

ASSEMBLY, PACKAGING & STERILIZATION

Components Through Finished Devices: Single components such as silicone punctal plugs and small joint implants function as complete medical devices. More often though a fabricated component is only one part of a larger and more complex device. SSF provides the medical device industry with the most complete suite of post-fabrication services including a range of secondary operations, complete device assembly, expert packaging as well as a choice of in-house and contract sterilization services.

Secondary Operations: SSF provides added value to our clients by offering an extensive range of secondary operations including post curing, printing, die cutting, drilling, tipping, bonding, slitting, trimming, coiling, and functional testing.

Complete Medical Device Assembly Services: SSF's device assembly expertise is as varied as the requirements of our clients. Our projects have ranged from routine sub-assemblies involving silicone, metal, plastic, and ceramic components to the assembly of shunts formed from porcine-derived polymer to the complete manufacture of fully functional neurological implants.



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Here's a look at two assembly projects that highlight our attention to efficiency, precision, and customer satisfaction.

SSF was chosen as a total solution partner for the manufacture of an implantable neurological sensing device. Silicone components including die-cut reinforced sheeting, a molded electrode positioner, and tubing were assembled into an eight electrode array. The assembly process included fixtured positioning, bonding, laser welding, micro-crimping, laser stripping, and custom tray packaging. Pass-fail functional testing evaluated both electrical resistance and capacitance.

We've also developed a complete assembly process for the construction of a novel mammary implant. The bill of materials involves 38 parts including dipped shells, precision molded valve components, and extruded tubing. The process batch record fully details 58 discrete assembly steps beginning with line clearance and ending with product release as sterile finished goods. Serialized inner tray and shelf box labels are printed and controlled on-site. Each implant is laser etched with corresponding serial identification.

Packaging and Sterilization

SSF engineers collaborate with our clients' product teams to design packaging solutions that are appropriate for various sterilization methods, device storage, and intended use. We provide pre-validated pouching and tray sealing services as well as work with trusted outside vendors to develop custom product packaging.

In 2013 we became the first silicone contract manufacturer to offer in-house dry heat sterilization. This on-site capability complements our relationships with outside vendors who provide sterilization via gamma, e-beam, and ethylene oxide technologies.