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A German manufacturer of extrusion machinery has developed a processing and systems engineering technology capable of producing catheter tubes with very small diameters using thermoplastic resins. Materials such as Pebax, polyamide, polyurethane, polyethylene and flexible PVC typically are processed using the EG 12-25D and EN 20-25D extrusion systems.

[Extrudex Kunststoffmaschinen GmbH](#) [4] (Mühlacker, Germany), a manufacturer of extrusion machinery, has developed a processing and systems engineering technology to produce single- and multi-lumen catheter tubes using thermoplastic resins. The technology is suited for miniaturisation projects and can produce multilumen tubes with very small diameters.

This process starts with each specialist product developed in cooperation with the customer. “In the beginning, there are the conditions and engineering specifications criteria, presented to us by the customer. Here, requirements regarding each individual product are specified, i.e. its accuracies, measurements, tolerances, output performance, surface quality or roughness – for instance “a cardiac catheter tube with an outer diameter of 0.55 mm and an inner diameter of 0.42 mm at a permitted deviation just +/- 0.015 mm,” explains Helmut Wahl, Business Manager at Extrudex. He adds that frequently the CPK value is required, which means deviation within the tolerances.



Lumen catheter tubes made with Extrudex Kunststoffmaschinen technology.

Commissioning, customer advice and support—predominantly European and Asian medical technology sectors—is controlled from the company’s head office in Mühlacker and implemented by distribution and service partners for customers abroad. Literally at the end of the line after materials processing extruder die calibration cooling bath winding and/or

the die, after material processing, extruder, die, calibration, cooling bath, winding and/or length-cutting, the 'Smiley', a nine-lumen tube, for example, with a 2.3 mm outer diameter (0.2 mm per lumen inner diameter) appears at the final specification test. Helmut Wahl can't help smiling: "Tolerances of +/- 0.03 mm are standard; the highest level of excellence begins at +/- 0.015 mm. We have extrusion experts and, in particular, die specialists, with many years of experience in the realisation of such intricate miniaturisation projects, where multilumen tube diameters of less than one millimetre are nothing out of the ordinary."

Extruding Tubes with Tight Tolerances

For the production of highprecision thermo-plastic polymer single and multi-lumen catheter tubes, as well as single or multilayered catheter tubes, the extruders EG 12-25D and EN 20-25D Medtec are employed frequently. Materials such as Pebax, polyamide, polyurethane, polyethylene or flexible PVC are considered for use. Frequently, several barium sulphate strips are embedded in the tube walling. This enables the surgeon to localise an implanted drainage or other surgical component with the aid of x-rays. In some medical applications, a multilumen tube can perform several functions in the same localised area simultaneously (syphoning and/or rinsing). "Tubes for this scope of application, for the administration of medicines, for microinvasive surgery, for the transmission of signals or as light conductors, and, last but not least, PTCA-catheters, are becoming ever more complex and filigree. With regard to miniaturisation, technology has to keep up with the rate at which medicine is advancing. This progress does include extrusion technology," says Wahl.

When extruding tubes of minute dimensions with tight tolerances, particularly high demands are made on the extruder, the die and the calibration path. The heart of the extrusion line is its processing unit. Both the EG 12-25D and the 20-25D extruder are equipped with a grooved intake cylinder and a plasticising screw adjusted within its geometry to suit the relevant granulated synthetic material applied. Through forced delivery, this unit enables the granulate to be delivered evenly, ensuring that the smelting is executed homogeneously—vital prerequisites for the adherence to the tolerances. Adjacent, in the die that sets the shape, the cross-head is aligned at 90° to the extrusion direction, so that the pre-blow support air connections can be set at the rear, sufficient connections essential for the relevant number of lumen within the tube. "Here, the rheological layout of the processing unit is important. The die should only process the 'essentially' required volume of material —no more, no less—just what is required for the product", emphasises the CEO at Extrudex.

Due to the company's strong focus on research and development, Extrudex has developed numerous materials and processing methods. Furthermore, close cooperation with customers when it comes to the development of extrusion components and processes for medical technology is strongly supported. Dialogue between design and technology homes in on the target, the correct solutions for the most crucial elements – distribution system, ratio between pin and die, volume in the head etc. The engineers transfer the results into 3 D CAD. All extrusion dies (spray head, pin and die, calibration units ...) are exclusively designed and produced in-house by Extrudex. The manufacture of the know-how components are passed on to the 'extended work bench', i.e. to subcontractors. "We have experimented and searched around for a long time. Now we are working closely with a specialist in this field who, incidentally, works for Formula 1 as well. Such expertise is just right for high precision and process-critical extrusion components", says Helmut Wahl.

Ensuring Vacuum Criteria

The newly extruded catheter tube gets its precision in the calibration die and in the multichamber calibration unit. Here, the tube retains its precise outer diameter under vacuum, pre-set by the calibration die. At the same time, the tube is cooled and thus made dimensionally stable, so that all dimensions can finally be confirmed by laser and ultrasound. The fully automatic vacuum control unit VR-3, developed by Extrudex, with Siemens SPS (Statistical Process Control) process control, ensures the stability of process parameters.

(Statistical Process Control) screen control, ensures the stability of pre-set vacuum criteria during the entire production process when in 'Vacuum Stability' mode—even with wearing tank seals and unavoidable reduction in pump performance caused by warming. The control constantly compares the predefined vacuum nominal value with the actual value via a high-precision digital vacuum sensor. Any deviation from the set value of more than 5 mbar and the control intervenes immediately and automatically adjusts the actual value to the pre-set value via the VR-3 unit. The vacuum value ideal for the product is stored in the subordinate SPS control system with touch-screen display. Therefore a reliable process control is guaranteed with the provision of continuously stabilising control and checking measurements. A further advantage: Via this control—in mode 'control/measurement of outer diameter'—in conjunction with a laser measuring head to measure the outer diameter, the diameter of the tube can also be kept within predetermined tolerances. If, for example, the outer diameter was to deviate towards the upper tolerance value, the vacuum control valve would make minimal adjustments downwards, until the diameter is again within optimum product specifications—less vacuum means reduced diameter and vice versa.

At variations either above or below given specifications, the vacuum within the vacuum tank is automatically increased or decreased. In this segment of the machine, highest levels of process precision are essential to constantly maintain the accuracy of the tube dimensions. To guarantee this, the discharge conveyor is equipped with electronically synchronised servomotors, thus infinitely adjustable. Discharge conveyors are exclusively made from physiologically safe materials, certified for use in medical products. "Again, this is a sensitive subject", says Helmut Wahl, "depending on the tube materials, the conveyors must not be either too firm or too soft, they have to grip without slipping—abrasion is simply not permitted—and they must not alter the product quality. We have the relevant types of conveyor coatings for the multiplicity of tube specifications in stock. In any case, the safety sensors in the central control and feedback control system protect the end product," says Wahl.

"When it comes to control and feedback control matters, we adhere to the possibilities offered by the best hardware manufacturers. In the context of software, we communicate and cooperate with experts at the other side of the desk, so that we can respond to and fulfil customer requirements. With relatively more frequent changes in products, materials and individual batches, it is equally important, based on the wide variety of specialised tubes and the associated costs, how their quality and safety criteria have to be aligned and how to proceed with both personnel and materials in mind. The subject of material wastage and energy costs, with particular awareness to the environment, is gaining in importance," says Wahl.

"It may be healthy to keep fit, but there is no point in staff running from station to station along an installation measuring up to 20 m during the commissioning and synchronising process in order to set the appropriate production process", explains Wahl and points at the integral control and feedback control unit. The most vital settings, such as parameters, measurements, settings, pre-set and actual values, operating data, including operating times, are contained in this microprocessor controlled Medtec control system, with a touch-screen panel, all stored in the programmable logic controller. All data are precisely retrievable on demand, i.e. at product and/or material switchover. All these values are available via an OPC server and provide the facility management with a protocol of the instruments required for the safest and most economical operation.

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