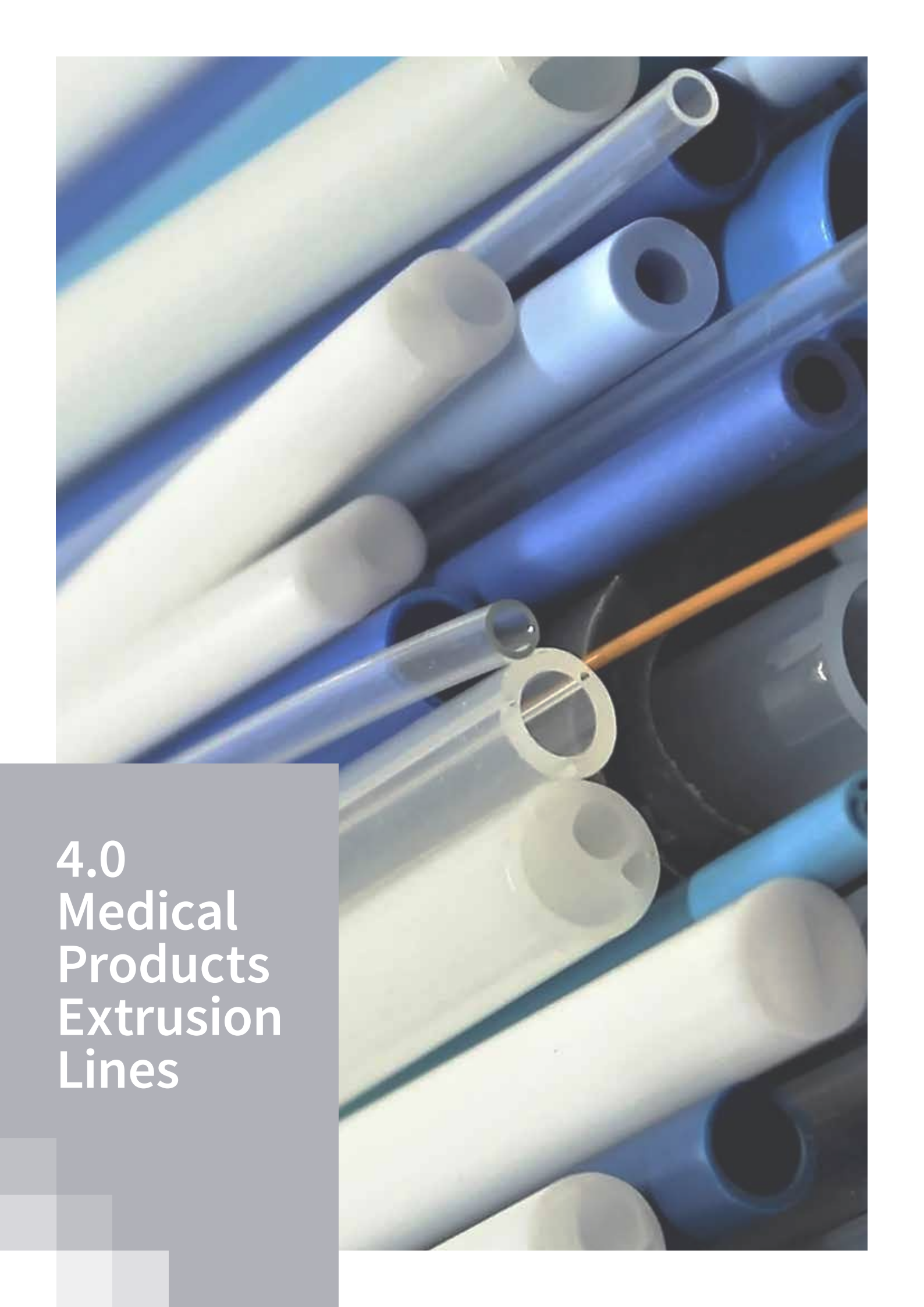


# Your Extrusion Allies

 **bausano**

M E D I C A L   E X T R U S I O N   L I N E S





## 4.0 Medical Products Extrusion Lines

# Complete Extrusion Lines for Medical Devices

## Made in Italy Quality

Choosing Bausano means pick out a strategic partner that can help you to process plastics. We design and manufacture customised extrusion lines completely MADE IN ITALY for the production of pipes, granules, profiles, medical tubes and pockets in thermoplastic materials.

The quality of the extruders and the products is unquestionable: the best technology at the service of the plastic industry, to improve productivity and reduce energy consumption.

The medical industry requires instruments that are safe, reliable, and custom-designed for processing of PVC and other non-toxic materials for sanitary use permissible under the Pharmacopoeia regulations

The medical sector requires also high productivity and high quality. The products must have reduced dimensional tolerances and be free of contamination.

The extrusion lines for medical devices are composed of extruders of different sizes depending on the production requested by the customer. In particular, Bausano offers various customizable solutions which include single-screw and twin-screw extruders and a wide range of accessories for the construction of high production and efficiency systems.

In medical Extrusion not only, material is important but for extruded medical devices, highly precision processing is required to ensure high quality of the end product. Bausano's constant technical development and innovation of the MD and E-GO series can ensure this sort of high quality of your products.

Bausano extruders, in addition to innovation, are also constantly tested to meet the requirements of the pharmaceutical industry and multiple sectors of the medical industry. These systems, thanks to constant quality control and strict internal production

standards, are designed to comply with the requirements of the legislation in force. The resilience of the polymers ensures that the finished products made are suitable for prolonged use in demanding applications such as medical ones. In addition, the use of steels with specific surface treatments allows to eliminate the risk of contamination and facilitate cleaning operations.

At Bausano, we are committed to manufacturing high quality extrusion tools that meet your expectations, are delivered on time and on budget – all supported by superior customer service. We understand that the extrusion lines components and parts we deliver to you are critical to the performance of your finished products and that the quality of our extrusion lines impacts the quality of your products. We have a fully equipped in-house CNC machine facility, which allows us to be very efficient in the production process of customized extrusions. This is particularly helpful for our customers because we can easily make modifications to the tooling prior to approval. It also gives us complete control over quality as we are accredited with the ISO 9001:2015 Quality Management System.

We specialized over the year in the extrusion of medical devices, especially for medical tubing, bags and sheets.

# Medical Products made by Extrusion Process

## MEDICAL TUBE

Medical tubes require the highest quality in terms of dimensional accuracy, the type of surface and the complete absence of contamination. The technology of the MD Plus and TM extruders ensure thermal and plasticization stability at any production regime. Medical tubes are used for:

- infusion and transfusion
- dialysis
- bodily and extra-corporeal circulation of liquids and gases
- pharmaceutical industry
- hospital medicine
- non-invasive ventilation
- oncological medicine

## MEDICAL BAG

Bausano produces extruders for medical bags that are extruded from various plastic materials, such as PVC and PP. Special heads and water calibration systems allow to obtain tubulars for medical bags.

## MEDICAL SHEET

The medical sheets are used for transfusions, dialysis and infusions in non-toxic material with surface finishing of satin and embossing with a non-stick function. Thanks to the satin finish of the internal side, the two walls of the bag do not adhere, facilitating their detachment during use and ensuring greater safety.

Bausano Extrusion Lines are highly customizable with a wide range of downstream equipment to choose. Medical Extrusion is one of our strong points and we know that highly efficient extruders are needed for our customers.



# Extrusion System for Medical Tube production

Safe processes and utmost reliability: the medical industry sets strict criteria for the production of medical devices. Medical tubes, in particular, require the highest quality in terms of dimensional accuracy, surface type and complete absence of contamination. With the technology of the Bausano MD and E-GO extruders, the thermal and plasticizer stability of any production is guaranteed. We have decades of experience in medical devices extrusion that gives us a certain flexibility in designing and create your desired project.

Depending on the diameters, thickness, geometry and production desired by the customer, the extrusion lines for medical tubes can count on different models of extruders and heads.

Medical tubes consist of a surface layer, a base polymer, an adhesive layer and an inner layer.

Medical tubes can be of many types depending on the application and end use. The difference generally can be given of the number of lumens. Lumens are the inner spaces in tubes that transport liquids, gases, or surgical devices during a medical procedure.

Thanks to our extrusion technology and corresponding downstream accessories, tubing can be manufactured with internal diameters measuring from 0.8 mm up to 17 mm. (VERIFICARE)

In the medical sector, and especially for medical tubing the most used materials for medical tubes are:

**PVC / PP / PP-R / PE / HDPE / LDPE / PE-X / PE-RT /  
PMMA / PC / PA / TPE / EVA**

The materials choice depends on the end application of the medical device that will be extruded.



# Type of Medical Tubes

## SINGLE-LUMEN TUBING

Single lumen configurations are used for a wide variety of medical devices applications such as intravenous lines (IV) and drainage or urological catheters. These kinds of medical tubes have only one lumen, this means that the inner passage is only one.



## MULTI-LAYER EXTRUDED TUBING

The extrusion of multiple layers of material is done simultaneously to produce multi-layer tubing. Multi-layer extrusion is a process in which two or more polymers are extruded and simultaneously joined to form tubing with multiple layers. Multi-layer technology is primarily used to improve functionality; For example, if chemical inertness is most important for the interior of your tubing but you still require the mechanical strength and impact resistance of another polymer on the exterior, a co-extrusion may be your solution. These union of different polymers with different characteristics can also increase performance and reduce overall costs of material. Other key functionalities may include active material layers, such as hydrophilic, bioresorbable, or drug-eluting layers. Another co-extruded multi-layer tubing solution is to produce stripe tubing that can also combine materials with different but complementary properties, including durometer, color, opacity, radiopacity, or tensile strength, to provide custom solutions. For Example, a product can be stripe tubing with radiopaque stripes visible under x-ray.

The Bausano Co-Extruders for medical multi-layer tubing has advanced over the years thanks to the quality of our technical department and its constant research & development for innovation and creation of new possibilities.

## FLUOROPOLYMER EXTRUDED TUBING

Our Extruders are capable to extrude Fluoropolymer tubing, like FEP, PFA and PTFE in diameters from 1mm to 17 mm and Wall thicknesses range from 0.1mm – 3mm. Fluoropolymer tubing can withstand in general higher temperature and have a greater stretching flexibility. These materials are commonly used for the construction of medical catheters. Polytetrafluoroethylene (PTFE) is the material of choice for low friction, inner liners of guide catheters used in cardiology and neurology. Thanks to the higher temperature resistance and improved mechanical properties fluorinated ethylene propylene (FEP) is used for vascular access sheaths and shrink tubing.

# Extrusion Line based on Single Screw Extruder

Thanks to Bausano's E-GO technology, it is possible to produce tubes for a large number of applications starting from granules. The medical sector is certainly one of the applications for the production of medical tubes. Thanks to the wide range of Bausano accessories - all customizable - it is possible to create complete extrusion lines, to satisfy any specific need.

Allowing, at the same time, to:

- meet the various production requirements: pipe diameter, thickness, geometry
- best respond to the needs of the medical industry in terms of maximum dimensional accuracy
- increase performance and quality of both the process and the extrusions

## TECHNICAL DATA

Models		E-GO 45	E-GO 60	E-GO 70	E-GO75
Screw diameters	(mm)	45	60	70	75
L/D ratios	L/D	25-30	25-30	25-30	25-30
Heating zone	no.	4	4-5	4-5	4-5
Cooling zone	no.	4	4-5	4-5	4-5
Total power	(kW)	25-30	41-50	41-60	57-65

Data contained in this catalogue are purely indicative and may change.



# Extrusion Lines based on Twin Screw Extruder

Bausano twin-screw extruders equipped with counter-rotating parallel screws are designed and produced internally from mechanics to electronics with the utmost care.

Bausano can comply with medical industry standards such as dimensional accuracy, surfaces, minimum tolerances and absence of contamination using cutting-edge technologies.

Our Extrusion Lines guarantee high stability of the end products, while saving material and reducing energy consumption with our induction heating system.

## TECHNICAL DATA

Models		MD 66	MD 75	MD 92	MD 118	MD 130	MD 158	MD 170
Screw diameters	(mm)	66	75	92	118	130	158	170
L/D ratios	L/D	19-30	24-30	25-30	20-26-30	25-30	21-26-30	24-28
Heating zone	no.	4-6	5-6	5-6	5-7	7-9	8-11	7-9
Cooling zone	no.	3-4	3-4	4	4	5-6	6-11	7-9
Total power	(kW)	45-55	85-100	127-165	190-210	240-260	288-340	408-432

Each line is composed of:

- Cooling and calibration tanks
- Drive and cutting unit
- MULTIDRIVE SYSTEM
- 4.0 Digital Extruder Control for energy savings during extrusion process

Bausano Medical products Extruders are a technical guarantee for the future of your company. You can count on our support from the beginning of the configuration to after the installation thanks to our after sales department.



# New High-Speed Line for Medical Tube Extrusion

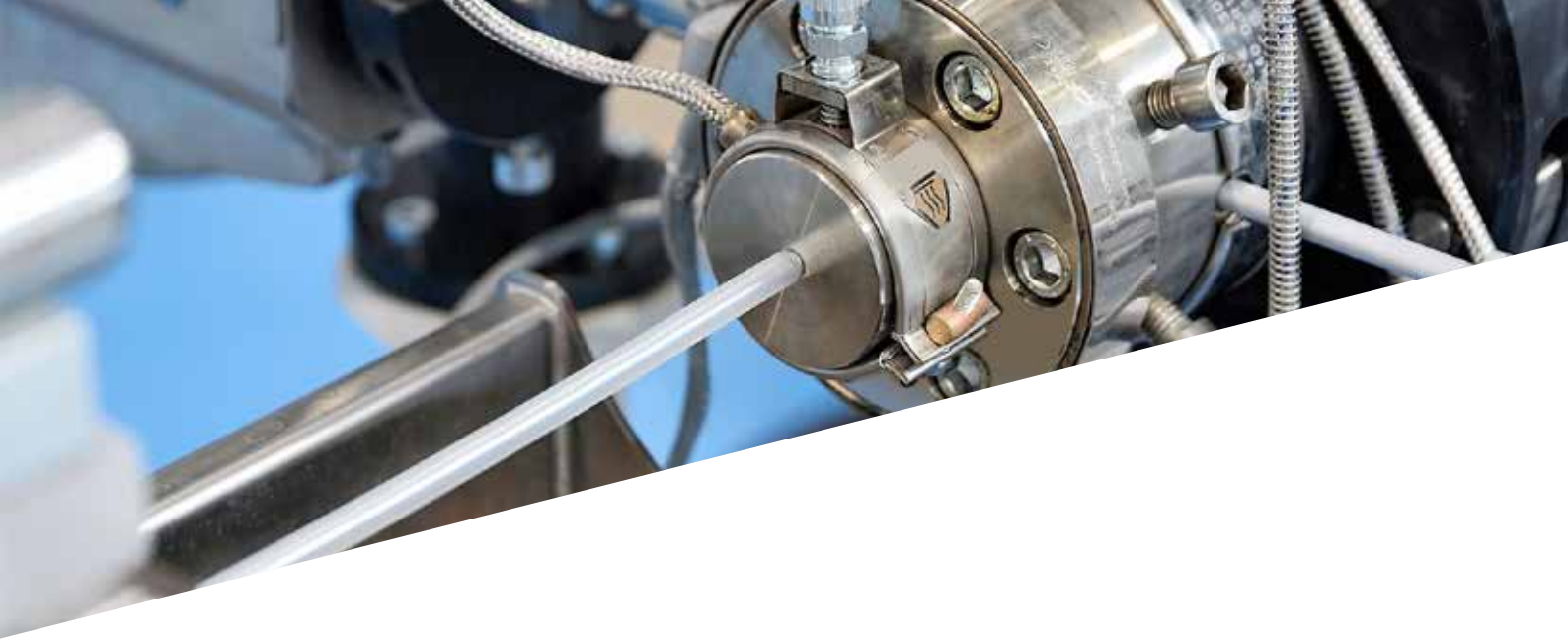
Probably the most used material in the healthcare sector, and with the Bausano medical extrusion lines, is PVC for medical tubes, bags and medical drapes. PVC is used in medical extrusion for its versatility, flexibility, safety, low cost and recyclability.

For this reason, one of Bausano's newest innovations in the medical sector is a new high-speed line for PVC medical tube.

In detail, the high-speed line is capable, even in the most compact configuration, of producing up to 120m of tube per minute.

This new solution is based on a twin-screw extruder from the MD Nextmover series, on which a specially designed stainless-steel head is installed. The cooling and calibration tanks are designed with a unique idler system to reduce the overall dimensions of the line. Ad-hoc idler systems allow for a threefold increase the time the tube remains under water, thus ensuring greater efficiency and extrusion speed, with an unrivalled final tube quality.

The new high-speed extrusion line for PVC medical tubes by Bausano meets the most stringent requirements, such as ISO 14644-1 Class 8 Cleanroom, thanks to the strict design criteria adopted, which also ensure high performance in terms of quantity and energy.



# Medical Tube: extrusion line composition

## DIE HEAD

A crucial component of the overall extrusion process for medical tube production is the die.

The extrusion heads are designed and produced according to the diameters, thicknesses and geometries required by the customer. Different sets of tooling are also considered in the designing process, with varying pin and bush dimensions, to match the rheological characteristics of the chosen polymer at the defined output rate and line speed. Also, streamlined flow paths are used to prevent holdup within the die, and to minimize degradation and dwell time.

Dies are designed for uniform flow of material and uniform production with minimal internal stresses. Bausano's die heads have dimensioning of the flow channels to ensure exact thickness for tube's layer.

## CO-EXTRUSION HEAD

Co-Extrusion heads are designed for multi-layer medical tube for co-extrusion of two or more polymers. From a single layer to complex multi-layer application Bausano designs customized extrusion heads for a wide range of co-extruded medical tubing.

Multilayer solutions can transform key material properties to create distinctly different materials with different properties for the medical tube.

# Cooling and Calibration Tank

The Bausano cooling and calibration tanks are designed with an exclusive system of references, to reduce the total footprint of the line. Specifically, the ad hoc transmission systems allow you to triple the residence time of the tube under water, thus ensuring a higher yield and extrusion speed, with an unmatched final quality of the tube.

The cooling and calibration tanks are designed with a unique idler system to reduce the overall dimensions of the line.

In particular, it is an insulated stainless-steel tank equipped with upper protections to avoid contamination, which can be used in clean and gray rooms. Designed to avoid condensation, it allows constant and uniform cooling of the extruded material.

- Water cooling system with special filters
- Movement on rail
- High regulation system
- Internal polyamide support rollers
- Motorized return system option
- Drying system with low energy consumption and maximum efficiency at any production regime

# Tube Measuring System

Bausano provides a complete range of measurement and control tools for dimensional parameters such as diameter, ovality, wall thickness (single and multiple layers), concentricity, eccentricity, rounding, length, expansion, cross-section, shape and capacity of the tube.

It is a sophisticated detection system that accurately measures the forementioned parameters by laser and ultrasound making it possible to rapidly reject non-compliant extrusions. High scan rate and screen update of the 4-point measuring system of the external diameter and thickness of the tube, with display on a 15" screen and automatic alarms on the maintenance of dimensional tolerances.



## Haul-off Unit

The haul-off unit is equipped with a Control Panel that, when fitted with the detection system, displays speed, measurement data and tolerances on the tube and its alarm systems. It is designed to allow constant drag and with precise pressure regulation.

Bench equipped with conveyor belt and accumulator for cutting pieces to desired length.

## Cutting Unit

A special high-speed cutting unit is offered that exploits a very high cutting speed provided by a rotating blade mounted on a high-performance motor to guarantee high cutting quality on a wide range of plastic materials. This high-speed cutting unit allow to maximise your production maintaining the production quality high.

## Winder

Bausano offers also automatic winders, whose speed is precisely controlled throughout the winding process. The spooler can be automatic or semi-automatic, to ensure effective collection of the product even at high production rates.

It is a special winder with automatic reel change to minimize operator contact with the finished product.



# Extrusion System for Medical Bag production

With the Bausano extrusion lines it is possible to obtain tubular elements for medical bags through special heads and water-cooled calibration systems. These medical bags are used for transfusions, dialysis or drips in non-toxic material, with surface finishing of satin or embossing with non-stick function during the sterilization phases in the autoclave.

Despite the excellent moisture barrier properties and high purity level of polypropylene, the prevailing intravenous solution bag concepts are based on plasticized polyvinyl chloride (PVC) and polyethylene. The finished product must be resistant to temperature, impact and corrosion to withstand the high wear and repeated sterilization cycles to which plastic medical devices are subject.

## MEDICAL BAG EXTRUSION HEAD

It is produced to reach high linear speeds and with maximum dimensional stability; it allows constant resistance with precise pressure regulation.

## COOLING SYSTEM, CALIBRATION AND TOWING

Water cooling system designed to obtain high linear speeds of the extrudate with maximum dimensional stability.

Calibration device with cooled rollers and pneumatic adjustment on the pressure of the extruded material.

## COILER AND WINDER

The reels are available from a range of standard reels or can be customized to suit the reels, as requested by the customer. The width and length are fully adjustable, ensuring a clean and tidy reel.

# Extrusion System for Medical Sheet production

The Bausano medical sheet, thanks to the satin finish of the internal side, ensures that the two internal walls of the pocket do not adhere, facilitating their separation during use and ensuring greater safety. Medical sheets are medical grade plastic sheets ranging from 80mm to 420mm in width and a thickness ranging from 0.1 to 0.65mm.

The Bausano medical sheet extrusion lines are composed of single-screw or twin-screw extruders for medical materials. Bausano extruders are used to produce non-toxic sheet for medical bags for transfusion, dialysis or drip. The process flow of the medical sheet extrusion is similar to that of medical bags, but the difference is that the extruded sheet is unique, and a medical bag is not created immediately, but only afterwards. At the end of the extrusion the sheets are wrapped.

## MEDICAL SHEET EXTRUSION HEAD

Each extrusion line for the medical sector is equipped with a special head for the production of an embossed (and non-embossed) medical sheet with an adjustable width variable thickness at to ensure correct transverse measurements.

## COOLING AND CALENDERING SYSTEM

To allow constant and uniform cooling of the extruded material a complete calendering system, composed of suitable steel rollers is available. The Cooling system designed to avoid condensation.

## HAUL OFF AND SIDE TRIMMING

To ensure correct transversal measurement a haul-off unit with double belt and side trimming device is possible to add.

## WINDING SYSTEM

Automatic or manual, with automatic adjustment of the pulling force, cutting and synchronized lateral movement.



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