Your Strategic OEM Partner in

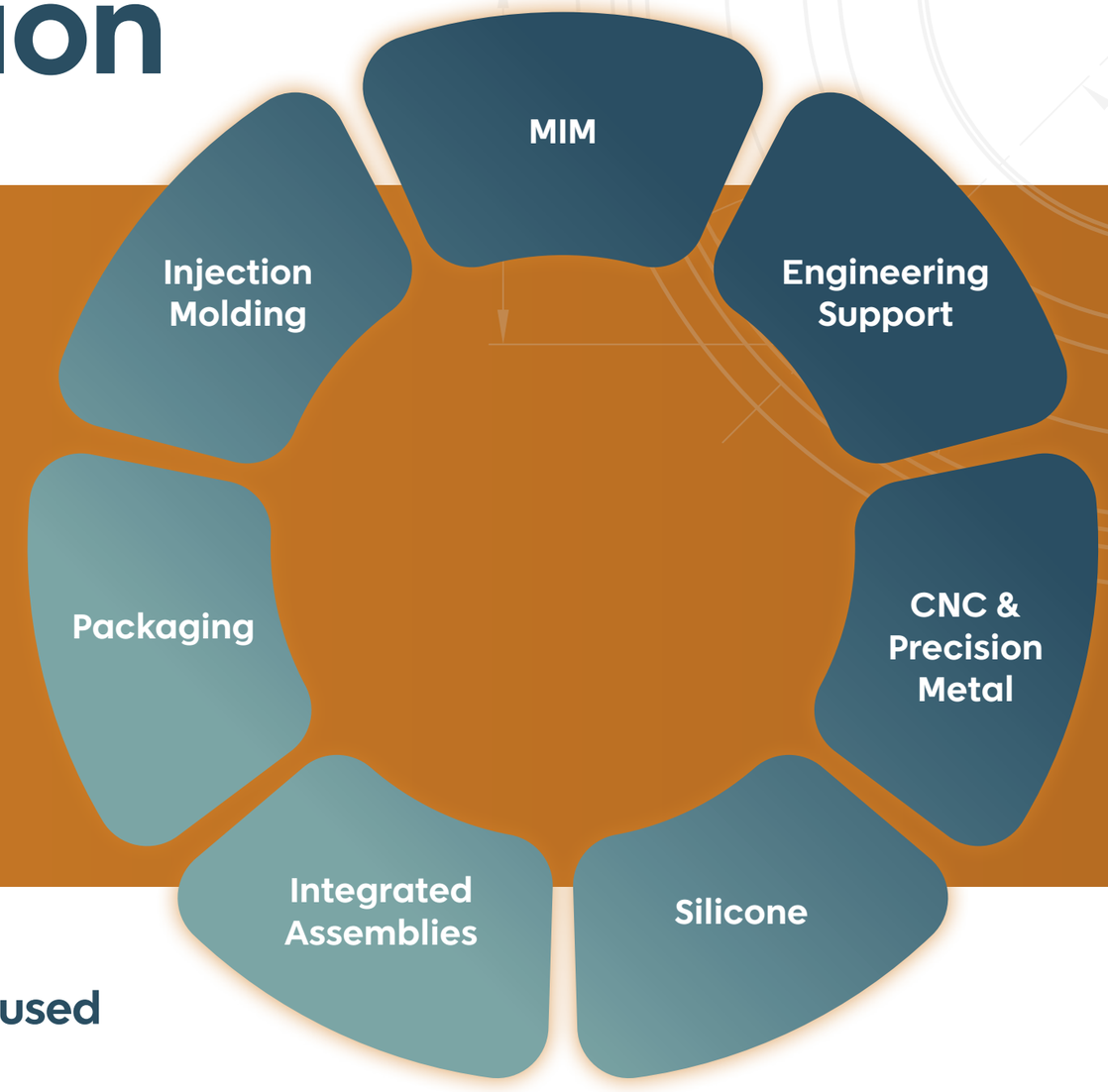
Medical Device Manufacturing

SIGMA Technologies

From concept validation
to full-scale production

SIX SIGMA Ltd.

Manufacturing Excellence
for Medical Innovation



SIX SIGMA Ltd. is an ISO 13485 and ISO 9001 certified OEM manufacturing partner delivering high-precision plastic and metal components and assemblies for the medical and high-tech industries.

We integrate deep engineering expertise, validated industrial processes, and a strictly controlled global manufacturing model under unified quality governance.

Our focus is not only on producing parts - but on building stable, scalable, and regulatory-aligned manufacturing solutions.

Engineering-driven. Risk-controlled. Industrialisation-focused

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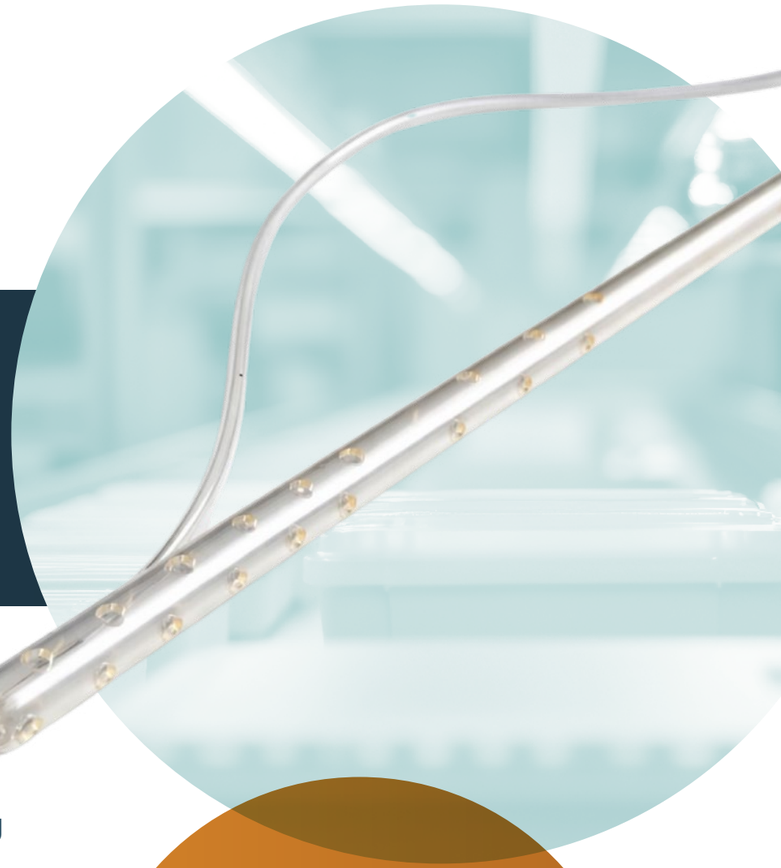
Who We Are

SIX SIGMA operates as a technology-oriented manufacturing partner supporting medical device companies from early-stage development through validated serial production.



ISO 13485 certified Quality Management System

ISO 9001 certified operational framework

Strong Design for Manufacturing (DFM) involvement from early design stages

Experience supporting Class I–III medical device components

Advanced metal and polymer processing capabilities

Controlled global supplier network with engineering oversight

Integrated engineering and manufacturing model

We function as an industrial extension of your R&D and Operations teams.

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Why Work With Us

Six Sigma operates as a strategic manufacturing partner for companies developing complex, high-precision products in regulated and high-performance industries.

Our advantage lies in combining engineering expertise, multi-technology manufacturing capabilities, and a controlled global production network under a single quality framework.

Our Goal

To help customers reduce development risk, accelerate industrialisation, and achieve stable long-term production.

Key Advantages

- Engineering-driven Design for Manufacturing (DFM) support
- Multi-technology manufacturing under one quality system
- Experience with regulated medical device components
- Controlled manufacturing network with engineering oversight
- Integrated development from prototype to serial production
- Transparent technical communication and fast feedback

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Development & Industrialisation Support

Our objective is to eliminate production risk before capital tooling investment.

Engineering-Led Development

- Design for Manufacturing (DFM) and cost-driven geometry optimisation
- Medical-grade material selection and performance evaluation
- Moldflow simulation and flow behaviour analysis
- Tolerance stack-up analysis
- Finite Element Analysis (FEA) – stress, deformation, fatigue evaluation
- Prototype tooling and validation tools
- Computational Fluid Dynamics (CFD) – flow and thermal modelling
- Functional validation samples

Industrialisation Strategy

- Multi-cavity tooling strategy planning
- Production cost modelling and scalability planning
- FMEA-based early risk mitigation
- Process validation roadmap (IQ / OQ / PQ)
- Packaging concept integration during development phase

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NPI & Industrial Transition

New Product Introduction (NPI)

SIX SIGMA supports the structured transition from R&D to validated serial manufacturing.

Structured NPI Framework

- Clearly defined stage gates from prototype to serial production
- Metallurgical validation support for MIM and casting components
- Early risk identification and mitigation (FMEA support)
- Dimensional capability studies (Cp/Cpk)
- Production-intent tooling strategy
- Process window definition and stability mapping
- Material validation using final production-grade resins
- IQ / OQ / PQ preparation support

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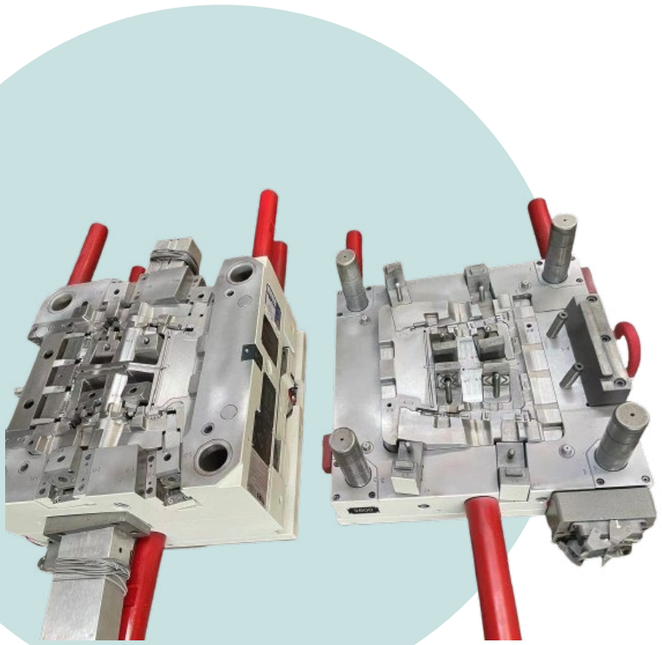
Small & Medium Series Production

- Bridge manufacturing prior to mass production
- Low-to-medium volume runs under ISO 13485 control
- Controlled ramp-up strategy
- Flexible capacity planning

We design validation tools aligned with future serial production - not as temporary prototypes.



Injection Molding Capabilities

High-precision medical and technical injection molding solutions.

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Technical Capabilities

- Single-shot molding
- Insert molding
- Overmolding (2K / multi-material)
- Micro-molding capabilities
- Thin-wall medical components
- Optical-grade components
- Tight tolerance production
- High-performance engineering polymers including PEEK, PPSU, PEI, PC, PA and specialty materials

Process focus:

- Cp/Cpk-driven process control
- Full material traceability
- Stable and repeatable validated processes
- Controlled process window development

Advanced Metal Technologies

Metal Injection Molding (MIM) – Core Competence

Precision sintered metal components for medical and high-tech applications.

MIM enables highly complex geometries with CNC-level precision in medium-to-high production volumes while optimizing material efficiency.

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MIM - Metal Injection Molding

Materials

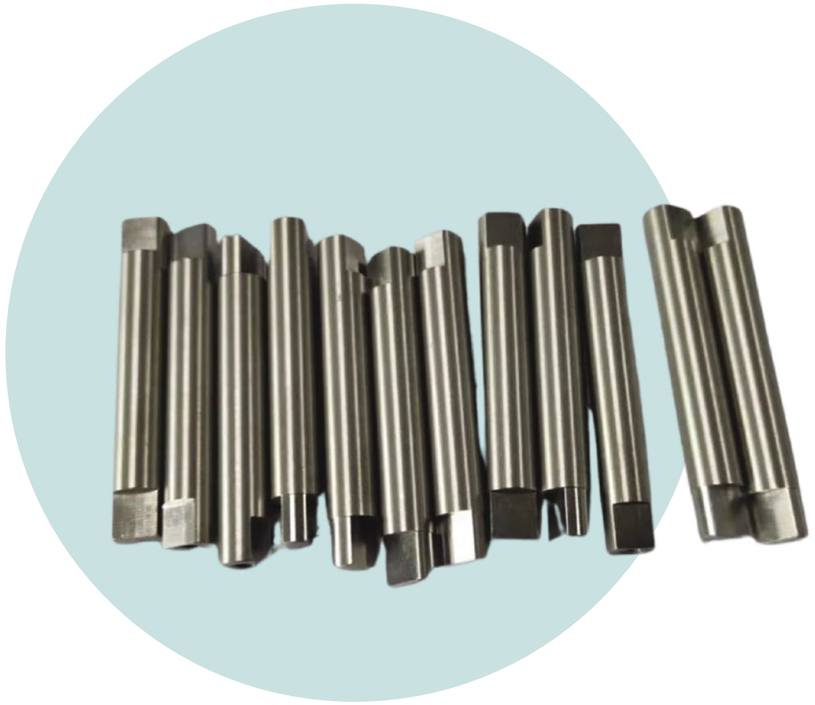
- Medical-grade stainless steels (17-4PH, 316L)
- Titanium (Ti-6Al-4V)
- Copper and high thermal conductivity alloys
- Tool steels and specialty high-performance alloys

Capabilities

- Small and highly complex geometries
- Thin-wall and micro-feature components
- Tight dimensional tolerances
- High-density sintering control (typically 96–99%)
- Controlled atmosphere sintering
- Post-sinter heat treatment
- Secondary CNC finishing when required

Medical Focus

- Biocompatible alloys
- Surgical components
- Minimally invasive device parts
- Complex mechanical subcomponents
- Implantable-grade materials (subject to application requirements)



CNC Machining
Expanded Capabilities

Precision machining from prototype through serial production.

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Machining Capabilities

- 3-axis and 5-axis CNC machining
- Swiss-type precision turning
- Stamping dies and progressive tooling
- Wire EDM
- Micro-machining
- Secondary finishing and anodizing
- Tight tolerance medical components

Materials include:

- Aluminum
- Stainless steel
- Titanium
- Copper alloys
- Tool steels

Silicone & Elastomer Solutions

Advanced medical-grade silicone and elastomer processing.

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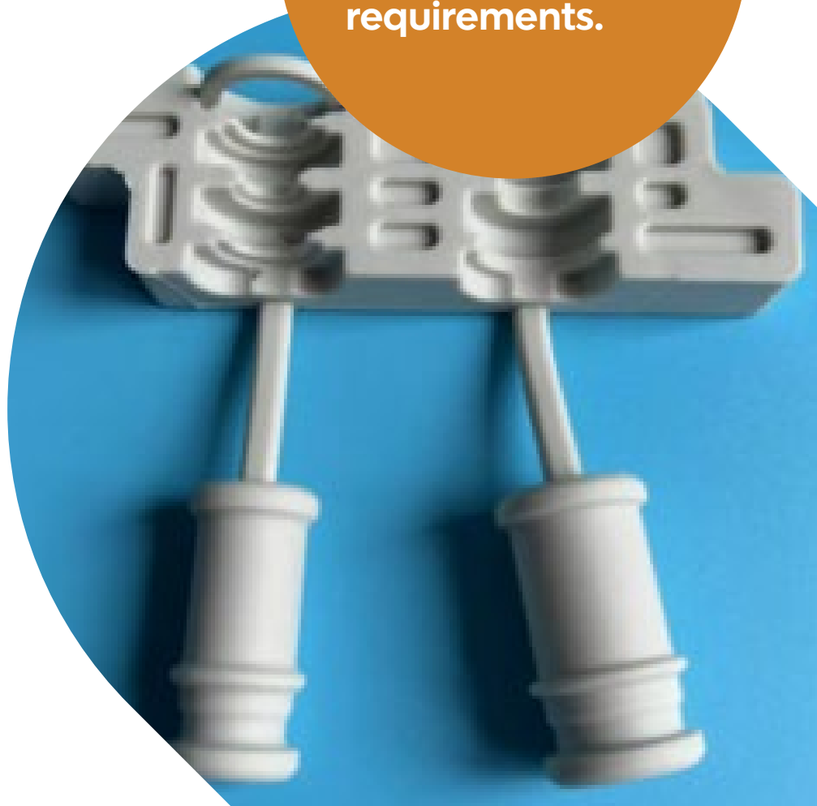
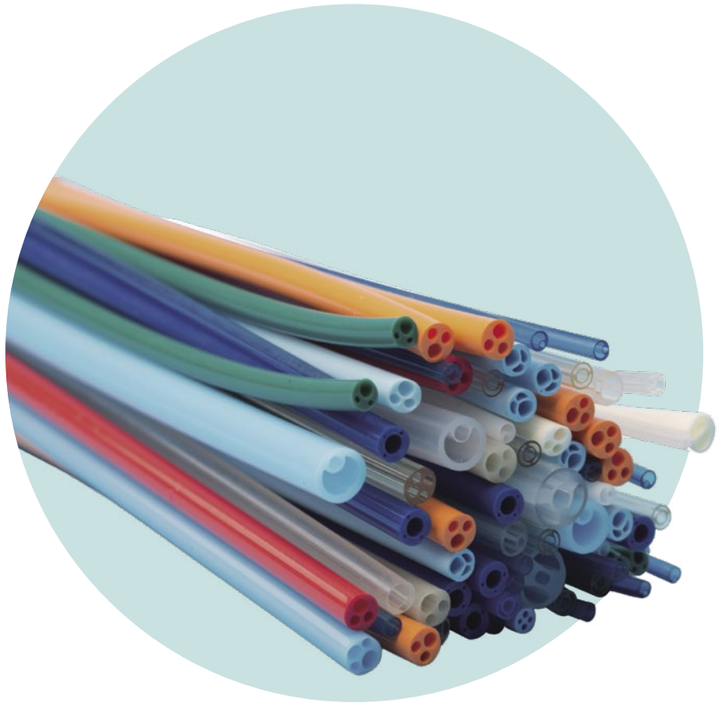
Processing Capabilities

- LSR (Liquid Silicone Rubber) injection molding
- HTV compression molding
- Platinum-cured medical materials
- USP Class VI grades
- Overmolded assemblies
- Seals, valves, strain relief components
- Medical tactile and interface components

All processes are aligned with medical regulatory requirements.





Medical Tube Extrusion

Precision medical extrusion solutions for catheter and device components requiring tight dimensional control and material consistency.

Six Sigma supports the development and manufacturing of high-performance medical tubing used in minimally invasive devices and advanced medical systems.

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Capabilities

- Single-lumen and multi-lumen tubing
- Thin-wall precision extrusion
- Micro-diameter tubing
- Tight OD / ID dimensional tolerances
- Radiopaque material integration (BaSO4, tungsten compounds)
- Co-extrusion and multi-layer structures
- Inline dimensional monitoring and quality control

Materials

- Pebax®
- TPU / medical polyurethanes
- Nylon 11 / Nylon 12
- Polyethylene and specialty medical polymers
- Custom compounded materials

Applications

- Catheter shafts
- Multi-lumen medical tubing
- Guidewire support tubes
- Fluid transfer and medical tubing systems
- Structural components for minimally invasive devices

Process Focus

- Tight dimensional stability and repeatability
- Medical-grade material traceability
- Support for secondary processes such as cutting, bonding, and assembly
- Integration with injection molded and machined components

Assembly & Integration

Customized device-level assembly solutions aligned with product architecture.

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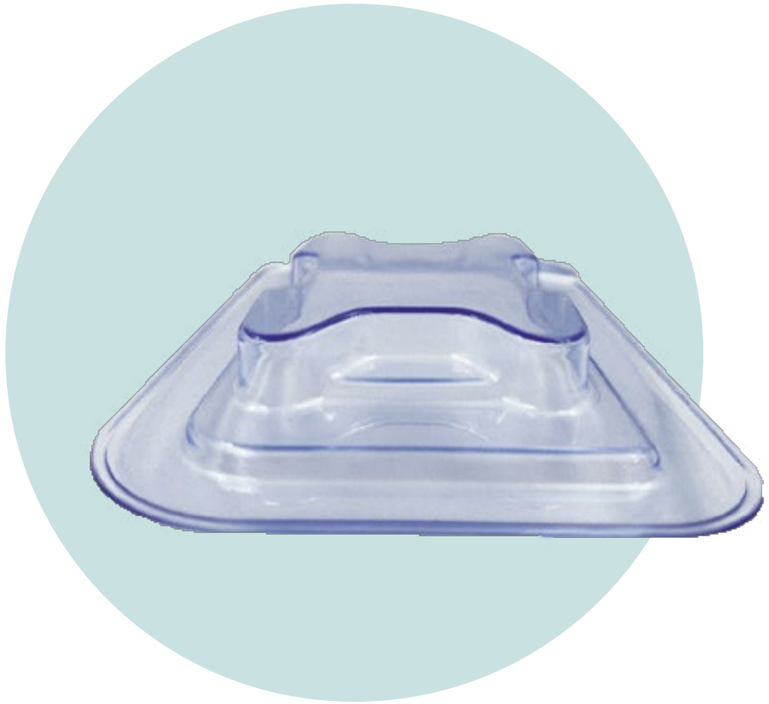
Assembly Capabilities

- Mechanical sub-assemblies
- Plastic-metal hybrid integration
- Ultrasonic welding
- Engineering adhesive bonding
- Pad printing
- Laser marking and traceability marking
- Functional testing
- Clean packaging preparation
- Device-level assemblies

Metrology & Quality Control

- Contact and vision CMM
- Gauge validation (Gauge R&R)
- Dimensional reporting
- Capability studies



Medical Packaging Solutions

Integrated packaging as part of the manufacturing strategy.

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Packaging Capabilities

- Tyvek® sterile barrier systems
- Blister and thermoformed trays
- Rigid protective packaging
- Medical-grade films
- Secondary packaging and cartoning
- UDI labeling
- ISO 11607 aligned validation support
- EtO sterilization compatible packaging
- Gamma sterilization compatible packaging

Packaging is developed in parallel with product industrialisation to ensure compliance and stability.

Regulatory & Quality Management

Quality is embedded at every stage of development and production.

- ISO 13485 certified Quality Management System
- ISO 9001 certified
- Structured risk management framework
- Process validation support
- SCAR / CAPA systems
- Full material and process traceability
- Supplier qualification program
- Statistical Process Control (SPC)

Engineering depth is applied to minimize production variability and ensure long-term stability.

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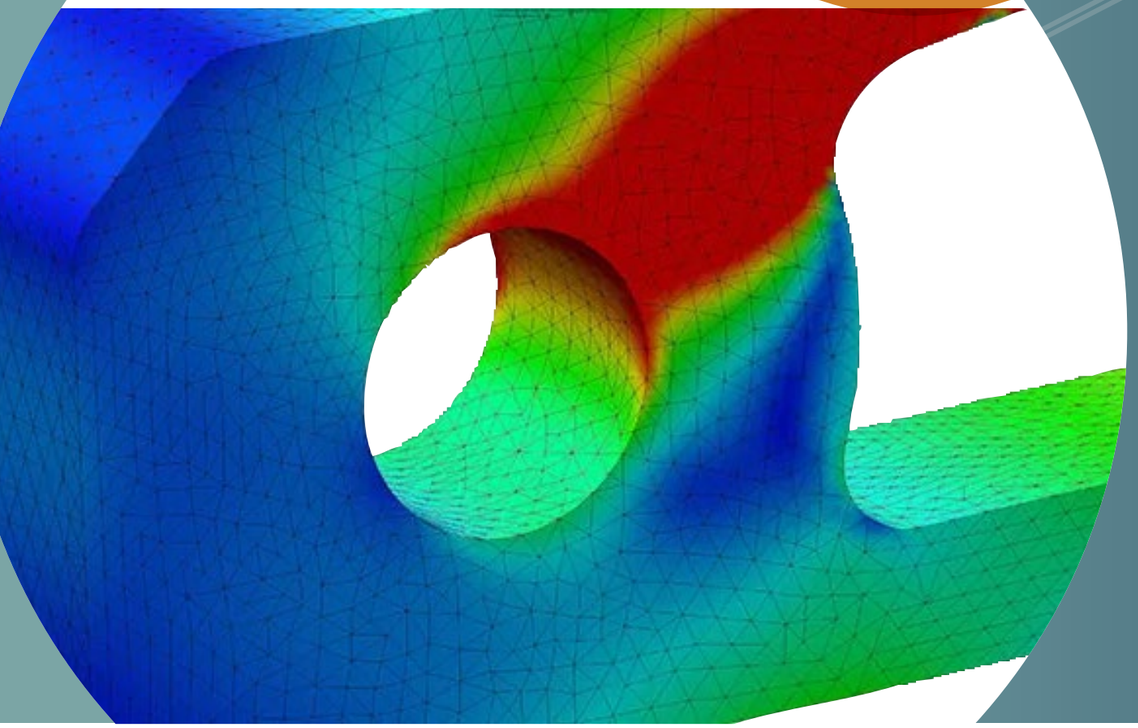
Engineering, Simulation & Process Validation



Technical modelling and process analysis reduce industrial risk prior to tooling investment.

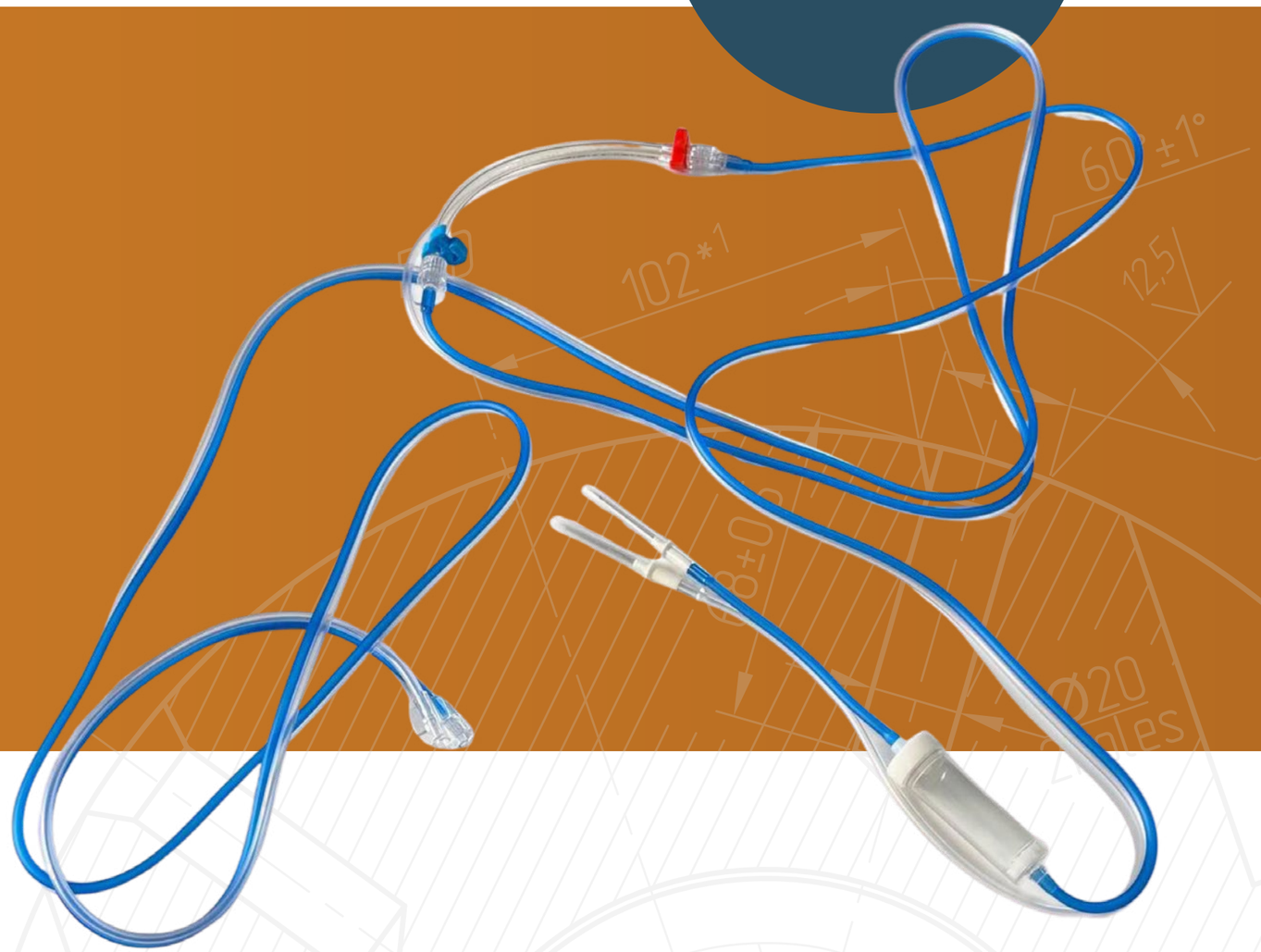
- Moldflow simulation
- Finite Element Analysis (FEA) structural validation
- Computational Fluid Dynamics (CFD) flow and thermal modelling
- Cp/Cpk capability analysis
- ANOVA studies
- Root cause investigations
- Tool optimisation and cycle time reduction
- Process window development and validation

Supply Chain & Global Integration

You receive flexibility with stability.

Controlled global manufacturing under strict quality governance.

- Approved manufacturing partners operating under Six Sigma engineering and quality oversight
- Dedicated quality oversight
- Dual-source strategies when required
- Cost optimisation without quality compromise
- Transparent technical communication



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Technology Integration Advantage

Multi-Technology Integration Under One Quality System

SIX SIGMA integrates multiple advanced technologies within one controlled engineering and quality framework.

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Single partner. Multiple technologies. One quality system.

- Injection molding combined with MIM assemblies
- CNC secondary finishing for sintered parts
- Silicone overmold on metal inserts
- Investment casting integrated with precision machining
- Packaging validation within the manufacturing flow

This integrated approach reduces:

- Interface risk
- Qualification time
- Vendor management complexity
- Validation duplication
- Supply chain fragmentation

One Quality System

Industry & Application Expertise

We work with:

- Early-stage technology start-ups
- Scale-up companies transitioning to serial production
- Established multinational OEM manufacturers
- Engineering-driven companies in regulated and high-performance markets

Our Focus

- Tight tolerances and dimensional stability
- Engineering-grade and medical-grade material expertise
- Thermal, structural, and flow performance considerations
- Process validation aligned with regulatory or industry standards
- Scalable manufacturing from pilot builds to commercial volumes
- Cross-technology integration under one quality framework

Key Application Areas

- Catheter hubs and minimally invasive device subcomponents
- Surgical instruments and precision mechanical parts
- Optical and electro-mechanical components
- Agricultural technology assemblies and precision structural parts
- Electronic device housings and thermal management components
- Hybrid plastic-metal assemblies
- High-conductivity copper-based solutions
- High-precision structural parts requiring MIM, CNC, or multi-process integration

Six Sigma supports technically demanding, high-precision applications across regulated medical and advanced high-tech industries, requiring reliability, material performance, and cross-technology integration.

SIGMA Technologies

Six Sigma
Our Approach

SIGMA Technologies

From feasibility assessment to validated serial production, we focus on industrial stability, scalability, and regulatory alignment.

- Engineering-first communication
- Fast technical feedback cycles
- Transparent decision-making
- Risk reduction methodology
- Long-term manufacturing strategy

We do not only manufacture components.
We build manufacturing platforms.

Advanced OEM Manufacturing Partner for Medical and High-Precision Devices

Engineering-driven manufacturing from concept validation to stable commercial production

We support customers developing complex products requiring precision, reliability, and scalable manufacturing

Engineering-Driven Development

Design for manufacturing, simulation and early risk reduction

Multi-Technology Manufacturing

Injection molding, MIM, CNC machining, silicone processing and integrated assemblies

Medical-Grade Quality System

ISO 13485 aligned manufacturing and validated production processes

Integrated Industrialisation

From prototype builds through validated serial production

From concept to validated production
one engineering and manufacturing partner

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