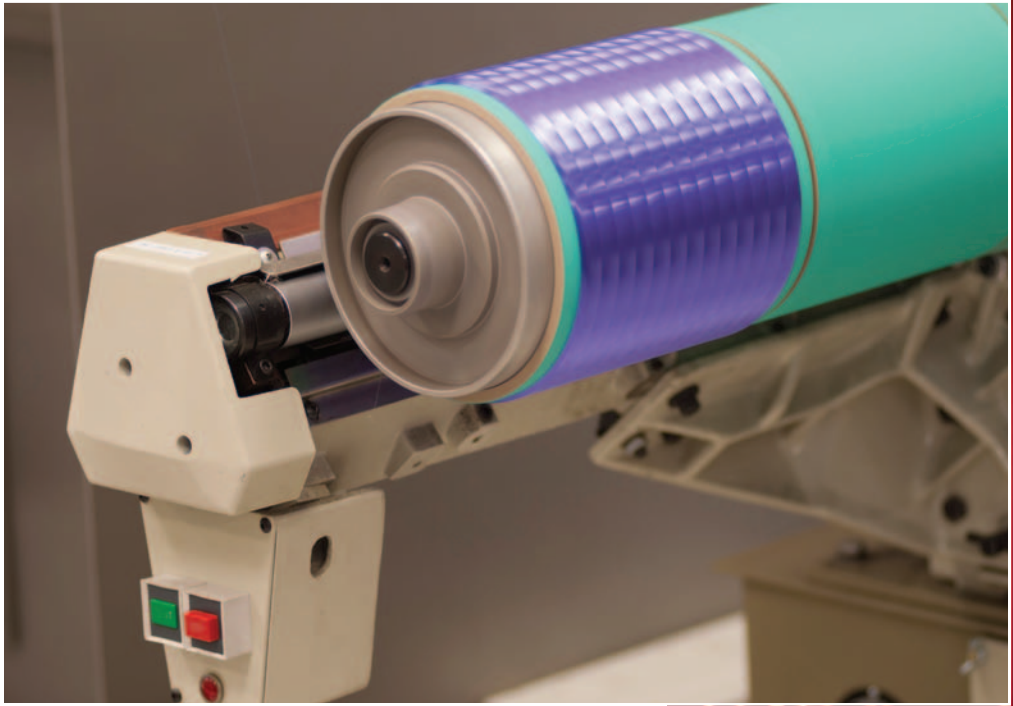
FET
FIBRE EXTRUSION TECHNOLOGY

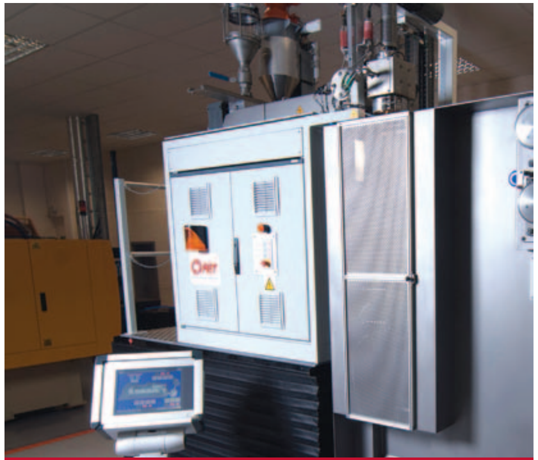
The Biomedical Market



"Your Partner in
Specialist Fibre Extrusion"

The Biomedical Market

1. INTRODUCTION



The biomedical industry is often described as comprising four main strands – pharmaceutical, medical device, biotech and diagnostics. Essentially, this covers those organisations which produce the drugs, therapies and equipment for the health care system in the global economy. Research and development will continue to drive this sector and the long term outlook for the biomedical industry is very strong.

FET has a long tradition in the biomedical sector, which is strongly regulated and demands consistently high standards across the board. We have built strong relationships with several multinational companies over many years, designing and supplying a wide range of equipment, ancillaries and turnkey solutions for biomedical applications. Our in-house process development laboratory is at the disposal of customers in this field for all aspects of testing and evaluation.

2. EXTRUDED FIBRES FOR BIOMEDICAL USE

Although FET serves the needs of many quality fibre manufactures, a particular speciality is the sector which produces high value textile materials for medical device applications. Our experience enables our customers to produce high quality fibres and yarns to the appropriate regulatory standards.

Melt spinning technology for medical device applications

FET has a world leading reputation for melt spinning medical grade textile materials from both synthetic resorbable and non absorbable polymers used in the manufacture of medical devices.

- Unique hardware design for processing absorbable polymers
- Experience of many types of both resorbable and non-resorbable polymers
- Real time experience of running these materials in production
- In depth knowledge about process conditions
- Used in the manufacture of sutures and other medical devices
- Material efficient with batch production in mind
- Technical collaboration with synthetic absorbable polymer suppliers
- Precision control and monitoring systems
- FET melt spinning technology being used by world class medical device manufacturers

3. CHALLENGES RELATED TO PROCESSING RESORBABLE POLYMERS

Although FET serves the needs of many quality fibre manufactures, a particular speciality is the sector which produces high value textile materials for medical device applications. Our experience enables our customers to produce high quality fibres and yarns to the appropriate regulatory standards.

Specifically, FET has developed unique melt spinning and melt blown technology for use with resorbable polymers, although non-resorbable polymers can be processed. The main resorbable polymers used are PGA Glycolide, PLLA L-Lactide, PGLA Glycolide & L-Lactide, PGCL Glycolide Caprolactone, PDO p-Dioxanone

FET can melt spin numerous material formats from resorbable polymers:

- Multifilament and Monofilaments
- Non-woven structures
- Bi-Component filaments
- Hollow filaments

These formats allow for the development and manufacture of numerous implantable devices. The material format is selected for the job in hand, for example, high strength continuous multifilament for braided synthetic absorbable sutures, monofilaments for surgical meshes, non-woven materials for tissue support.

Polymer selection determines both mechanical properties and rate of absorption. This versatility in both format and polymer selection is a powerful tool for the developer of medical devices. However an overriding factor is that to be useful the materials must have specific and exact mechanical properties.

4. BENEFITS OF RESORBABLE FIBRES

Why resorbable implants?

"They do their job, then go away". Furthermore to use a fibrous material has the advantage of lower mass of polymer compared to a solid implant. There are many benefits to this proposition:

- Resorbable polymers by their nature are degraded by hydrolysis or by enzymes, with their waste bi-products being metabolised naturally. Therefore there is no need for second surgical procedure to remove the implant.
- Natural metabolism allows for tissue re-growth to replace the implant. Additionally this enables full biomechanical function of the new tissue without risk of stress shielding. If future additional surgery is needed then there is no old implant to complicate this next procedure.
- There is the potential for sustained delivery of bioactives by release during the absorption period.
- Non-woven resorbable fibres are well proven in the biomedical sector and carry a wide range of benefits.

5. TURNKEY PROJECTS FOR THE PRODUCTION OF SYNTHETIC ABSORBABLE BRAIDS FOR SUTURE MANUFACTURING

FET can provide the process know-how, technology and bespoke equipment to satisfy the stringent demands associated with turnkey projects for suture manufacturing:

- Guarantee all suture manufacturing to USP or EP standard
- Know-how package from selection of third party supply polymer through to coated braided suture material
- Specification of all raw materials including polymer, coating materials, lubricants and pigments
- Specification and supply of all process hardware for extrusion, braiding, coating etc.
- Supply of all ancillary equipment for calibration, dry storage, polymer handling etc.
- Quality control, process documentation, commissioning and training

In addition, our customers enjoy the inherent benefits from the sustained research and development work already carried out with biomedical polymers, which has involved close collaboration with a number of absorbable polymer suppliers. Working with leading blue chip clients, we have developed in-depth knowledge about process conditions and have a proven track record of successful outcomes. We also provide a comprehensive after sales service and technical support. Our objective is to maintain a long term business relationship and to ensure your continued success.

6. FET PROCESS DEVELOPMENT LABORATORY SERVING THE BIOMEDICAL MARKET

FET is proud to have an enviable track record in providing melt spinning and melt blown technology to medical device manufacturers. Our in-house process development laboratory has been extensively utilised by biomedical companies for testing and evaluation. For more details, please contact FET for further advice.

CASE STUDY 1

RESORBABLE NONWOVENS FOR A MEDICAL DEVICE MANUFACTURER

A leading medical device manufacturer (MDM) was interested in applying the benefits of FET's meltblowing technology to produce new materials and products using their existing range of bioresorbable polymers.

The FET non-woven processing system was an in-house development, specifically designed to process high melt viscosity polymers, especially resorbable biomedical polymers, which are susceptible to degradation during processing. This case study provides an example of the Research Team at FET working closely with the MDM Project Team to provide a rapid and low risk route to complete the product development and achieve manufacturing capability.

Stage 1: Proof of capability

The first step was for FET to use the in-house melt blowing pilot line to run a Proof of Capability trial. This three day trial successfully demonstrated that the FET system could use one of their resins to produce a nonwoven web that matched their target structure.

Stage 2: Initial sample evaluation

A detailed confidentiality agreement was put in place and the MDM supplied a range of their polymers for further processing trials. These were attended by MDM staff who worked with FET to produce a range of samples with different structures and compositions. Each resin had different processing properties and the equipment configuration and processing conditions needed to be adapted for each one. Samples were provided for evaluation by the MDM along with a detailed report of the processing properties of each polymer formulation, allowing the MDM to select the best polymer for further work.

Stage 3: Lead option trials

The third stage was carried out on the lead option polymer, comprising a series of short trials to produce samples with different structures and properties. This also provided the opportunity for FET to refine the equipment design and processing conditions for the selected polymer and discover how to gain tight control over the filament and web formation processes. Modifications were made to the design of the spinneret and air blades, which improved the structure and consistency of the web. This iterative process lead to the specification of the preferred polymer formulation and web structure, generating the scale up data that was required to design and specify the production unit.

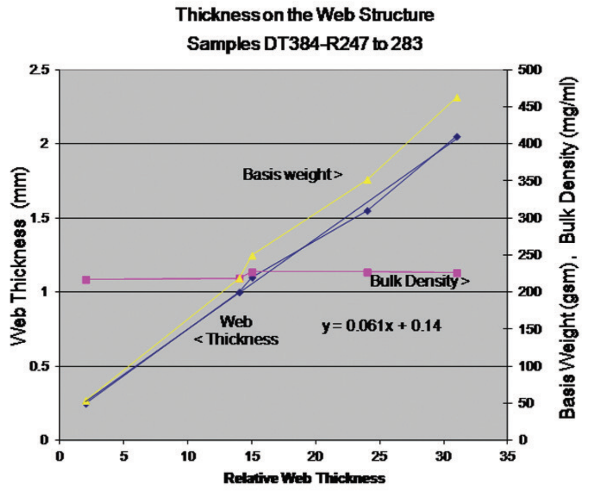
Step 4: Build and ongoing testing

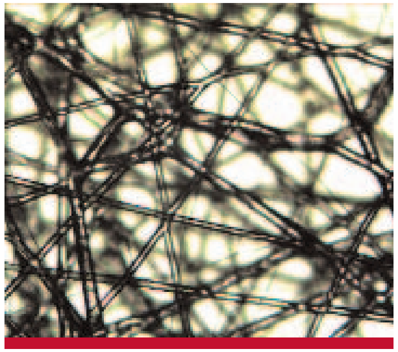
Whilst the Production Line was being built, the progress of the MDM's project was accelerated by FET producing batches of the specified nonwoven for the customer to continue trials and testing of their prototype product. The nonwovens were made to an agreed SOP covering all aspects of the machine preparation, sample production and data recording.

Stage 5: Verification and training

In the final stage, the R&D staff at FET helped the MDM complete a rigorous verification of the processing systems on the new production line and provided detailed training for the new operators.

Example of output from processing trials to investigating control of web structure





Micrograph of the web structure

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