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GERMAN ARTIFICIAL SPHINCTER SYSTEMS - GASS III: THE FIRST GENERATION OF REMOTE-CONTROLLED ARTIFICIAL SPHINCTER PROSTHESIS FOR THE THERAPY OF HIGH-GRADE FAECAL AND URINARY INCONTINENCE

Hypothesis / aims of study
We developed the first model of remote-controlled and automatically operated sphincter prosthesis for therapy of different incontinence disorders through microsystems technology.

Study design, materials and methods
The prototype integrates a fluid reservoir, a novel silicon high-power micropump designed based on multilayer piezo-technology, an online pressure management and a microprocessor controls in a single unit. The peristaltic silicon micropump consisted of three membranes, two small valve membranes and one a larger pump membrane. Different sizes of inflatable bodies are suitable for connection. A transcutaneous energy- and data transfer system (TET) was integrated.

Results
The system fulfills the following requirements: high flow rate (3,4 ml/min at 36Hz), maximum possible backpressure of 60.5 kPa, bidirectional operation, an absolutely bubble-tolerance, a small size for subcutaneously implantation and a low energy consumption (90 mWh/day). At present, the operation time is estimated at about 7-10 days without transcutaneously recharging of the battery.

Interpretation of results
We could show that 330 million cycles of the silicon membrane actuators (corresponding a life-time of 10 years) did not result in fatigue or breakage of material. The integrated fluid reservoir contains a volume of 20 cc. Furthermore, the telemetric interface guarantees a freely application programming for different therapies and a comfortable remote control for the patient.

Concluding message
GASS is the first remote-controlled prosthesis which is designed either for therapy of major fecal incontinence or placement around the urethra in patients with urinary incontinence.

Specify source of funding or grant	**Artificial Sphincter Prothesis, incontinence,**
Is this a clinical trial?	**No**
What were the subjects in the study?	**NONE**