

Software and hardware: development of a clinical system

The history of a medical devices company would not be complete without the story of the product it sells. Between the corporate structure and the clinical outcome lies the product, which requires a lot of engineering. Without product development, there is nothing to sell. The winding and rocky corporate road is matched by an equally winding and rocky R&D road.

A cochlear implant is a piece of implantable electronics but as a prosthesis it is much more than that. A surgical procedure is involved, and much work has been done to refine implantation techniques and reduce operation time from about eight hours to two hours. The length of the incision, the area of hair shaved and the duration of stay in hospital have all been dramatically reduced. In the early days of cochlear implants, children who were implanted still sounded deaf. Outsiders often assumed that it meant the device was not working. Today, many children are implanted at an early age and as a result develop speech of a quality that would have been unheard of a few years earlier. They can now sound like normal hearing children.

The implant system includes an externally worn sound processor, initially called a speech processor. The audiology and programming of the external device are crucial to a successful outcome, and the development of the hardware to perform that task is a story in itself. A considerable engineering effort is required to design and build that hardware, which is manufactured in relatively small numbers since each clinic will have only one or a small number of units. Although the world market for the device is relatively small, the demands on it increase. Each cochlear implant and