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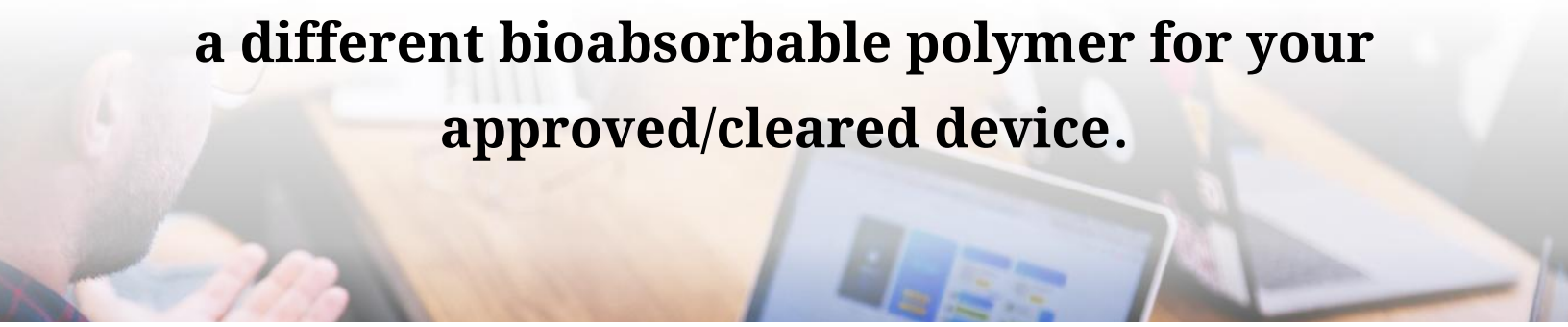
Change is Hard: How to make the switch to a different bioabsorbable polymer for your approved/cleared device.



After years in development, your medical device was finally approved or cleared by the FDA and is now on the market. Whether your device was 100% or partially made with a synthetic bioabsorbable polymer, you probably had to compromise with the polymer properties and functional performance because you could not find a polymer that met all your design requirements.

If you made significant compromises and are now ready to work on the next product iteration with a better biomaterial or if your post-market surveillance is finding issues with the polymer you selected, you may be ready to explore alternative bioabsorbable polymers.

But how do you make the change? Do you have to start all over? Truth is, it can feel pretty daunting, so unless you have product failures and adverse events reported that are related to the bioabsorbable polymer, you are reluctant to explore alternatives. Even if the alternatives appear better.

We've outlined the process in a few easy steps to help you navigate the change and mitigate risks.

But before you start, you need to consider the regulatory implications of the polymer material change.

Step 1: Assess the need for change.

How bad are things? Rank the need for change from 1 (no issues at all) to 5 (product failures and adverse events related to the polymer). The middle

rankings are harder to navigate, so we've put together the table below to help you figure out next steps.

Ranking	Definition	Action
1	No issues	Do nothing or complete Step 2 if you're planning a product design update.
2	No issues but polymer fell short of some nice-to-have requirements	Complete Step 2; complete Step 3 if you're working on a product design update.
3	Had issues but developed workarounds	Complete Steps 2 and 3; consider completing Step 4 if you're working on a product design update.
4	Have issues but they are not severe	Complete Steps 2-4; consider completing Step 5 based on issues severity.
5	Product failures and adverse events related to the polymer	Complete Steps 2-5.

Step 2: Research alternatives – paper exercise.

This step is a paper exercise where you collect information on alternative polymers. If you don't have one already, prepare a list of all the requirements you have for the bioabsorbable polymer you need. The list will include all the must-have and nice-to-have requirements. Pay close attention to properties and characteristics that will give your product a differentiated advantage over competitive products. Make sure your list is comprehensive and includes not only physical, chemical, and mechanical properties, but also manufacturability, biocompatibility, sterilization, biostability, shelf life, storage, cost, etc.

In addition to your polymer requirements list, prepare a bioabsorbable polymer supplier requirements list. You may want to consider the supplier's business stability (years in operation), location, quality system and certifications, order lead time, technical expertise, customer service, responsiveness, product documentation and testing results, medical device expertise, understanding of regulatory requirements, etc. Compliance with applicable standards such as ISO 13485 may also be required depending on your device and how much of the work you decide to outsource.

It is likely that the information you need is not going to be readily available on the vendors' websites, and you will need to reach out and contact them to ask further questions. While this can be time consuming as you wait for a response until you get all the information you need, it also gives you an opportunity to assess how a working relationship with that vendor will be

like. Are they responsive? Collaborative? Willing to help? Do they have the technical expertise you're looking for? Take notes about your experience and organize all the information you receive to save yourself time down the road. And share this information with colleagues you think might benefit from your research, so they won't have to repeat all this work for their project that may require a bioabsorbable polymer.

If the vendor does not have all the information you need about the polymer you're researching, expand your research to other sources (e.g., research journals, regulatory websites with information about other products with the same or similar material, etc.). These other sources may not contain information about the exact formulation you'd be using so the data you collect may indicate properties and performance but not guarantee it.

While this is just a paper exercise, take your time and be thorough. Avoid doing just cursory research and stopping after finding the first few vendors. Dig deep and find as many suitable alternatives as you can. Medical device design has a lot of constraints that can narrow down a list quickly.

Once you collect all this information, you can rank polymers and suppliers to identify your top 2-3 bioabsorbable polymer alternatives for Step 3.

Step 3: Evaluate top 2-3 alternatives – preliminary benchtop testing.

Most likely, the vendors you contact won't have all the properties and functional performance information you need to make a decision. You will need to perform your own preliminary benchtop testing to evaluate the alternative polymers.

Design your experimental plan carefully. What are the critical benchtop tests you need to perform that would rule out any polymers that are not a fit? It's easy to get into scope creep in this step as most of us love more data. But this is a preliminary evaluation that will help you select the top polymer alternative for further testing. Consult your must-have requirements list. Are there any items you don't have any information on? Or perhaps the information you found is for a different enough formulation that is hard to rely on. Consider preliminary testing that would provide you some data on those must-have requirements.

Let's say that degradation rate is a key requirement where you have a very specific target. You may have collected data about the material's degradation rate as a wide range, for example 1-3 months, that may be too broad for your specific application. In this case, you could design an experiment that mimics the conditions of your device's intended use,

including motion and fluid flow that may accelerate how fast the material degrades.

But what if one of the must-have requirements you have relates to in vivo performance? In this case, your test strategy needs careful consideration. How time- and cost-intensive is the test? Is it a simple cytotoxicity or a long-term in vivo safety test? You may decide to include short, inexpensive, preclinical in vivo assessments in your preliminary test plan and postpone long term, expensive in vivo tests for later, depending on the results from the preliminary test step.

As you develop your test plan, think about controls. Your current bioabsorbable polymer serves as an excellent control that you can use to compare the new polymer against. Running multiple polymers side by side increases cost and time but provides excellent insights, especially if you know the results you should get with your current polymer based on previous testing. It helps you validate your test method and perform a direct comparison between polymers.

And finally, plan your sample size and statistical analysis so you can actually draw conclusions from your testing. Hopefully I don't need to mention this but n=3 is probably too low ☺

Step 4: Select top alternative and evaluate in depth.

Out of the 2-3 alternative polymers you evaluated in Step 3, select the top alternative to continue testing with. You may be tempted at this point to continue testing with two alternative polymers and not just one. If time and budget allow for it, continue evaluating two alternatives, especially if both performed well during preliminary testing. But if any of the alternative polymers failed any must-have requirements, they are not worth continuing testing.

While this evaluation is more in depth than the preliminary testing you did in Step 3, it's not the same as the complete testing you would do in Step 5. So again, prioritize the tests you absolutely need to be able to decide if the new polymer should replace your existing polymer.

In Step 4, you will include more functional performance tests. A short, in vivo preclinical study is also most likely going to be part of this test plan.

Pay close attention to shortcomings of your existing polymer that you're looking to replace. Does the alternative polymer offer clear benefits and performance advantages?

At this stage, you will need to actively engage with your regulatory group to better understand what data will be required for the design change. When Step 4 is completed, you will have enough data to make a decision on whether the alternative polymer should replace your current polymer in your medical device design.

Step 5: Make design change and follow your product development process.

Congratulations! The alternative polymer you have found and evaluated is a better option compared to your existing polymer, and you have decided to make the design change.

Depending on your device and the role of the bioabsorbable polymer in it, this design change may go through your new product development process and require a new regulatory submission. The FDA has provided a guidance document for 510(k) devices, Deciding When to Submit a 510(k) for a Change to an Existing Device, and a guidance document for PMA devices, Modifications to Devices Subject to Premarket Approval (PMA) – The PMA Supplement Decision-Making Process. Consult your regulatory group for guidance to determine what will be needed.

Bezwada Biomedical as your Partner

While Steps 1 and 5 are internal, Bezwada Biomedical can help you with Steps 2 through 4 as your partner. In Step 2, we can explore alternative bioabsorbable polymers with you that meet your design requirements. We can draw from off-the-shelf formulations we have developed over the last several decades or customize a formulation to meet your specific needs. In Steps 3 and 4, we can perform some or all of your preliminary testing and polymer evaluation to accelerate your timeline to market. Contact us to combine our bioabsorbable polymer expertise with your medical device know-how to launch better products for patients.