

Case Study #7 – Medical Device Yield



The Circumstance:

The product is an implantable medical device. The problem is scrap at the final step of the manufacturing process. The value of a unit at this point is substantial. Production volumes are going up, increasing the stakes associated with this situation. The mission is to substantially improve yield ASAP, without deviations from already approved product and process specifications.

The Approach:

In two brainstorm sessions, 187 ‘anything goes’ ideas are procured to remedy the problem. Each of these is reviewed and 21 of them are deemed doable immediately (on shippable goods.) Ten of these are raw material attributes, the others involve slight changes in various processing steps. All tested levels are within specifications and are zero cost to implement as well.

An experiment is designed which calls for 48 treatment combinations. Doing these enables us to learn about 2,000,000+ combinations of these idea’s settings, along with 210 two-factor interactions between them. (A two-factor interaction is where the influence an input has on an output is dependent on the setting of another input.)

Over the next few weeks hundreds of units are produced under these 48 experimental combinations. Yield during this time is higher on two sub-assemblies but lower on the critical last step.

The Outcome:

Once all experimental runs are complete, analyses are performed to determine the impacts of the 21 factors on 20 metrics of product & process performance. Three factors emerge as highly influential on the final processing step. The most influential is a raw material characteristic which is the primary reason for the lower yield during the experiment. A newly prescribed SOP, based on experimental findings, is immediately implemented (only readily implementable solutions were tested, so this could be easily done.) A double digit yield increase is forecast and immediately obtained.

