CFD software addresses rare valve design problem

Computational fluid dynamics (CFD) software recently helped **Enfield Technologies** *(enfieldtech.com)* Trumbull, CT, solve a flow problem in the control valve of a medical respirator.

The software provided a detailed picture of the flow in the early design stages of the lightweight and portable (about the size of a toaster) respirator. The valve was the primary control element for inhaling and exhaling. Typically, Enfield deals with valve designs for choked-flow pneumatic applications, where the upstream pressure is usually much higher than the outlet pressure. It's easier to design for choked-flow applications because flow profiles are simplified and the equations governing flow are well-behaved.

The respirator valve, however, needed to operate with a nonlinear flow profile in relation to the poppet position. The design challenge was to get an extremely shallow and well-behaved flow control for the first 50% of the valve stroke, followed by a rather steep flow profile for the remaining 50%.

The first step was to gather details regarding the entire system and how it would interact. Discussions with the customer helped provide an understanding of the end product's different modes of operation, if lung dynamics would come into play, and whether upstream conditions varied, as well as other features that dramatically affect system dynamics.

Several physical prototypes were built to help specify performance, prove the valve concept, and determine the necessary flow profiles. Solid models of the valve were built with complex poppet profiles in Autodesk Inventor 3D CAD software and were imported directly into CFdesign. Because Inventor and CFdesign work are tightly integrated, it was simple to make changes to the geometry and then see the effect of the changes on streamlines, mass flows, and flow velocities.

Enfield engineers tested the valves in CFdesign at various positions and in different upstream and downstream conditions to develop preliminary flow profiles. Useful features that increased their understanding of the design as it evolved included the capability to cut a plane through visual representations of velocity and pressure to see flow characteristics at exact points, display bulk parameter mass flow, and view particle trajectories using cylinders and spheres.

After several design iterations, Enfield obtained an acceptable flow profile and built a refined physical prototype. However, further testing revealed a discontinuity in the flow data. The valve was controlled by a microprocessor with an analog sensor to report valve position. Communication to the valve was digital, provided by a PC connected to a proprietary USB-to-SPI translator. The discontinuity could lie anywhere in the system. Possibilities included the PC software, either Enfield's firmware or the customer's, analog signals, interference, pressure anomalies, and mechanical physics.

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US/Japan 'OSPREY' seeks to streamline product approval process

The Bradenton (FL) Cardiology Center is the first center in the U.S. to implant the MISAGO Peripheral Self-expanding Stent System as part of the Occlusive/Stenotic Peripheral artery REvascularization StudY (OSPREY), which will evaluate the safety and efficacy of the MISAGO Stent System for use in the superficial femoral artery (SFA).

The OSPREY clinical trial will simultaneously enroll patients in the US and Japan. Referred to as "Medical Device Collaborative Consultation and Review of Premarketing Applications" under the larger Harmonization by Doing (HBD) initiative, the OSPREY trial was selected as one of two projects to pilot this approach, which is intended to shorten the gap between product approvals in the US and Japan. The pilot program is a cooperative effort led by FDA, MHLW-PMDA (Japan's regulatory bodies), Tokyo-based **Terumo Corp** (MISAGO's manufacturer), *(www.terumomedical.com)*, and Somerset-NJ-based link to Terumo Medical Corporation, a subsidiary of Terumo Corporation.

In the US, OSPREY is a single-arm, multi-