

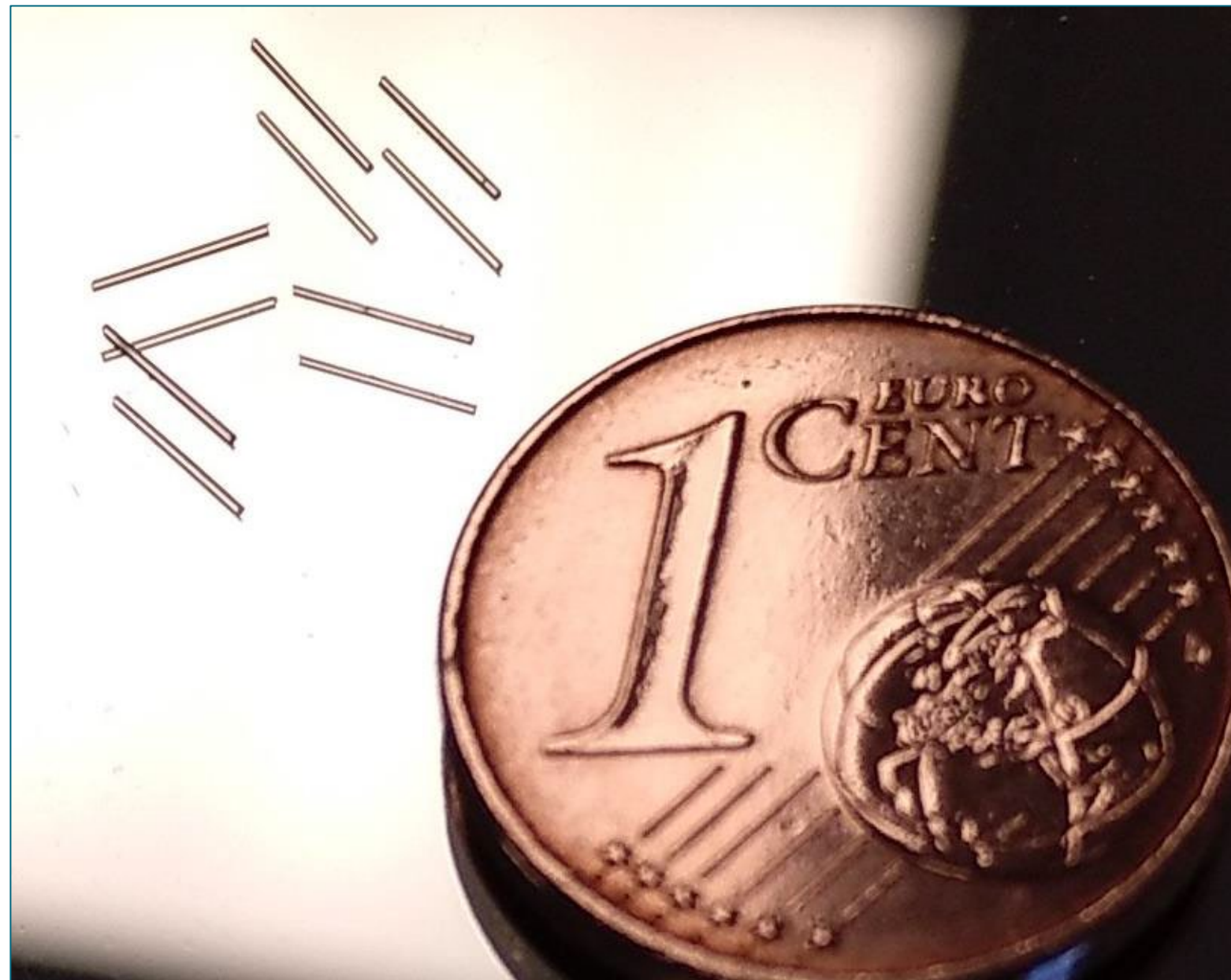
Manufacturing of Injectable Implants for Drug Delivery

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Introduction

- Subcutaneous implants are injectable drug delivery systems for treatment of weeks up to years
- Cylindrical rods made from polymer loaded with API
- Typical dimensions depend on the application (diameter 0.1 mm - 3 mm / length: 3 - 40 mm)
- Polymer material can be biodegradable or biocompatible

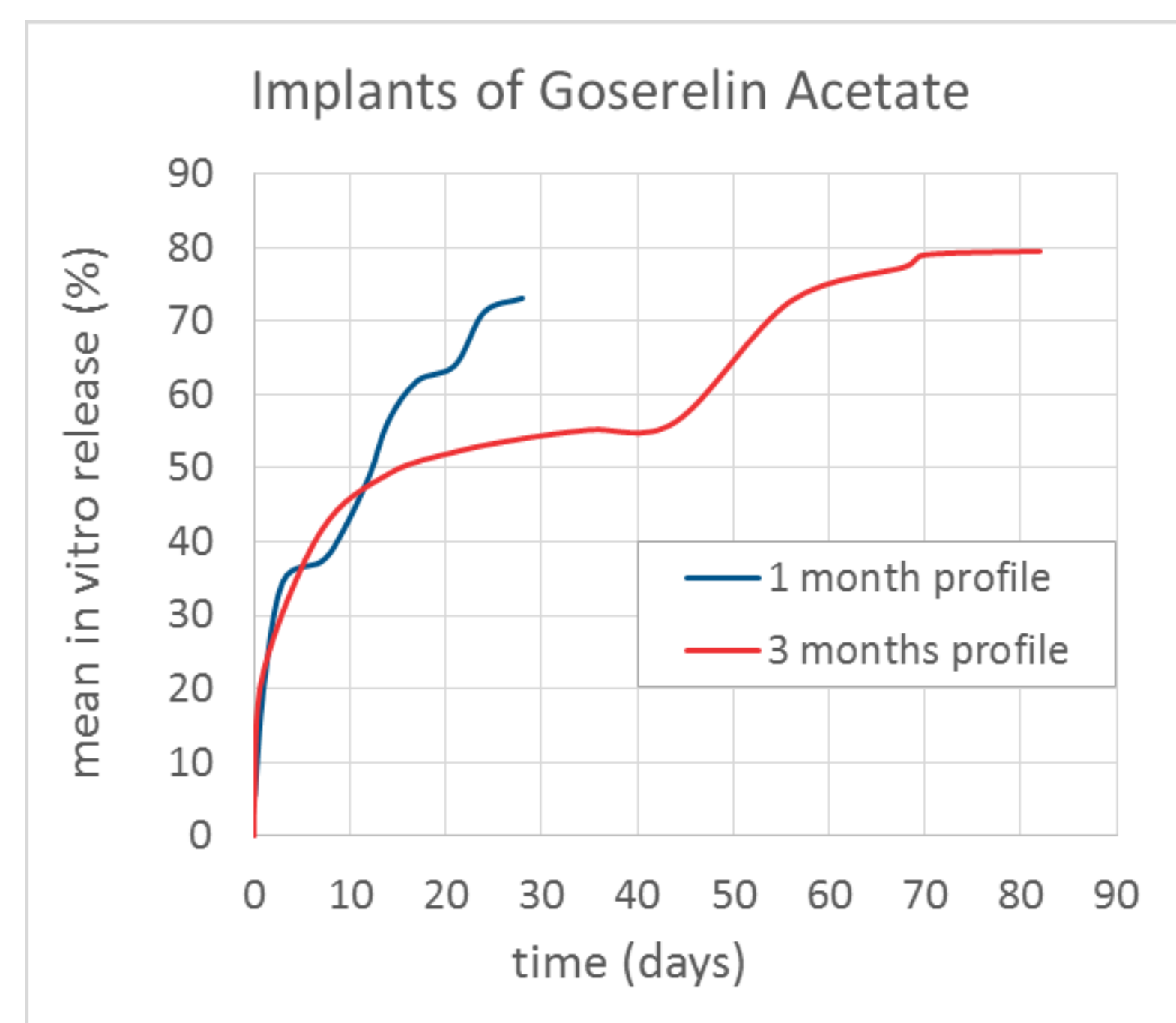
Ophthalmic Implants



Oncological Implants

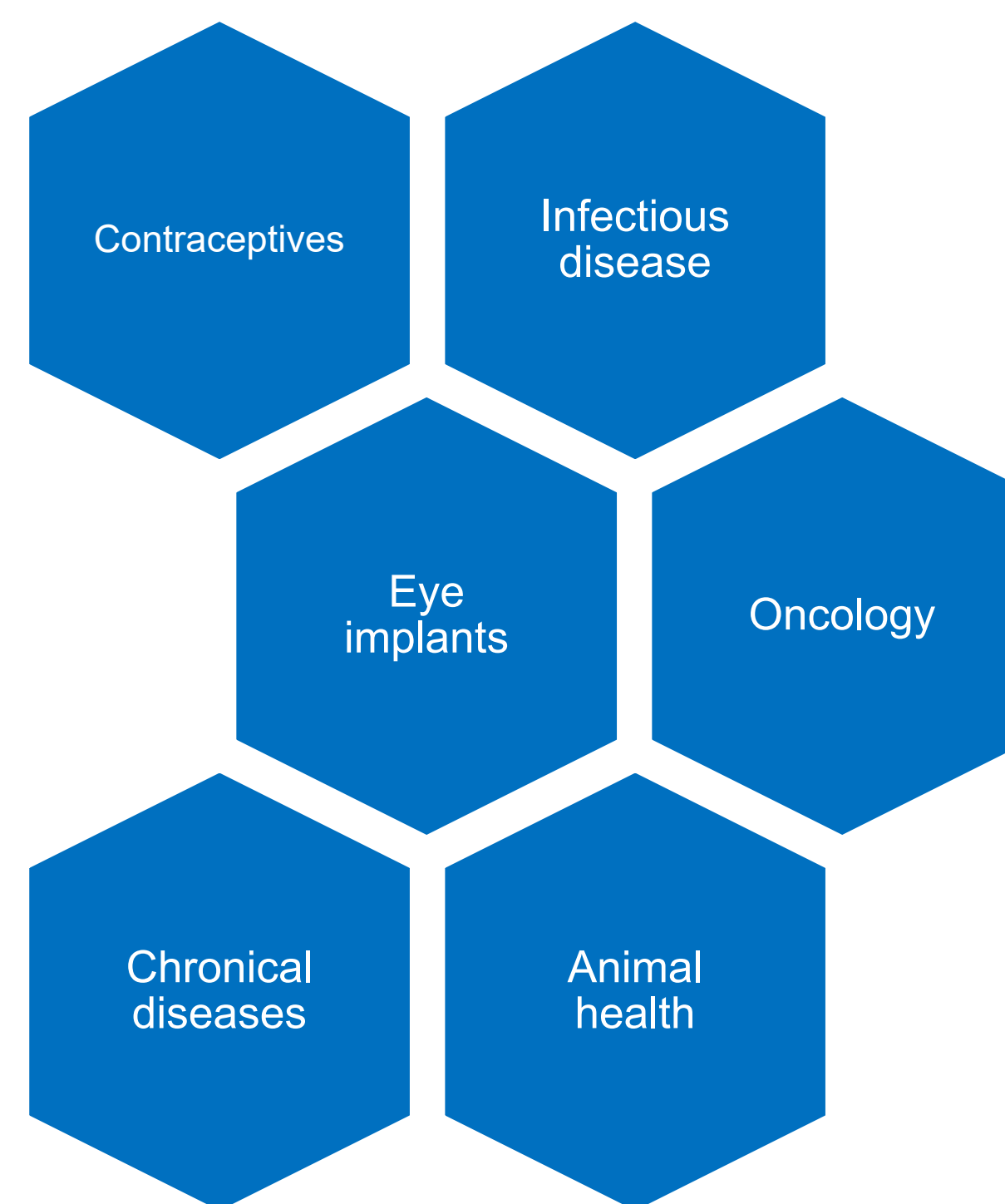


In vitro release profiles of oncological implants (Patent US9364518B2)



Advantages and applications

- Site-specific controlled release of APIs
- Increase patient compliance
- Safe drug delivery of high potent APIs
- Wide range of indications/applications:



Manufacturing technology

- Over the past decade hot melt extrusion (HME) saw rapid growth in the pharmaceutical industry due to a unique set of benefits over conventional production methods:
 - ✓ Solvent-free process
 - ✓ Dust free
 - ✓ Reduced number of processing steps
 - ✓ Reproducible
 - ✓ Continuous manufacturing
- In HME the API is homogeneously incorporated into a melted polymer.

HME process steps:

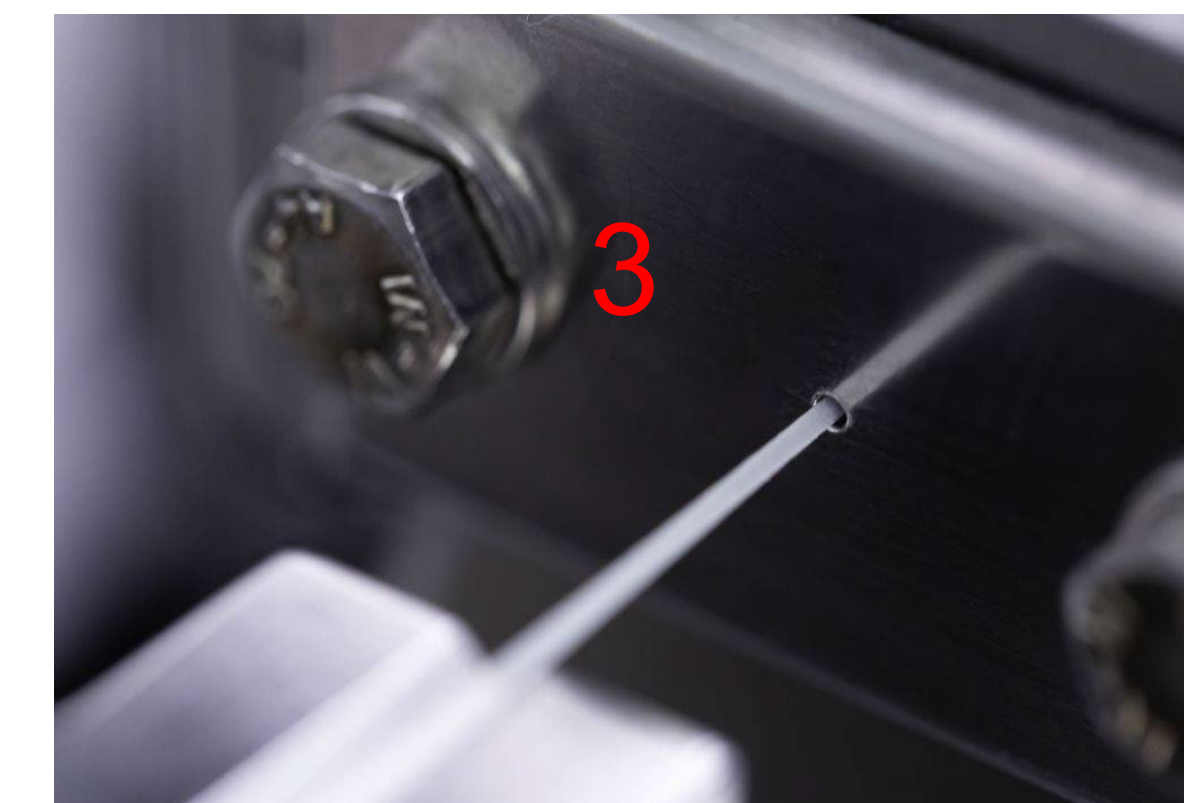
 - 1) Accurate gravimetric feeding
 - 2) Homogeneous melting and compounding
 - 3) Extrusion and shaping
- Manufacturing of injectable implants requires in addition:
 - 4) Precise diameter measurement
 - 5) Diameter control loop to conveying mechanism
 - 6) Precise cutting
 - 7) Sorting according to predefined specifications of implant dimensions



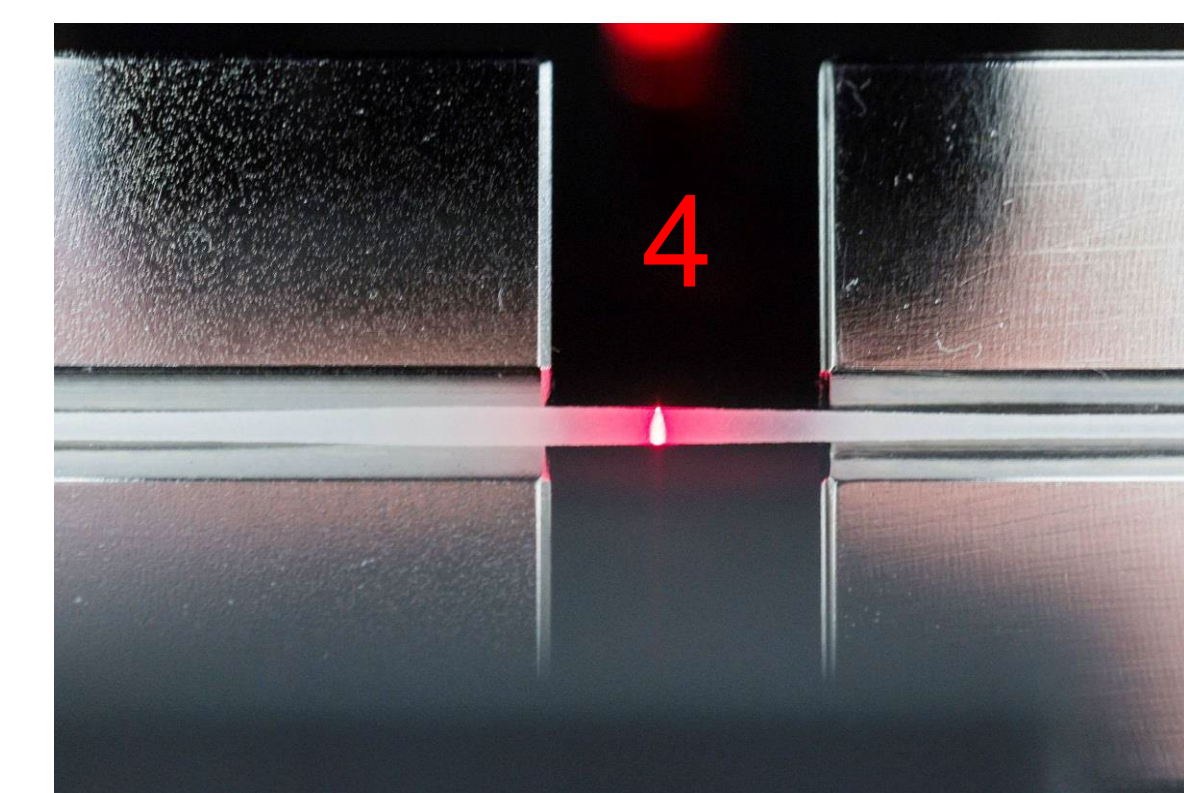
1. A powder blend of API and excipients is continuously fed into the extruder. Accurate powder feeding is essential to obtain implants with small tolerances in dimensions.



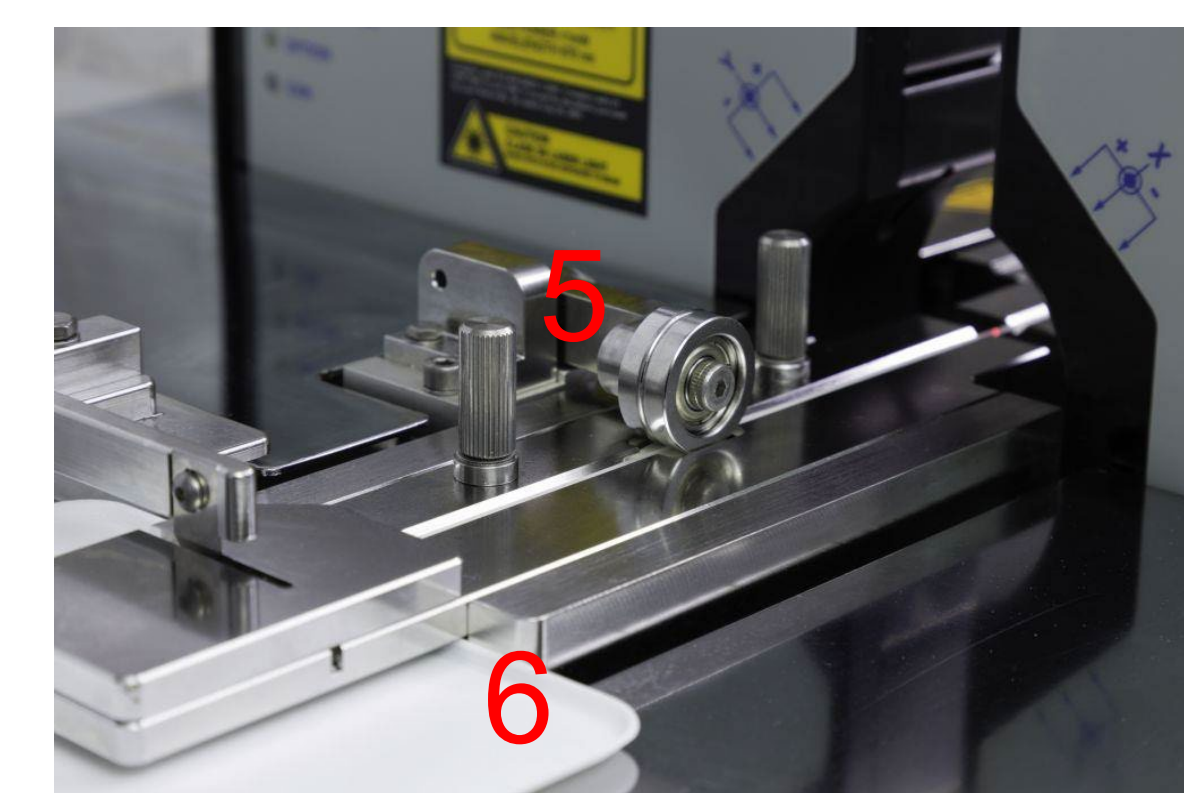
2. The polymer is melted, and all ingredients are compounded homogeneously by the twin screw extruder.



3. The material is extruded through a die with a defined diameter to shape the implant accurately.



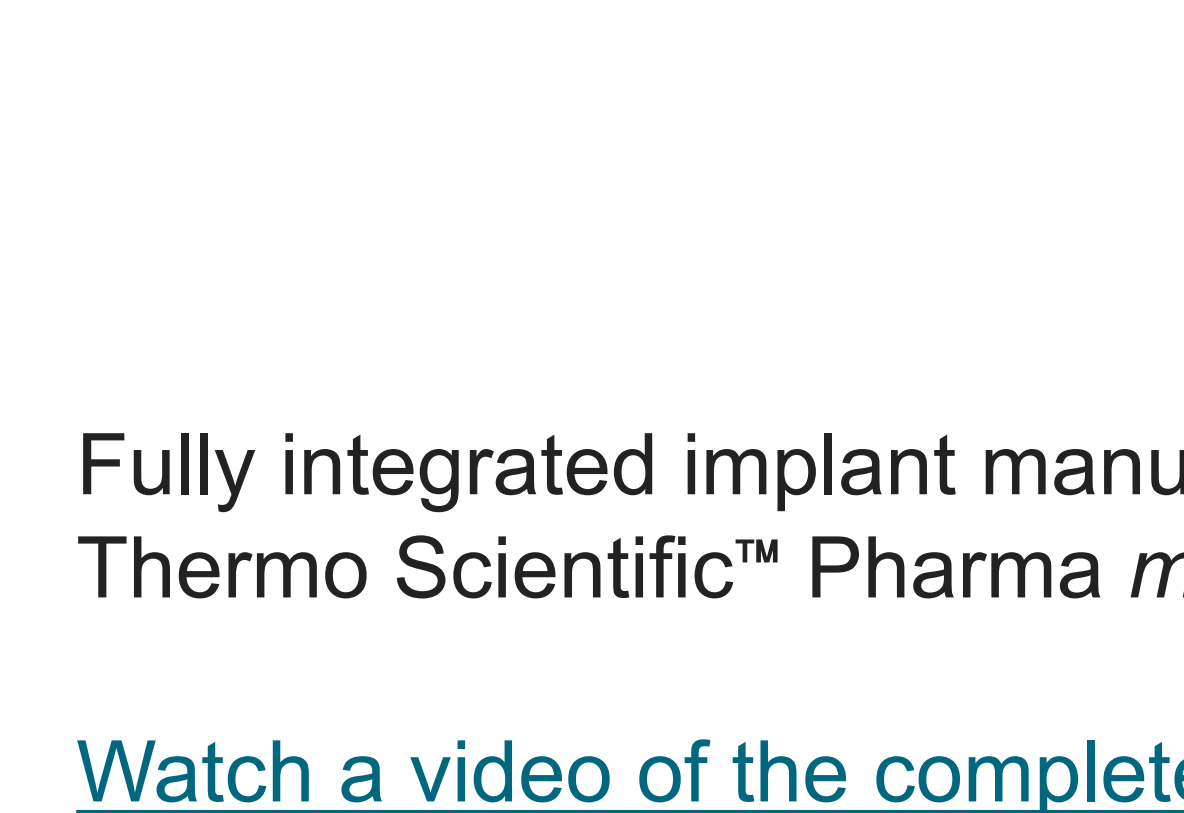
4. The diameter is measured by a 2-axis laser gauge to check diameter and ovality.



5. The pulling wheel adjusts the line speed based on the diameter measurement.



6. The strand cools down, solidifies, and is cut precisely.



7. All implants are sorted automatically. Only implants that fulfill diameter specifications are packed into syringes after.



Fully integrated implant manufacturing line:
Thermo Scientific™ Pharma *mini* Implant Line

[Watch a video of the complete process](#)



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