Product Engineering, Quality and the Design of Mechanical Oscillation Vest Therapy

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. Participating in the interview is Geoff Marcek, the Vice President of Engineering and Quality at International Biophysics.

Respiratory Therapy: Tell us a little about International Biophysics and your commitment to quality.
Geoff Marcek: International Biophysics is an FDA-registered and ISO 13485 certified medical device manufacturer. We are a 26-year-old company that manufactures, and markets medical devices across the globe. What that means, in terms of quality, for products such as the AffloVest, is that every product goes through a rigorous design and manufacturing process, inspection process, periodic audits by the FDA and other regulatory bodies to verify compliance with all the various regulations.

When we look at new technologies and applications, we really focus on what we feel are disruptive technologies and not minor incremental improvements. In the example of the AffloVest, we see a product category that doesn't have a lot of evolution over time, and we really want to bring something that really disrupts the market and results ultimately in improving patient care for the entire population that uses these types of products.

RT: The AffloVest was the first HFCWO Airway Clearance Vest on the market that uses mechanical oscillation technology as opposed to the traditional compressor-based vests. What do you see as the advantages to that?
GM: There are two types of HFCWO devices, the traditional air bladder or compressor based and mechanical (motor based). Air bladder HFCWO is an older technology and more restrictive for the patient as far as ease of use and portability, things that people would expect in today's world for something they use in their home. Mechanical oscillation vest therapy allows them to get the same type of therapy with full mobility during use and more flexibility to promote adherence to the therapy.

At this year's NACFC conference in Denver, a major HFCWO vest manufacturer, known for decades for their compressor-based technology, presented data showing that mechanical oscillation vest therapy was better than traditional compressor-based. We agree and have from the start. We are thrilled to have been the pioneer in bringing mechanical oscillation HFCWO vest therapy to the market.

RT: In the last issue we published a recent IRB study you conducted on HFCWO vest therapy with Dr Thomas O'Brien. What are the key findings in that study?
GM: For the FDA, clearance for these devices are all classified the same, and companies are expected to provide the same safety and performance data for the FDA to review prior to clearing for sale on the market. The FDA classifies all HFCWO vests on the market as oscillation vests, which are intended to operate through vibration of the patient's abdomen and thorax. During an FDA review process, that's what their interest is, the vibration forces on the torso of the patient.

Our study challenged the hypothesis of some manufacturers that increased cephalad airflow bias was a mode of action for HFCWO vest therapy. The data we gathered does not support that hypothesis and demonstrated in fact that on some spirometry measures lung unction decreased during use while wearing compressor style vests. We believe that all vests operate on the same principle, producing oscillation waveforms on the torso that can thin, mobilize and help clear secretions from the lungs.

RT: What is the product design and development process at International Biophysics?
GM: The design of the AffloVest here at International Biophysics starts with the patients and the users to gather all their feedback about HFCWO devices, and what's lacking out in the current market and what the patients and clinicians themselves would like to see. So, the first step in the design process is to gather all that customer feedback, and then feed that into design process. We then bring the product back to the users and conduct additional surveys and interviews to make sure that what we're delivering ultimately is what they are looking for.

We make sure to cover a broad range of patient factors. For example, the fact that there are many different patient sizes and anatomies led us to offer seven different sizes of AffloVests to make sure that we correctly fit every patient, regardless of their body type. And we make sure that even the motor placement on every size is anatomically correct to ensure that we're targeting the upper lobes and lower lobes of the lungs with four motors on the front and four on the back.

Other engineering driven features include patient flexibility in how they program and operate the AffloVest. There are 3 different operating modes that were designed to mimic the gold standard of hand CPT and provide choices to the patient, so they can customize their treatment into different sequences and save that based on their dialogue with their physician and what they feel ultimately is working best for them with airway clearance.
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If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

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RT: What are the advantages of being in full control of the product development process?

GM: The AffloVest is a sophisticated and highly-engineered product, which required a lot of investment and quite a lot of time, working with many, many suppliers, consultants, contractors, during the entire development cycle. We have three patents issued for the AffloVest, and several others that are currently pending.

Being in control of the design of the AffloVest allows us to respond quickly to patient and clinician feedback. We're able to continuously improve the AffloVest product over time and deliver a better and better product.