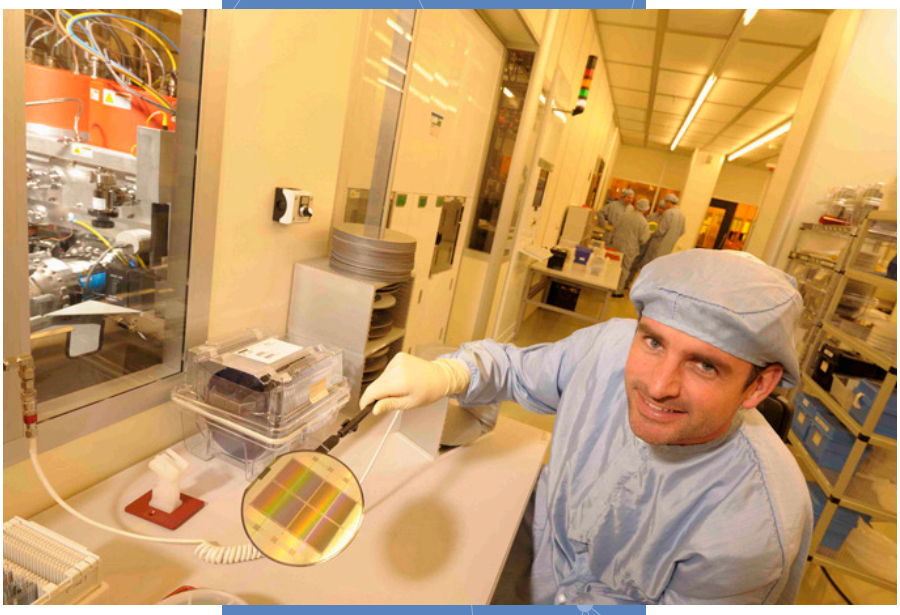
Smart catheters reaching the tipping point

Ronald Dekker knows a great deal about medical technology, particularly when it's being used to treat heart disease. However, this is not only because he works for Philips Medical as a technologist in their catheter laboratory division. His knowledge also comes from personal experience, as he was successfully treated for a heart arrhythmia a few years ago.

In line with many such procedures, the physicians treating Ronald used a minimally invasive technique. This involves guiding a catheter through a vein and into the heart, following its progress on a screen. The advantages of such an approach are immense. No longer do cardiovascular surgeons need to open a patient's chest; instead they can be treated under local anaesthetic and often sent home the same day. These techniques dramatically lower the risk of complications or infections and offer a much more rapid recovery.

Fast forward

However, as Ronald himself noted, although the surgical procedure at the time was state-of-the-art, the catheters his doctors used were something of a blunt instrument compared to current technology. Fast forward a few years and catheters are increasingly 'smart'. The tips can incorporate a range of sensors such as miniaturised ultrasound probes; for a physician dealing with a blocked artery, this can provide vital information. Knowing the size and shape of the occlusion can help tailor the treatment required.



Yet despite the clear advantages these smart catheters offer, they are only just beginning to realise their potential. This is because virtually all the smart catheters currently available rely on technology that is practically obsolete. Given the rapid advances in so many areas of technology, this may seem surprising. However, it reflects a particular challenge that their development poses.

Valuable tools

Historically, many of these devices were usually the result of individual manufacturers choosing to add extra functionality to their products. Normally, this was to address a specific problem or situation; a so-called 'point solution'. To do this, they went to local electronic developers to get them to add the relevant technology to their specification. Once validated, it turned out that these were genuinely valuable tools. However, as one-off solutions, further incremental improvements were not an option, since little, if any, thought was given to how to mass-produce or improve the technology.

If the potential of smart catheters was to be fully realised, it needed an approach to the technology that makes mass production feasible. Herein lay the problem; the capacity to squeeze more and more components onto silicon wafers has increased dramatically. However, the area of silicon wafer available within a smart catheter is tiny. Without economies of scale, innovation at this level is bespoke and prohibitively expensive.

Individual needs

The solution lay in developing an open technology platform for smart catheters. Correctly structured, using an open specification would offer sufficient commonalities to make mass production of relevant silicon wafers viable, while allowing tailor-made

solutions to be introduced for specific applications. By way of illustration, Ronald Dekker offered the appealing analogy of pizza production (as everybody likes pizza); “All pizzas share a common type of base, and you can use a single production facility for all”, he explained. “However, by varying the toppings, you can still provide bespoke products to meet individual needs.”

Pizza analogies aside, it is this exactly the type of collaboration where the ECSEL JU model could play a key role. The unique Public-Private Partnership model allows it to bring together the wide range of stakeholders needed to make such a platform a success; application developers in academia and SMEs, larger companies with expertise in mass fabrication and scalable electronic technologies as well as potential end users. This was the concept behind the INCITE project, which set out to agree and develop the open platform for developing the ‘base’ capable of creating the economies of scale needed. In so doing, it allowed all parties – and the outside world – to see the potential of microfabrication. Importantly, by making it clear that this would be an open technology platform it encouraged access from the widest number of potential producers.

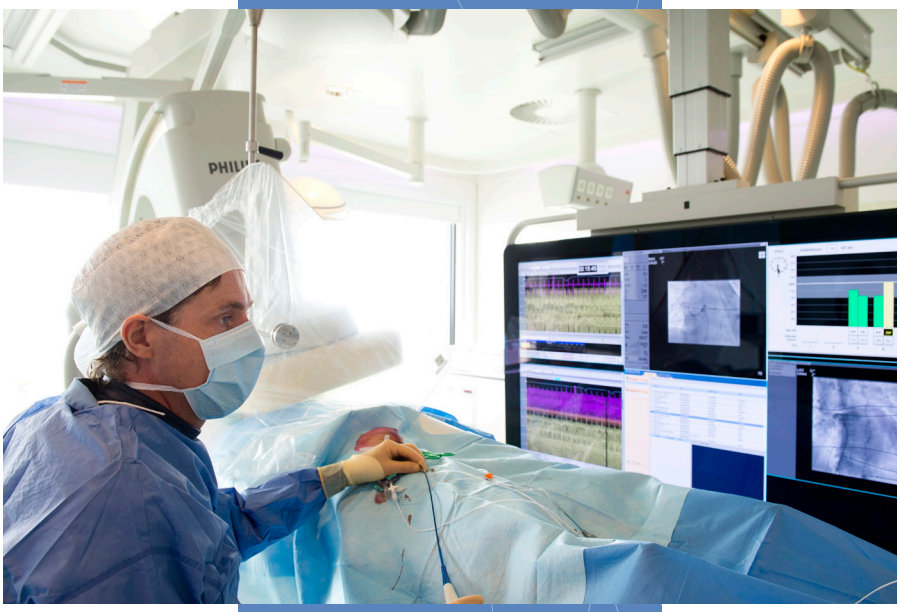
The INCITE tip is 1.2 mm wide, and about 5 mm long. It has 96 ultra-sound transducers (compared to 64 in the previous generation technology) working at higher frequency, resulting with better resolution images.

Collaborative approaches

However, the open platform was only part of the solution. Having established the feasibility, the next step was to address manufacturing infrastructure. For medical devices, particularly invasive devices, this is a major consideration. They need to be manufactured to highly-specific standards, covering not simply materials but also the need to deploy clean room facilities, etc. In addition, smart catheters create challenges of their own, as they need to combine silicon-based electronics with polymers. The ECSEL JU-sponsored InForMed project has helped assemble the critical mass of expertise needed to tackle these challenges, ultimately developing a pilot manufacturing facility in the Netherlands.

For Dekker, these collaborative approaches are a core reason why the ECSEL JU projects work so well. “As a technologist, I’m always excited by the idea of combining technological advances to make new things; these projects give me the reason and opportunity to engage with different partners.” He acknowledges that ECSEL JU funding clearly plays a role, but he sees it as a facilitator of collaboration aiming to create breakthrough innovations,

rather than a motivation in itself. “The funding is extremely welcome but for most collaborations it’s not pivotal. Undoubtedly it acts as an oil to help ease the process of engagement, opening doors to other companies, providing a ‘hook’ to become involved. It allows the projects to become larger, but also more concrete and impactful. In the end, the real value for all of us is in what comes out of the collaboration.”



Small is the new big

As a part-time professor at the University of Delft, he also recognises a specific opportunity for academia in collaborating more formally with industry. By allowing them to look ‘over the shoulder’ of industry, they can see the kind of technologies and applications they are pursuing. This will help fine-tune research programmes in universities to allow them to find traction in real world applications.

The next step will be to advance the technology closer to deployment. The latest ECSEL JU project submission intends to address this challenge of establishing a pilot production line for the next generation of smart catheters and implants. Success in this area will allow Europe to break the existing US hegemony in the field. For Dekker, however, it’s the potential of collaboration for technology that excites him. “When I compare what can now be achieved compared to the instruments used to treat my arrhythmia, it has been spectacular progress. It looks like small is the new big thing; we can already fit more computing power on the tip of a smart catheter than took the Apollo mission to the moon. Then think where the power of collaboration in Europe can take us from there.”

Ronald Dekker (right), project leader of InForMed, receiving recognition for the best project exhibited at the ECSEL JU Symposium 2017 in Malta, from ECSEL JU Executive director, Bert De Colvenaer (left).

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