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Q&A with Craig D. Allmendinger, CEO of Northeast Scientific, Inc. a Specialized Reprocessor of Single-Use Surgical Instruments and Medical Devices including Cleaning, Packaging, Sterilization and FDA Approval for Multiple-Use

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"Our continued success can be attributed to the fact that we have developed proprietary validated and verified technologies and processes that are very effective in the reprocessing of single-use devices."- Craig D. Allmendinger

CEOCFO: ***Mr. Allmendinger, would you tell us about Northeast Scientific?***
Mr. Allmendinger: Northeast Scientific was started by me about fourteen years ago. We are a specialized reprocessor of single-use devices. We take a single-use device and reprocess it so it can be used again sometimes multiple times. These devices can be used between three and ten times depending on the materials that make up the device. This is all done under FDA oversight. We must get an FDA clearance, which is nearly identical to the original device, in order to do what we do.

CEOCFO: ***If it is single-use, why do you recycle?***
Mr. Allmendinger: The industry officially started maybe thirty years ago when single-use devices started showing up in hospitals. The hospitals were looking at some of these devices and saying it is so robust that they did not know why it was single-use and that they could clean it and reuse it. That had been going on for many years until the FDA stepped in and said "Wait a minute, these are deemed single-use so why are you reusing them?" The quick answer was that they were saving money. The cost of healthcare has gone up considerably and continues to rise exponentially. It was originally an approach by the hospitals to try to reduce the overall costs in the operating room. The FDA stepped in about sixteen years ago and said we have to do something about this because it is becoming an unregulated process and patient safety could be compromised. There was no oversight and it was sort of a free-for-all. So the FDA understood that this was a necessity because of the high cost of healthcare, specifically the high cost of the single-use devices, so they decided to regulate it. This meant that if you wanted to reprocess a device you must validate that process and verify the efficacy of that process. This is known as substantially equivalence. When the FDA regulations were put into place, all the hospitals stopped doing it

because they could not meet those requirements. There were about twenty companies that popped up during the regulation phase and tried to become regulated reprocessors. This resulted in a massive fallout because none of them could meet the requirements that the FDA laid out. These companies all disappeared and a few remained and these few were technologically savvy and were able to satisfy the FDA by meeting those requirements through various exhaustive studies including cleaning, packaging and sterilization. Essentially all of the same studies the original manufacturer would go through in order to receive clearance.

CEOCFO: ***How do you know when it is safe and what do you have to do to get it back to pristine condition?***
Mr. Allmendinger: First we have to prove that it is functionally safe. After cleaning and re-sterilizing we must put the device through a long list of tests. This can include lab testing, simulated use and even sometimes animal studies where the device is stressed well beyond any clinical application. Only after the device can pass all the tests would we deem it usable again. The other part of our testing includes biocompatibility and sterility testing to make sure there is nothing left on the device that could hinder sterilization or ultimately affect the patient in subsequent uses.

CEOCFO: ***Is this each individual device or a group of devices?***
Mr. Allmendinger: We are testing each type of device during validation studies. We usually test about 250-400 devices in any one application to the FDA. Those studies stand as a validation for all the same devices to be reused again. We are essentially testing a statistically significant number of same devices to prove that our reprocessing is safe and effective. Even similar devices require all new validation studies.

CEOCFO: ***What are you doing physically to rehabilitate a device?***
Mr. Allmendinger: It starts with multiple exacting inspections. In our facility every single device is inspected. They are received from the customer inspected immediately for anything that might be and apparent failure such as cracks, kinks, broken parts, separated handles, and exposed wiring; anything that would be obvious. From there they will go through a decontamination and cleaning process which leads to another inspection. If they pass that inspection they will go into functional testing and then on to packaging and sterilization. Each device will go through over fifteen unique inspections. If they pass all of those steps the device is ready for use.

CEOCFO: ***What is the economics with the hospitals?***
Mr. Allmendinger: Our specialty is in the vascular market and we work a lot with vein centers and office based labs. The economics about twenty years was about saving at least 50% of the original cost of each device. So if you pay $100 for a device, you pay $50 for a reprocessed device. You can imagine the economics in a hospital, how much money they were saving. They were cutting 50% of a bottom line cost in the operating room. Today we are seeing more of a hybrid where it might be more like 30% to 40% of savings. I think that is just a maturation of the market where the reprocessors are coming in at a price that is not exactly 50% due to manufacturers lowering the new cost to compete with the considerable price drop. We are seeing about a 40% on average savings on a number of devices that the operating room and labs would purchase.

CEOCFO: ***Does a hospital tend to use a fair number of your devices, all of their devices or is there a tendency to pick and choose?***
Mr. Allmendinger: There is definitely a need to pick and choose. Reprocessing does not work on all of the devices found in the operating room or in the ambulatory surgery center or in the vascular center. This is because there are so many different devices with different uses and these require a wide mix of materials and many of them cannot be reprocessed because they are too fragile. There are a solid number of single-use devices, probably between twenty and thirty that are used every day in the operating room/lab that are being reprocessed.

CEOCFO: ***How often might you add a device when a new device comes on the market?***
Mr. Allmendinger: We try to give the market a chance to decide whether that device is going to be a success. We see a lot of devices come on the market and then within six months you never see them again. Generally you look for one or two years use. We specifically do that because the market is changing all the time. There are new technologies coming out so we keep an eye on the market closely. Sometimes you see a device come out and you know it is going to work, you know it is going to be popular, so we will go out and target that

CEOCFO: ***Do hospitals or facilities get back what they sent you or might a hospital just say they are going to buy new but want some extra income by providing devices to reprocess?***
Mr. Allmendinger: It is a combination of both because what we see in the market is that some doctors want their own devices back while others are not concerned where the devices were first used. Today it is definitely trending more to just buying from the reprocessor whatever they have in stock. There are still the holdouts that say they feel more comfortable knowing that they use the device over again and they know where it has come from.

CEOCFO: ***How do you reach out, is it directly to hospitals, buying groups or distributors?***
Mr. Allmendinger: The reprocessing industry utilizes all three of those. We work with the distributors who will handle all of the sales activities. You need to get in front of the doctor and explain to them what kind of savings they are looking at, that it is safe and sound and it is going to work. Some reprocessors have their own sales force to do that while others will use a combination of GPOs, distributors and an outside sales force.

CEOCFO: ***Your site indicates you have developed some proprietary processes to ensure safe and effective reprocessed products. What might you do that is different from your competitors?***
Mr. Allmendinger: I think the main thing for us is working with devices that have lumens. These are long catheters that have a tube down the middle of them. For years, the FDA was very much against it because no one had proven that they could be cleaned effectively. Some of them are very small lumens that require some very small tools and proprietary techniques in order to clean them effectively. I have seen one other reprocessor starting to get into the market of these lumen devices but for us it is what sets us apart. Our continued success can be attributed to the fact that we have developed proprietary validated and verified technologies and processes that are very effective in the reprocessing of single-use devices.

CEOCFO: ***What is your geographic range?***
Mr. Allmendinger: We are in the US and South America. We have some reach into the Caribbean, Europe and Africa. I would say 95% of our business is in the United States.

CEOCFO: ***What surprised you as Northeast Scientific has grown and evolved?***
Mr. Allmendinger: I think the market and the separation of specialized reprocessing and generalist reprocessing. It seems like for many years it was always going to be a hospital based industry but what has happened is now we have seen a real growth in the cardiovascular market and the vascular market. That kind of specialization back when it started was unheard of. The reluctance, especially in high risk areas, to get into reprocessing was very high. What has happened is our science has proven that we can address that market. I have seen our company become very adept in the technological approach to reprocessing. Before it was a dip and clean and wash process but now it has become a real technological industry. To me, that is surprising and exciting.