

MedPLAST

EINE SONDERAUSGABE DES FACHMAGAZINS PLASTVERARBEITER

PRODUKTION

Risiken eliminieren:
Maschinen für die GMP-
gerechte Fertigung
Seite **26**

PRODUKTENTWICKLUNG

Infektionen verhindern:
Schonende Herstellung
resorbierbarer Implantate
Seite **86**

TRENDS+MARKTCHANCEN

Einwegartikel für die
Medizintechnik:
Einstieg mit Augenmaß
Seite **16**



RUNDUM SAUBER GELÖST

Reinraumfertigung mit hydraulischen Spritzgieß-
maschinen, Seite 16



SECURE JOINTS

ATMOSPHERIC-PRESSURE PLASMA IN MEDICAL TECHNOLOGY Different materials are increasingly being combined in complex components so that they can fulfil their function. Plastics, metals, glass or ceramics have to be joined to one another. In doing so, particularly in medical technology, the demands imposed on cleanliness, sterility and corrosion resistance present a real challenge to methods of production. In-line atmospheric-pressure plasma technology allows new and efficient production strategies for parts used in medical technology.

Medical technology demands the very highest standards in production which go well beyond the requirements of most other sectors. Here surfaces must not just be clean, they have to be immaculate and sterile. The latter in particular, i.e. freedom from germs, plays a major role in the prevention of infections in humans who come into contact with medical equipment or products. Moreover, the materials employed frequently have to be biocompatible. Reliability is also equally important: the joints between the different materials in a product must be secure, impermeable and durable. Finally, imprinted lettering or symbols must be clear and enduring in order to avoid incorrect dosage or use.

Zero-potential plasma beam

In medicine the term plasma is usually associated with blood plasma. In the process described here, however, it is what is also known as the "fourth state of matter", i.e. an atmospheric-pressure plasma which is applied to the surface of a material by means of special plasma jets. In the Openair process developed by Plasmacreat, Steinhagen, the jets are operated solely by air, if need be with a desired process gas also, and by high voltage. The emergent plasma is effectively available according to jet geometry over a working range of up to 25 mm in width or at a treatment spacing of 40 mm.

A special feature is that the emergent plasma beam is electrically neutral

which extends and simplifies its range of applications. Its intensity is so high that treatment speeds of several 100 m/min can be achieved. Typical rises in the temperature of plastic surfaces during treatment amount to $\Delta T < 20$ °C. The process for surface finishing has a threefold effect:

- it activates the surface by selective oxidation processes,
- simultaneously discharges it,
- and brings about microfine cleaning.

By adding a process gas it can also be used for providing surfaces with a nanometre-thick coating. The jet systems can be integrated in-line not only in new production lines but also in already existing ones.

Author

Inès A. Melamies, free journalist, Bochum

The metal insert that measures the blood temperature during the operation is placed in the mould as an insert part and encapsulated with PC. By means of microfine precleaning of the insert in an in-line process Openair plasma guarantees absolute leak-tightness between the metal and polycarbonate. (Photos: Gira)





Working under aseptic conditions: The finished components are examined in the clean room under high safety precautions.

Plasma technology joins hitherto incompatible materials

Due to its wide range of potential applications plasma technology is numbered among the key technologies in surface treatment. Use of the process results in a high level of quality in different products and product functionalities while a reliable sequence of process operations is ensured. The potential of this versatile technology is wide-ranging. Materials such as plastics, metals, glass and ceramics are cleaned, activated or coated by means of atmospheric-pressure plasma. Hitherto incompatible substrates can be joined which means that completely novel composite materials can be created. Innovative and low-cost surface treatments are being implemented in production without the use of chemicals and without substantial intervention in the existing process workflow. These advantages are supplemented by good compatibility with the environment.

In recent years numerous applications in medical technology have opened up. These include, inter alia, bonding and imprinting, surface treatment for improved adhesion and sterilisation.

Plasma treatment for improving adhesion in bonding and printing is well known in medical technology. Before the introduction of Openair technology, however, this process could only be carried out using so-called low-pressure plasma in a vacuum chamber. Generating a vacuum, however, frequently entails slow, costly and discontinuous production workflows.

The composite bonding of TPU membranes for injection closures is greatly increased by means of plasma. During a heart operation the heart-lung machine temporarily assumes the functions of these vital organs. Supplying oxygen to the blood ensues via membranes whose quality makes the difference between life and death. For several years now atmospheric-pressure plasma technology has allowed their reliable production and embedding.

Working under aseptic conditions in medicine is the highest standard in which every patient trusts, especially when visiting a doctor or in the course of a stay in hospital. Medicines and instruments must be packaged to the highest quality in an absolutely germ-free state. Plasma technology makes an important contribution in this regard. When applied at the correct intensity micro-organisms are killed without the starting material being altered by this. Just about a year ago an application for a patent for the process of sterilising surfaces was filed. "This is the result of a successful partnership with the Fraunhofer IVV (Institute for Process Technology and Packaging) in Freising. We have established that our plasma contains a high concentration of atomic oxygen. The Fraunhofer Institute played a substantial part in proving that this oxygen can effectively disable a whole series of micro-organisms on surfaces," declares Christian Buske, CEO, Plasmatreat.



Stringent requirements in medical technology: The entire volume of air in the clean room is exchanged 80 times per hour.



The finished components with the encapsulated metal insert are removed from the cavity in pairs.

Biocompatible coatings for improved growth in tissue

Furthermore, plasma-polymerised layers have already proved their worth in the coating of implants, whether these be wear-resistant coatings or biocompatible coatings that allow simple growth of tissues. Here the manufacturer of this plasma technology is going down this trail as a pioneer with atmospheric-pressure plasma solutions.

The plasma polymerisation process PlasmaPlus developed by the company is used for coating plastics with functional and vitreous layers. By this means the permeation properties of these plastics are altered and the storage life of medicinal drug packs is extended.

Use in two-component and multicomponent injection moulding

Two-component injection moulding processes together with preceding and following processes are target technologies for plasma treatment. Pretreatment with atmospheric-pressure plasma is not just limited to the joining of incompatible materials. Integral joints between combinations that hitherto adhered only moderately or not at all can be achieved. At the same time the achievable level of adhesion is increased. The plasma assumes the task of cleaning and activating the individual elements of the components in such a way that not only more secure bonding is guaranteed, but also the additional assembly steps otherwise required are rendered unnecessary.

Multicomponent injection moulding is a production process that allows the most varied materials to be joined to one another in one system. By means of rigid-flexible composites it is possible, for example, to provide housing parts with a seal, to back inject decorative films with a support material or to produce hybrid parts (metal-plastic composites). The aim is to join as many individual parts as possible in a single cycle. To ensure that the various materials and parts adhere well to one another they are pretreated with plasma.

Single-step manufacture of hybrid components for medicine

The company Gira extended its Plastics Technology Division some years ago to medical technology. Today this processor exploits the combination of injection moulding and atmospheric-pressure plasma technology to manufacture complicated fittings for use on oxygenators reliably and at low cost. This is a component which is adapted to the oxygenator – an important part of a heart-lung machine. Inside this workpiece there is a metal insert which constantly measures the temperature of the blood during an operation. In order to avoid external assembly the metal insert is placed in the mould as an insert part and encapsulated with PC. The joint between the metal and thermoplastic must be perfect to guarantee absolute leak-tightness. Tests have shown that pretreatment with atmospheric-pressure plasma is the only possible procedure here for fulfilling this requirement. Use of adhesion-modified compounds or an additional layer of bonding agent would not be permitted by medical regulations.

Capability of in-line integration assists clean room production

In the processor's clean room (Class 10,000) not only is the entire volume of air exchanged 80 times per hour, but additional filters and laminar flow modules must guarantee a constant quality of air during the whole of production over the handling and mould area of the externally linked injection moulding machine. The number components of the plant in this area should be reduced to a minimum. In that respect it proved to be advantageous that the plasma jets can be integrated in-line into the production line. For manufacturing the component connected to the oxygenator at Gira the metal parts are isolated in a spiral conveyor and picked up from the collection point by means of a handling system and deposited in the plasma treatment station. The pulsed plasma beam activates and cleans the rotating workpieces over their entire surface before the inserts are placed in the mould by the handling system and at the same time the finished components are removed from the cavity. Plasma is used here as a complete in-line solution for cleaning and activating surfaces. Neither the surface structure nor the technical properties of the insert part are altered.

The atmospheric-pressure plasma acts directly on the surface and ensures that the metal surface is wetted by the melt. Organic contaminants are removed by oxidation and as a result the surface tension is increased to > 72 mN/m. Integrated process control ensures that this process step is carried out reliably. The handling system allows simple adaptation to the production process in question and flexible and reliable production. Due to the plasma process described Gira is so far the sole company able to manufacture the parts described by multicomponent injection moulding.

CONTACT

Joachim Schübler, Key Account Manager Injection Moulding and Application Support, Plasmamatreat, Steinhagen,
mail@plasmamatreat.de
Gira, Radevormwald, info@gira.de