

DRUG DELIVERY SYSTEM EXPERIENCE

ISO 9001 & 13485 CERTIFIED

PRIOR DRUG DELIVERY EXPERIENCE

Working on injectors for 15 years

Involved with 20+ pen platforms

Worked for several major pharmaceutical & medical device companies

involved in injector design & manufacture

Worked on re-usable & disposable pen injectors & auto injectors

40+ Engineers in the Cincinnati office

FAILURE INVESTIGATIONS

DESIGN SUPPORT ACTIVITY

3rd party independent review

Technology evaluation

Material selection (including elastomers)

Component design including conceptual design
(mechanical and electrical)

Component analysis (stress & fluid flow)

Risk assessment (FMEA, FTA)

Reliability & 'robust' engineering

Should-cost assessment

Industrial design & human factors design

Package design

Rapid Prototyping

Proof of concept testing

User testing

MANUFACTURING SUPPORT ACTIVITY

DFM review support

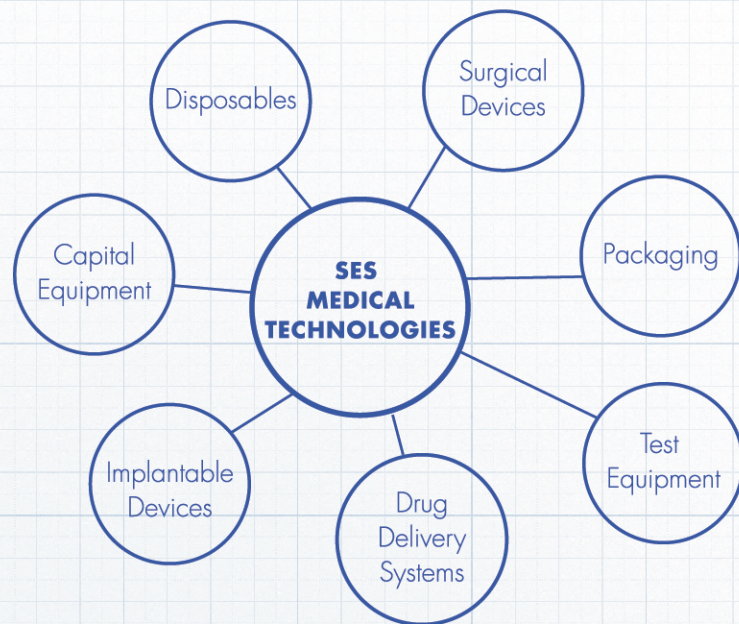
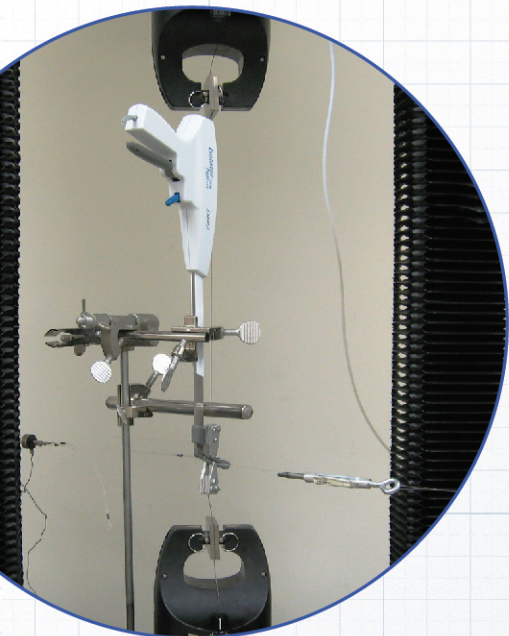
Process simulation (mold flow analysis, fluid filling analysis)

Mold design review

Mold qualification support

Supplier selection & management





TESTING

Product life assessment testing
 Device functional testing
 Material behavior testing
 Client test method review
 Evaluation of the effects of sterilization methods



SYRINGES -- PREFILLED & UNFILLED

Develop custom test equipment to characterize syringe performance in an environment that replicates the auto injector conditions (i.e. forces, velocities, fluid behavior)
 Elastomeric stopper computational analysis & experimental performance characterization
 Studies of glass loads & breakage causes
 Testing & analysis of plastic syringes
 Characterization of materials & time or environment dependent effects such as aging, relaxation, environmental stress cracking & temperature
 Investigation of the interaction between syringes, syringe components & other elements in drug delivery systems to identify failure modes & effects
 Support for molding, forming, filling, processing issues & tooling design



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