Medical Device Assembly CASE STUDY

OVERVIEW

A leading, US-based medical device manufacturer was experiencing significant product failure. The surgical device, which included a plastic gear was melting during surgery requiring the surgeon to use two devices during each procedure. Not only was this diminishing the end users' desire to use the product, it was increasing hospital costs. At $1,000.00 per device, this was an expensive, premature failure issue. If this failure could be eliminated, the manufacturer had an opportunity to gain significant market share.

The manufacturer suspected that part of the problem was friction created by the gear-only design. They sought out a bearing manufacturer to see if the current design could be modified to include a bearing, thus eliminating the cause of product failure at the same or comparable assembly cost.

National Bearings Company was the only bearing manufacturer that said 'yes' to the challenge, thus launching a highly successful 1.5-year collaborative design process that eliminated the premature failure.

The Challenge

National Bearings' initial challenge was meeting the specifications identified by the product engineer as necessary to resolving the issue: evolving from plastic gear-only to a plastic bearing and gear assembly.

National Bearings first attempted to follow the specifications by creating a plain bearing using thermally conductive plastic to avoid the melting problem. This failed.

National Bearings then worked with the original product designer to change the specs, using a stainless steel bearing and a plastic gear. The bearing worked but the plastic gear failed. The shoulders of the gear had to be reduced in diameter significantly in order to accommodate the new bearing, causing the gear to become structurally unstable.

The Solution

Realizing the original design was insufficient for the application, the manufacturer assigned a new engineer who specified an expensive metal gear with a high-end stainless steel bearing. Product longevity, not component cost, was now the priority. The new metal gear design was $20.00 per assembly, as compared to less than $1.00 for the original, inadequate design.

A new challenge immediately presented itself: The heavy-duty gear and high-precision bearings would last forever but were also enormously expensive. National Bearings had to find a balance that provided enough performance to complete the surgery and a cost that didn't blow up the budget.

The traditional, highly-precise, highly expensive hobbing process used to manufacture gears had to be abandoned. Instead, National Bearings used an aluminum extrusion with an exaggerated tooth profile. National Bearings could then machine the gear stock to the tight tolerances necessary to mount the bearings, while achieving the required gear tooth shape and controlling overall cost. National Bearings then built a robotic assembly machine, working in a clean environment, to build and inspect the assembly prior to packaging.

The Result

1. After 1.5 years of highly collaborative development including weekly meetings, dozens of design iterations and a rigorous production qualification process; National Bearings succeeded in developing a gear assembly that worked for the duration of the surgical procedure and saved the manufacturer money:

   The new engineer specified an assembly that would have cost $20.00 per assembly.

   National Bearings' custom-designed gear assembly cost less than $8 per assembly.

2. Premature product failure is no longer an issue and National Bearings has proven its ability to troubleshoot and resolve significant design issues through a highly collaborative process.

The Unique National Bearings Approach

The National Bearings engineers applied their knowledge of materials and manufacturing processes to help the manufacturer achieve a workable design. National Bearings' engineering team collaborated with the manufacturer's product designer to identify problems and possible solutions. Only through close collaboration and the tireless application of knowledge could this significant challenge have been solved.