WHAT WE CONSIDER

- choice of material based on assay conditions
- compatibility of shape/design with devices
- standardized formats of production and packaging (e.g. credit card format, microscope slide format)
- robustness of manufacturing process
- small footprint
- the 3 C’s (cost, cost and cost)

WHAT WE OFFER

- design optimization for mass-production
- application driven design optimization
- simulation of computational fluid dynamics

VARIETY OF POLYMERS

Proven expertise to convert glass, silicon and metal to polymer e.g.

- PP
- PC
- COC/COP
- PMMA
- PS

YOUR BENEFITS

- various prototyping solutions for time and cost efficient implementation
- close interaction with the customer to optimize at an early stage: design of plastic parts - production conditions - biochemical assay conditions
- design history file for medical or IVD products
- proven collaboration with instrument manufacturers

close interaction between instrument and consumable manufacturer

Simoa HD-I Analyzer by STRATEC SE
Simoa disc by STRATEC Consumables
**REALISTIC PROTOTYPING**

**Application**

- step 1: CD molding
- step 2: milling/cutting
- step 3: bonding/lamination
- step 4: coating

**PRINTABLE MATERIALS**

- rapid and efficient de-novo prototype development with short iteration cycles
- injection molded prototypes enable biochemical assays and production processes to be optimized at an early stage
  - injection molding with existing tools
  - subsequent laser machining or micro milling
  - fast and cost effective alternative to pure injection molding

**YOUR BENEFITS**

- prototypes with the dimensions of the final product
- optimizing biochemical assay conditions with the final material
- optimizing high-volume production conditions with the final material
- rapid iteration time

**OPTIONS FOR 3D PRINTING**

- hard plastic for chips or caddies
- soft plastic for gaskets
- different colors or transparent options
- multilayer structure options

**YOUR BENEFITS**

- earlier final product impact evaluation
- injects realism to partnering and fundraising activities
- optimizes mechanical fit and ease of handling
  - chip-adapter
  - chip-caddy
  - chip-instrument
  - chip-packaging

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**PROTOTYPING BY 3D PRINTING**

**Application**

- visualize your ideas with 3D printing

**OPTIONS FOR 3D PRINTING**

- gold coated and transparent prototypes for Axela

**chip adapter for measurements**
**WHAT WE CONSIDER**

- standard methods
  - precision milling
  - diamond milling
- advanced methods
  - mask based lithography
  - phase transition mastering – based on high resolution master technology for Blu-ray discs
  - silicon etching (DRIE)
  - electroforming of silicon or glass master supplied by customer

**YOUR BENEFITS**

- design review and design for manufacturing
- reliable manufacturing of micro/nano features
  - high aspect ratio, low side wall roughness and adjustable draft angle (less than 0°-10°)
- realization of sophisticated multi-level designs for microfluidic components
  - e.g. flow rate controller, mixer/merging chambers, particle filter, cell sorter, well arrays
- combination of micro-/nanometer features with fluidic components
  - e.g. surface structured fluidic channels
- high-class measurement equipment to verify customer design specifications (e.g. AFM, SEM, laser microscope, optical profilometry)

**Application**

multi height structures, aspect ratios up to 12:1, structure sizes down to 150nm
MOLDING

POLYMER INJECTION MOLDING
FOR SMART CONSUMABLES

Application

efficient mass production of customized products from quantities as low as hundreds up to millions of units

HIGH LEVEL OF QUALITY

More and more high quality components for life science and diagnostic applications are produced using polymers. Three key factors are driving this trend:

- After creating a mold, polymer chips can be manufactured in high volumes more cost effectively than glass with a minimum of working steps.
- A wide variety of polymers with different physical and chemical properties are now available in the market, enabling the replacement of traditional materials such as glass, metal or silicon etc.
- Plastics offer greater scope in terms of product design. Even highly complex structures can be reproducibly manufactured in high volumes.

The challenge is to strike the right balance between superior quality and high cost effectiveness.

CORE CAPABILITIES

- prototypes can be molded in disc format with short lead time
- specific molding technologies (e.g. variotherm, injection compression)
- aspect-ratio > 10:1 is possible

YOUR BENEFITS

- OEM manufacturing – set-up process & manufacturing
- co-development – part & process development
- dimensions & tolerances
- physical properties
- fully automated scaleable one-step production with optimizing cycle times
- no demolding agents used – minimal influence of polymer on assays
- low background fluorescence
- superior flatness similar to the best microscope slides
- high replication accuracy
- extensive in-line QC
COATING

INDUSTRIALIZATION OF FUNCTIONALIZED SURFACES

OPTIONS OF FUNCTIONALIZATION

- **chemical properties**
  - linking of functional groups
  - prevention of unspecific adhesion (e.g. protein adhesion)
  - adhesive layer (e.g. SiO₂ for amino-silane or epoxy silane coating)
  - glass like coating – mimic glass like reaction conditions
  - chemical resistance

- **physical properties**
  - optical coatings – e.g. filters for light, waveguide layers, antireflection coating, silvering
  - defined wetting behavior for reproducible sample preparation
  - tight vapor barrier avoids interaction between sample and plastic or its additives
  - conductivity avoid build up of static charges
  - super hydrophobic surfaces (e.g. electrowetting applications)
  - change of surface energy (e.g. hydrophilic)

- **biological properties**
  - immobilization of biomolecules
  - tissue culture applications

**YOUR BENEFITS**

- robust and reproducibility processes for mass production
- various coating solutions
  - single or multilayer coating
  - uniform or pattern coating
- almost endless options by coating
- controlled processes by automation
- high expertise in materials & applications
- ISO 13485 certified and GMP ready

**COATING SERVICES**

- sputter coating
- chemical or physical coating
- plasma treatment

Application

many options of coating solutions based on your requirements

Application
FUNCTIONAL PRINTING

PRINTING OF CONDUCTIVE AND FUNCTIONAL MATERIALS

Application

biosensors printed electrodes
modification of surface properties
product codes/graphics

PRINTABLE MATERIALS

- conductive materials (silver, gold, platinum)
- functional materials ($\text{Al}_2\text{O}_3$, fluorophores)
- graphical printing

SUITABLE TECHNOLOGIES

- inkjet (contact-free, lines & spaces >5 µm)
- offset printing
- screen printing
- micro dispensing

PRINTING PROCESS

- modification of surface properties
  plasma treatment, coatings, microstructured surfaces
- modification of printing materials
  choice of organic solvents, adjustment of solid content or viscosity and surface tension
- drying and sintering
  thermal, UV/IR
- inline vision inspection systems

YOUR BENEFITS

- wide range of printable materials
- different printing/deposition techniques depending on application
- form resistant and edge definition
- perfect alignment to other functional structures
- customized solutions from prototyping to high volume production
- in-line QC with vision inspection systems
- cleanroom conditions

high edge definition and perfect alignment to other functional structures
BONDING

FOR FULLY AUTOMATED AND INTEGRATED MANUFACTURING

Application

fully automated bonding solutions - reproducible and clean

CUSTOMIZED BONDING

- thermal fusion bonding
- solvent bonding
- pressure sensitive adhesive bonding
- continues laser welding
- mask laser welding
- UV activated gluing
- ultrasonic welding
- lamination
- combination of the above

FULLY INTEGRATED BONDING LINES

- formats between cover glass and MTP size
  - rigid parts
  - elastic parts
  - thin film
  - membranes
- hybrid part bonding (e.g., plastic-glass)

YOUR BENEFITS

- reproducibility and precision
  - microstructure bonding (down to 5 µm)
  - exact structure geometry
  - accurate component alignment (down to 20 µm)
  - high bonding force
  - high optical quality
- annealing/tempered/conditioned
  - decreases the risk of shape change during shipping
  - stress reduction in the plastic parts
- in-line QC
  - visual check for flatness, contamination & structure shape
- cleanroom conditions

optimizing bonding processes
CONTENT LOADING

INDUSTRIALIZATION OF
FUNCTIONALIZED CONSUMABLES

Application

many options for customized content loading

CONTENT FILLING

- customized content filling or pre-loading of lab-on-a-chip consumables
  - liquids and solids, planar or localized on chip
  - variable volumes (pl to ml)
  - contactless dispensing/spotting
  - diverse reagents (biological, chemical)
- in combination with suitable packaging
  - packaging of reagents-kits
  - sterile – dust-free – shock proof – non degassing – waterfree
  - blister packaging – vacuum – inert gas filled e.g. N₂
  - chilled products and frozen cargo

YOUR BENEFITS

- industrialization
  - robust and reproducibility processes for mass production
- customized solutions
  - design for manufacturing
  - prototype test spotting to high volume production
- optimizing processes
  - large choice of systems (pl to ml)
  - content gets optimized on substrate properties
  - high expertise in materials and applications
- distribution (e.g. frozen cargo)
ASSEMBLY

CUSTOM / SEMI-AUTOMATED
FULLY AUTOMATED

IN-LINE QC (selected options)
- optical checks for defects and completeness
- pressure checks
- flow checks for droplet formation
- adhesion checks
- manual checks
- fully automated QC including automated check and feedback loop from database

YOUR BENEFITS
- fully automated assembly
- fully integrated into manufacturing process
- seamless in-line QC
- dealing with full range of product features, from low to high volume and complexity

WHAT DO WE ASSEMBLE?
- chips
- caddies
- carriers
- adapters

Application
made-to-measure assembly solution, full integration into manufacturing process with in-line QC

OUR SERVICES
- insertions of pins or gaskets
- integration of MEMS, electrodes, etc.
- mounting of chips into caddies
- gluing
- laser welding
- sealing
- application of stickers
- laser engraving

fully automated assembly line developed by STRATEC Consumables

fully automated insertion of pins
PACKAGING

PROTECT AND PROMOTE YOUR PRODUCT WITH THE RIGHT PACKAGING

Application

standard or fully customized, robust cost-effective packaging solutions

STANDARDIZED VS. INDIVIDUAL

Our standard solutions will suit most applications, e.g. standard microscope slide-sized chips can fit in sets of five in automated packaging with labels and barcodes on demand. However, if you have an innovative product that is literally “out of the box”, we can design a customized solution:

- sterile – dust-free – shock proof – non degassing
- vacuum – gas filled e.g. He, N₂
- different materials e.g. cardboard or plastic

STRATEC Consumables works customer-oriented and ensures that all corporate design needs are met.

SINGLE VS. MULTI PACKAGING

Depending on your specific requirements, we supply your custom chips in single or group packaging:

- stacked or tubular pouches
- blister for individual shaped chips
- holders for multiple CD-shaped chips
- boxes with customized comb slots in 90 degree placements for individually sized chips

LABELING AND BARCODING

Labels and box designs are offered as an integral part of our packaging solutions:

- instruction sheets and seals
- sticker coding for lot batch tracking or temperature logging
- RFID tags
AUTOMATION

COST-EFFECTIVE SYSTEM ENGINEERING

YOUR BENEFITS

- reproducibility and precision
  - high quality through close interaction between processes
  - integration of customer in planning process
- in parallel to product development
  - pilot batches can be manufactured automatically
  - matching investment with cost reduction
- customized solutions
  - from development to mass production
  - individual formats
- in-line QC
  - optical checks including reporting
- cleanroom conditions
  - QA, reliability & conformity with ISO13485

Application

focus on our customer’s needs and cover all necessary manufacturing processes

OUR OFFER

- seamless integration of automation solutions with scale-up scenarios
- we fit the level of automation to the productivity required
- in-house engineering and set-up team
- engineers design and optimize on the basis of your individual production processes
- full integration of customer in planning process

CUSTOMIZED SOLUTIONS

- semi-/ fully automated production line including packaging of complex medical devices & plastic products
- integrated in-line quality control
- creation of new automation solutions if standard systems are no longer suitable
QUALITY ASSURANCE & QUALITY CONTROL

OUR DEDICATION TO QA&QC GUARANTEES YOUR SUCCESS

PARAMETERS YOU CAN TRUST

QA for IVD and FDA markets
- Six Sigma
- Kaizen
- ISO 13485

QA & QC – Services
- risk assessment (FMEA according ISO 14971)
- functional application QC
- optical and mechanical metrology at micron level
- material characterization
- surface profiling at nm resolution
- CAQ system
- CAPA management

QC – Equipment
- SEM (scanning electron microscope)
- confocal microscope
- light microscopy
- optical profilers
- in-line visual checker, ...

HIGH LEVEL OF QUALITY

In life sciences and IVD diagnostics, such a best-in-class quality system enables us to comply with the requirements of both small and large manufacturers. All development and product realization processes are controlled by key performance indicators. The QA system is fully integrated and comprises all raw material and component suppliers as well as transport operations. Our continuous focus on meeting and exceeding customer requirements, and continuous improvement in our product and service provision is enabled by Six Sigma improvement projects and controlled by a corrective action/preventive action system in order to maximize quality and service standards within all of our operations. Naturally, all our activities for the in-vitro diagnostics industry are ISO 13485 certified.

Application

each employee is responsible for the quality of his/her work individually and as part of a team

YOUR BENEFITS

- highest & consistent quality
- high-speed inspection
- functional check for final products
- optical in-line quality check for each product
- ISO 13485 certification