APPLICATION NOTE A097-ME01 FLOW-PRESSURE SIMULATION OF THE HUMAN BODY TO TEST BIORESORBABLE SEALANT

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FLOW PRESSURE SIMULATION OF THE HUMAN BODY TO TEST BIORESORBABLE SEALANT PATCHES

After a surgical procedure, it is very unpleasant to be operated once more in order to remove implants after they facilitated the repair and regeneration of natural, human body tissue. It would be much more convenient if such implants are made of a bioresorbable material - that is biologically degraded by the human body after it has done its job.



The Groningen (NL) based company Polyganics develops several kinds of bioresorbable patches that seal the tissue which was subjected to surgery during the subsequent period of healing. To facilitate brain surgery, for example, their bioresorbable dura sealant patch aims at preventing leakage of the colourless fluid around and inside the brain that acts as a shock-absorbing cushion for the brain. In addition , their bioresorbable liver sealant patch aims at preventing post-operative complications such as aggressive pancreatic and bile fluids leaking from the surgery site into the abdomen. Furthermore, research is performed to prevent leaking from other fluids as well.

Bronkhorst devices are a part of the R&D and quality control setup in which functionality of these products is tested by means of simulation.

Application requirements

When applied inside the human body, the flexible bioresorbable patches follow the shape of the body tissue to which they are attached. They have to keep their sealing function for the wound healing period after which the human body will resorb the patch.

To test the patches as realistically as possible after manufacturing, the conditions inside the human body at the intended location of the patch have to be simulated. Therefore, a setup is necessary that operates at a conditioned temperature, and that has the ability to determine accurately which small pressure difference the patch can withstand when supplying a controlled flow of simulated body fluid to one side of the patch. This requires a combined flow-pressure control of the setup.

Every organ in the human body operates at, and needs to withstand different pressures calling for a setup with a large, but very precise pressure and flow range.

To get an idea of the pressure values we are dealing with here: Pressure in the brain is very low (mbar range), while blood pressure is much higher. A typical systolic blood pressure value of 120 stands for the pressure of 120 mmHg (or about 0.16 bar) that acts on the blood vessel wall, each time the heart contracts. This systolic pressure is an overpressure, i.e. it indicates how much the absolute blood pressure is higher than the ambient air pressure outside your body. Such a value for the overpressure is typical, but you also may have to deal with people under surgery who have a high blood pressure. So the maximum pressure difference that the patch has to withstand is higher.

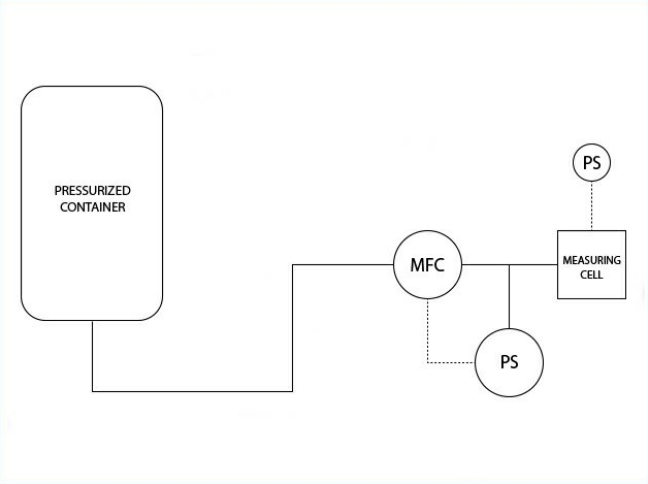
Important topics

- Being able to control small pressure differences
- Accurate control of pressure and liquid flow
- Combined flow-pressure control

Process solution

Bronkhorst supplied a Coriolis Mass Flow Meter (MFC) with control valve (series mini CORI-FLOW), so operating in mass flow control mode, together with an IN-PRESS pressure sensor (PS). This combination acts as a flow-pressure control. The IN-PRESS pressure sensor is the industrial version of the digital electronic pressure meter EL-PRESS series. This device is ideal to operate at low pressures, such as the pressure inside the human body.

In the test setup that has been developed by a third party, patches are mounted in holders inside a climate chamber that is kept at a constant temperature, representing the bodily conditions. A pressure difference is applied over the patches by allowing the Coriolis flow meter to accurately supply a liquid from a small vessel to one side of the patch. The IN-PRESS pressure sensor measures the pressure difference and what maximum pressure the patch can take.



Flow scheme

Polyganics manufactures an entire batch of patches, which are tested randomly for quality control purposes. During initial tests, Polyganics investigated at what pressure the patches burst. In secondary tests, a somewhat lower pressure is set. It is then measured if the products can withstand this pressure for a prolonged period of time, thereby investigating the long term performance.

Setting flow and measuring pressure, or setting pressure and measuring flow: both methods are used, for which a script has been written in a PLC environment, which is followed to conduct the entire test procedure. Pressure-flow data are displayed graphically. The current test unit consists of multiple holders.

It is important to be able to detect small pressure variations, but also to control the flow very accurately with the control valve as part of the setup. The volume of the chamber next to the patch-under-test is very small, which does not require large flows - even when all patches are tested in one setup. This has to be controlled fast and accurately, and that is where the mini CORI-FLOW Mass Flow Meter comes into play.

Currently, the setup has been used for over a year. The Bronkhorst devices help Polyganics to guarantee proper research and the quality of their product, and they are very satisfied with the way these devices do their job. The patches are produced in large volumes for product development, and it is expected that a second test setup will be delivered.

Recommended Products



MINI CORI-FLOW™ M12V14I

Min. flow 0,1…5 g/h
Max. flow 2…200 g/h
Pressure rating 100 bar
Independent of fluid properties
High accuracy, fast control



MINI CORI-FLOW™ M13V14I

Min. flow 1…50 g/h
Max. flow 20…2000 g/h
Pressure rating 100 bar
Independent of fluid properties
High accuracy, fast control



MINI CORI-FLOW™ M14V14I

Min. flow 0,03…1 kg/h
Max. flow 0,3…30 kg/h
Pressure rating 100 bar
Independent of fluid properties
High accuracy, fast control



IN-PRESS P-502CI

Min. pressure 2...100 mbar
Max. pressure 1,28...64 bar
Absolute or gauge pressure
Compact IP65 design

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