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Near Anjugramam - Kanyakumari Main Road, Palkulam, Variyoor P.O.-629401, Kanyakumari Dist, Tamil Nadu.

DEPARTMENT OF BIOMEDICAL ENGINEERING

VI Semester

24BM501 BIOMEDICAL DEVICE DESIGN

4.2 Rapid Prototyping and 3D Printing

➢ 4.2.1 Rapid Prototyping (RP)

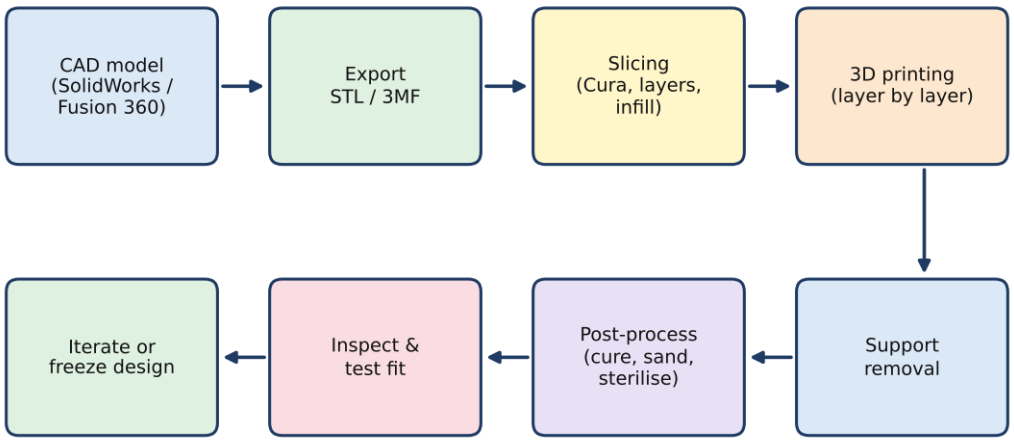
Rapid prototyping is a group of techniques that quickly fabricate a physical part or model directly from 3D CAD data, usually by adding material layer by layer. It is also called **additive manufacturing (AM)** or **solid freeform fabrication**.

➢ 4.2.2 Principle of Additive Manufacturing

- ✓ The CAD model is sliced into thin horizontal layers (typically 0.05 - 0.3 mm).
- ✓ A machine deposits, cures or fuses material one layer at a time.
- ✓ Layers bond to the previous layer until the full 3D object is built.
- ✓ Complex internal channels, lattices and patient-specific shapes can be made without special tools.

➢ 4.2.3 Rapid Prototyping Workflow

Fig. 4.3 Rapid Prototyping Workflow



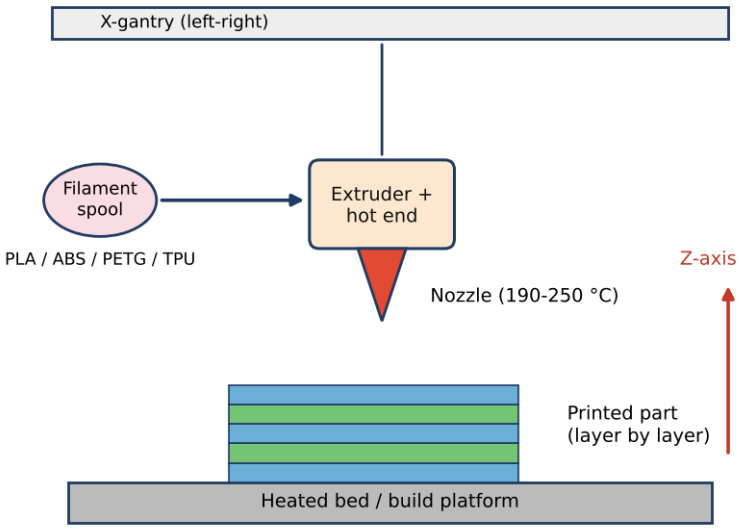
Step	Description
1. 3D CAD model	Designed in SolidWorks, Fusion 360 or generated from CT/MRI scans using 3D Slicer or Mimics
2. STL / 3MF export	Surface is converted to a triangle mesh; resolution is controlled
3. Slicing	Software (Cura, PrusaSlicer) divides the model into layers; sets infill, supports, speed, temperature
4. Printing	Machine builds the part layer by layer
5. Support removal	Break-away or dissolvable supports are taken out
6. Post-processing	Washing, UV curing, sanding, polishing, coating, sterilisation
7. Inspection and testing	Dimensional check, fit test, functional test

➢ 4.2.4 Classification of 3D Printing Technologies (ISO/ASTM 52900)

Process	Material state	Common materials	Medical use
Material extrusion (FDM/FFF)	Solid filament	PLA, ABS, PETG, TPU	Enclosures, anatomical models, jigs
Vat photopolymerisation (SLA/DLP)	Liquid resin	Photopolymer resins, biocompatible resins	Surgical guides, dental models, hearing aids
Powder bed fusion (SLS/SLM/EBM)	Powder	Nylon PA12, Ti-6Al-4V, CoCr	Prosthetics, orthopaedic implants
Material jetting (PolyJet)	Liquid droplets	Multi-material photopolymers	Colour, multi-material anatomical models
Binder jetting	Powder + binder	Gypsum, sand, metal	Full-colour models, casting moulds
Directed energy deposition	Wire/powder + energy	Titanium, steel	Repair of implants
Sheet lamination	Sheets	Paper, polymer, metal foil	Low-cost visual models
Bioprinting	Bio-ink with cells	Hydrogels, cells	Tissue scaffolds, skin, research organoids

➢ 4.2.5 Fused Deposition Modelling (FDM)

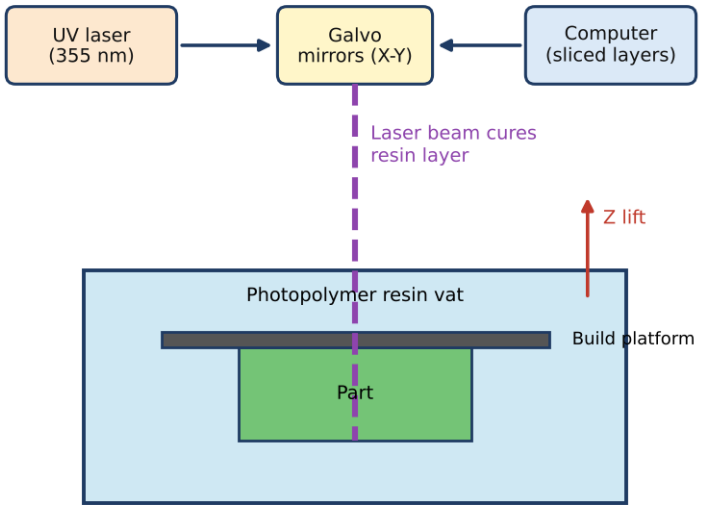
Fig. 4.4 Fused Deposition Modelling (FDM) Principle



- ✓ A thermoplastic filament is pushed into a **heated nozzle** (190 - 250 °C), melts, and is deposited along the sliced path.
- ✓ The platform moves down (or the head moves up) by one layer and the process repeats.
- ✓ **Advantages:** low cost, wide range of materials, easy to use, good for enclosures and jigs.
- ✓ **Limitations:** visible layer lines, lower accuracy (±0.2 mm), anisotropic strength, porous surface that is difficult to sterilise.

➢ 4.2.6 Stereolithography (SLA) / DLP

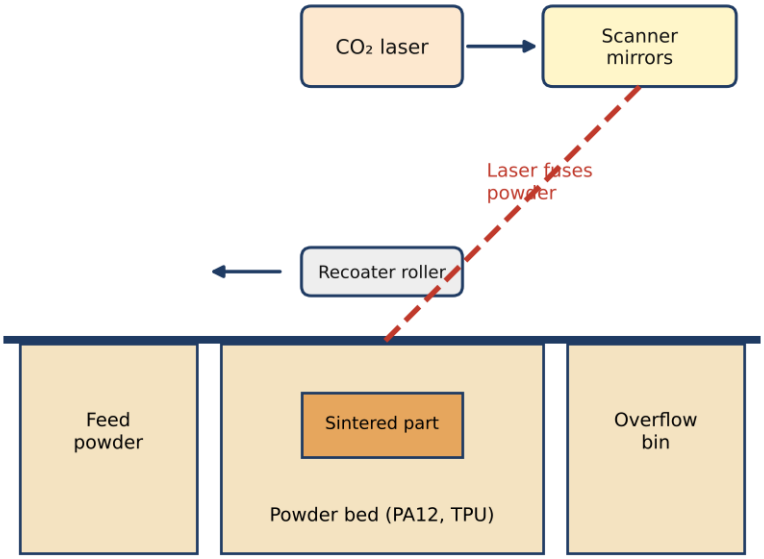
Fig. 4.5 Stereolithography (SLA) Principle



- ✓ A **UV laser** (or projector in DLP) traces each layer on a vat of liquid photopolymer; the resin **solidifies (photopolymerisation)**.
- ✓ The platform lifts by one layer thickness and the next layer is cured.
- ✓ **Advantages:** very high accuracy (±0.05 mm), smooth surface, fine details; biocompatible resins available.
- ✓ **Limitations:** resins are costly and need washing and post-curing; supports are required; some resins are toxic before curing.

➢ 4.2.7 Selective Laser Sintering (SLS)

Fig. 4.6 Selective Laser Sintering (SLS) Principle



- ✓ A **CO_2 laser** fuses powder (nylon, TPU) in the powder bed; unsintered powder supports the part.
- ✓ A roller spreads a fresh powder layer after each scan.
- ✓ **Advantages:** no support structures, strong functional parts, good for complex geometries.
- ✓ **Limitations:** expensive machines, rough surface, powder handling hazards.

➢ 4.2.8 Comparison of FDM, SLA and SLS

Parameter	FDM	SLA	SLS
Accuracy	±0.2 mm	±0.05 mm	±0.1 mm
Surface finish	Layer lines visible	Very smooth	Grainy
Material	Thermoplastic filament	Photopolymer resin	Nylon powder
Support needed	Yes	Yes	No
Cost	Low	Medium	High
Strength	Moderate, anisotropic	Brittle to tough resins	High, near isotropic
Typical medical use	Enclosures, training models	Dental, surgical guides	Prosthetics, functional parts

➢ 4.2.9 Medical Applications of 3D Printing

- ✓ **Anatomical models** from CT/MRI for surgical planning and training.
- ✓ **Patient-specific surgical guides** for orthopaedic and dental surgery.

- ✓ **Custom implants** (cranial plates, hip cups, spinal cages) in titanium.
- ✓ **Prosthetics and orthotics:** low-cost custom sockets and hands.
- ✓ **Device enclosures** for wearables, monitors and diagnostic kits.
- ✓ **Hearing aids and dental aligners** manufactured in large volume.
- ✓ **Bioprinting** of skin, cartilage and tissue scaffolds (research stage).
- ✓ **Drug delivery:** printed tablets with patient-specific doses.

➢ **4.2.10 Design Considerations for 3D-Printable Medical Enclosures**

- ✓ **Liquid resistance:** use wall thickness ≥ 2 mm, continuous perimeters, gaskets and post-print sealing for IP-rated housings.
- ✓ **Orientation:** print direction affects strength and surface finish.
- ✓ **Tolerances:** allow 0.2 - 0.4 mm clearance for snap-fits and screws.
- ✓ **Wall thickness and ribs** for stiffness and cable routing.
- ✓ **Material choice:** PETG/ABS for toughness, medical-grade resins for skin contact, TPU for soft grips.
- ✓ **Sterilisation:** autoclave tolerant materials (PEI, PP, certain resins) or surface disinfectable materials.

➢ **4.2.11 Advantages and Limitations of Rapid Prototyping**

Advantages	Limitations
❖ Fast turnaround (hours to days) ❖ Complex shapes without tooling ❖ Customisation for each patient ❖ Lower prototype cost ❖ Reduced waste	❖ Limited material strength and biocompatibility ❖ Layer-line surface roughness ❖ Size limits of the build volume ❖ Post-processing is required ❖ Not always economical for mass production

➢ **4.2.12 Regulatory Aspects of 3D-Printed Devices**

- ✓ **Patient-matched devices:** need validated design and printing processes (FDA guidance on Technical Considerations for AM Medical Devices).
- ✓ Process parameters (laser power, layer height, build orientation) must be **validated and controlled**.
- ✓ Cleaning, residual powder/resin removal and sterilisation have to be validated.
- ✓ The 3D printer itself is treated as **production equipment** under the QMS (ISO 13485).