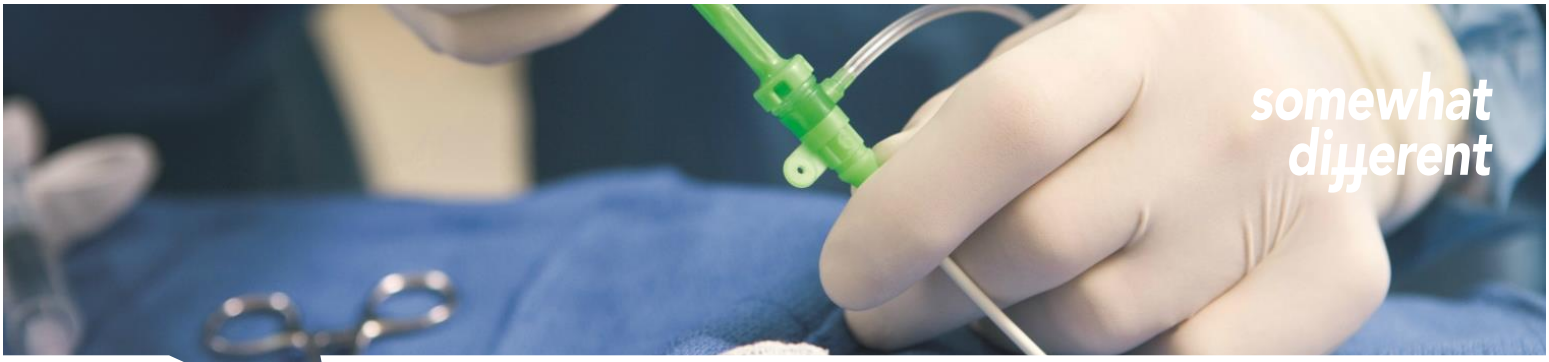

Medical progress and aging societies lead to an increase in demand for medical implants.

Implants

As life expectancy increases worldwide, there is a steady rise in demand for medical devices and in particular for medical implants. Medical implants are devices or tissues that are placed inside the body. Well-known implants are prosthetics, which replace missing body parts. Other implants deliver medication, monitor body functions or provide support to organs. Most implants are made from metal, ceramic or plastic but they may also be made from human or animal tissues like skin or bone. In certain cases, implants contain electronics e.g. in pacemakers. Some implants are bioactive, such as subcutaneous drug delivery systems.

Implants can be placed permanently or they can be removed once they are no longer needed. Knee or hip implants for instance are intended to be permanent, but chemotherapy ports or screws to repair broken bones can be removed when they are no longer needed. Risks arising from medical implants include typical surgical risks like bleeding or infection during placement or removal, and implant failure. Some patients also suffer from allergic or incompatibility reactions to the materials used in implants. Over time, implants may move, break, or cease to work properly. If this happens, patients may require additional surgery to repair, replace or remove the implant.

In the past, several classes of implants were associated with severe side effects and complications. This led to substantial product liability claims worldwide. Examples of such implants are:

- Breast implants
- Surgical mesh implants
- Metal-on-metal hip implants
- Birth control implants
- Spinal implants
- Implantable cardiac defibrillators
- Weight reduction devices
- Inferior vena cava (IVC) filters

New device applications become increasingly complex which makes it demanding to use them properly. In most cases of complications, human error is the leading cause. Even error-reducing systems build into new devices may not prevent critical or life-threatening incidents, as human factors such as inadequate technical understanding and excessive demand are essential contributing factors to serious complications. When new devices are introduced to the market, knowledge of possible side effects, complications and long-term safety is often limited. This is of course always the case with new products, but related to the utilization of implants there is a special need for thorough training and education of end-users. There is scientific evidence that the learning process takes longer the more complex the technologies and applications are. In addition, the informed consent process for patients must reflect these aspects. In particular, if diagnosis and/or therapy have any experimental character the special provisions and issues have to be discussed in detail. Possible future applications of new implants are 3D printed orthopedic implants and so called “smart” or “intelligent” implants, which provide real-time feedback to physicians on how an implant is performing.

Implant claims predominantly affect product liability and product recall policies. First and foremost, product liability is at risk. Over the last decades, several product liability claims led to substantial payouts. As implants are intended to remain within the body for a prolonged time or lifelong, the possible side effects and complications can be severe as the entire body may be affected due to systemic effects related to the respective implant. Once severe side effects and complications with an implant are observed, recall of the respective device typically occurs. Therefore, product recall insurance is likely to be triggered together with the product liability policy.