Securos Surgical® AmerisourceBergen

We build *our* work around the way *you* work.

Product Development

Article by Olivia Doane, BS Biomedical & Mechanical Engineering. Edited by Steven M. Fox, MS, DVM, MBA, PhD.

Issue 1 of 3: Design Process

As Securos Surgical grows, our perspective on product development matures. Each new catalog presents the upshot of carefully conducted clinical research, responsible testing, and a corporate mandate that superior quality is the only acceptable standard. Direct interaction with veterinary surgeons and observation of countless procedures inspire our R&D team progress from drawing board to surgical table. Blending specific biomedical and bioengineering strengths with experience and ingenuity drives our team to product success. Product designs center on efficiency and affordability so that veterinary surgeons, and ultimately their clients, benefit from the cost-efficient implementation of best medicine.

IDENTIFY
- Background and market research
- Specify requirements

INVENT
- Brainstorm, evaluate and choose solution
- Develop and prototype solution
- Test solution

IMPLEMENT
- Quality control
- Marketing
- Sales and distribution

In order to meet the goals noted above, it is important to follow a design process whereby each phase of a project is closely analyzed and tracked to ensure goals, timelines, and budgets are met. Incomplete attention to any of these phases presents the potential for designing an inappropriate prototype that does not address user need, excessive costs and presentation of an end product that is likely commercially unacceptable. To avoid these circumstances, the Securos Surgical R&D team follows a design process that can be broken into three main phases that govern the project.

The first step is the IDENTIFICATION phase. During this phase, the goal is to identify the market need for a new product. Identifying this need may appear simplistic, however it is important to note that all further resourcing and activities are wasted if the need is incorrectly or incompletely defined. This exercise is focused to an extensive analysis of historical and present methodologies (to include advantages and short-comings), projected changes in methodologies (and for what reasons and with what potential complications), receptivity of such changes, and return on investment for the research and development to bring the new 'product' to market.

Once the innovation has been fully defined and is deemed technically feasible and a marketable project, it begins the second and most robust phase of the design process–the INVENT phase. The invent phase includes several sub-phases. First, is development of several conceptual designs. It is important to introduce multiple options; with each option critically assessed. From here only one design moves forward as the *preliminary design*, which undergoes the rigors of initial testing/validation. Initial validation typically goes hand-in-hand with the prototyping process, and can be as streamlined as getting prototypes into the hands of multiple surgeons.

DESIGN VERIFICATION and VALIDATION steps, thereafter, include preliminary design review, laboratory testing and data analysis. Laboratory testing is

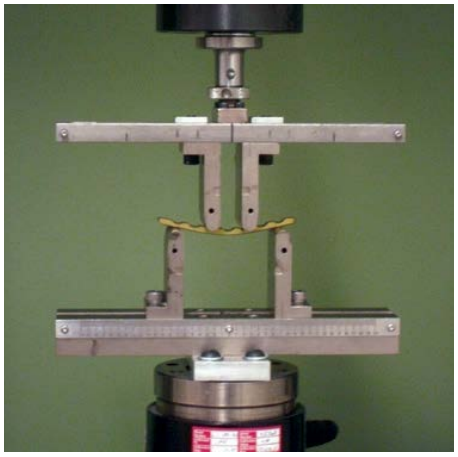

Figure 1: 3-Point bending of a PAX locking fracture fixation plate.

the first critical pass-or-fail hurdle for the new innovation before it is trialed *In Vivo* by trained veterinary surgeons conducting clinical trials. Once introduced to clinical trialing, the innovation may undergo multiple iterations of modification and each modification may require laboratory assessment before inclusion to the clinical trialing process. There are a variety of different verifications and validation challenges, depending on what features are to be analyzed; whether it is a plate in bending or a crimp tube in tension/ compression (see Figures 1-3).

Following completion of the design iterations between conceptual design and prototyping/ design verification, the innovation moves into the DETAILED DESIGN phase. This is where the final changes are made, the computer-aided design models are finalized, and manufacturer drawings are created for production.

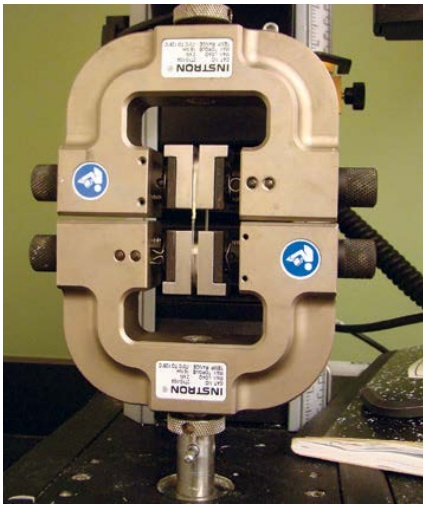

Figure 2: Crimp tube construct tensile test.

At this point the project is in the third and final phase of the design process, which is referred to as the IMPLEMENTATION phase. At this point design is complete, production materials are purchased and detailed product design is communicated to the manufacturer. Critical quality control is essential at this phase. Product marketing and sales, as well as distribution thereafter follow in compliance to the structured marketing plan for new product introduction to the market.

From reviewing this process, it is apparent that product development is an extensive, time and resource-consuming process; necessary to ensure product accuracy and developmental efficiency throughout the design phases; yet essential to ensure the need is defined properly, the design addresses the needs, and the product is commercially viable.

Figure 3: Crimp tube compression test.

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Issue 2 of 3: Manufacturing

Upon completion of the extensive, time and resource-consuming product development process discussed in the previous issue, it is then time to communicate the detailed product design and specifications to the manufacturer for production. Detailed drawings with all specifications including, but not limited to material, finish, and allowable tolerance, are submitted.

Depending on the product design, material and cost requirements, several different manufacturing methods are available. Processes such as machining, casting, grinding, polishing, injection molding, and rapid manufacturing are commonly used in the veterinary instrument/implant industry.

Machining refers to any process that cuts a piece of raw material (blank) into a final shape by removal of material. There are several different types of machines that can achieve this -- depending on design of the product. Such fashioning is achieved through a series of cutting, drilling, forming, grinding, and/or shaping steps. For example, a screw is machined using a Computer Numerical Control (CNC) Lathe, which operates by spinning on a very quickly rotating lathe. This rotation results in sculpting the 'blank' material down to the desired specifications.

Figure 1: CNC Lathe

Figure 2: Example of a screw machined by a CNC Lathe. (Note: the core diameter of the screw, 2.4mm, is cut from a larger diameter that now remains as the thread outer diameter, 3.5mm.)

In contrast, a Tibial Tuberosity Advancement (TTA) cage is machined on a CNC 5-Axis machine, with the ability to sequentially position a blank along 5 different axes, so as to sculpture the blank from all directions.

Figure 3: CNC 5-Axis machine

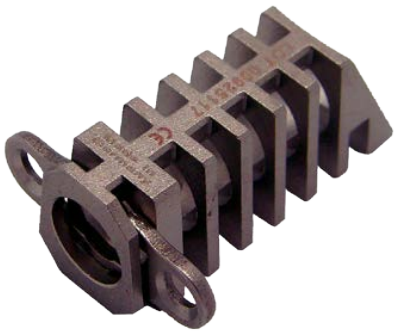
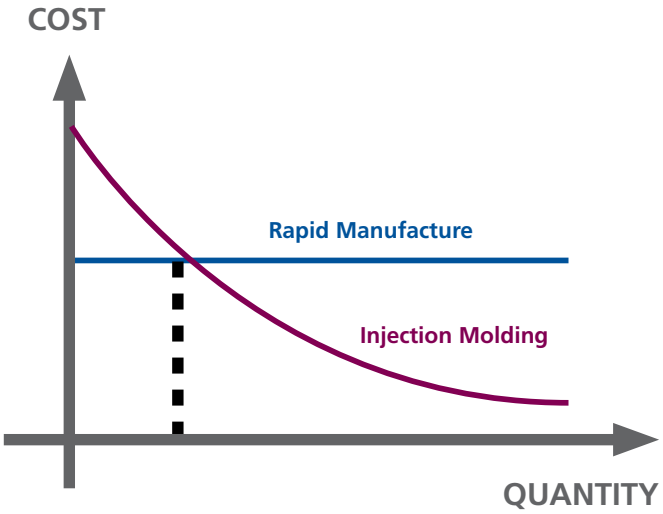


Figure 4: Example of a TTA cage manufactured using a CNC 5-Axis machine.



Rather than sculpturing material from a blank to make the end product, casting or injection molding are other options, whereby a liquid material is poured into a mold and processed to harden. Casting/molding are preferred options for complex designs that would be difficult or cost prohibitive to machine; however, the development of molds can be costly if large volumes of finished product are not anticipated.

Rapid manufacturing is a process commonly used in the industry for prototyping and patient-specific applications. This is an additive fabrication technique that essentially divides a product concept into formed layers and builds a physical model one layer at a time using a melted, liquid media. A constraint for rapid manufacturing is the high cost for large quantities, wherein other options such as injection molding would be more economical for production runs.

Figure 5: Rapid Prototyping Machine

These are just a few examples of common manufacturing techniques; however, it is important to note that there are other processes available as well. For product development purposes in the veterinary industry, rapid prototyping is used frequently. Once development reaches production, the commercial product is typically machined or cast. Communication between the product developer and manufacturer is essential for efficiencies in bringing the product to market.

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Issue 3 of 3: Quality Management

Quality Management at Securos

Securos is known for quality. Our products are trusted and relied upon. And, we take this responsibility seriously. A key component to our process–and to our approach to design and production in general–is our Quality Management System (QMS). In this article we share with you the core elements of our QMS and examples of QMS implementation in our processes. The result of the QMS program we discuss in this article can be seen in the quality of the product you hold in your hands when it comes time to perform a surgery.

What is a QMS?

Throughout the entire product development, design and production process, a quality management system sets the standards for all stages. A company's QMS is unique to each stage of a product's lifecycle, ensuring that specifications are developed and communicated, products are manufactured according to those specifications, and that finished products perform as intended once in clinical use.

The term 'quality' in this context refers to a company's processes and actions to guarantee that the end products delivered to the customer are safe and reliable. There are two different aspects of a QMS; quality assurance and quality control.

Quality Assurance (QA)

QA refers to processes that a company implements to ensure in advance of production that the end products will meet required specifications and perform as intended. At Securos, QA is built into our design process, product development, manufacturing, shipping and receiving, documentation and service. In addition, our QA incorporates employee training and development of standard operating protocols so as to meet all aspired requirements.

Quality Control (QC)

Quality Control refers to the specific activities that occur after the QA processes have been implemented. These are post-production but pre-sales activities. An example of a QC activity is unit testing, wherein a certain representative percentage of products is inspected for defects and tested accordingly to meet established specifications.

One example of Securos Surgical's Quality Control methods is shown below. These images demonstrate inspection of items utilizing a Manufacturing Process Control Plan and Receiving Inspection Report. The specifications required for each item are outlined including the method of measurement and sample size per lot required for inspection.

Figure 1: TTA Plate Manufacturing Process Control Plan and Receiving Inspection Report.

Figure 2: Cortical Bone Screw Manufacturing Process Control Plan and Receiving Inspection Report.

The Importance of QMS

Companies that implement a quality management system are likely to save a significant amount of time and money, which translates to savings to you, our customer. As well, a QMS builds in the necessary product acceptability and clinical performance testing that prevents product recalls and safety concerns.

The Securos Quality Management System is a vital part of why our customers have confidence in our product quality. From our manufacturing teams, to our office staff and on to our distribution through sister-company, MWI, quality is built into each part of the process from design to delivery.

Figure 3: This sign is posted in the Securos building as a reminder of the vital role that you, our customer, plays in our QMS process.

Ultimately, you are the final step in our QMS process. If you ever receive a Securos product that is not 100% up to standard, we want to hear from you.

Zenios, S. A., Makower, J., & Yock, P. G. (2010). *Biodesign: The process of innovating medical technologies*. Cambridge: Cambridge University Press.