



A Roadmap to Success for Surgeon Inventors, Part 5: The Top Ten Things to Avoid

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In previous installments of this series, we touched on pointers for optimizing your chances of success as a surgeon inventor while developing your own ideas. We also introduced tools for saving time and money along the way. Today we continue with a different approach. In this article and the next, we'll review potential landmines in the product development process that may trip you up or, worse, derail the project and cause you to give up entirely.

Here are the five of the top ten missteps that I have seen surgeon inventors make during the course of almost 20 years of orthopaedic product development. Next time, we'll cover the other five. These are listed in no particular order and all of them can happen with regular frequency if you're not careful.

#1: Shortcutting the Process

Taking one step at a time can be challenging when you want to run with your exciting idea—but a word of caution. Don't let your enthusiasm for seeing a finished part in your hand overshadow the methodical but necessary steps of brainstorming multiple viable solutions to the clinical need that you are trying to address. Undergo a critical assessment of your idea through a feasibility study or assemble a quality team of experts to guide you along the way. Too often I have seen a surgeon inventor take an idea to the closest machine shop (sometimes completely outside of the medical device field) for a quick prototype. "What next?" is the inevitable question that follows, because there was no plan in place for the process. Often, the early crude prototypes must be scrapped as there were too many unknowns at the time to have prototyped a single solution in a single material using manufacturing methods and the limited skill set and equipment found at the shop. This is a generalization, of course, but more often than not, the surgeon inventor is better served to hold off until background work can be finished.

Going straight to prototype without any design concept or analysis may provide instant gratification, but may also cause you to miss a viable solution to the problem you are

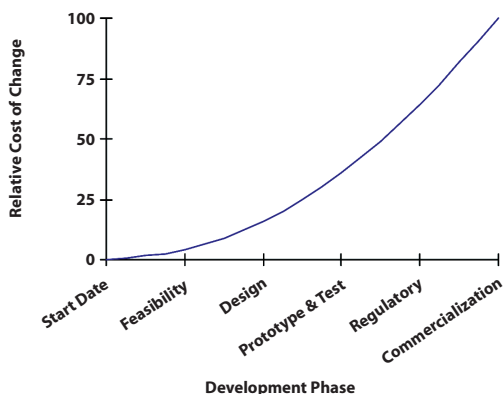
trying to solve by focusing too early on a single design. More than likely you will have to play catch-up later to fix mistakes, overlooked items, etc. And of course, making changes down the road is not free, in terms of time or money. We will look deeper into the cost issue next. Worst of all perhaps, the best solution to a clinical need may be sacrificed for the first one that comes to mind.

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#2: The Cost of Change

Product development experts will tell you that it is exponentially more expensive to make changes later in the process of device development vs. earlier. In fact, some suggest that the cost of changes when a product is near to commercialization is 100 times the cost of changes at the beginning of a project! Exhibit 1 depicts this phenomenon. Along the bottom are the typical phases of product development as discussed in the last article. Along the side is a relative scale of the cost of design changes, starting at zero. While I would bet that few of you are actively involved in project management at the corporate level, this law of cost of change vs. time is still very relevant to the surgeon inventor. Why? Because this relationship tells us that it is far less costly to try out different designs at the beginning of a project while still brainstorming, than to change direction downstream. If you keep this relationship in the back of your mind, my guess is that you will strongly consider exhausting all possible design options—while the cost to do so is negligible—before zoning in on a single design to run with. In addition, this relationship will help to gauge cost vs. benefit for changes you would like to make once your team has moved down the process into prototyping, testing and regulatory clearance.

Exhibit 1: The Cost of Change



#3: Poor Documentation (or none at all)

While surgeon inventors spend a great deal of time considering the clinical benefits of their ideas, often far less time is spent actually documenting the clinical need, the thought process in arriving at solutions, or the details that describe the solution. You are the expert and you know your idea better than anyone else. Unless you adequately document your thoughts and ideas, those around you will have a very difficult time helping you achieve your goals. If you decide along the way that you want a dedicated team to help you flesh out your idea, they will want to get their hands on everything that you've created to date. Most often that will include handwritten notes, concept sketches, perhaps a provisional patent application or some other form of written record.

Remember, the quality of the finished product (not to mention the time and money it takes to get there!) will be directly related to the amount and quality of information you are able to convey from the beginning. Of course, good documentation is a key ingredient to solid patent protection as well. Whether you spend time documenting your thoughts and ideas at the beginning or poring over a patent attorney's description of the same later on, the work needs to be done if you expect a patent to protect you.

#4: Inadequate Funding

As you might expect, funding can make or break a great idea, just like access to capital (or lack thereof) is a major reason that small businesses fail. In the previous installment of this series, I indicated that the cost of developing your idea (including design, prototyping, testing, intellectual property work, etc) can easily reach \$100,000 or more. Thankfully, a well-crafted feasibility study conducted early in the process should lend a good sense of your idea's viability for a fraction of this amount. Whether you will be funding the project from your own pocket or hitting up friends and family for seed money, knowing the major cost drivers and being realistic about total cost potential are two keys to success. The familiar adage *you get what you pay for* certainly applies in product development.

#5: No one has ever thought of this before

"There is nothing new under the sun but there are lots of old things we don't know." -Ambrose Bierce

What was true in the early 20th century is still relevant today. Much of what we see in terms of "new" designs for orthopaedic implants has been attempted before in some form. That is not to say that innovation does not occur; of course it does. And technologies, materials and surgical techniques continue to advance and push the envelope of what is possible in the operating room. However, it is not uncommon for an inventor to find that his or her idea has been anticipated, at least in part, by someone else trying to solve the same or a similar problem in the past. The trick lies in differentiating your idea by developing something novel and not obvious. A wealth of information is available using simple Internet searches of industry product catalogs, clinical literature and patent databases. It is imperative to do your homework up front in order to know what is out there in the public domain. Perhaps someone has your idea covered in an issued patent or patent application. Or maybe the clinical literature contains an article about a similar device that never got off the ground because it was associated with a high failure rate. Big and small companies have teams of engineers working with surgeons every day to continue to differentiate product lines and advance the state of the art. Chances are good that they are working in or around your field of interest. Keeping in touch with industry contacts and combing through booths at the large conferences are good ways to keep your finger on the pulse of what is happening.

If you do your homework and still find that your idea is unique, congratulations. You are in the minority and poised for success as an inventor.

Conclusion

I've stated that, just like surgery, product development requires meticulous planning and execution. While it doesn't have to be cumbersome, there are a few key things to remember along the way. Spend enough time to get your documentation and funding in order. Don't try to short-circuit the process. Recognize the impact of changes on the cost of developing your idea. And don't be surprised or disappointed that someone else may have already thought of your idea. Instead, see it as an opportunity to push beyond what is already known.

In the next article, we will highlight the remaining five of the top ten missteps that surgeon inventors make.

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