



BASSINET FOR HOSPITALS



PROBLEM

An entrepreneur devoted his career to creating products to protect newborns and infants. He identified a new opportunity in birthing centers to improve workflow in birth wards for mothers recovering from c-section births, reducing drops of infants, improving patient satisfaction, and reducing the burden on hospital staff. The company previously sold commercial, non-medical products and did not have the experience in the product requirements and regulatory pathways for medical devices. They had a Class II medical device concept but no path to design, validate, approve, and produce a solution for the healthcare market.

SOLUTION

MPE created design concepts and prototypes that we knew would be viable in a medical environment. MPE built functional prototypes and conducted VOC activity on behalf of the customer to validate and refine the design with all hospital stakeholders. Customer leveraged MPE's QMS and guidance to navigate regulatory requirements. MPE provided 3PL services to warehouse and ship directly to the customer's end users. MPE used strategic sourcing to hit product launch and design to cost goals.

RESULT

Initial concept was transformed to a product that better fit the intended environment and workflow. Product was brought to market with 510(k) approval within 14 months of initial engagement. Launch year to following year, sales increased 385% without requiring customer to create any infrastructure to support scale. Product success led to partnership with major medical OEM.

CUSTOMER VALUE

INCREASE REVENUE

- Accelerated time to market (drives revenue growth) via efficiencies stemming from a single partner (avoid multiple handoffs)

LOWER COST

- Lower development cost by avoiding handoffs and resets
- Lower ongoing TCO through operational efficiencies in product delivery

LOWER RISK

- Reduce product delivery disruption due to design changes
- Reduce risk of new product market launch (timing/design)
- Reduce regulatory risk via revision management control (PDM)...simplified via Concept to Completion model