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Design for Assembly (DFA) – Using a DFSS Approach for Cost Reduction of an Existing Product

Thomas M Kriska
Zimmer Biomet Op Ex Associate Director –Design for Six Sigma (DFSS)
Master Black Belt (MBB)
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Zimmer Biomet is a global medical technology leader offering innovative implants and digital technologies across all stages of the patient's journey. Our Mission is to "Alleviate pain and improve the quality of life for people around the world." We do this by following 5 guiding principles.

- *Respect and show gratitude for the contributions and diverse perspectives of others.*
- *Commit to the highest standards of patient safety, quality and integrity.*
- *Focus our resources in areas where we will make a difference.*
- *Ensure the company's return is equivalent to the value we provide for our customers and patients.*
- *Give back to our communities and people in need.*

As part of those principles and in the Interest of Continuous Improvement, Zimmer Biomet has implemented a Design for Six Sigma approach to our new Product Introduction and an important part of that implementation is Design for Manufacture and Assembly. This paper is about using the DFSS approach and a Design for Assembly tools to bring about a cost reduction on a legacy product that is facing inflationary resistance. Specifically, this paper addresses the Torniquet Cuff Design to help make it more affordable while maintaining quality. To quote Paul G Yock

***" …a fundamental shift in the healthcare sector. <u>The affordability of care relative to its quality</u> is now a primary focus in both developed and developing markets"* – Yock et al,**

Bio design: The Process of Innovating Medical Technologies**, Second edition 2015.**

To start this approach, we wanted to start with a loose framework of how to approach a Value-added effort to reduce the cost of an existing product. In Operational Excellence terms many of the efforts will rely on process changes that are supported by Lean and Six Sigma (DMAIC) efforts. These efforts are not ignored but do eventually come back with diminishing returns. So specifically, we will focus this paper on a Design approach – meaning how can we add value /reduce cost of the product through Design changes, specifically without diminishing Quality. To do this with a higher probability of success, we looked at the Design for Six Sigma (DFSS) Principles and selected tools to facilitate a Design change approach.

Before we get started, let's review some concepts and a little DFSS Background.

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A quick review of the three rules of Complexity (Modified for Design here)

1. Eliminate complexity that the customer will not pay for*
   DFA looks for parts to eliminate / simplify (Waste)
   Sometimes the part is over-designed and material waste can be removed.
2. Exploit the complexity customers will pay for*
   DFSS can help preserves key Product Function/Performance Requirements (Strategic)
3. Minimize the cost of the complexity you offer*
   DFA looks to simplify and eliminate potential mistakes, but listing known cost will help you focus on (DFM) material cost for selection/reduction (Tactical)

   *** From the Book "*Conquering Complexity in your Business*"**
   by Michael L. George and Stephen A. Wilson

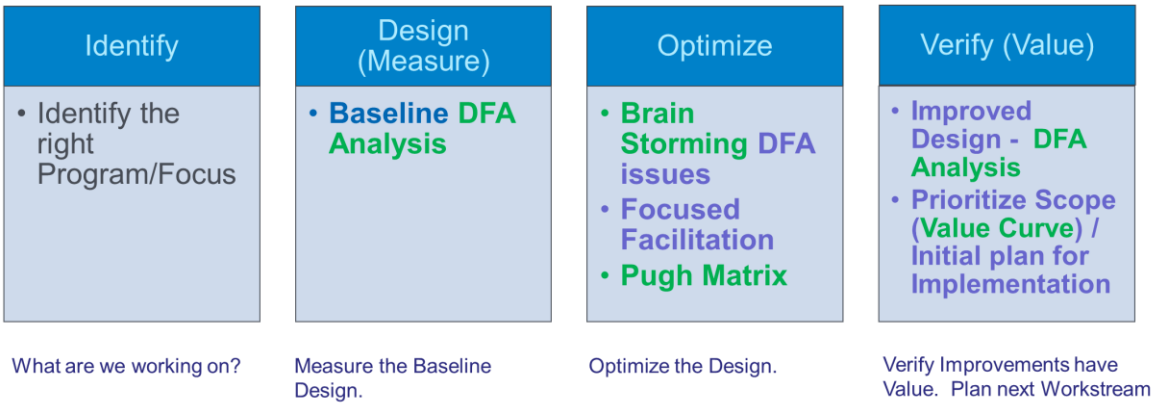
A short definition of what DFSS is given below.

- A Methodology to enable improvement in the Design and Development of new Products and/or Processes.
- Employs a Strategic and Tactical Systems approach for 1st effective and 2nd efficient Projects.
- A way to Implement the Six Sigma methodology early in the product or service life cycle to add value.
- A way to exceed customer expectations and gain market shares.
- A proactive strategy to reduce COPQ for designed products or processes.
- Not the same as DMAIC

Why this approach is important.

- DFSS integrates with a new product development or a change in an existing Product or Process
- DMAIC is a specific methodology that is more prescriptive in solving a problem or Issue within the parameters of an existing Design/Product.
- DFMA is a tool / approach that is taught as part of the DFSS Methodology for the specific purpose of changing a Design to make it easier to produce.
- For a value-added activity –the IDOV framework adjust to focus of reducing cost while maintaining Quality of the Design Capabilities
- The IDOV workstream reflects the principles of a Stage Gate Process without all the baggage – this allows for a proactive approach to de-risk your Stage Gate and optimize faster.

What does the approach look like?



Identifying the right project is key to getting started. I have personally had experiences where no savings could be found due to the long history of improvements and attempts to reduce costs. Every Idea was met with – "We tried that" or "we Did that". These projects have been oversaturated with improvement efforts and would require massive re-designs / Innovation to change. On the other had, I have walked into situations where a legacy product has been built for years without looking at any Design changes, A virtual candy shop of ideas to reduce cost can come out. The Key here is to choose your project carefully. To quote W. Edwards Deming ***"It's not enough to do your best; you must know what to do and then do your best."*** Part of doing your best is to select the right product. This is a High-level Identity step outlined in the IDOV approach/workstream. Lower-level Identity steps will be identified below to better understand the Product under investigation. To support this, I have given my thoughts below.

Why would we do this?

- Looking for Value - Benefits/Cost and for Design Changes, Time is money.

Historically what gives us the most Value?

- Priority of Cost Reductions 1 – Eliminate Waste, 2 – Tactical changes, 3 – Strategic Changes only when necessary (typically these should be rolled into New Products)

What to look for

- Fat products
  - 1st to market under pressure and no or limited DFMA
  - Product has been in Production for many years with no or limited design revisions.
- Product that has a future

    - Design that is has 2 years before revision/end of life- need time for V&V and payback.
- Matter of Survival
    - Margins are getting Tighter – Due to inflation of cost or market pressures to reduce price.
    - Process Improvements have been exhausted – Limit to Leaning out the process without Design.

Note ALL selections come with Risk and results can vary.

The Process – the process I am sharing with you is the same DFSS IDOV Framework we saw above, put in more specific detail to support the DFA tools. I will confess that we did not use the DFMA software here, but I would highly recommend that you do. It is the best software for this type of work, we had to do a work around specific to Zimmer Biomet. In addition, I might point out that the software, although a great tool, will not set up your exercise, give you the details context that will be required or assess Design Validity of ideas. This support system is the focus of this paper and requires leadership and facilitation skills to accomplish with significant results. Also good to note that for this type of effort is recommended that a Lean Kaizen also be applied to look at process improvements, these can lead to significant savings in their own but with a different path for implementation.

The DFSS IDOV workstream or process flow is given below with the IDOV steps identified in **Red**.

Step 1 – Understand the Design Intent and assembly process – (Identify)

- **Product Information: Review *functional /performance requirements, Drawings***
- **Functional analysis, P Diagram review**
- **Process Map of Assembly, Review Quality issues, Actual COGs breakdown**

Step 2 – Perform the Initial DFA Analysis– Identify Opportunities for (Design – Measure)

- **Part count reduction**
- **Quality (mistake proofing)**
- **Handling and Insertion**
- **Secondary Operations**
- **Part cost reduction opportunities – No change to fit performance or function.**

Step 3 – Create solutions based on analysis (with solution risk ranking) (Optimize - -Improvements)

- **Methodically brainstorm ideas based on Opportunities (Line by Line)**

- **Use additional Creativity Tools for stubborn High Value Opportunities**

Step 4 - Select Best Solutions with considerations for Risk, Cost and Schedule (Optimize – Selection)

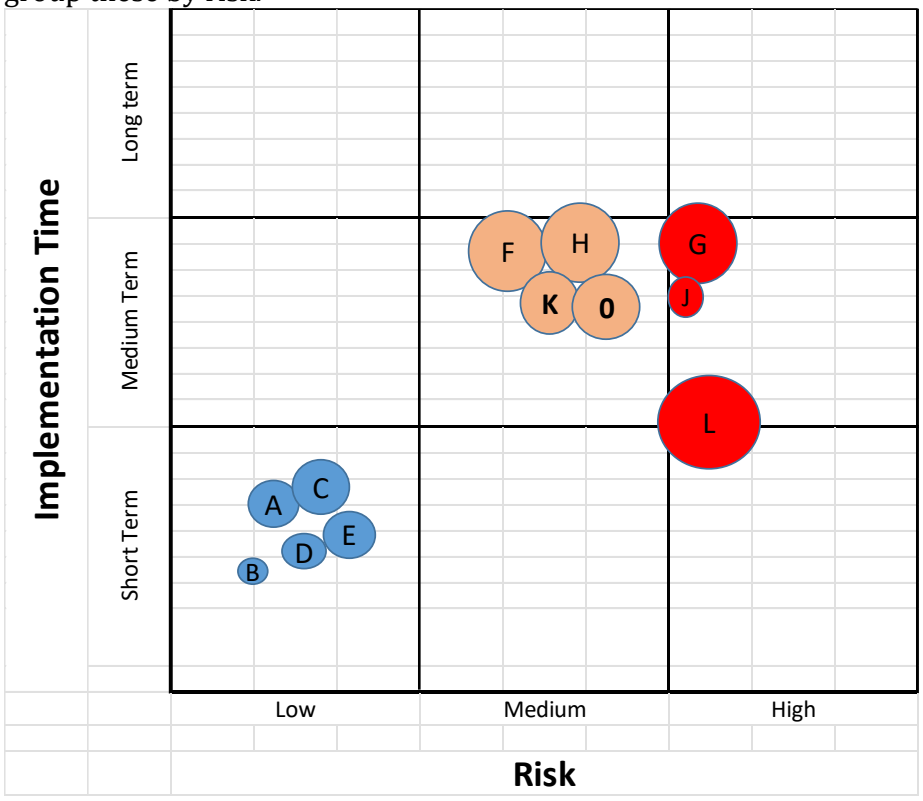
- **Use Risk Vs Implementation Time to sort solutions**
- **Use Pugh Matrix or AHP matrix for difficult decisions.**

Step 5 - Evaluation of expected results with final DFA Analysis (Verify –Estimated Results)

Step 6 - Implement Solutions and communicate unresolved issue to Manufacturing (Verify – Plan)

Stepps 1-4 – Zimmer Biomet Specific Details, the DFA Process and Brainstorming will not be reviewed here since this is specific to Zimmer Biomet and the DFMA forum has multiple examples and training available to complete the best DFA analysis. We will, however, do a high-level review of Steps 4-6 to better explain the systematic approach here.

For Step 4, Following a systematic Brainstorming event, we looked at the initial evaluation of ideas based on Risk and Time to implement. We used a color coding to group these by risk.



The team felt that the low risk short time ideas could all be grouped together for further evaluation in the Pugh matrix. The Pugh matrix allowed us to evaluate these Items in more detail with weighted criteria (Across the top) . By comparing each group or individual Idea to the wieghted criteria and cross multiplying the score to the weights , an overall score was used to rank the ideas to aid in future implementation decisions. This work should be part of your output showing rational and unbiased assessments of the cost reduction ideas.

Idea Number (Weight)	Biggest Concern	Risk (technical and project) (6)		Time to Implement (Time to release and Inventory) (6)		Cost Savings %total/year (rough estimation with estimations) (8)		Quality (Customer and internal) (10)		Strategic Alignment (7)		Cost to Implement (Capital and resources) (8)		Overall Score
A-E - Low risk	Still need to send a wwcn to all customer and notified Body for all changes - for approval	No foreseen tech risk	5	TBD - No aging	5	9.6%	4	Only concern is mixing of product	4	No change	3	Mold Modifications (<20K)- Pins only plus V&V test (Supplier cost is 40K) Validation minus lite NPI/CPI)	4	185
F	- Strength of the new/alternate material going to be comparable? - Biocompatibility?	Re-executing design verification protocols to verify functional requirements are still met with new material	3	18 - 24 months Full design verification. Assy verification. Age verification.	3	10.2%	5	- Customer acceptance (stretchy/sticky /cosmetic difference)	3.5			- Engineering support - Samples - Tooling - Validations	4	143
O	- Cutting into sterile pouches when opening outer box?	Customer acceptance? With potential for cutting bags and no small boxes	3	6-12 months	5	4.3%	3	Need marketing / customer feedback	3			Cost for packaging testing	5	142
H	- Age testing required - Biocompatibility required - Adhesive strength vs. stitching??	- New method of fixation - technical concerns on passing	2	18 - 24 months Full design verification. Assy verification. Age verification.	3	9.9%	5	- Messy? - Quantity of adhesive vs. # of stitches	3			- Engineering support - Samples - Tooling - Validations	4	132

When implementation is outside the team's span of control, i.e. time, money and resources are required, the Value-Added Task Force will not have the authority to make the final decision on what ideas will be implemented. To that effect, it is better to have good rational for evaluating and ranking ideas to support a final decision by corporate leadership. It is also wise to give a summary by groups to demonstrate the potential changes, Quality opportunities and estimated cost savings. This chart is given below.

Design level	Part Count	Poke Yoke Opportunities	# Part with Cost Reductions	Overall % Cost Savings
Baseline	18	15	0	NA
Low Risk	18	15	5	9.6%
Med/High Risk	13	9	3	51.9%

Processing Changes were calculated separately by the supplier ad included Lean workshop results

To start wrapping up the Value-added Task Force, the team documented the top lessons learned and captured the Next Steps prior to closing the event.

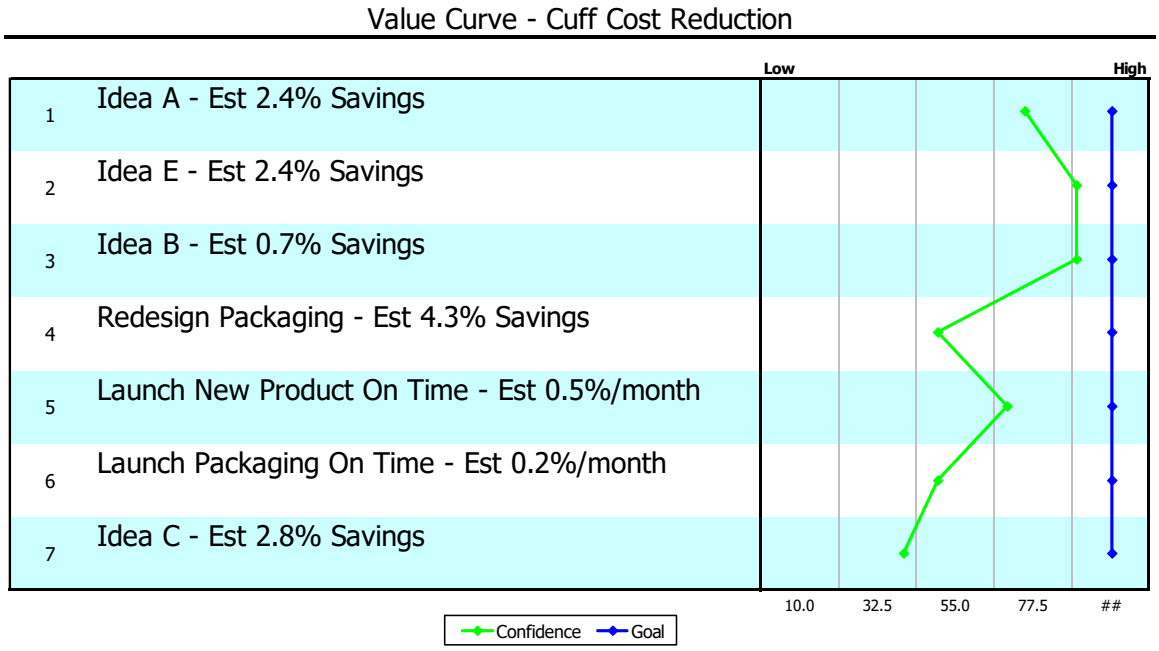
Lesson's Learned

- Gain as much information as possible before the event.
- A good Cross functional Approach is very helpful.
- Listen – sometimes the best ideas are not expected – Material vs Part count reduction.

Next Steps

- Start planning the next steps at the event.
- Once agreed to a Value Curve is a great tool to keep priorities in focus.

For this specific project, the Low-risk ideas were given approval for a Design change project and the medium and High-risk ideas were held for implementation in a new product later on. Kicking off the Project required a mutual understanding of the priorities and importance of the schdule, so the team completed a modified Value Curve using the X axis to reflect the initial confidence in achieving the goal.



The Project is now underway with a scope, schedule and assigned resources. It may be good to note here that not all low-risk ideas were accepted, and one idea was dropped due to technical risk of performance. We also added the packaging redesign idea as a parallel path for added cost savings after the project was started. Some final thoughts about the whole process including implementation are given below to reinforce the statement that implementation of design changes will be more difficult than identifying the creative solutions. That is to be expected and accepted as part of a Highly regulated

industry that will not compromise Quality. A closing thought about the VATF event and the implementation as an overall process is referenced below.

The (DFA) Event[+]

- Encourages decisions.
- Motivates and Challenges People
- Is a Calendar issue.
- Is the easier part of this Process.

Execute[+] **- to Implement the Design Changes**

- Encourages Development
- Changes and Matures People
- Is a Culture Issue
- Is the harder part of this Process.
- Should verify no changes to Design Quality

[+] Reference: John C Maxwell "21 Irrefutable Laws of Leadership" Chapter 3 "The Law of Process", 1998

Conclusion

We learned that applying the DFA tools in an existing product and production system requires a lot more investigation and planning. That presenting the changes requires an assessment of Risk and Timing along with other factors to ensure the company will make the right decisions to support the business. That quality is not negotiable and needs to be proven again, especially in a highly regulated business. However, the value added through cost reductions and future developed product development can make these efforts more than worth it.