

# SOLVAY SPECIALTY POLYMERS

High Performance Polymers for  
Healthcare  
Applications, Regulatory,  
Processing Methods

Sep. 2020, Lyon



# A GLOBAL PRESENCE CLOSE TO OUR CUSTOMERS

1



Headquarters

14



Production sites

9



Research & Innovation  
Centers

15



Sales & Marketing  
Offices



**~3,600**  
Employees



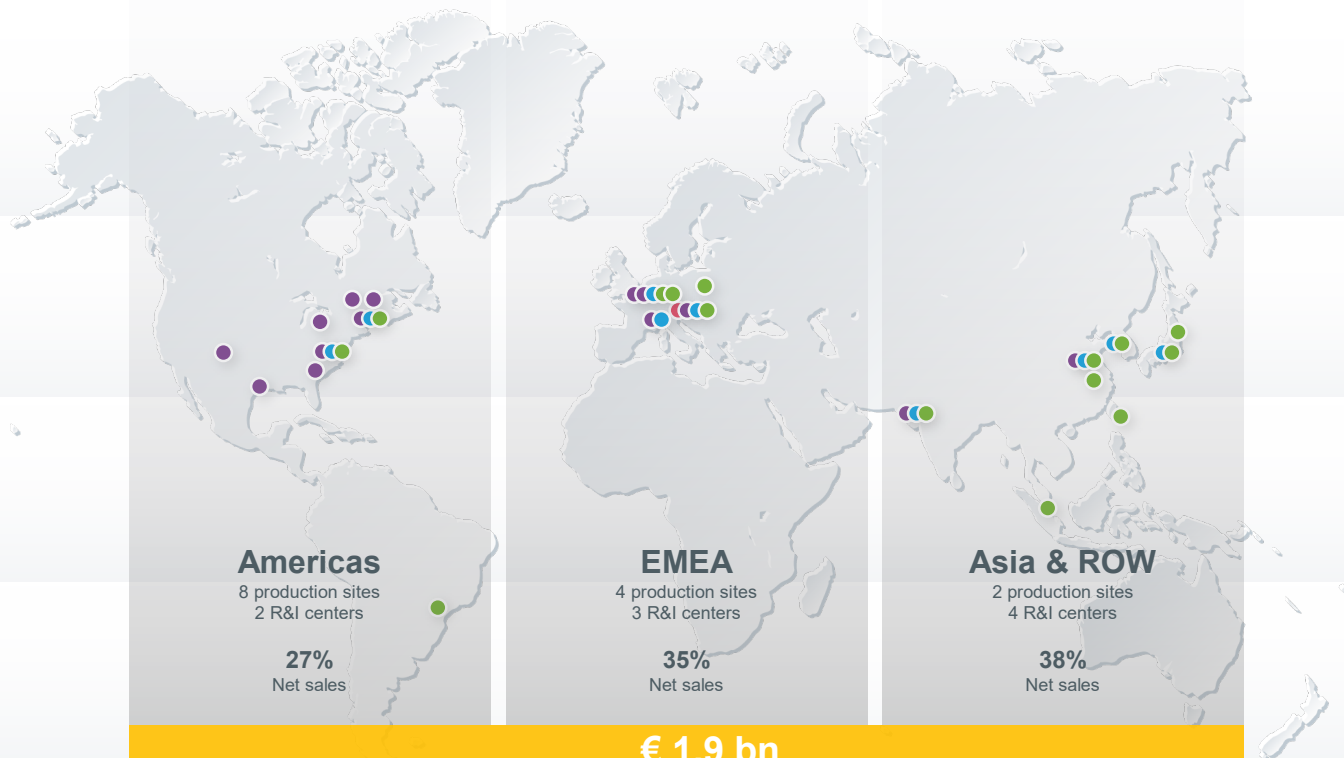
**~ 600**  
Researchers



**40-44**  
Average Age



**80%**  
Employee  
Engagement

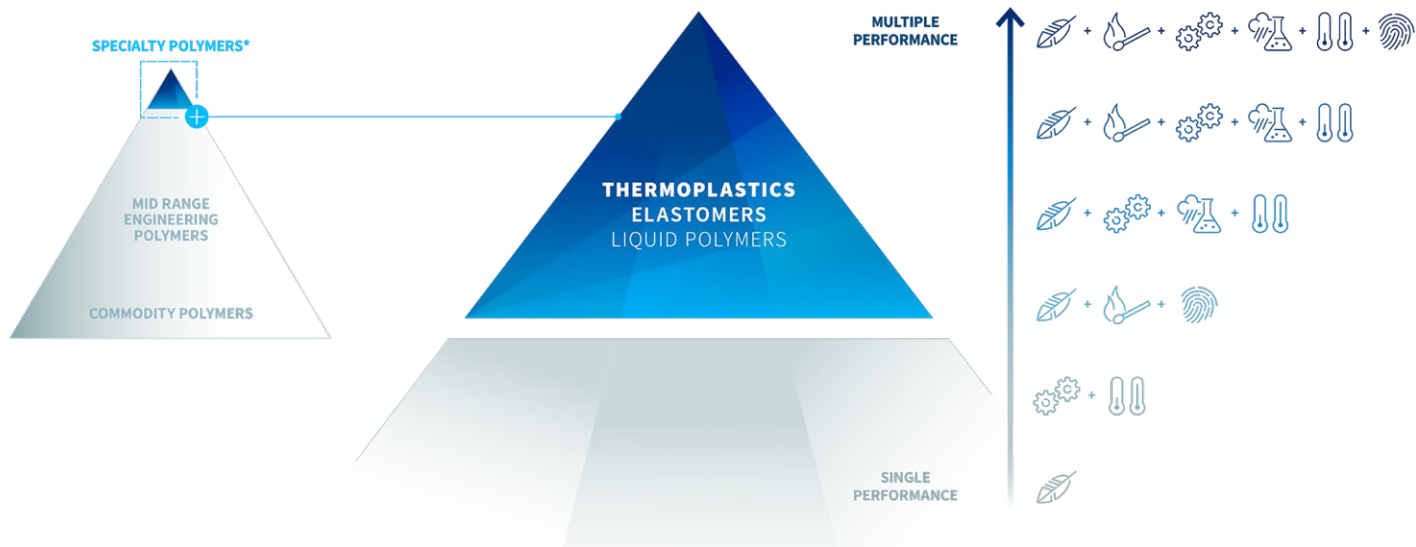


**€ 1.9 bn**

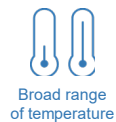
Net sales 2019

# INDUSTRY LEADER IN SPECIALTY POLYMERS

## TINY MOLECULES, HUGE IMPACT



A combination of Key Performance Factors



# Product Families

## Advanced Lightweighting Solutions

### TegraLite™

- TegraCore™ PPSU Structural Foam
- Films
- Composites
- Virantage® PESU Tougheners

## Biomaterials for Implantable Devices

### Solviva® Biomaterials

- Eviva® PSU
- Veriva® PPSU
- Zeniva® PEEK

## Films

Ajedium™ Films

## Fluorinated Elastomers

### Tecnoflon® FKM

- Base Resistant
- Ionic Curable
- Low Temperature
- Peroxide Curable

Tecnoflon® PFR FFKM

## Fluorinated Fluids

Fomblin® HC PFPE

Fomblin® PFPE Lubricants

Galden® PFPE

Solvera® PFPE

## Fluoropolymers

### Algoflon® PTFE

- Dispersions
- Fine Coagulated Powders
- Granulars
- Micronized Powders

Halar® ECTFE

Hyflon® PFA & MFA®

Hyflon® AD

Hylar® PVDF

Hylar® 5000 PVDF for Architectural Coatings

Polymist® PTFE

Solef® PVDF

## Functional Fluids

Fluorolink® PFPE

Fomblin® PFPE Functional

## Liquid Crystal Polymers

Xydar® LCP

## Polyamide-imides

Torlon® PAI

## Polyamides, Aromatic

Amodel® PPA

Ixef® PARA

Kalix® HPPA

Omnix® HPPA

## Polyesters, High-performance

Lavanta® HPP

## Polyketones, Aromatic

AvaSpire® PAEK

KetaSpire® PEEK

## Polymer Processing Aids

Solef® 11010 PVDF

Tecnoflon® NM FKM

## Polyphenylene, Sulfide

Ryton® PPS

## Polyvinylidene Chloride

Diofan® PVDC

Ixan® PVDC Extrusion

Resins

Ixan® PVDC Soluble Powders

## Sulfone Polymers

Acudel® modified PPSU

Radel® PPSU

Udel® PSU

Veradel® PESU

## Specialty Materials

Aquivion® PFSA

Hyflon® AD

Xencor™ LFT

Solvane® EAP

Torlon® AI for Coatings

# Healthcare: Key Areas of Activity

## Hemo membranes



## Medical equipment



## Surgical instruments



## Long term implants



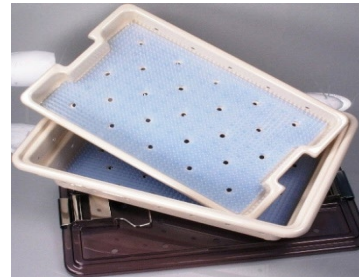
## Packaging



## Laboratory/Analytical



## Cases & Trays



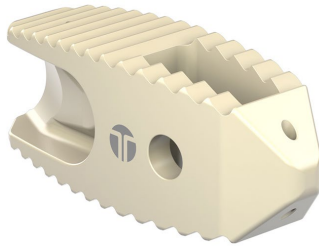
## Biopharma Processing



# BIOMATERIALS POLYMER RANGE FOR IMPLANTABLE DEVICES

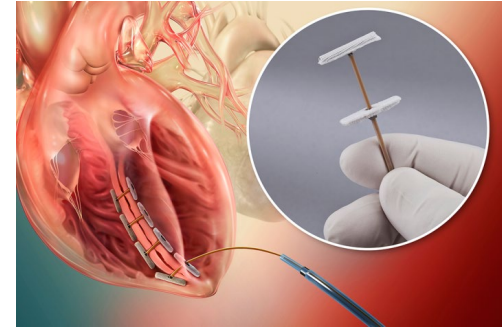
## Solviva® Biomaterials

- Zeniva® PEEK
- Veriva® PPSU
- Eviva® PSU



## Key Applications : Implantable Devices

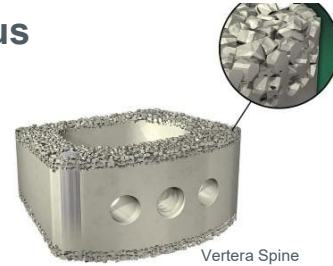
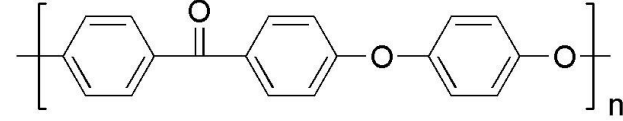
- For prolonged and permanent exposure to body fluids and tissue in the human body
- Orthopedic implants : hip, knee, spinal, wrist, ankle, shoulder, toe, cranomaxillofacial
- Dental implants, Cardiovascular implants



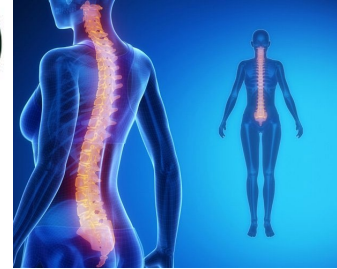
# PEEK INNOVATIVE SOLUTIONS FOR IMPLANTATION DEVICES

## PEEK polyetheretherketone

- Highly **biostable** polymer with high strength and stiffness plus excellent toughness and fatigue resistance, as well as a **modulus close to bone**
- **X-ray transparency or X-ray visible**
- **Novel surface technology** for stable intervertebral joint fusion, porous character facilitates **integration of bone tissue** offering excellent biocompatibility
- **New lubricated grades** present viscosities suited for injection, offering broader concept possibilities for new implants, integrating smaller components, thinner and lighter
- **New PEEK reinforced** with carbon fibers present high mechanical properties, used for structural implants for knees, hips and spine.



Vertebra Spine





# PPSU AND PSU PROVIDING SOLUTIONS FOR IMPLANTATION DEVICES

## PPSU polyphenylsulfone

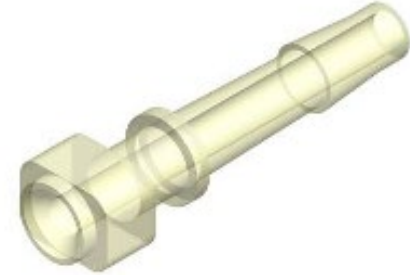
- High toughness combined with **transparency** and excellent biocompatibility

## PSU polysulfone

- toughness in a strong, transparent polymer, also available in opaque white

## Uses

- implantable catheter ports
- implantable wire coatings
- cardiovascular, neurovascular, drug delivery and dental application



Eviva PSU Brain Shunts



Catheter Ports



Cochlear Implant

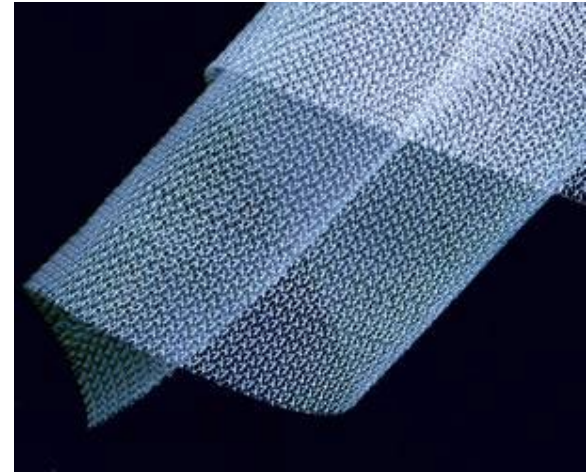


# BIOMEDICAL FABRICS

PEEK for a range of woven, knitted, and braided fabrics for implantable devices

**Custom** applications include

- high-strength sutures, bone anchoring devices, rotator cuff and arthroscopic joint repair, spinal stabilization and disc repair and replacement
- textile-based heart valves and vascular grafts
- and lightweight textile mesh structures for a variety of surgical procedures that require tissue reinforcement and wound support.



# BIOCOMPATIBLE POLYMERS NON IMPLANTABLE

- PAEK Avaspire®
- PEEK Ketaspire®
- PARA Ixef®
- PPSU Radel®
- PSU Udel®
- PESU Veradel®



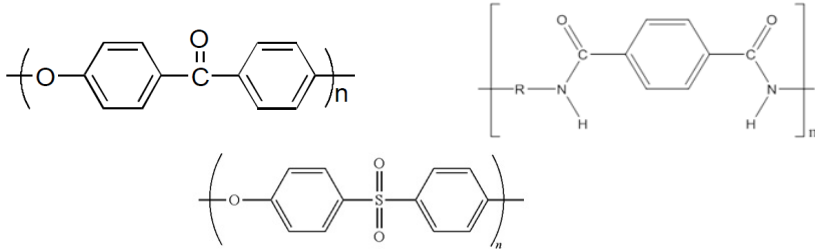
Reusable pliers for spinal surgeries  
AvaSpire® PAEK



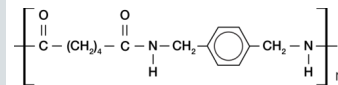
Handle of dental scaler  
Radel® PPSU



Single Use Instrument for adenoidectomies  
Ixef® PARA



Provides unique combination of strength and aesthetics, making it ideal for thin, complex shapes needing overall strength, rigidity and an excellent surface appearance



## Key Features

- High strength and rigidity
- Excellent surface appearance
- High flow for thin-walled parts
- Low and slow moisture uptake
- Lubricated grades



## Key Applications

- Healthcare, Aircraft, Smart Devices lightweight structural components
- Single-use Instruments and Devices
- Metal replacement applications
- Housings (chem res., stiffness)

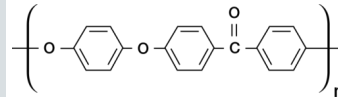


Single Use Instrument for adenoidectomies  
Ixef® PARA



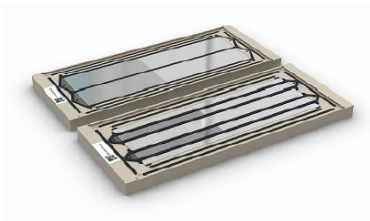
# KetaSpire® PEEK and AvaSpire® PAEK

One of the industry's most chemically resistant plastics with excellent strength and fatigue resistance along with a continuous-use temperature of 240°C



## Key Features

- Exceptional resistance to organics, acids and bases
- Improved ductility and toughness
- Best-in class fatigue resistance
- Very good wear and abrasion resistance
- Excellent dimensional stability
- High-purity



Genome Sequencer  
KetaSpire® PEEK

## Key Applications

- Healthcare: instruments, operating room equipment, Orthopedics, Trauma
- Re-usable application; compatible with all sterilization methods



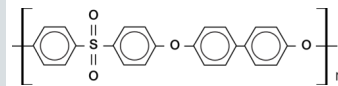
Reusable pliers for spinal surgeries  
AvaSpire® PAEK



Reusable rodbender for spinal surgeries  
AvaSpire® PAEK

# Sulfones: Radel® PPSU, Udel® PSU, Veradel® PESU

Provides the highest performance of sulfone polymers, offering best impact strength and chemical resistance hydrolytic stability and heat resistance



## Key Features

- Toughness and high impact strength
- Long-term hydrolytic stability
- Steam sterilizable over 1,000 cycles (PPSU) without significant loss of properties
- Inherently flame retardant
- Transparent
- Colorable



Humidifier housing & end-expiratory pressure chamber  
Udel® PSU

## Key Applications

- Sterilization cases and trays
- Medical devices
- Dental instruments
- Hemodialysis membranes
- Biopharma processing



High pressure impeller  
Radel® PPSU



Panels for in-house sterilization unit  
Udel® PSU



Flow sensors in medical, laboratory and biopharma  
Veradel® PESU

# Ajedium™ Films

Made from a variety of engineering and fluorine-based polymers, these films may be mono- or multi-layer structures to meet the most demanding specifications

## Key Features

- Mechanical strength
- Chemical resistance
- Wear and abrasion resistance
- Electrical insulation
- Thermal properties

## Key Applications

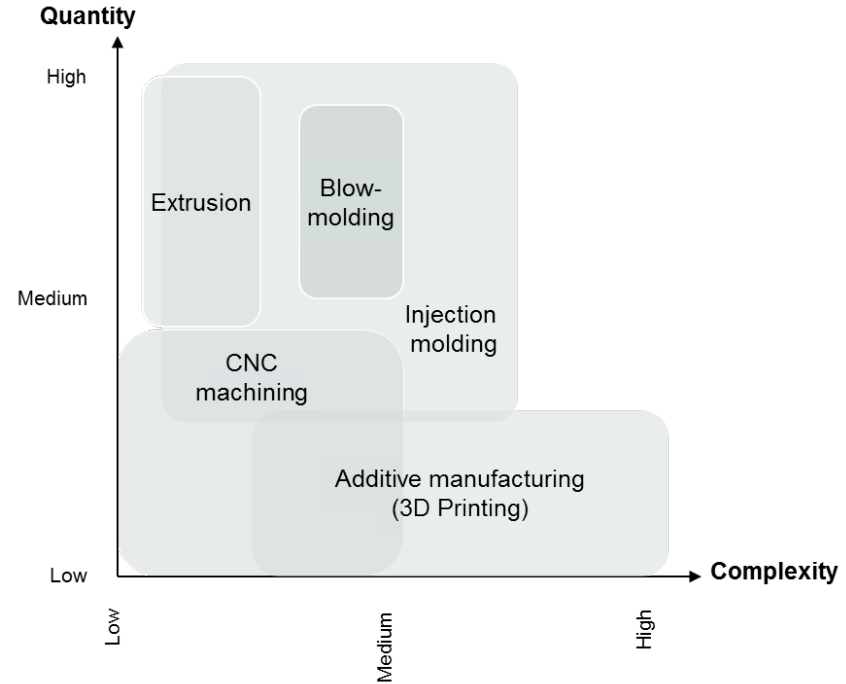
- Photovoltaics front- and back-sheets
- Architectural films
- Aerospace thermal acoustic insulation blankets
- Shields in medical application

Ajedium™ Films - Key properties comparison

	KetaSpire® PEEK	AvaSpire® PAEK	Radel® PPSU	PEI	TPI	Halar® ECTFE	Solef® PVDF
Mechanical properties	Very good	Very good	Very good	Good	Excellent	Very good	Good
Chemical resistance	Excellent	Excellent	Good	Fair	Fair	Very good	Good
Tear resistance	Good	Excellent	Good	Very good	Excellent	Fair	Fair
Flammability	Very good	Excellent	Very good	Very good	Excellent	Excellent	Very good
Dielectric properties	Very good	Very good	Very good	Good	Good	Good	Excellent

# MOST COMMON PROCESSING METHODS

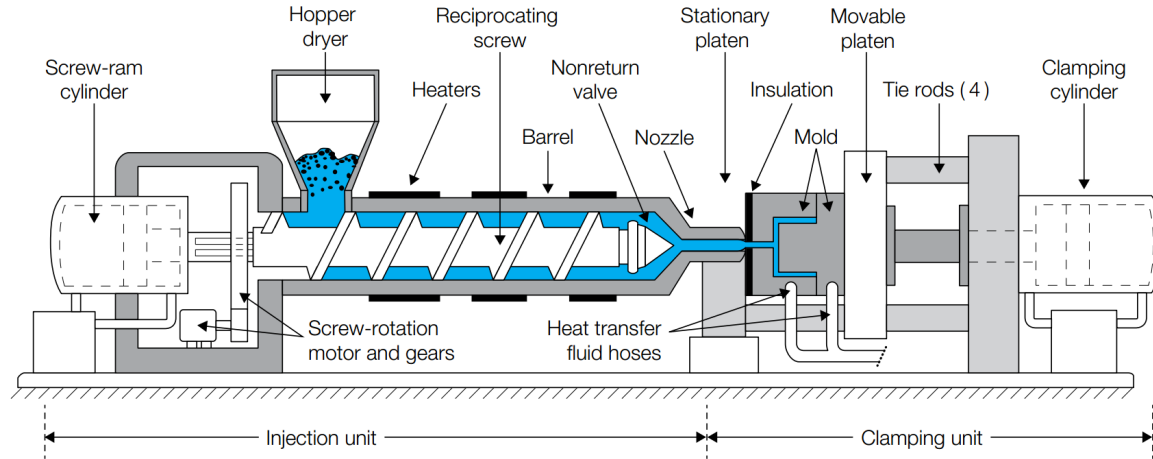
- Injection molding
- Extrusion
- Compression molding
- Machining process
- 3D Printing





# Injection Molding

Simple or complex 3D shapes



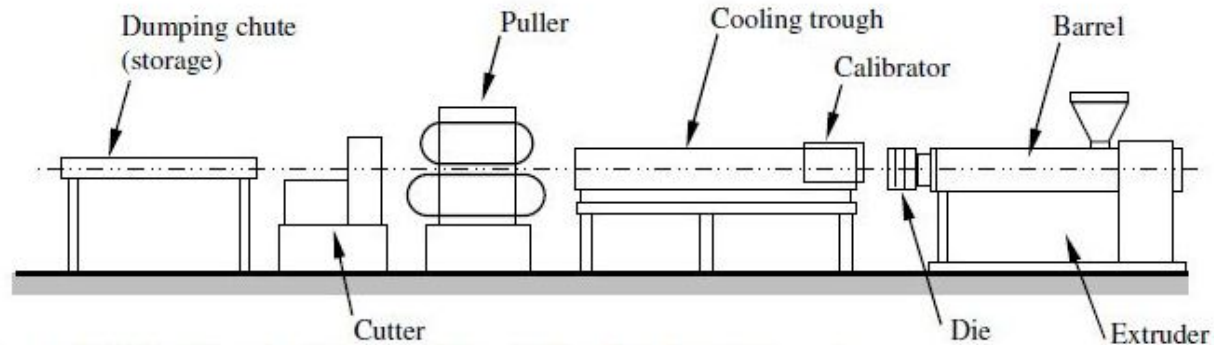
# Extrusion

2D stock shapes

Film

Tube

Rods

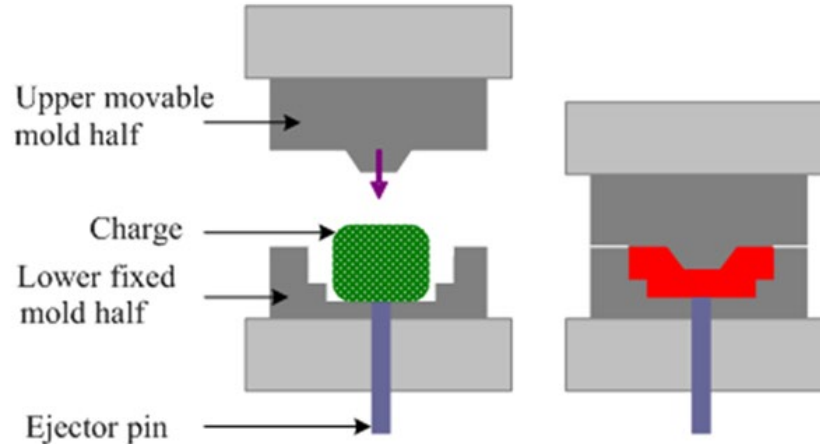


# Compression Molding

2D stock shapes

Large thickness

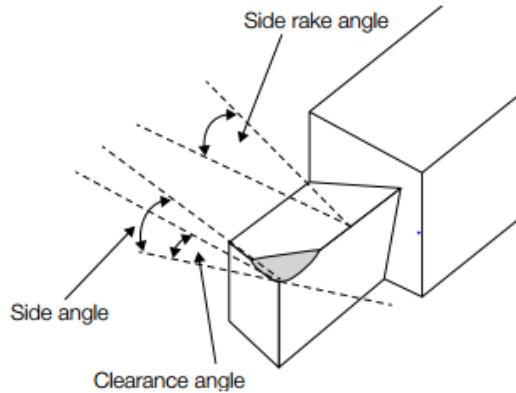
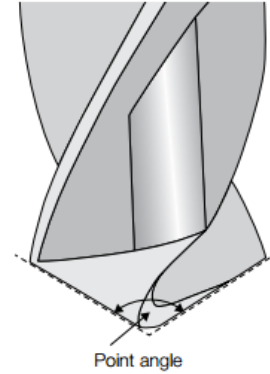
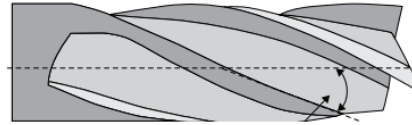
Near net shape



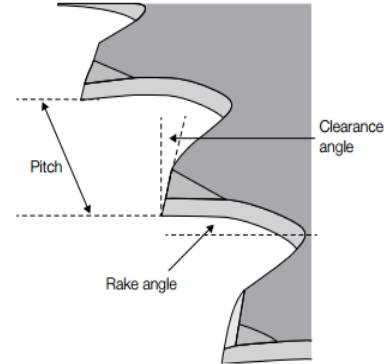
# Machining

2D form could be machined to get the desired final shape

- Drilling
- Milling
- Turning
- Sawing



**Figure 4:** Details of band saw

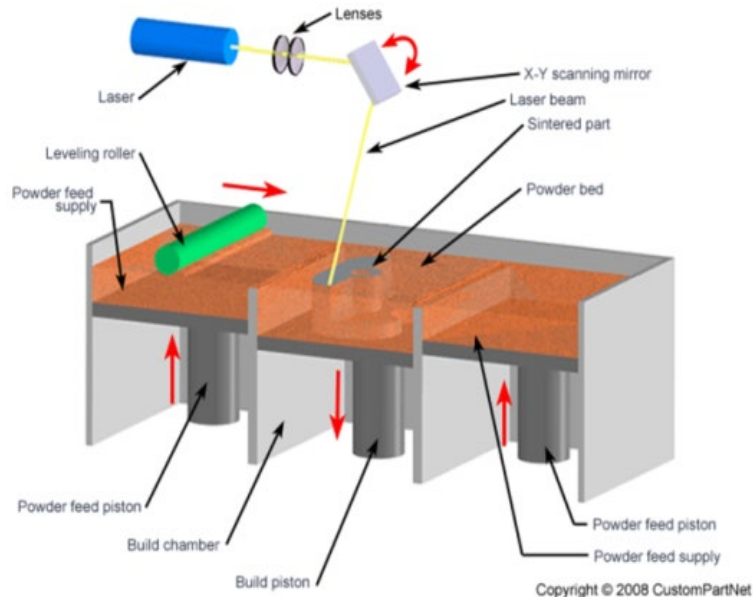


Details of band saw

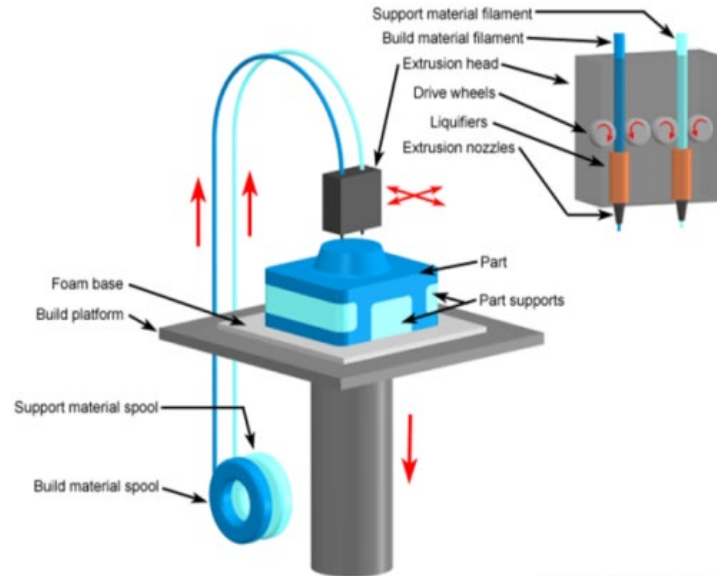
# 3D Printing

Many different techniques exist:

## Selective Laser Sintering (SLS)

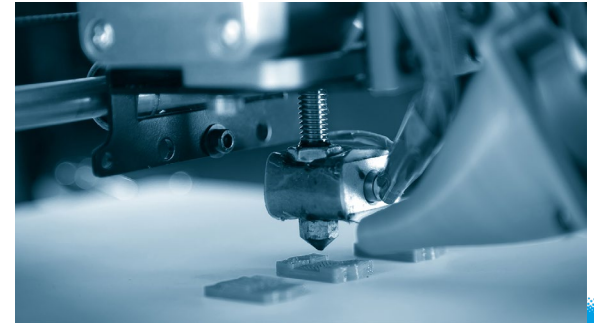


## Fused Filament Fabrication (FFF)



# NEW MEDICAL-GRADE ADDITIVE MANUFACTURING FILAMENTS

- KetaSpire® PEEK HC AM Filaments
- KetaSpire® PEEK HC AM Filaments CF10
- Radel® PPSU HC AM Filaments
- Solef® PVDF HC AM Filaments
- used for a range of healthcare applications
  - patient-specific cutting guides for surgery
  - complex components
  - Trials for spine, knee, etc.
  - Implantable grades to come very soon
  - ...



# REGULATORY APPROVALS

	Aromatics						Fluoro-polymers
	Veradel® HC PESU	Radel® PPSU	Udel® PSU	AvaSpire® PAEK	KetaSpire® PEEK	Ixef® PARA	Solef® PVDF Hyflon® MFA®, PFA
<b>USP Class VI Letter Standard</b>							✓
<b>USP Class VI Letter</b> Post $\gamma$ -irradiation at 50 kGY	✓	✓	✓		✓	in progress	
<b>Physio-chemical</b> ISO 10993-18	✓	✓	✓	✓	✓	✓	
<b>Cytotoxicity</b> ISO 10993-5	✓	✓	✓	✓	✓	✓	
<b>Sensitization</b> ISO 10993-10	✓	✓	✓	✓	✓	✓	
<b>Intracutaneous Toxicity</b> ISO 10993-10	✓	✓	✓	✓	✓	✓	
<b>Acute Systemic Toxicity</b> ISO 10993-11	✓	✓	✓	✓	✓	✓	





# REGULATORY APPROVALS – THE RIGHT PARTNER

## Device Submission Support – Master Access File

### Documents Provided by Customer

- Post market activities
- Cleaning, sterilization and packaging (including validation)
- Risk management for device
- Clinical evaluation for device
- Cleaning, sterilization and packaging (including validation)
- Labelling, IFU
- **Reference Letter to Master File**

### Documents Provided by Component Supplier (SOLVAY)

- Case Study – PEEK Polymer used in IBF device
- Reference letter to Master File:
  - Material specifications
  - Material composition and manufacturing
  - Technical information (Mechanical, Thermal, etc.)
  - Biological evaluation
  - Risk assessment

# REGULATORY APPROVALS – THE RIGHT PARTNER

## **Biomaterials**

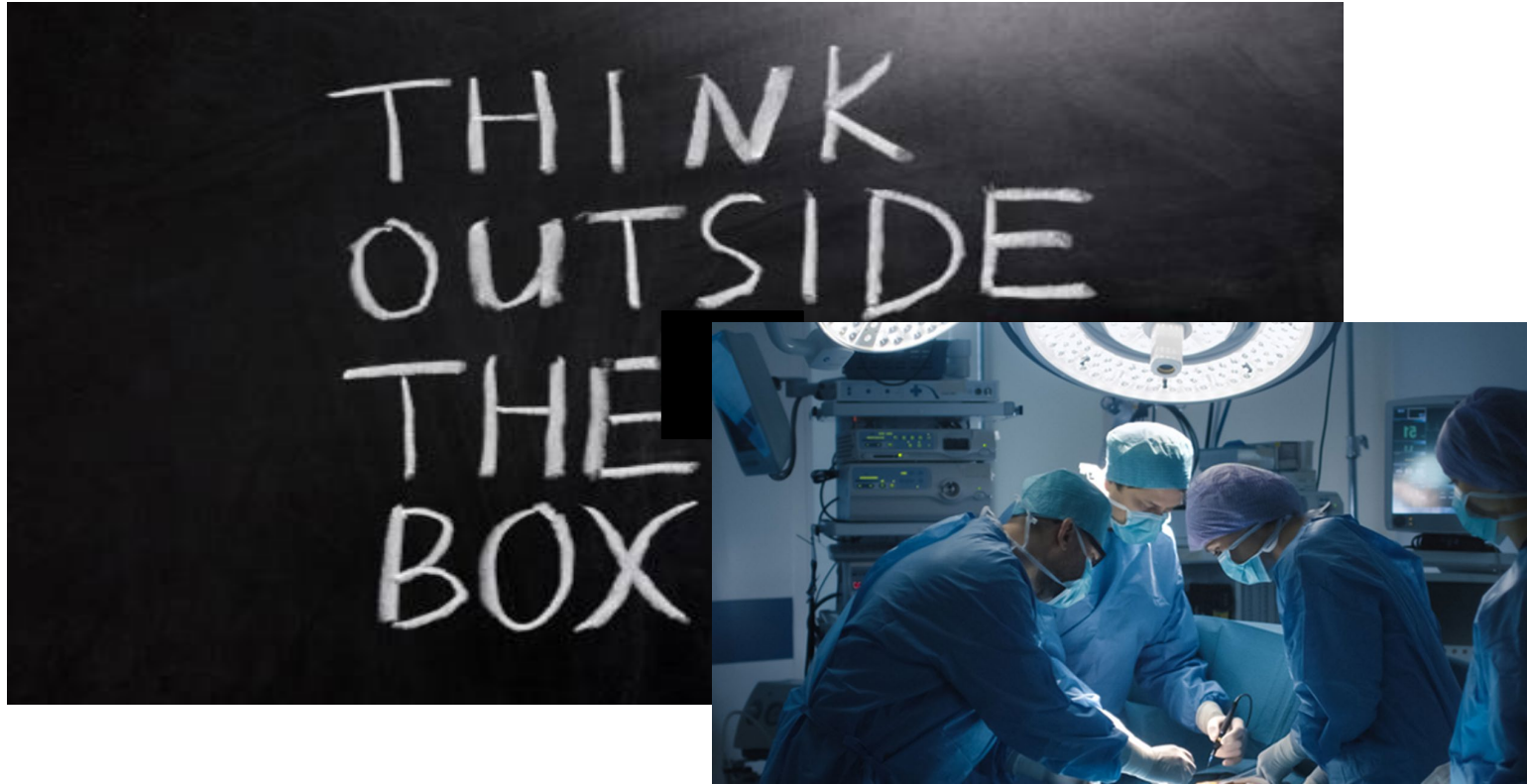
- Zeniva® PEEK MAF#1524
- Eviva® PSU MAF#1655
- Veriva® PPSU MAF#1729

## **Medical Grade Polymers**

- KetaSpire® PEEK MAF#2620
- AvaSpire® PAEK MAF#2629
- Ixef® PARA MAF#2045
- Veradel® PESU MAF#2719
- Udel® PSU MAF#2647
- Radel® PPSU MAF#2122



# THINK OUTSIDE THE BOX WITH SOLVAY FOR COLLABORATION





[www.solvay.com](http://www.solvay.com)

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