How a medical device for minimal invasive surgery was enhanced with the help of an new generation of gas control units by Bürkert

White Paper
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How a medical device for minimal invasive surgery was enhanced with the help of a new generation of gas control units by Bürkert

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Minimal invasive surgery (MIS) offers patients many advantages and is constantly being further developed. With the help of insufflators, which make it possible to raise the abdominal wall in specific areas by pumping CO2, minimal invasive surgery is now possible in places formerly considered unsuitable for this surgical method. For use in such devices, Bürkert, the fluid technology specialist, has developed a new generation of gas control units that are especially compact, lightweight and costeffective.

As much as necessary, as little as possible – that is the basic principle on which minimal invasive surgery has been based since its introduction. Today, state-of-the-art technology helps surgeons to achieve their goal – fast recovery of the patient with as few complaints as possible after the operation – to the greatest extent possible. Instead of large incisions in the stomach, rib cage or joints, which are unavoidable when using conventional, open surgery methods, minimal invasive surgery requires only very small skin incisions. The actual operation is conducted inside the body with the aid of inserted video cameras, light sources and endoscopic surgical instruments. This surgical method, also known as “keyhole surgery”, offers many advantages for the patient: The pain after an operation and the length of the hospital stay often can be reduced to a minimum, plus the scars resulting from an operation are very small and hardly visible. In addition to the obvious cosmetic advantages, the risk of scar hernias, deformations or other post-surgical complications are also

reduced. The shorter stay in bed also reduces costs for hospitals and insurance companies. However, the technical and instrumental requirements for minimal invasive surgery are very high compared with conventional surgical methods. Ultra-modern surgical technology and special instruments such as special endoscopic video cameras and powerful light sources are necessary for the surgeon to be able to see the surgical area. High demands are also placed on the surgeons – minimal invasive surgery requires a great deal of experience and excellent spatial visualization in order to perform complex operations inside the body based only on video images.

The older version of the insufflator block made of milled aluminium, partially equipped with specially manufactured valves

Gently creating space for the operation

In laparascopic examinations (also known as endoscopy), to remove the appendix or gall bladder, for example, additional technical aids are required to create the space needed for the surgery. The patient‘s abdominal wall must be raised and space for the operation must be created inside the body by applying pressure. To achieve this, instruments known as insufflators are used. With these instruments, CO2 can be pumped in to raise the patient‘s abdominal wall. This is done as gently as possible and in compliance with very stringent safety standards. The procedure enlarges the surgical area, enables the insertion of trocars and therefore of medical instruments, thus creating the space needed for a risk-free operation. The core element of these instruments is the insufflator block, which controls the pumping and removal of the gases by means of valves and which is equipped with an additional low-pressure switch. The newest generation of insufflators from the medical instrument manufacturer WORLD OF MEDICINE (W.O.M.) in Berlin, one of the world‘s leading suppliers for the field of minimal invasive surgery, uses an insufflator block developed jointly in cooperation with the Ingelfingen Systemhaus of the fluid technology specialist Bürkert. During the development process the valve concept suggested by Bürkert was first examined by W.O.M. and then a prototype was manufactured from milled polycarbonate. In the next step Bürkert used an ultra-modern 3D printer to manufacture another prototype, which served as a model for the SLA sample. The valve unit consists of two Type 6013 DN 6 direct-acting 2/2-way mini solenoid valves, a Type 2873 DN 2 frictionless 2/2-way solenoid control valve and a low-pressure switch safety from W.O.M., all mounted on an injection moulded plastic block. The Type 2833 valve first regulates the input pressure down to a few millibar (0-40 mbar), since the human

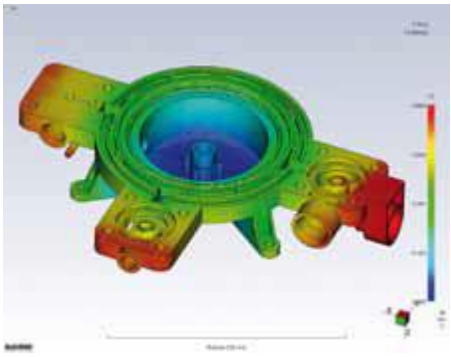
stomach can withstand only very low pressures. A Type 6013 valve serves as a direct output valve for pumping the gas into the body. The second valve of the same type functions purely as a safety valve, which can be switched immediately, if necessary, to release the pressure into the environment. The similarly integrated low-pressure safety switch is a fully mechanical unit that opens automatically if a configured maximum pressure is exceeded.

A prototype of the new, compact insufflator block with two Type 6013 vlaves and one Type 2833 solenoid control valve on an injection moulded plastic block

Smaller, more lightweight and less expensive

The new insufflator block is a further development of the valve unit used in W.O.M. insufflators in the past, which were also supplied by Bürkert. The goal was to reduce the manufacturing costs, the size and the weight of the insufflator block while maintaining the same high performance and safety. The specialists at Bürkert achieved this goal by modifying the design and replacing the previously used specially manufactured solenoid control valve without a valve body with a Type 2873 valve equipped with a standard body. In the old version of the insufflator block the three valves were screwed onto a milled aluminium block, which was flange-mounted on a second block from W.O.M., on which two low-pressure safety switches and the control board were also mounted. Altogether, a rather heavy and large construction. The basis of the new insufflator block is an injection moulded plastic block made of polycarbonate, a completely harmless material that fulfils the UL approval for flammability required by W.O.M. Also, it was possible to eliminate the use of a second pressure stage directly upstream from the solenoid control valve. The new design reduced the size of the valve unit by 29%. The replacement of the milled aluminium block for a plastic injection moulded part and the use of a solenoid control valve in a standard valve body, enabled even more significant reduction in terms of weight – instead of 2,600 g as before, the new insufflator block, at only 870 g, weighs 64% less. That results in a total savings of about 30% in production costs.

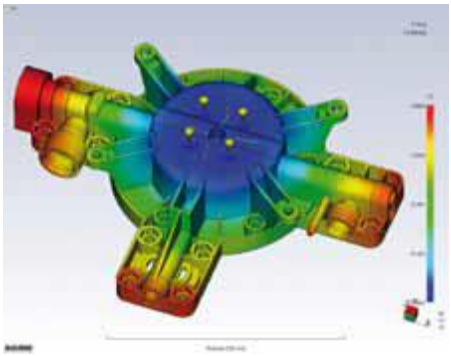
Der neue Insufflator von W.O.M. WORLD OF MEDICINE AG, Foto: W.O.M.



Results of the MoldFlow analysis with respect to the filling time of the injection mould during the production process for the new insulfflator block made of polycarbonate (view from above)

Comprehensive simulations in the development phase

During the development phase, Bürkert conducted extensive tests and simulations in order to optimize the design of the insufflator block. This included flow optimization by means of a CFD test (Computational Fluid Dynamics) to determine whether the flow rate required by W.O.M. would actually be achieved in the insufflator block. “Based on the results of the simulation we enlarged the so-called ‚kidney‘ around the seat of the output valve on the plastic block, to optimize the flow rate,” Product Engineer Julia Adelmann of Global Marketing at Bürkert explains. The production process for injection moulding of the new insufflator block made of polycarbonate was also examined closely by Bürkert in the development phase. A computer-aided MoldFlow analysis, which simulates filling of the injection mould with liquid plastic, determined that the geometry of the kidney on the output valve also needed to be modified. “The valve seats are always especially critical in moulded parts,” says Julia Adelmann. “To determine that the valve seat is always filled correctly during injection moulding, a contour that rises at an angle to the valve seat was necessary.” The new insufflator block has meanwhile been certified for medical use and is already being installed in the W.O.M. insufflator. The solution has since successfully passed pre-clinical trails and is now being used with great success in medical facilities in Germany and the United States.



Results of the MoldFlow analysis with respect to the filling time of the injection mould during the production process for the new insufflator block made of polycarbonate (view from below)

Contact

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