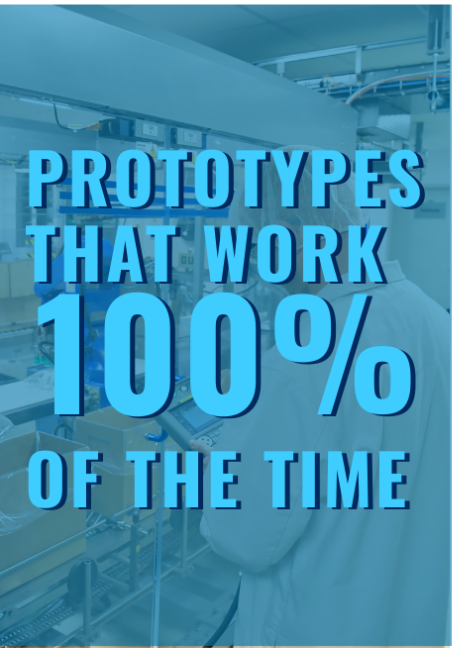
How do you ensure your product is going to "work" every time? Will every staple align with its anvil in your surgical stapler or linear cutter? Will drilled screw holes line up with holes in your orthopedic pin implant?

When you order prototype parts, do you order hundreds to get 1 or 2 working prototypes? Do you learn why the prototypes do not go together 100% of the time? How can you ensure problems found in prototyping do not appear in production?

Are you awake at night worrying about recalls, field failures, or litigation? How do you mitigate the chance that each part in all of your builds assembles properly?



CHALLENGES

Can your medical device execute its function 100% of the time in the field?

Can you ensure error-free surgeries?

Will 100% of your medical device prototype builds be assembled and tested without modification to the prototype parts?

SOLUTIONS

Using Variation Analysis, perform 3D tolerance analysis to predict the combined variation of the parts produced, the process used to put them together, and the variables of usage in the operating theatre.

By simulating manufacturing and assembly processes, Variation Analysis predicts the amounts and causes of variation and helps reduce negative impacts on cost, the quality of product dimensions, and time-to-market.

Using kinematic functions with Variation Analysis software, you can actuate parts to determine if everything "lines up" allowing functions to be properly executed.

RESULTS

Variation Analysis is used to mitigate the risks of failure in the field. Design flaws can be caught before committing to prototypes or production tooling. Instead, users identify dimensional problems early in the design cycle to avoid assembly build and quality issues resulting from excessive variation.

Once variation is identified, the internal Design of Experiments tools point out root causes so the product or assembly build process can be modified and optimized to mitigate identified risks.

Minimize prototypes and increase your speed-to-market using Variation Analysis.

CASE STUDIES

ORTHOPEDIC NAIL IMPLANT

Challenge:

The implant is inserted into a larger diameter bone and it has multiple screw holes crossing through the implant that helps secure the nail inside the bone.

Once the nail is inside, a targeting guide is used to insert multiple screws. The targeting guide connects to the top of the nail with some orientation tabs and a bolt.

Once it is connected to the nail, holes are drilled through the bone using drill bushings on the targeting guide. Tolerances are very tight and the guide needs to accurately target holes every time. The drilled holes must align with the holes in the implant to have an error-free surgery.

Results and Business Impact:

First targeting guide prototypes did not drill holes that aligned with the holes inside the implant. A Variation Analysis study was performed to analyze the problem. The simulation showed that over 75% of the builds would have at least one hole drilled in the wrong location and 30% of the builds would have all the holes drilled in the wrong locations.

Multiple "what if" scenarios were tested, and manufacturing costs and repeatability were optimized. Interfaces were redesigned from the targeting guide to the implant, and how the multi-piece targeting guide was constructed for assembly by the surgeon. Resulting in 100% reliability for the targeting guide to drill holes in the bone that aligned with the existing holes in the implant

Added Benefit:

The product went to market successfully and has zero reported incidents for mislocated holes.

MEDICAL STAPLER

Challenge:

Improve product quality and "feel" of the tool-working smoothly in the surgeon's hands.

Ensure 100% success of all staples correctly forming and aligning.

Results and Business Impact:

Through multiple iterations of improvement (part design, tolerancing, and assembly method), Variation Analysis Software (VSA) showed all staples will have a 100% success rate of aligning.

Added Benefit:

In prior builds, 200 sets of parts were ordered to make 1 or 2 working prototypes.

They would mix and match parts until they fit together and worked.

In this program, all 200 working prototypes were created since every part went together the first time.

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