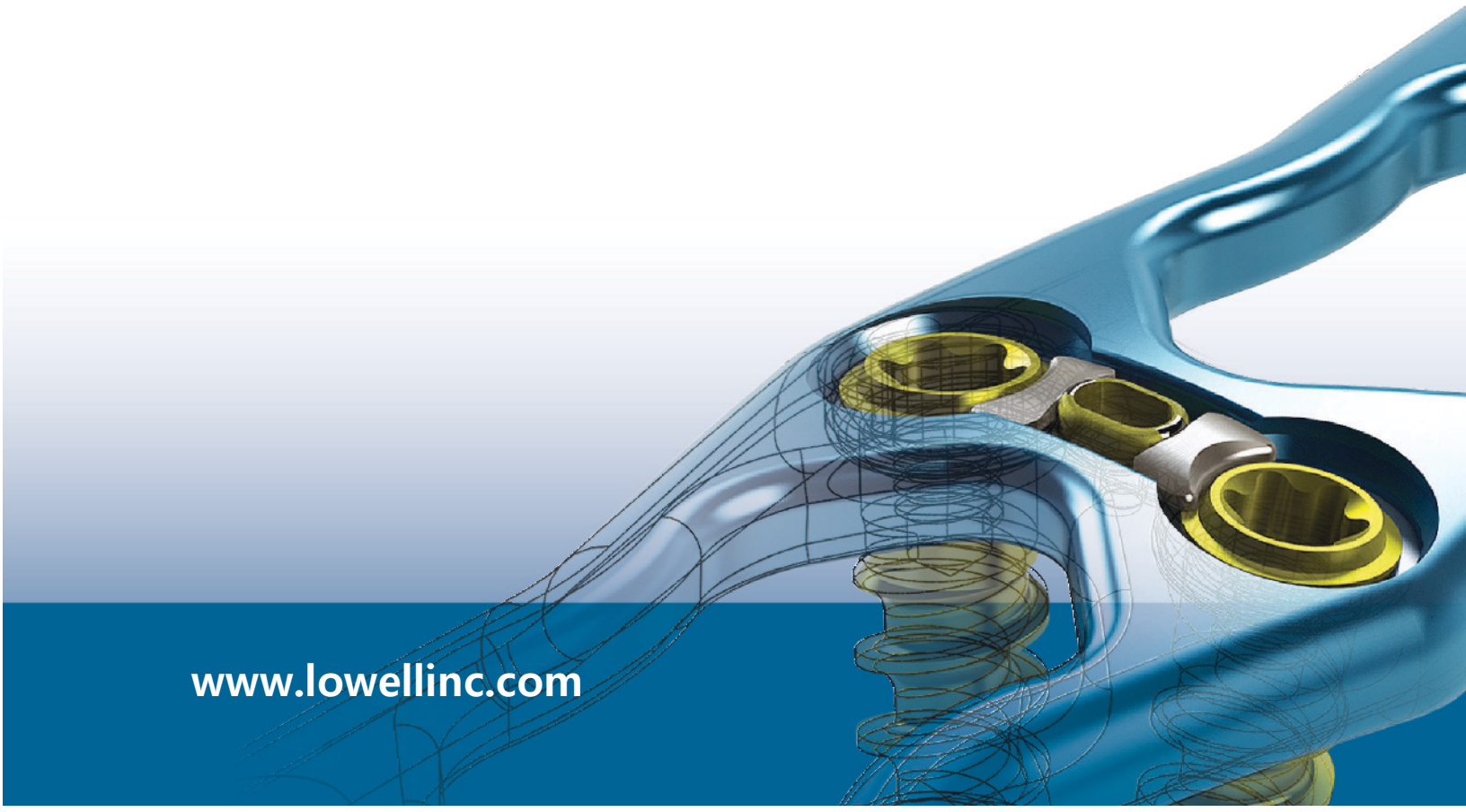
LOWELL

WHITE PAPER

IMPROVE DEVICE DEVELOPMENT WITH A CLEAR DESIGN INTENT STRATEGY



www.lowellinc.com

COMMUNICATING CLEAR DESIGN INTENT CAN MAKE ALL THE DIFFERENCE IN MEDICAL DEVICE DEVELOPMENT

With good communication, manufacturers and customers both perfectly understand what's required and product development runs smoothly. When design intent is miscommunicated or lost, it can lead to revisions and delays in time to market.

Despite its importance, all too often communication of design intent is not shared between medical device companies and contract manufacturers. The internal knowledge of how a device should work and what is key in the focus to start production.

Adding a design intent strategy to your process can help.

The basis of this strategy is shared understanding, clear communication and straightforward drawings, which work together to enhance product development and results for everyone involved. Engineers, surgeons and medical staff can get devices that work as designed in the operating room. Quality and inspection focus only on critical features, which can make this work more efficient and less time consuming. Manufacturers can improve customer satisfaction.

While the strategy's details should be specific to your company, we have found three efforts that are important to success:

- Having the right discussions at the right time
- Ensuring that drawings communicate only what is critical to the device's function, measurement and inspection, through Geometric Dimensioning and Tolerancing (GD&T)
- Simplifying drawings by pairing GD&T with 3D solid model

To help companies define their design intent strategy, this white paper offers a detailed look at how to apply design intent discussions and GD&T into your product development process.

By investing time into developing a design intent strategy, device companies and manufacturers can ensure this critical information isn't left out of production conversations, and drive better device results that lead to better patient care.

DESIGN INTENT: WHEN, HOW AND WHAT TO DISCUSS

A design intent strategy formalizes your approach to communicating how a product should work and why, and the methods used to communicate this information. Design intent is a blend of engineering and design knowledge, coupled with a clear approach to dimensioning drawings.

Design intent discussions are best at the very beginning of a project, before any manufacturing work begins.

Pre-production meetings (PPMs) are an ideal time for these discussions. During a PPM, key stakeholders from the manufacturer and customer discuss all aspects of manufacturing and inspecting a device, from how it functions to finishing and packaging, and validation and data requirements.

From a design intent point of view, this meeting is a valuable time to better understand the engineering and purpose of a product, and how it will be used in the operating room or ASC.

Before the meeting, the supplier will review the design and inspection requirements, and develop ideas for how to make the device easier to manufacture and inspect.

During the PPM, the customer's team will share the part's design intent. This typically includes:

- How the part will be used
- How the mating parts fit
- What instruments are used to properly implant the device

The customer's engineering team can review the product features, and discuss the design intent of the product and its intended function. The supplier may share ideas for how to produce the device efficiently for manufacturing and inspection. Because everyone is together at the same time, the customer can provide immediate feedback about a recommendation and whether to reject or adopt it.

For example, a Lowell customer requested masking threads when components were bead blasted so the parts would work as designed. We were able to demonstrate, based on past project experience, that bead blasting does not affect the threads' conformance or functionality. The masking step was removed from the manufacturing process, which saved the customer significant expense and time.

Creating a physical sample to use during the meeting can also help to move discussions forward, especially for elements of a device that may be subjective or visual. This is especially true for features such as anodization color match, surface finish match, and blasting media and grit.

CLARIFY DESIGN INTENT WITH GD&T AND 3D SOLID MODELS

Because the goal of design intent is to drive better product results and functionality, creating a drawing that clearly communicates device dimensions, tolerances, and conformance criteria is essential.

Historically, there was a more-is-better approach to dimensioning a drawing. This led to drawings becoming cluttered with multiple datums and tolerance schemes.

The lack of clarity created problems and delays throughout design, manufacturing and inspection. It was difficult to determine which measurements actually affected function unless the customer specifically discussed the product's design intent with the manufacturer.

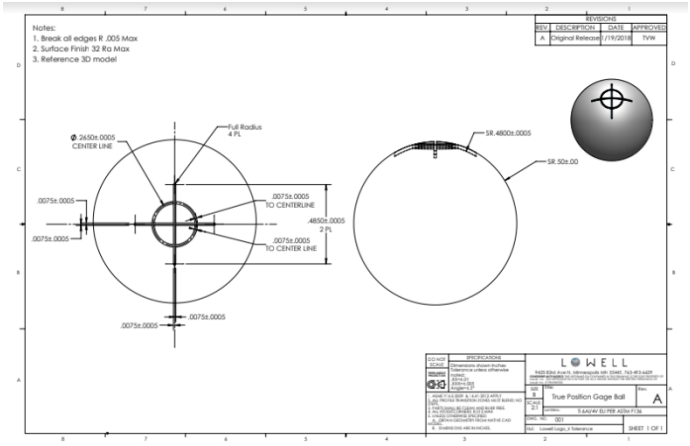


Figure 1:

An example of a +/- tolerancing scheme showing the Lowell Position Gage Ball

Figure 1 was created as an example of potential issues raised by overly dimensioned drawings. As the number of measured points increases, so does the likelihood of introducing error and confusion. The design intent is lost.

Geometric Dimensioning and Tolerancing (GD&T) is one way to simplify drawings and ensure design intent is clear to everyone involved in product development. GD&T can transform Figure 1 into the much simpler drawing and 3D solid model in Figure 2.

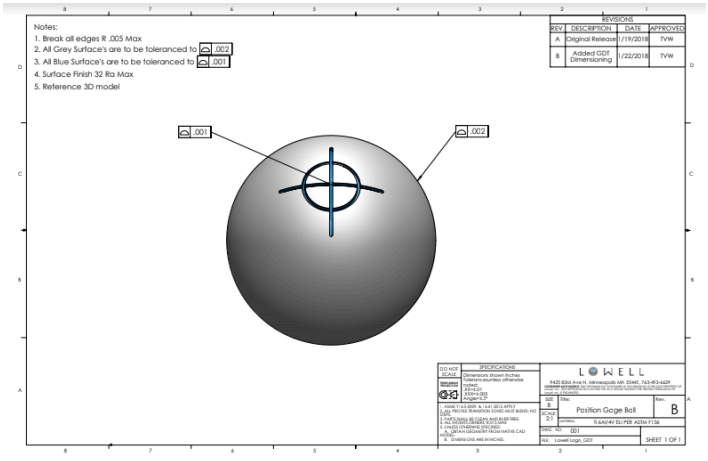


Figure 2

A 3D model-based drawing of the Lowell Position Gage Ball in Figure 1.

GD&T brings focus and clarity to designs, and conveys the design intent of the engineer. 3D solid models, when paired with GD&T, provides a clear understanding of the conformance criteria of the part.

CAD/CAM software is used to design the mathematically nominal part and depict it in the 3D solid model. The model contains nominal geometry of the mathematically perfect part. Querying digital elements provide the dimensions, relationships and attributes necessary to manufacture and inspect the part. The model is only one component of the model-based definition, used in parallel with the drawing graphic sheet and external documentation.

The 3D solid model becomes the baseline for the drawing in Figure 2. The print reflects the model in describing the conformance criteria of the part, not just dimensioning features.

It starts by focusing on the information that relays the engineer's design intent. In the drawing, only GD&T reference frames, datums and engineering specifications are shown. Figure 2 clearly conveys how the gage ball should be toleranced, defined, measured and analyzed. When executed correctly, GD&T results in a more robust drawing with more clearly defined information and less clutter than the traditional +/- drawing. The 3D solid model used in tandem with 3D model-based drawings eliminates many questions and ensures clarity at every step in the manufacturing process.

Clarity at this stage is critical for successful manufacturing because the models are used for computer-aided manufacturing and inspection, including machining programs and advanced CMM inspection protocols.

Only one 3D solid model is used to generate design, manufacturing and inspection data, ensuring harmonization between all disciplines. All this information is stored within the design history file for a clean record of all lifecycle activity, and can easily be shared with manufacturers.

CLEAR DESIGN INTENT BUILDS RELATIONSHIPS BETWEEN DEVICE COMPANIES AND MANUFACTURERS

There are many long-term benefits for companies that adopt a design intent strategy supported by GD&T and 3D model-based drawings. One of the greatest advantages is that an engineer's design intent survives changes in personnel, manufacturing and inspection equipment.

It also builds relationships between device companies and manufacturers. When design intent is clear and understood, it can provide a path to a smooth product development process that meets time-to-market timelines. Simple, straightforward drawings that include conformance criteria are easier to interpret, manufacture and inspect, which can reduce production delays.

Understanding design intent is a fundamental part of every Lowell project, from the pre-production meeting to device development. We work with customers to ensure a clear understanding of what's needed for a device's success.

To learn more about how a design intent strategy can support your processes and product development, contact us at requestinfo@lowellinc.com or 763-425-3355.

CREATING A PARTNERSHIP IN REALIZING DESIGN INTENT

The commitment to communicating design intent is a true partnership between a medical device company and its manufacturer. Below are several considerations that may arise during pre-production meetings to help your contract manufacturing partner realize your design intent.

- How the device is supposed to function and its intended use
- If components of a complex assembly should have free or restricted movement
- What instruments will interface with the device, and how they operate together
- How the surface finish and anodizing should look compared to a physical sample
- Complete review of the drawing and models, agreement on datums, and a focus on critical features
- The required UDI part marking specs, fonts or timing marks
- Validation, first article requirements, sampling strategy and metrology matching
- Shipping and packaging instructions

Only by partnering with a manufacturer that understands, invests in and is committed to clear communication of design intent can you experience its full benefits – designers and suppliers speaking in a common language that leads to better device results

ABOUT THE AUTHOR

Ed Yaris is a Project Engineer at Lowell with extensive experience in Metrology, Management, and CMM Software development. His experience includes leadership positions at National Security Technologies, Helmel Engineering Products, Renishaw and GE. In addition, Ed is a member in good standing of twelve ASME/B89 standards committees including Coordinate Metrology, Uncertainty and vice-chair of the main B89 committee. He is on the steering committee for the North American Coordinate Metrology Association (NACMA) made up of the standards committees and leading industry experts from the United States, Canada and Mexico. In his off hours, Ed enjoys craft beers, his new pleasure boat and the Green Bay Packers. Not necessarily in that order

You can contact Ed at ed.yaris@lowellinc.com.

Acknowledgements page

Parts of this white paper may have first appeared in other Lowell content.

This white paper is an introduction to design intent strategy and communication of design intent. It is meant as a brief summary of the topic. Further research on the subject is highly recommended.