



PLASTICS FOR MEDICAL DEVICES

Micro Múnlaí na hEireann Teo.
Irish Micro Mouldings Ltd.

"To the Heart of Medical Devices"





Injection Moulding a Process of Choice

Injection Moulding as a base process has become a process of choice to manufacture medical devices from catheters to all manner of functional medical mouldings. We at Irish Micro Mouldings – IMM have several years experience in the use of the process for medical device manufacture. In particular over-moulding has become more popular for the purpose of joining catheter tips to hypo-tubes of plastic shafts. For example moulding Pebax tips onto metal or plastic shafts or moulding PEEK onto a PEEK shaft. See Figure 1.

The Basic Process

Injection moulding is the process of polymer resins/materials (metals and ceramics are also possible) heated, melted and injected, under high pressure, into a mould, allowed to cool and the product extracted. See Figure 2.

Over-Moulding/Insert Moulding

Now imagine placing objects/inserts into the mould and moulding around them – typically called Insert Moulding. The inserts could be brass inserts to form threads or hypo-tubes or indeed polymer tubes/extrusions. When we use hypo-tubes or long polymer extrusions we call it Over-Moulding. Over-Moulding can be done in stages – that is, once a part is over-moulded it can be over-moulded again to achieve various properties. At Irish Micro Mouldings IMM we have made a product which involves over-moulding 4 times with 4 different materials and also incorporating an insert into the product. This sophisticated product was made like this to achieve the desired mechanical and functional properties. The product is in use today as the key part of a life saving catheter. One particular area where over-moulding has gained popularity is in the assembly of tips onto hypo-tubes or extrusions. See Figure 3.

In this example this tip is fixed to the shaft by one simple over-moulding operation. This process replaces an older and much used process of glue bonding the tip to the shaft. This has the advantage of making a part of higher mechanical integrity, longer shelf life and lower profile. It also reduces the cost and adds considerable value to the part, cutting out several production steps involved in

SYRINGE LIKE OVER-MOULD
ONTO HYPER-TUBE

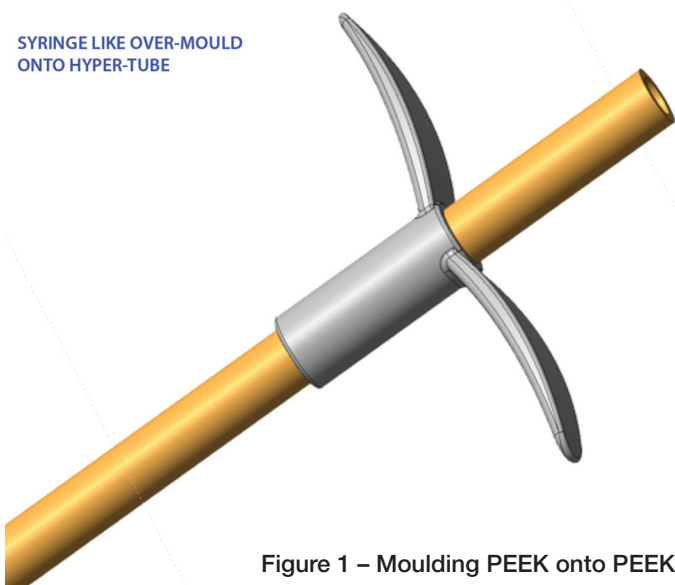


Figure 1 – Moulding PEEK onto PEEK



making a discrete moulding and then bonding it to the shaft. Lower profile for catheters and tips is very important as surgeons try to get to even smaller and remote parts of the body – like getting to sites closer to the brain to carry out procedures. Lower profile tips and catheters are needed to do this and over-moulding of tips will become a more important process in this area in the future. Apart from having a high precision moulding machine with the ability in some cases to deliver micro shot sizes for very small parts the moulds for over-moulding are very important. These are high precision instruments and need to incorporate a lot of technology to accommodate various inserts – hypo-tubes and extrusions and allow for the over-moulding of various materials onto them.

There are three components to the injection moulding system; they are 1) the moulding machine, 2) the mould,

3) the material. 1) Moulding machines vary from hydraulic, electrical and hybrid machines with different capacities from big heavy high tonnage machines down to low tonnage machines and smaller again to micro moulding machines and can be specifically built and set up to do different jobs. 2) The Mould is a precision instrument that is individually designed and manufactured for each individual product, integrating a way of filling cavities, cooling the plastic and ejecting the parts. The Mould is the heart of the system. 3) Materials today are hugely diverse and there are many selections of different types of materials to choose from and a huge range within each type for different applications. You can also add other types of fillers to materials for example, glass or steel, or combine different materials to achieve different desirable properties or even as a cost saving measure. You can also add additives such as barium sulphate to give the material radiocontrast

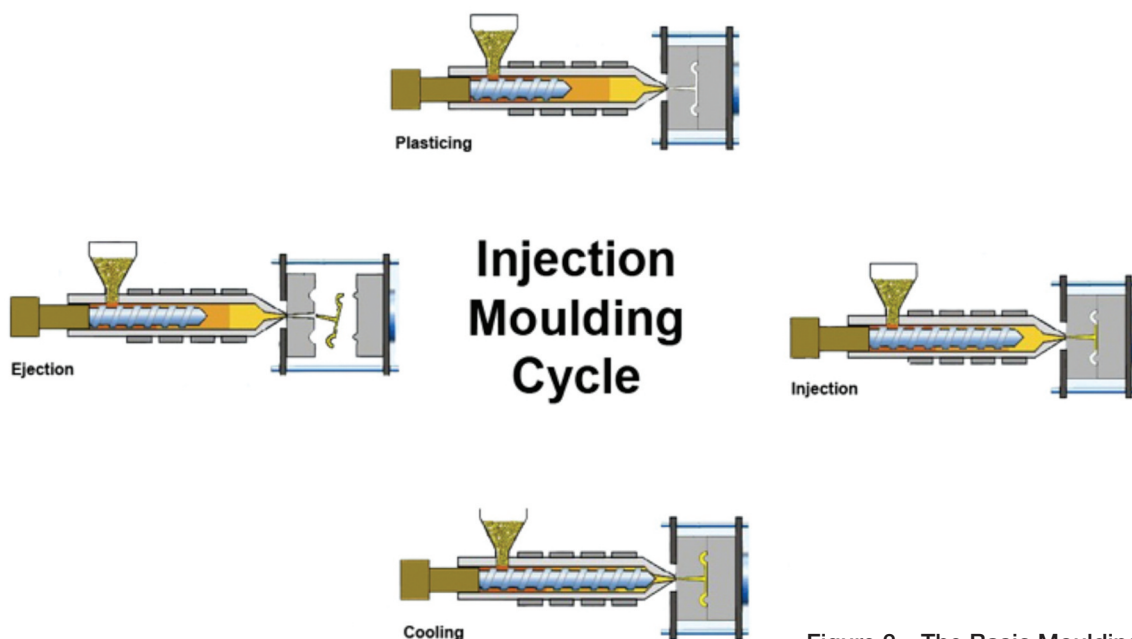


Figure 2 – The Basic Moulding Cycle

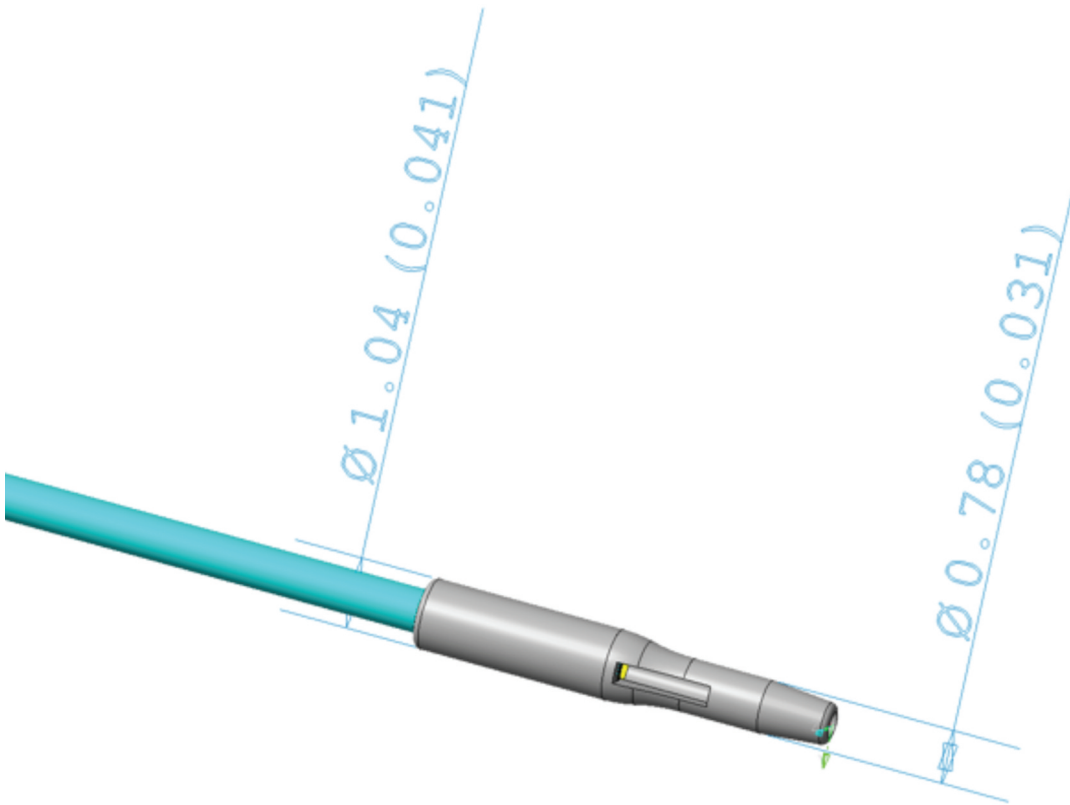


Figure 3 – Tip Over-moulded onto an extrusion

properties which allow it to be traced through the body if being used in an operation.

There are also pre moulding treatments you can carry out on materials to greatly extend the capabilities of, application of and the 'workability' of different materials. They provide more scope with a wider variety of materials, a good example of such a treatment at work is the Plasma Treatment of polymer resin to give material better 'stick-ability' for over-moulding. It can also be as simple as putting a finish or an undercut on a tube or an extrusion to improve the bond. The key to producing a high quality product and to truly add high value is to successfully combine these different elements of the system – the machine, the mould and the material; this gives the customer a larger scope of possibilities and is the essential

activity for anyone looking to get added value using the injection moulding process. Post moulding activities can also add value like annealing, printing, marking, etc.

Not Always Over-Moulding

In some cases where over-moulding is prescribed by the customer as a solution it should be carefully scrutinised. For example if a product required 2 over-moulding stages and perhaps a gluing operation also you may be able by choosing the right materials and design to make the part in one piece and avoid a complicated over-moulding operation. What you are doing is replacing a complicated over-moulding operation with a sophisticated high precision mould to mould the product of one piece instead of maybe 4 individual pieces bonded or over-moulded together.



Bio-Absorbable Materials/Implants

The use of bio-absorbable implants is beginning to get traction. The moulding of these materials has become possible by the use of precision moulding machines, particularly micro machines as the products are small and the material is expensive. (Typically can be up to 5,000 to 20,000 times more expensive than say a basic polyethylene). We have found the ease of moulding of these materials has greatly improved with experience and know-how, and developing processes to handle these materials efficiently. Bio-absorbable materials have been used to support the body while it is healing – so there are a lot of possibilities for the future.

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Product Development

In the design of plastic product it is important the customer, the product designer and the mould designer work closely together. When designing a plastic component it is important that you design not only for the product, the purpose and application of the product but also for the manufacture and assembly (to leave as little as possible to do after moulding) of the product. This will improve the integrity and functionality of the end product as well making the production as easy and as smooth a process as possible with less steps to validate and control. The key to faster product development is to have all the elements as close as possible to each other or better still all under the one roof. At Irish Micro Mouldings – IMM we

have product design, prototyping, mould design, mould manufacture and moulding machine processing under one area to reduce cost but particularly the time needed for development.

Today Injection Moulding is a highly controlled, exceedingly exact and sophisticated manufacturing process, allowing us to produce ever smaller, highly complex and multifunctional products with integrated features. This means that we are able to make products such as very reliable catheters that are deployed to install stents and heart valves, micro parts that allow the miniaturisation so necessary for development in today's world and implants that may be either a permanent piece or a temporarily supportive structure that could be bio absorbable. For certain types of Medical Devices The Injection Moulding Process itself is the process of choice to enable manufacture and incorporates pre-moulding activity, the moulding machine, the mould, the material and post moulding activities. Integrated over-moulding, insert moulding and micro moulding of a host of materials will form a major element in the design and manufacture of medical devices into the future.



Pat Whyte
Director

Irish Micro Mouldings Ltd

Getting Ireland innovating



Dr Imelda Lambkin, National Director of FP7 at Enterprise Ireland, explores the assistance available for the business and SMEs that form the backbone of the Irish economy...

This century has been full of innovation. New technologies, new products, new services and whole new industries have emerged. Yet the call for innovation in business has never been more intense. It is a hugely challenging and competitive time for businesses, so what is Ireland doing in this space?

Enterprise Ireland is the Irish government agency charged with developing and promoting Irish enterprise. It partners with entrepreneurs, businesses, and the research and investment communities to develop Ireland's international trade, innovation, leadership and competitiveness. The ultimate objectives are increased exports, employment and prosperity in Ireland. Enterprise Ireland is also the agency responsible for helping Irish companies and researchers to participate in the EU's 7th Framework Programme (FP7).

The key research and innovation priority for Ireland's Presidency of the European Council 2013 has been to achieve political agreement on all the measures within

Horizon 2020 (2014-20), the EU programme for research and innovation, and successor to FP7. Horizon 2020 can play a decisive role in helping to create jobs, growth and the European economy of the future. The programme seeks to secure major investment in key technologies, bridging the gap between research and the market, and promoting real commercial partnerships between member states and the private sector. Linking in with other EU programmes, it aims to increase participation by SME's from 15% to 20% in Horizon 2020.

SMEs have in recent years proved themselves to be the engines of economic growth and the principle sources of new employment. They are the backbone of the Irish economy and key contributors to growth and employment. SMEs make up over 99% of businesses in the enterprise economy in Ireland and account for almost 70% of people employed.

Their ability to exploit new technologies, and to respond quickly to changing market needs, gives SMEs a pivotal



role in the success of the Irish economy. Support for the creation of new ventures and spin-offs from research institutions and large companies, as well as the removal of barriers to their rapid growth and support for the transfer of know-how, also deserve to be afforded the highest priority.

Enterprise Ireland's client companies achieved record levels of exports in 2012. Total export figures, at €16.2bn, were the highest ever annual export gain achieved by Enterprise Ireland clients. Driving this is research and innovation; for many of our client companies, science and technology is what they are all about – it's in their DNA. For others, innovation is a tool they will employ more strategically, for example, for new product development, to make manufacturing or business processes more efficient or to respond to disruptive waves.

This is why innovation is at the heart of everything Enterprise Ireland does – providing financial incentives from €5,000 Innovation Vouchers to suit a smaller

company beginning their journey on the road of innovation, right through to support for major R&D projects from larger companies, involving investment in the million-plus category.

In the words of Minister of State for Small Business John Perry TD: "Innovation is one of the key strategic advantages that Irish companies can harness to gain a competitive edge and win in world markets". Enterprise Ireland is committed to helping companies get a foot on the innovation ladder.

Dr Imelda Lambkin
National Director of FP7
Enterprise Ireland
www.enterprise-ireland.com

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THE COMPLETE MOULDING SOLUTIONS PROVIDER

Irish Micro Mouldings is an expert overmoulder, micromoulder and moulder of all thermoplastics and bio-absorbable materials. Irish Micro Mouldings offers creative design solutions and a quick turnaround in a one-stop-shop involving some or all of the following carefully controlled steps.

Concept and prototyping

- Research design and concepts;
- Prototype tooling and testing;
- Customer requirements.

Product design

- Detailed product design;
- Mould flow analysis;
- Material selection;
- Design verification.

Mould design and manufacture

- Low volume tooling;
- Process selection – standard moulding, overmoulding, micromoulding, insert moulding;
- Cavitation – single or multi-impression;
- Gating options – cold/hot runner;
- Mould manufacture.

Qualification

- Design of experiments;
- Process validation;
- Measurement systems analysis;
- Statistical analysis.

Production

- Production ramp up – low to high volume capabilities;
- Value add opportunities for medical devices;
- Finishing processes – EMI/RFI shielding, cosmetic painting, printing, welding, ultrasonics, assembly;
- Class 8 cleanroom;
- ISO 9001:2008 and EN ISO 13485:2012 certified.

