



## biotechne<sup>®</sup> CASE STUDY

# CREATING A RELIABLE BLOOD TESTING DEVICE WITH THE HELP OF COMAR'S DESIGN TEAM

## Situation

Bio-Techne is a leading provider of reagents, diagnostic tools, and clinical controls. The forward-thinking company empowers those in the life science and healthcare industries by providing high-quality reagents and instruments, custom therapeutic manufacturing, and advanced testing services.

For several years, diagnostic instrument manufacturers asked Bio-Techne to improve the diagnostic controls method used to detect blood clotting abnormalities before surgery.

"A number of our customers sought a more user-friendly way to test for coagulation," said Steve Hjelm, Operations Manager at Bio-Techne.

The clinical analysis required a diluent to be precisely mixed with a powder reagent in preparation for testing. According to Tom Pizza, Senior Manufacturing Engineer, one existing approach was to use "two separate vials that hold diluent and lyophilized reagent, stable but separate, until time of use."

The limitations of this technique were that the process of accurately measuring, combining, and dispensing was susceptible to human error or even sample contamination.

Bio-Techne needed a more robust solution, one that delivered on the objective of accuracy and ease-of-use while controlling for human error.

## CHALLENGE HIGHLIGHTS

- **Create dual-compartment functionality in a single device**
- **Hold materials separate until time of use**
- **Make it simple and user-friendly**
- **Stay within fabrication cost targets**

"Comar is an excellent partner. The work they have done for us has been outstanding!"

**Steve Hjelm**  
**Operations Manager**  
**Bio-Techne**

Aware of the depth and expertise of Comar's in-house design and development team, Bio-Techne turned to Comar for assistance.



## Solution

Fortunately, Bio-Techne engaged Comar at the very beginning of the ideation process. This early interaction is an essential feature of Comar's IDworks® process, which takes a project from concept to commercialization—all in-house. Comar was able to gain an indepth understanding of the needs and clearly define the success criteria. It gave their designers the freedom to be creative.

Comar's Innovation & Design Team is physically embedded within its engineering department, allowing for the simultaneous consideration of those design elements focused on form and function with the more practical concerns of manufacture and assembly. In the molding industry, these steps are typically performed sequentially by two independent teams. Having highly skilled industrial designers working alongside experienced tooling and processing engineers is the key to success for the IDworks® approach. Comar has proven that this unique organizational structure improves speed-to-market and lowers the overall commercialization costs by reducing the number and frequency of revisions.

Comar conceptualized molding a dual-chamber device with an embedded mechanism that pierces the partition between them upon rotation.

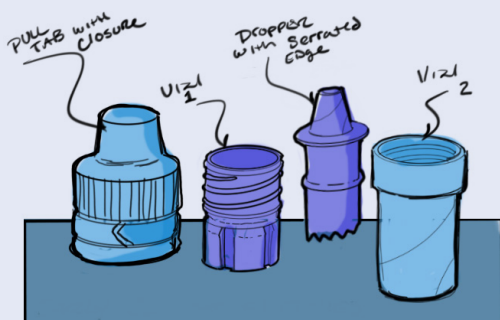


"We found Comar's design and development process to be very satisfying. Comar's robust approach resulted in an elegant and novel solution for our customers."

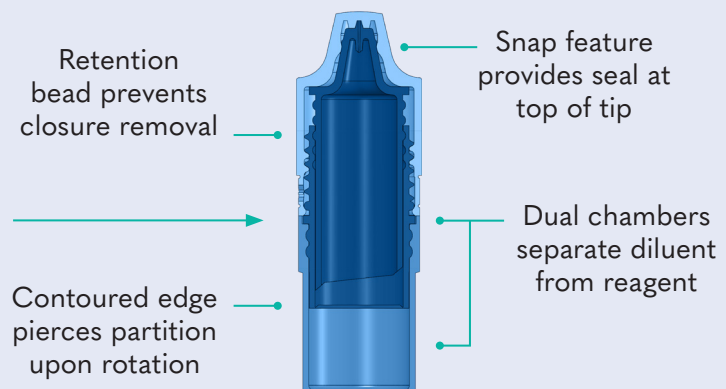
**Steve Hjelm**  
Operations Manager  
Bio-Techne

## PRODUCT DESIGN EVOLUTION

### EARLY CONCEPT SKETCHES



### FINAL DESIGN



## Results

Three-dimensional visual renderings of early sketches, including computer-aided solid modeling, helped the team identify potential pitfalls like air venting and wall thickness concerns. A 3D printed prototype allowed Comar to test and prove the effectiveness of the new piercing technique. Comar then created samples of the final design that were similar to a production piece. Bio-Techne used them to test the functionality and perform preliminary design verification studies before investing in a mold. Comar provided a design history file to support the intellectual property and pave the way toward regulatory approvals.

Bio-Techne's team was delighted with Comar's IDworks® process, the team, and its final deliverables.

"Comar did a lot of work that was above and beyond our expectations. Whenever you are trying to create a mold, changes cost time and money. Comar worked hard and delivered a perfect design."

**Tom Pizza**  
**Senior Manufacturing Engineer**  
**Bio-Techne**



Developed a reliable diagnostic device ready for regulatory approvals



Met or exceeded all design requirements; including manufacturing cost targets



Avoided the traditional pitfalls of molding by utilizing engineering tools such as solid modeling, Moldflow® simulation software, and finite element analysis



Reduced risk of costly redesigns through early engagement and rapid prototyping



Provided extended product stability and shelf-life



Generated intellectual property that was granted a U.S. patent

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