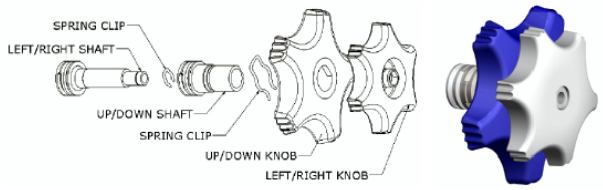
Interplex Medical Tech Bulletin

Meeting the Challenge of Medical Device Re-Design

Optimizing Product Lifecycle Improvements by Outsourcing Design Update Processes

In the medical industry, the ongoing pace of innovation and changing market demands has to be balanced against the need to derive optimal ROI from product development efforts. From a product improvement standpoint, there are always ideas and opportunities for both small engineering changes and more extensive redesigns that could potentially make existing products better. However, there are not always resources available to conduct a proper analysis on ROI or to undertake designing the changes when deemed worthwhile.

This Tech Bulletin provides an overview of how teaming with an experienced partner for outsourced feasibility assessments, design concepts, development and product improvements can cost-effectively augment your internal resources and help extend the profitability of existing products.



Key topics include:

- Assessing Needs and Unmet Opportunities for Product Improvement
- Augmenting and Coordinating with Internal Resources
- What to look for in a Design and Product Improvement Partner
- Best Practices in Design for Manufacturing
- Summary

Assessing Needs and Unmet Opportunities for Product Improvement

Fresh ideas and driving forces for product improvement can come from a myriad of sources, including customer feedback, field sales reps observations, internal R&D staff, external regulatory changes, etc. In most companies, these inputs and ideas converge within the product management organization and ideally are tracked, accessed, evaluated and prioritized. Ideas that make-the-cut are then formalized as approved projects and scheduled based on R&D resource availability. This is the nominal scenario.

However, in the real world, the process of determining what makes the cut is too often driven from the back-end, where lack of available R&D resources automatically trumps the actual merits of product improvement ideas. In the worst case, product improvements only jump to the front of the line when a crisis situation emerges, such as excessive field failures or plummeting sales numbers.

To get the highest return on existing product lines and make the best use of internal R&D resources, it is critical to have an efficient, proactive methodology for capturing and evaluating improvement ideas.

This process can be effectively supported by leveraging knowledgeable partners with the ability to help you assess the opportunities and, if necessary, to either take the lead or provide assistance for a full range of concept-to-production steps.

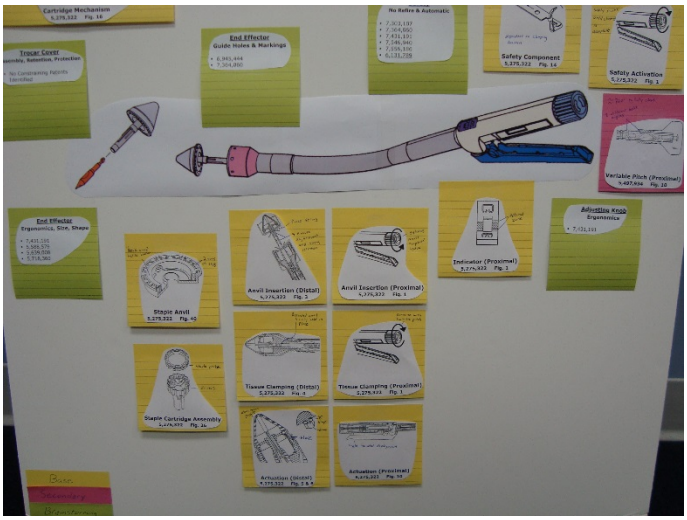
Augmenting and Coordinating with Your Internal Resources
Every company has a unique set of needs, which are also constantly changing. Therefore, your outside partner often needs to play a variety of roles in the lifecycle product improvement process.

In some cases, it's helpful for the partner to act as the "voice of the customer" in order to crystalize what changes are needed from the market perspective.

In other scenarios, you may have a relatively clear definition of the proposed changes but need the partner to take the lead on design concepts, tradeoffs, feasibility and ROI analysis.

Depending on the maturity of the products and your overall marketing and production strategies, it may even make sense for the partner to take a turn-key approach for the whole redesign and manufacturing responsibility.

In essence, your product lifecycle improvement partner should be a seamless extension of your existing organization, filling the gaps and adding capabilities without duplicating or displacing internal resources.



Product Feature Assessment
Planning

What to Look for in a Design and Product Improvement Partner
To achieve the desired objectives your outside partner needs to bring the specific skills, knowledge and experience to get the job done right the first time.

Some of the key attributes include:

- Hands-on approach to concept and analysis
- Broad design and manufacturing expertise
- Experience with medical manufacturing quality and standards requirements
- Flexibility to mesh with your internal team across multi-functional areas
- Proven track record of successes with medical designs and manufacturing
- Ability to deliver rapid prototyping and, if needed, production ramp-up
- Adaptable engagement models, ranging from full turn-key services to consultative design

Voice of Customer (VOC) Meeting with Surgeon
Validation

Best Practices in Design for Manufacturing

Best practices in Design for Manufacturing (DFM) call for early involvement of all key participants to assure that all of the design and production processes achieve the product specifications and will also provide optimal production efficiency.

With product improvement projects, DFM needs to take into account any issues within the existing production environment and/or any planned changes such as migrating to a different production scenario. This is where it can be very useful to work with a partner that brings a wide perspective on both design and production, along with the ability to tailor the product improvements to yield the highest return. Taking a broad view and thinking out-of-the-box on the entire approach can often result in added benefits beyond the initially targeted changes including cost-reductions, better utilization of resources, etc.

Bringing Your Ideas to Life
Development

Summary:

The bottom line is most companies have a lot of unrealized opportunities for product improvements that can yield better profitability, improved sales results and/or better customer satisfaction.

However, all too often, these valuable veins of opportunity are not mined sufficiently because of either a lack of available resources or the demands of other competing priorities.

By judiciously using knowledgeable outside partners, companies in the medical sector can breathe new life into existing products and reap the benefits, without having to turn their internal organizations inside out.

ISO 14644 Class 8 – Clean Room Assembly
Production

More information regarding Interplex Medical technologies, service and products can also be found on the web by visiting http://interplexmedical.com or contacting Craig Berky at (513) 248-5120 extension 302, craig.berky@interplexmedical.com