

Secrets to a Successful Product Launch

EARLY
INTERVENTIONS
TO ENSURE
BEST OUTCOMES



EWI
We Manufacture Innovation

The Product Development Cycle

Bringing a new product to market requires a significant investment in time, money, and engineering resources. With so much at stake, ensuring the success of the venture is vital at every step of the process. The stages of development can be split into several distinct phases:

1. Concept
2. Design
3. Prototype
4. Validation
5. Production

IT SOUNDS SIMPLE, but each of these phases represents distinct challenges, especially in the transition between them. The **concept** phase includes research, feasibility testing, and process selection. During **design**, manufacturing limitations must be taken into consideration as well as the expected cost of materials and equipment. **Prototyping** offers the opportunity to discover unexpected problems in the design before moving to the manufacturing processes. The **validation** phase should be simply ensuring that the changes implemented during prototyping are effective. Unfortunately, it's not uncommon for new problems to be discovered at this point that must be resolved before **production** can begin.

The cost of making changes to the product increases exponentially at each phase, as diagrammed in Figure 1. Everything that can be anticipated is one less problem to solve later. Therefore, the concept phase is the best time to seek expertise and guidance from all available resources. Contacting EWI as early in development as possible is one way to expedite production and save money.

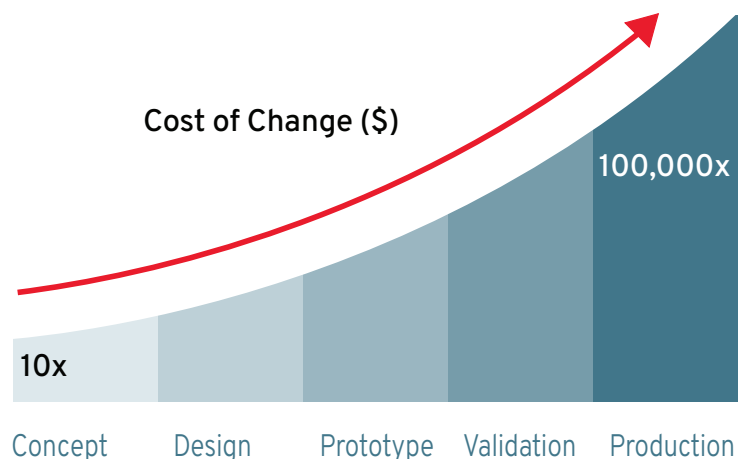


Figure 1:
The cost of change grows exponentially as it gets closer to production

AT ANY STAGE, the risk of failure can be mitigated by applying a systematic approach toward production, as shown in Figure 2. During phases 1 and 2 (concept and design) the development cycle revolves around material selection, process selection, and design. These three inputs are interdependent; changing one will affect the other two. For example, choosing a glass-filled, semi-crystalline polymer will influence a part's design for welding differently than an unfilled, amorphous polymer would. At the design stage, it is crucial to incorporate as many of the final product requirements as possible to ensure that the correct materials and processes are chosen.

During phases 3 and 4 (prototype and validation), materials, processes, and design are first implemented, then “aged” (or “conditioned”) to represent the expected use environment, and then

tested. This process is iterative. Testing results may indicate that the implementation needs adjusting (e.g., changing injection molding or welding parameters). In some cases, the results of testing lead back to the design or material and process selection cycle for reconsideration.

Even when validation is successful and production begins, problems can still arise due to unexpected changes in the manufacturing environment, differences between operators, field failures, and more. When these issues occur, the approach to resolution begins with characterizing the failure mechanism to understand it and to identify the root cause. Problems can sometimes be resolved through manufacturing processes, but occasionally a return to phase 1 is required. Thus, development becomes a cycle of continuous improvement.

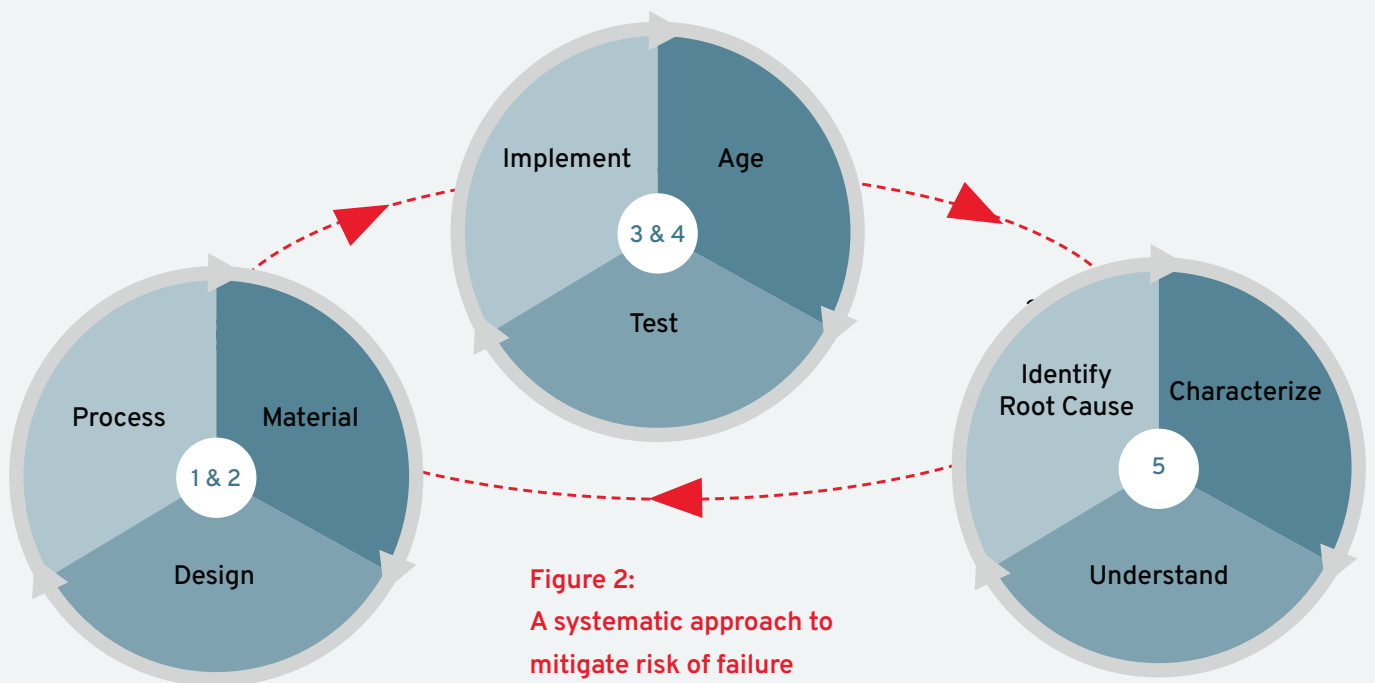


Figure 2:
A systematic approach to
mitigate risk of failure

There are a variety of early interventions – from modeling and testing approaches to feasibility experiments – that can produce a better outcome and result in a smoother production launch. Some examples are described on the following pages.

Solution-oriented Interventions

Material and Process Selection	Page 5
Material Feasibility	Page 6
Process Feasibility	Page 7
Finite Element Modeling (FEM)	Page 8
Design Feasibility	Page 9
Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ)	Page 10
Automation	Page 11
Failure Analysis	Page 12
Testing	Page 13
Novel Technical Solution: Polymer-to-metal Joining	Page 14
Novel Technical Solution: Data Science for Process Improvement	Page 15

Material and Process Selection

Material and process selection are fundamental in determining overall production expenses in manufacturing, where efficiency and cost-effectiveness are vital. It involves choosing the most appropriate materials for a particular application based on various factors, such as mechanical properties, environmental conditions, cost, availability, and the intended function of the final product. It should also be noted that the manufacturing process can alter these properties. Thus, selecting the optimum manufacturing process and parameters is very important to shorten production time and sustain the optimum material properties.

Industry: Energy

APPLICATION: Electrical junction housing
PRODUCTION RATE: 200k-300k per year
PROBLEM: Bringing production of a key component in house required development of a process and a new production line.

SOLUTION: Developed approach to seal the part via welding.

BENEFIT: Eliminated the need for epoxy, saving cost of consumables and reducing cycle time.

PROJECT COST: \$40k-\$60k

SAVINGS: Continuous, up to \$10M

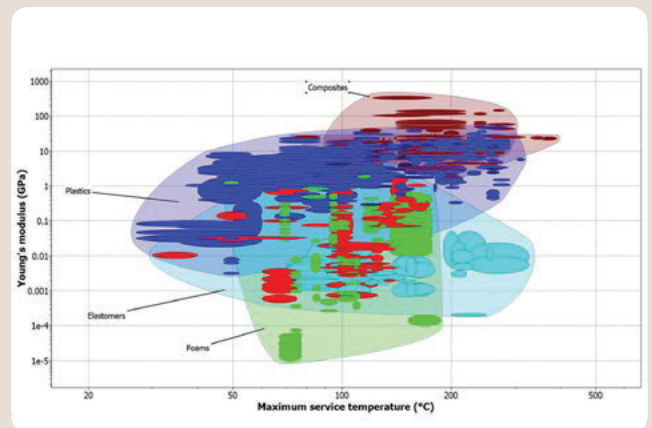


Figure 3: Example of polymer property distribution used for material selection

Material Feasibility

During stage 1 (concept), it's important to select the optimum material and to shorten design time. Changing the material is increasingly expensive further along in development, and can create the potential for a recall – which can lead to a 10% drop in share price.¹ By translating the product requirements to specific properties, appropriate materials can be targeted for early testing. Notably, 30-40% of FDA recalls are related to material issues.²

Industry: Nuclear and Solar Power

APPLICATION: Nuclear applications and solar thermal applications

PRODUCTION VOLUME: \$150B per year

PROBLEM: Many approaches have been developed for joining silicon carbide in nuclear environments, but none survived irradiation and flowing water tests mimicking in-service reactor conditions.

SOLUTION: Developed a multiphase braze consisting predominately of silicon and aluminum with a two-phase joined microstructure.

BENEFIT: This microstructure provided crack-arresting paths enabling high toughness of the joined assembly. Compared to other processes, this approach did not require high pressure.

PROJECT COST: \$50k-\$55k

SAVINGS: \$100k-\$300k

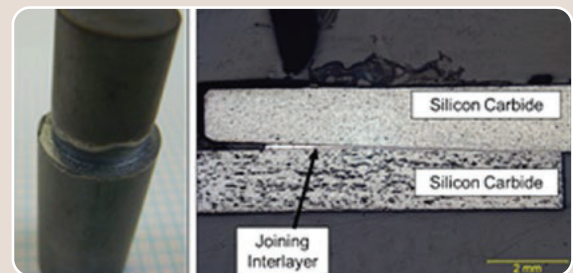


Figure 4: Brazed assembly and cross-section of SiC insert plug and tube

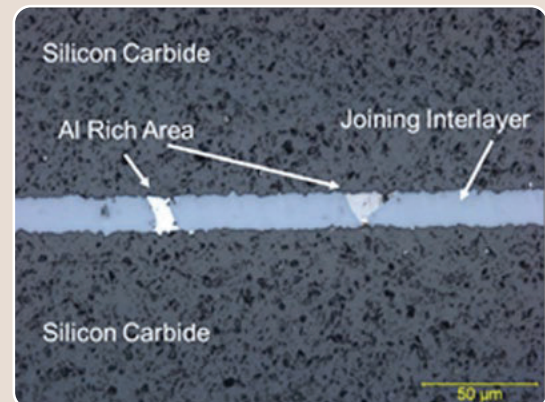


Figure 5: Microstructure of the Al-Si brazed joint. The braze fully wetted and infiltrated all asperities on the silicon carbide surface

Process Feasibility

In thick metal welding, it is difficult to avoid warping and distortion. After an extensive study of potential joining methods, hybrid laser arc welding (HLAW) was identified as the most likely joining process to reduce heat input and limit distortion and the resulting rework. EWI worked closely with a naval shipbuilder to develop robust HLAW parameter sets for each desired material type and welded qualification test specimens while a welding system was manufactured and installed with the same welding capabilities. This improved approach reduces rework and results in significantly less distortion. The flatter panels improve the fit-up and manufacturing process for subsequent ship building steps such as joining decks to bulkheads and stacking units.

Industry: Ship Building

APPLICATION: Large panel and plate joining
PRODUCTION RATE: 700 joints per year
PROBLEM: Traditional arc welding processes produced severely distorted panels, requiring significant rework and additional fitting in subsequent manufacturing steps.

SOLUTION: EWI worked with the customer to develop a HLAW process (Figure 6) to minimize heat input and distortion, followed by demonstration of a qualified process and parameters for final qualification on the production equipment.

BENEFIT: The HLAW process significantly reduced the required heat input when compared with the traditional submerged arc welding (SAW) process, significantly reducing the required rework (see Figures 7 and 8).

PROJECT COST: EWI – \$1.3M Total Navy ManTech Investment – \$2.37M

SAVINGS: Estimated \$4.6M per year

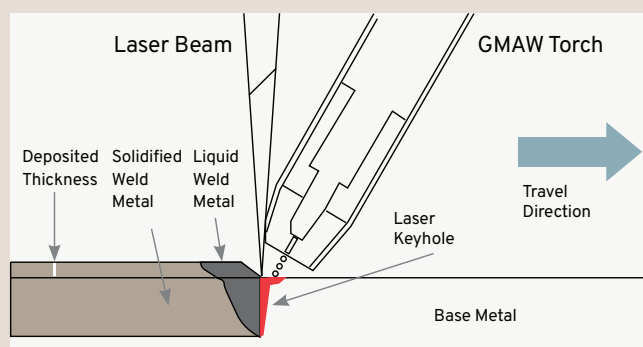


Figure 6: Diagram of the HLAW process



Figure 7: Conventional submerged arc welding (SAW)



Figure 8: Hybrid laser arc welding (HLAW)

Finite Element Modeling (FEM)

Finite element modeling is a key element of EWI's integrated computational engineering (ICME) strategy. FEM tools can help validate designs and facilitate smooth launch cycles for new products. Initial benefits of these techniques include reducing product development times, the need for extensive testing and re-design, and optimizing performance prior to prototyping. A typical example of using finite element analysis (FEA)/ICME tools for addressing a cracking problem on an industrial gear is provided below.

Industry: Automotive

APPLICATION: Welding geartrain assemblies

PRODUCTION RATE: ~100k per year

PROBLEM: A gear assembly was electron-beam welded for use in automotive transmissions. The welds were inspected via NDE techniques immediately after welding, and no flaws were detected. However, a delayed-onset cracking phenomenon occurred a few weeks after completion of the welding process. While a very limited number of weldments were affected, all welded components were quarantined and required re-inspection after a couple of weeks, adding significant cost and time delays to the manufacturing process.

SOLUTION: Using FEA and ICME techniques, a model was developed to predict susceptibility to cracking by optimizing the process parameters.

BENEFIT: Rapid demonstration of solution paths replaced time-intensive iterative approaches. The resulting tools specific to the application also offered potential to prevent future problems with emerging gear designs.

PROJECT COST: \$100k-\$150k

SAVINGS: Up to millions of dollars per year

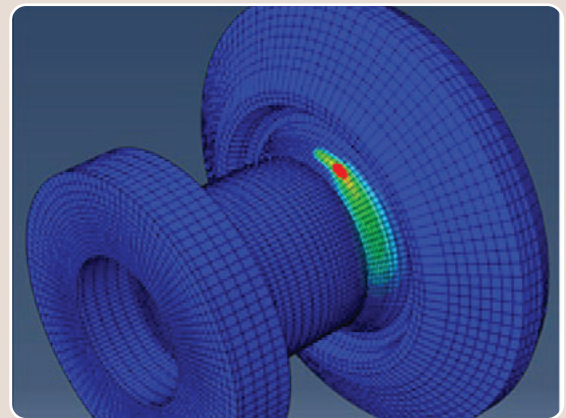


Figure 9: FE modeling of welding of gear assembly

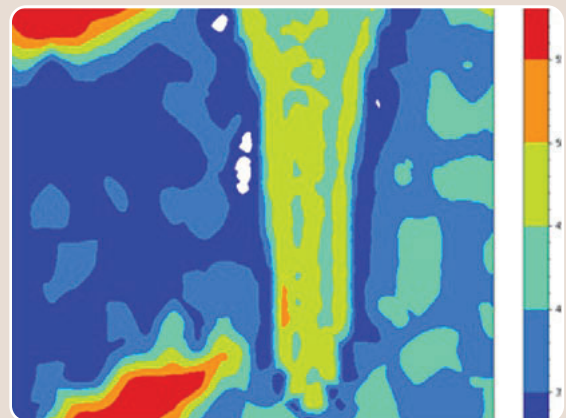


Figure 10: Predicted hardness verified with experimental data

Design Feasibility

For some products, the design criteria results in questionable feasibility for assembly processes. In these cases, feasibility testing using test geometries can be performed. For example, medical and electronic applications increasingly require very small, very strong polymer bonds, and the application of heat and motion must be controlled and delicate to achieve strong welds without causing damage. Figures 11 and 12 show some examples of challenging small-scale geometries EWI has tested.

Industry: Consumer Products

APPLICATION: Personal hygiene product
PRODUCTION RATE: ~100 million per year
PROBLEM: A startup company had a novel product design concept which required a creative and innovative joining solution.

SOLUTION: Proved capability to join foam to a compressible elastomer with minimal flash to maintain dimensional tolerances.

BENEFIT: Establishing the weldability of a questionable geometry before committing to injection molding tooling and welding equipment saves on tooling, equipment, and engineering time.

PROJECT COST: \$20k-\$50k
SAVINGS: \$75k-\$300k

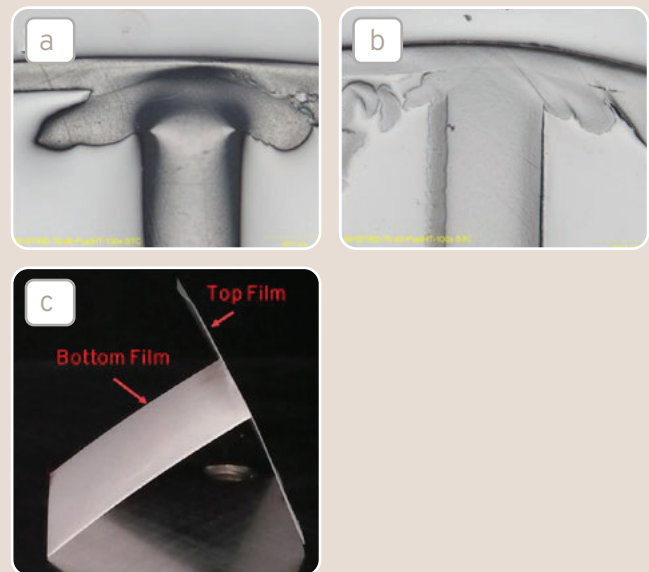


Figure 11: Ultrasonic welded film in T-joint configuration
 (a) 0.25-0.08 mm thick acrylonitrile butadiene styrene
 (b) 0.25-0.08 mm thick polyoxymethylene
 (c) perspective view of the joined films

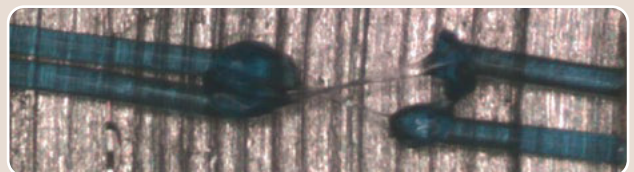


Figure 12: Laser welded 0.25 mm diameter suture

Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ)

As a process is moved from phase 4 (validation) to phase 5 (production), performing IQ, OQ, and PQ ensure a successful launch, as described in Figure 13. EWI can travel to the manufacturing facility to directly support IQ and OQ, then provide consultation via phone and email to support PQ. IQ is performed to ensure that the equipment is properly installed and set up. OQ is performed to verify that the process is operating similarly to during development. PQ is performed to monitor the part quality as production starts to head off any issues early.

Industry: Medical

APPLICATION:	Dialysis equipment
PRODUCTION RATE:	~1 million per year
PROBLEM:	The product was redesigned and relaunched on a new production line to reduce defect rates and increase production rates.
SOLUTION:	Developed process parameters and supported a successful product launch.
BENEFIT:	Expert assistance during the transition from stage 4 (validation) to stage 5 (production) ensures a smoother transition, quicker troubleshooting, and faster ramp up.
PROJECT COST:	\$20k-\$50k
SAVINGS:	\$50k-\$100k

IQ

Verify Installation
Establish Baseline



OQ

Validate Parameters
Perform Testing



PQ

Ensure Reliability
Analyze Data



Figure 13:
Installation Qualification (IQ),
Operational Qualification (OQ),
Performance Qualification (PQ)

Automation

The first step in many robotic pick-and-place applications is understanding the feasibility of interacting with unique parts. Identifying methods to translate manual assembly or fabrication processes to fully automated solutions is critical to reduce errors and ensure consistency. An example of early development of a part-handling strategy is seen below.

Industry: Multiple Manufacturing Sectors

APPLICATION: Robotic Pick-and-place
PRODUCTION RATE: 10k-100k parts per year
PROBLEM: Accurately and repeatably gripping parts for robotic processing, introducing automated functions into manual operations.

SOLUTION: Evaluation of potential to directly translate manual tooling to an automated solution; development of interface between application and robot.

BENEFIT: Application-specific testing for identification of barriers toward automation; verification of part processing prior to implementation.

PROJECT COST: \$10k-\$50k

SAVINGS: \$75k-\$250k



Figure 14: Fixturing and inner diameter grip for robotic deburring

Failure Analysis

Heated After Cross Section (HACS) analysis is the only quality assessment technique that can be used to check for intermolecular diffusion. This is critical as fatigue or creep field failure are often traced back to a lack of intermolecular diffusion which can be due to material incompatibility, insufficient heating, surface contamination, or process parameters. An example of this evaluation method is shown in Figure 15 of a hot-plate weld with good intermolecular diffusion and in Figure 16 where the change over time was too long and allowed the melt surfaces to cool too much.

Industry: Consumer Products

APPLICATION: Electrical adapter housing
PRODUCTION RATE: Over 200 million per year
PROBLEM: A failure rate of <0.001% was being experienced, over 500 parts per day at full production volume.

SOLUTION: EWI identified a design flaw that was causing unacceptable failures.
BENEFIT: Identifying and resolving a welding issue in production prevents product recalls, reduces liability, and preserves brand reputation.

PROJECT COST: \$10k-\$50k

SAVINGS: \$100k-\$1M

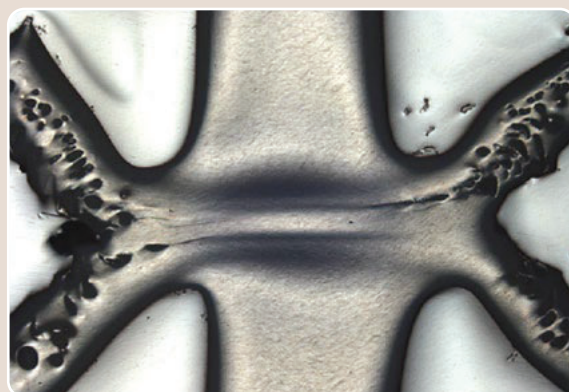


Figure 15: Hot-plate weld where intermolecular diffusion occurred

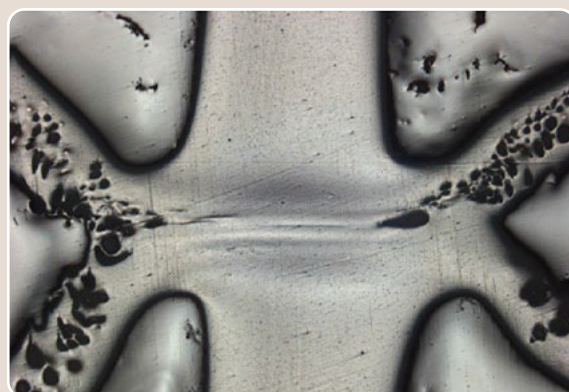


Figure 16: Hot-plate weld where intermolecular diffusion did not occur

Testing

Many parts in different industries must be hermetically sealed; some examples include pipes, medical drug delivery devices, and HVAC components. The LeakSight™ detection marking system works by first placing the color-change reagent on the exterior of the part over the welded or sealed areas. Next, the reactive gas is pumped into the part at 1 psi. The gas then diffuses through any holes in the part and to the reagent, which responds by changing color. The color change is distinct and permanent and marks the leak locations. This marking allows the part manufacturer to quickly and easily identify defective parts.

Industry: Automotive

APPLICATION: HVAC
PRODUCTION RATE: 100k parts per year
PROBLEM: Inconsistent joining of metal tubing caused leaky heat transfer systems, which were not identified until the entire system was fabricated.

SOLUTION: LeakSight™ was proven feasible to implement on the manufacturing line immediately after each joining process to catch leaks earlier in production.

BENEFIT: Parts could be pulled from moving to the next joining station and reworked, thus saving the number of systems that were scraped at the end of fabrication.

PROJECT COST: \$230k

SAVINGS: \$200k per year per manufacturing line



Figure 17a: Box with 300 µm hole



Figure 17b: LeakSight tape applied

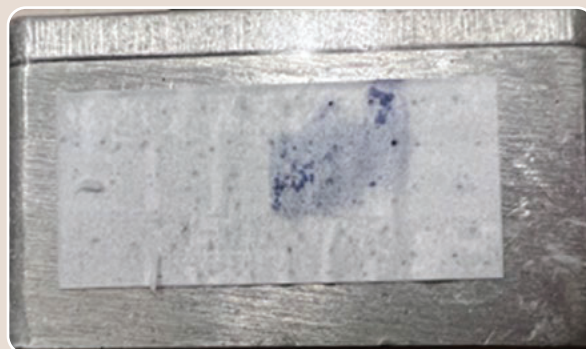


Figure 17c: LeakSight color-change

Novel Technical Solution: Polymer-to-metal Joining

Sometimes, to bring a new product to market or to create a dramatic shift in technological possibility, developing new manufacturing processes is needed. An example of this is the use of a high-speed laser to create a texture that allows for a strong and leak tight bond to polymers, as shown in Figure 18. This direct joining of metal to polymer solution eliminates the need for messy and expensive consumables like polyurethane adhesives or epoxies as well as reducing assembly weight by eliminating mechanical fasteners.

Industry: Medical

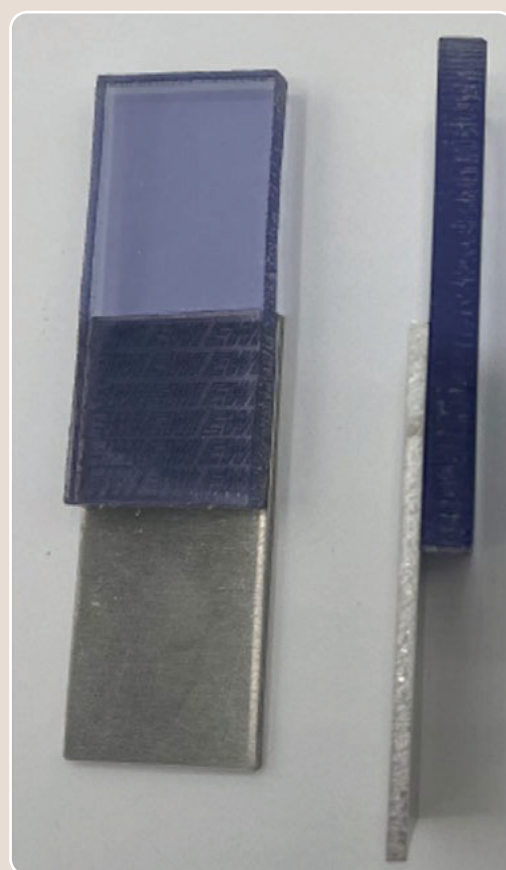
APPLICATION: Drug Delivery
PRODUCTION RATE: ~500k per year
PROBLEM: A device for internal use was being developed which required a non-adhesive, precise joining process for dissimilar polymers.

SOLUTION: Recommended and demonstrated novel joining approach for unique geometry and material combination.

BENEFIT: Development of a novel manufacturing solution allows breaking into a new market with improved functionality or lowered costs, potentially leading to millions of dollars in sales.

PROJECT COST: \$75k-\$200k

SAVINGS: Up to \$50M



**Figure 18: Polyvinylchloride (PVC)
bonded to Aluminum 5052**

Novel Technical Solution: Data Science for Process Improvement

Electric vehicle lightweighting can be achieved with new high strength steels. However, these steels are known to have highly variable material properties, even within one coil of material. Developing a strategy to intelligently select a servo motion profile based on in-line measurements improves forming results and greatly increases revenue.

Industry: Automotive

APPLICATION: Electric Vehicle Lightweighting

PRODUCTION RATE: ~4.5 million parts per press per year

PROBLEM: The high variability of high-strength steel material properties means using a single press motion profile leads to unpredictable results and high costs.

SOLUTION: Machine learning techniques were applied to find material property process windows for three different servo press motion profiles. Material properties of the high-strength steel are measured in-line and nondestructively. The servo press motion profile that yields the best forming results and cost efficiency is then selected.

BENEFIT: This methodology results in better forming results and uses the most time-efficient servo press motion profile to achieve quality, resulting in larger returns.

PROJECT COST: \$50-500k

SAVINGS: Up to \$1.5M (3x ROI)

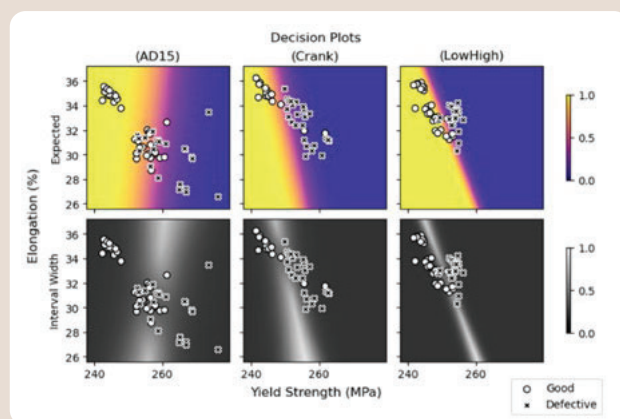


Figure 19: Process windows for different servo press motion profiles

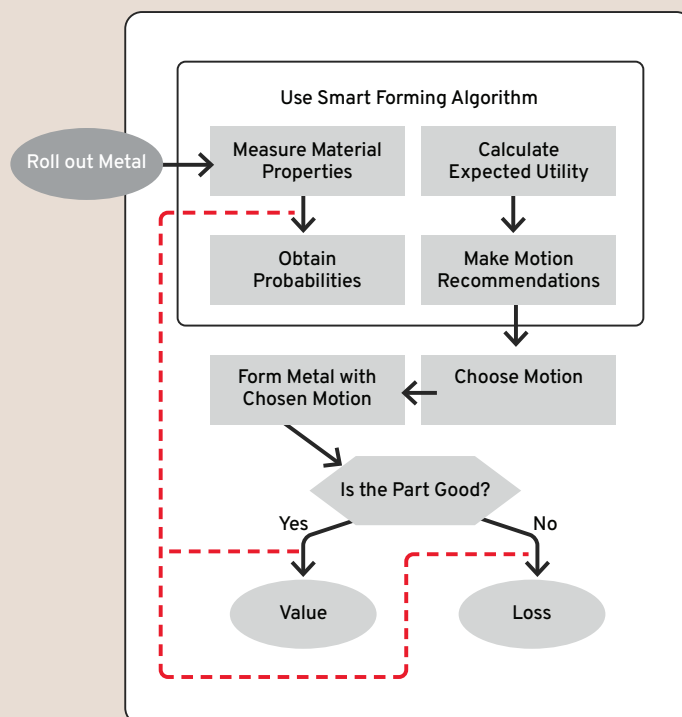


Figure 20: Smart forming workflow

EWI Can Help

The benefits of early intervention well justify the cost. By identifying the key risk areas in a specific development process and targeting interventions to mitigate them, a successful product launch can be realized. Contact EWI at info@ewi.org or **614.688.5152** to find out how we can best support you to save money through early intervention and development support.

References:

- 1) McKinsey, The Business Case for Medical Quality
- 2) Ellis, J., Material Evidence: Examining Mysterious Design Failures, Med Device Online, May 15, 2017



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