, we will integrate them into the assembly. Otherwise, we need to stick with standard screw sizes that can be sourced through supply catalogs (i.e. McMaster-Carr). Please advise.

another feature if you look at the other designs with and without expansile mechanisms you will notice that there is no need for such protective casing around the screw. You can leave that part open please look at those other designs, It also might be better to put the screws in one piece instead of seperating them to 2

The female component around the screw is used with a retaining ring to position the fixed (lower) wedge in-place while the moving (upper) wedge advances via

screw. Without this retaining ring there will be excessive play in the mechanism, and it will not function properly.

We tested the boxes and it did not have a protective casing (without the expansible mechanism) and it did great)

I do not understand this comment. Please elaborate. If you have physical samples that you have already fabricated, why did you not provide them to us for reference in this project?

also it is not bullet shaped please do a google image search for PLIF bullet and you will know what I mean

If you would like a "bullet shape" please provide a dimensioned sketch, and we will try to implement the feature. "Googling" PLIF provides insufficient data.

with regards to taperdness. Please look at the solidwork of the long boxes 18mm (without an expansible mechanism.

Please specify by file name or resend the correct file that illustrates the taper. We reviewed the files and could not identify any of the fixed fusion boxes with the tapered geometry.

as you will notice the frontal part is 10x11 the rest is tapered to 10x10 as with here if the smallest you can get it down to is 13x10 then the frontal area should be 13x10mm and the rest should be 10x10 I have a pdf file of the drawings if this would be of any help let us know. Also what of the design without screws?

The non-screw version was already provided awhile back. As we pointed out (and you agreed), the concept was flawed. The engineering work was completed for this concept, and it will be provided to Flexispine at the end of the project along with the screwed version.

also the angles of the screws are 25 degrees right? because that is what is needed for a surgeon

Yes, the angle of the screws are 25 degrees.

Andy & Nathan - we have already spent much more time on this project than I had anticipated. I am taking a huge loss here. Most of these details that are being requested now were never part of the original proposal request. Moreover, we are spending a great deal of time trying to decipher these messages and translate them into output that can be used for engineering. I have suggested several times that we communicate via web conference. I

understand that timing may be difficult, but using a visual-based method to have these conversations is *much* more efficient than trying to describe mechanical aspects through words. I would like to continue working with you guys, but this mode of communication is making it very difficult for me. I am curious to hear your thoughts and understand how you have resolved these issues in your other collaborations.

Regards,

Eric

Andy

On Mon, May 23, 2011 at 3:03 PM, Eric Sugalski <eric@bostondevice.com> wrote:

Andy & Nathan -

Please see the attached e-drawings for the revised spinal fusion device. A few notes:

1. A large hole has been added to the center of each part for the bone paste. We have tried to maximize the size of this hole while still maintaining the structural integrity of the upper and lower components.
2. Regarding the dimensions, we are at 13mm wide, 18mm long, and 10-13 tall. We are using #1 screws (very small) to reduce the head diameter, and we have reduced wall thicknesses to minimize overall width. Reducing the width any further will require custom bone screws and/or will weaken the strength of the parts.
3. We have tried to design in the "bullet" shape as best as we understand based on prior emails. Additionally, there has been mention of a "taper" which we have tried to represent in this design. If we are still not getting these details right, please provide visual and dimensional information. If you need to fax a hand sketch, please send to (617) 279-0057.

If there are any other modifications needed, please let me know asap. I would like to get this prototype released in the next day or two if possible.

Thanks,

Eric

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