

## Spine Surgery Products for Anterior and Posterior Fusion Procedures



**John Stephani**  
CEO  
NeuroStructures Inc.

**CEOCFO:** *Mr. Stephani, what is the concept behind NeuroStructures?*

**Mr. Stephani:** NeuroStructures is an employee owned and operated USA company which is focused on adapting to the needs of neurosurgeons and orthopedic surgeons as well as improving the economic and operative process in the hospitals. We cooperate with surgeons to design and manufacture very high quality products that are reliable and include value added features which are unique and have been awarded or have pending USA patents. I stress the emphasis on high quality as this is the paramount goal at NeuroStructures for our design and manufacturing. We strive to provide products which are making the current fusion technique's easier and reliable while adding value by patenting these features.

**CEOCFO:** *Are surgeons turning to you with an idea or are you going to surgeons?*

**Mr. Stephani:** It is both. We are focusing on current trends in the fusion market and we do offer the ability of the surgeon or an individual with an idea to develop that product through us. NeuroStructures capabilities span the product development spectrum from product definition and metrics to portfolio management. We cover all the steps needed to get the product to market (design, prototyping, testing and regulatory approval). Furthermore, we actively work with our partners to ensure that their business, products and services grow successfully in the marketplace.

**CEOCFO:** *Are there many companies that focus in your arena?*

**Mr. Stephani:** Absolutely, it is a very mature market at this time. Most of them will have the same products we have and many of them are striving for new technologies or "disruptive" technologies.

**CEOCFO:** *What do understand about this type of product that gives you an edge?*

**Mr. Stephani:** Our edge will be that we are entering the market later. We have seen what works and what doesn't and we have heard what the surgeons are asking for as improvements. We are able to pick all the best features of what has been done previously and then look at the Intellectual Property field and see if we can find something that will give us an added advantage or at least an attractive feature.

**CEOCFO:** *Is it often a matter of different materials?*

**Mr. Stephani:** Materials play a big part. Materials have changed and there are different opinions on materials. In several of our products, we have tried to incorporate as broad a spectrum of materials that we can. In other words, we can offer a product in PEEK material or we can offer it in titanium. We try to cover a larger percentage of what the market is using.

**CEOCFO:** *Is there a consensus among surgeons as to what works best? How much variety is there?*

**Mr. Stephani:** I would say that there are really safe schools of thought and there are multiple schools of thought when it comes to technique or what implants to use. I think the common thread is everyone wants the best thing for the patient and at times, you have to adapt what you use with the particular surgical strategy for the patient.

**CEOCFO:** *What are the determining factors of what a surgeon uses?*

**Mr. Stephani:** Level of training and/or product familiarity plays a big role in what surgeons' uses. What is available in the hospital also plays another role. Some hospitals are not wanting to use the more expensive, newest technologies and are sticking with the classical approaches.

**CEOCFO:** *Are patients given choices or do they just go with what the doctor chooses?*

**Mr. Stephani:** In this industry, many of the patients are aging and not as internet savvy as some of the younger, active patients. They may take what the surgeon recommends or what the surgeon's reputation has dictated. I think in the USA

as a whole, more people are researching what is being done medically and what is coming on the forefront. I have to say that the USA patient population is becoming more educated and would have an opinion or second opinion on what is being prescribed to them.

**CEOCFO: *What are you working on now?***

**Mr. Stephani:** We are still filling out our fusion line, which is focused on products that the majority of the clinicians and cases that are being done use. We do not have any exotic products at this point. We are a profitable company and we are not carrying any dept. Once we are able to free up enough capital, we will start working on products that are the latest "Break Away" technology, which require longer more capital intensive R&D and FDA Regulatory requirements. These products usually require a much longer timeframe to market than the base fusion products.

**CEOCFO: *How do you stand out from the crowd when you are approaching potential buyers?***

**Mr. Stephani:** When you are ten million dollar company and competing against billion dollar companies, it is really hard to stand out. The big companies just have all the products and services to offer which we cannot. They have all the horse power needed. I believe what has given us the biggest recognition is that some of our products are distributed or under license by these big billion dollar companies. This arrangement or partnering has demonstrated to our customers that we are a serious player and we have products which are of the highest quality and our processes ISO/GMP/FDA are recognized by the Stryker's and SeaSpines/Integra's of the world. This is a unique and highly valued endorsement that our products are as good as theirs because they are selling them. I think that is probably what at this stage in our development has most stood out as our signature.

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**CEOCFO: *What is your geographic reach today?***

**Mr. Stephani:** We are entirely focused on keeping up and managing our business only domestically in the US. We have been approached by many ASIA/Pacific, Latin American and EMEA distribution partners but we have stayed focused in the USA.

**CEOCFO: *Where do you manufacture?***

**Mr. Stephani:** Everything is designed and manufactured in the USA. We are a 100% USA owned and operated company. Spine companies do not typically machine their own products, they use vendors. Even the billion dollar companies do not manufacture their own stuff, they go to what they call qualified vendors and we use some very highest quality, qualified vendors in the United States.

**CEOCFO: *Do you need to maintain a large inventory or are you able to manufacture as needed?***

**Mr. Stephani:** That is the downfall of most of our competitors. Many of them are not profitable. Many of them are struggling with the need for capital infusions forcing them to seek private money or debt financing. We have not had to do that. I believe that our ability to manage our assets and manage our growth has allowed us not to have to seek additional funding. Utilization of our current inventory is key and we seek distribution channels where they efficiently utilize our consignment equipment. Some of the larger companies are so focused on sales growth that much of their inventory is underutilized with slower moving distribution partners The NeuroStructures partners will turn our inventory more frequently and do more surgeries per set than many of the other companies.

**CEOCFO: *What products are not getting the traction that you would expect?***

**Mr. Stephani:** We have a product called Resolute an MIS Facet Fusion System. Even though it is a great product, I believe that this surgical procedure has decreased dramatically in the last five years. We have not seen much use of that one.

**CEOCFO: *What is your most unusual product?***

**Mr. Stephani:** None of our products are really viewed as "unusual" because we have tried to stay within the current state of the art fusion market which is a pretty well established mature market. What I could say is that our new lateral plate has some unique features to it, which would be viewed as unique or unusual.

**CEO CFO: *Unique in what way?***

**Mr. Stephani:** It is an adjustable plate which allows the surgeon to select a size to fit the levels of the spine more adequately and more efficiently as it allows for micro adjustments to the length and it has a very unique patent pending locking mechanism.

**CEO CFO: *Might a particular surgeon use all of your products?***

**Mr. Stephani:** Because we have a small customer base, yes, most of them are using all of our products. I would say nowadays that our customers, the distributor and the surgeon would have access to ten or more spine lines that they choose the most appropriate implant for the particular surgical strategy for the patient's condition. Therefore, they will spread the business over multiple companies. NeuroStructures is a young company and our portfolio of products is growing. As we bring more products online these surgeons will be able to utilize more and more of the NeuroStructures products for their patients.

**CEO CFO: *How do you measure the results? If someone is using a screw from you and a plate from someone else, how do you measure what has worked well when there are many physical pieces involved along with surgeon skill and patient compliance?***

**Mr. Stephani:** I would say there are different components by which to measure this success. One of them would be ease of use. If the surgeon is not exhibiting difficulty using the hardware and is successfully implanting the hardware into the patient, that is a good thing. If he has many complaints that it does not fit or bend or the screw backs out etc, that would be a sign that you are not succeeding. The other component to measuring the success of the product would be clinical results. If the surgeon was not able to obtain the fusion that he was looking for with a patient that may be due to hardware failure. If you have those, that is not a good thing either. You would measure your success in this way. Positive Outcomes and intended results are pretty solid criteria with which to measure the success of your products.

**CEO CFO: *How important is the individual receiving the surgery? What factors are in play?***

**Mr. Stephani:** Absolutely the patient selection or patient condition most dictates what products will be selected for surgery by the clinician. There is use of the products for degenerative diseases. You have a patient that might have genetic defects in the body. You have various stages of bone density. The anatomy changes slightly with every person and you have a product that can adapt to it or have an instrumentation that can change the product to adapt to it.

**CEO CFO: *Why choose NeuroStructures?***

**Mr. Stephani:** For a doctor, we have reputable, clinical results. We have instrumentation which we believe was designed with a surgeon in mind and the efficiency of the operating room. We are ISO certified, which announces firm confidence in our quality. Some companies out there are not ISO certified. We are USA made, which is another attribute. We are a company of individuals that have 35 years plus of experience in this field. We know the field and are managing it correctly. We are managing our business and growth efficiently. We have established a solid base business supporting our efforts and growth. We have a highly adaptive platform for surgeons and industry colleagues to bring new ideas to fruition. We have a sustainable growth model which puts Quality, the surgeon and the Distributor at the forefront of our focus.

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Interview conducted by: Lynn Fosse, Senior Editor, CEO CFO Magazine



**NeuroStructures Inc.**

For more information visit:  
[www.neurostructures.com](http://www.neurostructures.com)

Contact:  
John Stephani  
(800) 352-6103  
[js@neurostructures.com](mailto:js@neurostructures.com)