Eucomed Medical Technology

Focus on Innovation

Quarterly newsletter - Issue 66 - January/April 2009

In this issue:

Medical Technology and Innovation: Fostering good health in Europe

Healthcare technologies save, prolong, and improve life. But how are they invented and by whom? Creating a new innovative product requires a lot of inspiration, a great understanding of patients' needs and many years of research. Typically, this research centers around collaborative working relationships between clinicians, healthcare workers, researchers and the industry in order to develop and manufacture safe, reliable and cost-effective devices.

The medical technology industry is one of the most innovative industries in Europe and a major contributor to Europe's competitiveness. The EU is currently faced with changing demographics such as an ageing population which will increase demand for new, lower-cost diagnosis, monitoring and treatment procedures. Innovation in medical technology enables Europe to meet these challenges. According to a survey conducted by McKinsey & Company in October 2008, there are six fundamental trends shaping the world and bringing new challenges for the years to come [1].

6 Fundamental Trends that will shape the future

1. Shifting centers of economic activity
Emerging markets will account for nearly 50% of GDP growth by 2025

2. Growing and ageing population
Over 90% population growth outside OECD, over 240m over 65 years in OECD countries in 2025 (vs. 98m in 1980), median age in Japan >50 in 2025

3. Over-burdened public sector
Tax increases required to protect benefit levels in 2030 (Italy 140%-Germany 90%)

4. New consumer
Over 1 billion new consumers by 2015

5. Connectivity changing the way we live and interact
E-mail traffic from 40b in 1997 to 8,800b in 2007, double-edged sword (service/experience improves, price transparancy creates challenges)

6. Social costs of the free market
Disenfranchised populations, consumer activation

In 2007, up to 8% (or 5.8bn) of medical technology sales were reinvested in Research & Development (R&D), ranking this industry amongst the ones which add the most value and drive growth in Europe. Making up more than 80% of the medical technology industry in Europe, small and medium-sized enterprises (SMEs) are the drivers of innovation. They represent approximately 8,800 companies of the 11,000 companies operating in the medical device sector in Europe [2]. According to European Patent Office 2006 data, medical technology is top in patent applications, with over 15,700 inventions' patents registered. This represents 11.4 percent of all patent applications. Telecommunications and Data Processing were following medical technologies, with respectively 10 and 7.6 percent [3].

Comprising more than 500,000 products used in the diagnosis, prevention, treatment and amelioration of disease and disability, the medical devices industry constantly strives to innovate and to improve products for the benefit of patients. Each new generation of devices is less invasive, has better clinical outcomes, reduces recovery times and even allows patients to monitor their health conditions themselves from home or wherever they are.

Medical technologies are the result of close and long-lasting collaboration between the medical device industry and doctors, as well as professors and researchers from medical institutions and universities, and patients.

However, with an economic downturn affecting the global economy, how will the medical technology industry manage to find enough resources to continue to innovate?

In the context of the global crisis, the European Commission designated 2009 as the Year of Creativity and Innovation. The "Small Business Act", which aims at strengthening SMEs' sustainable growth and competitiveness, has been introduced and the first European SME week will take place in May.

Many actions are being taken to shed some light on innovation and SMEs but will these be enough to fight the crisis and allow innovators to transform their visions and ideas into effective solutions and products?

Small and medium-sized enterprises (SMEs): Keys to innovation and prosperity

Did you know?

Companies classified as small and medium-sized enterprises (SMEs) are defined officially by the EU as those with fewer than 250 employees and which are independent from larger companies. Furthermore, their annual turnover may not exceed 50 million and their annual balance sheet may not exceed 43 million. This definition is critical in establishing which companies may benefit from EU programmes aimed at SMEs, and from certain policies such as SME-specific competition rules.

SMEs may be divided into three categories according to their size: micro-enterprises have fewer than 10 employees, small enterprises have between 10 and 49 employees, and medium-sized enterprises have between 50 and 249 employees [4].

In recent years, SMEs are increasingly recognised as the main drivers of the EU's economic performance since they are engines of structural change, innovation and employment growth. In Europe, SMEs account for over 99% of all European businesses and in many fields provide the channels through which new technologies develop. Their ability to exploit new technologies and to respond quickly to changing market conditions give SMEs a pivotal role in the success of the European economy [5].

SMEs and the medical technology industry

The European medical device market is highly fragmented, with numerous niche product lines representing modest market sizes. Companies involved in medical device manufacturing range from large corporations producing a broad range of devices and pursuing a global marketing strategy, to small and medium-sized companies concentrating on a single product line in a specific geographic region.

Built prominently around innovation derived from the ideas of doctors in hospitals, the vast majority of groundbreaking early-stage research and development takes place in the small and medium-sized enterprises sector. There are several reasons why small companies take the lead in innovation in the medical device industry while large companies are dominant in the drug industry.

A small company can bring a new product to market in a fraction of the time required by a large company. In a small company, the innovator usually is also a key decision maker and can take risks based upon his first-hand knowledge of the technology and its applications. In a larger organisation, the decision makers often are several management layers away from the innovators and they cannot feel the reassurance provided by direct involvement in the process. Without this involvement these decision makers do not have the tools to assess the risks and tend to operate in a risk-averse manner. Moreover, small and medium-sized companies generally tend to possess better prerequisites to adopt new technologies rapidly and to respond more flexibly to market demands. It is particularly important that small companies are able to establish an early pot-hole in the market, often in high-yield market niches which do not generate attractive volumes for large companies, and to hold on to this position with customer-oriented innovation. Large corporations tend to acquire the innovations developed by the small companies rather than engaging themselves in high-risk R&D and subsequent validation of the business model [6].

Promotion of SMEs at EU level

SBA - The Small Business Act [7]

Encouraging the growth potential of SMEs is crucial as they are the drivers of innovation in the medical device industry. The role of SMEs in the European economy has been repeatedly acknowledged at the highest political level. The current financial market crisis has made the shortcomings of the present framework for SMEs even more obvious and has heightened the urgency of having their needs better taken into account.

The March 2008 European Council expressed strong support for an initiative developed by DG Enterprise & Industry to further strengthen SMEs' sustainable growth and competitiveness, named the "Small Business Act" (SBA). Adopted in June 2008, the SBA reflects the Commission's political will to recognise the central role of SMEs in the EU economy and for the first time puts into place a comprehensive SME policy framework for the EU and its member states.

The SBA aims to improve the overall approach to entrepreneurship, to irreversibly anchor the "Think Small First" principle in policymaking from regulation to public service, and to promote SMEs' growth by helping them tackle the remaining problems which hamper their development.

More specifically, this initiative aims to:

- Create an environment in which entrepreneurs can thrive and entrepreneurship is rewarded;
- Design rules according to the "Think Small First Principle";
- Adapt public policy tools to SME needs;
- Facilitate SMEs' access to finance;
- Help SMEs to benefit more from the opportunities offered by the Single Market and third-country markets.

Since last June, steps have been taken by the European Institutions to move the SBA forward.

Member States

Committed to implement the SBA by adopting the Competitiveness Council Conclusions of 1 December 2008, the SBA Action Plan was developed. This Plan focuses on short and medium-term measures to improve SMEs' access to finance, to improve the regulatory environment and to enhance market access for SMEs.
On 11-12 December 2008, the European Council supported the full implementation of the Action Plan for the SBA adopted by the Competitiveness Council.
Member States are also expected to report on their implementation measures in their Lisbon National Reform programmes, starting in 2009.

The European Parliament

It has given strong support to the Commission to make the SBA politically binding. It is preparing a report on the SBA (rapporteur: Ms Herczog/PSE/HU) to be adopted in March 2009.
The European Parliament stated in December 2008 that "the proposal for a Small Business Act (SBA) for Europe is to be warmly welcomed but will only be effective if there is a concrete commitment to its implementation at Member State and Community level".

The European Commission

The SBA includes a large number of measures which require the Commission to take actions which take the form of legislative proposals and policy actions.
The Commision is also organising the first European SME week which will take place in May 2009.

Other Consultative Bodies

The European Economic and Social Committee adopted the proposal on 14 January 2009, the European Committee of the Regions on 12 February 2009.

SME week [8]

The first European SME Week, taking place from 6 to 14 May 2009, is a campaign to promote entrepreneurship across Europe and to inform entrepreneurs about support available for them at European, national and local level. It allows SMEs to discover an array of information, advice, support and ideas to help them develop their activities. Anyone can get involved in this week: existing entrepreneurs, potential entrepreneurs, young people, business organisations, support providers, public authorities, educational institutions, etc. who can choose either to organise an event or to participate in one.

SME case study

A start-up company specialised in gastroesophageal reflux disease (GERD) was founded in 2006 in Galway (Ireland). GERD is a disorder reaching epidemic proportions worldwide, affecting 5-7% of the population daily. Dysfunction of the valve between the oesophagus and stomach, known as the gastroesophageal junction, is thought to be the prime cause of GERD. With a staff of 18, the R&D driven company has filed seven patents over the past two years covering various aspects of the novel technology they have developed and for which they have recently received a CE mark. The technology is an imaging system initially targeted at providing a new means for assessing the gastroesophageal junction both during clinical workup of patients with GERD and for providing surgeons with a new way to measure the distensibility and diameter of the gastroesophageal junction during the surgery. The company is also repurposing this platform technology for measuring pouches created in a variety of bariatric surgery procedures. Led by an experienced medical device management team, the company has also formed a subsidiary which is developing a novel active transdermal drug delivery patch based on technology acquired from an international IT firm [**9**].

Innovation in medical technology: How does it come to life?

Collaboration with clinicians, healthcare workers, researchers and patients

Each medical device has a history of research carried out by clinicians, academics and engineers. It is only through this collaboration that the industry is able to produce devices which are reliable and safe, and meet the needs of patients. It is also common to see that surgeons and doctors decide to create their own companies in order to market the devices that they invent. A few of these have lead to some of the companies operating in the medical device industry today.

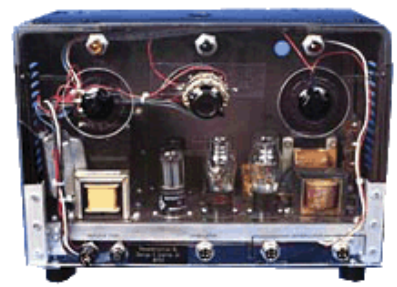
For some devices, the history can be long and involve many actors but it is only by trying, testing and listening to what patients and clinicians have to say that you can achieve the best results.

The history of the pacemaker

The pacemaker is a device used to regulate the beating of the heart in people with an irregular heart rate. In 2007, the number of new implants of pacemakers ranged from 419 to 1200 per million across Europe. Germany was the country with the highest rate with 1200 new implants per million population, followed by Belgium with 1116 [**10**].

Its inception was seen as early as the late 1800s when it was found that electrical impulses caused the heart to beat.

John Hopps, a Canadian electrical engineer from the Banting Institute in the University of Toronto, is considered to be the inventor of the first practical pacemaker. While experimenting with radio frequency heating to restore body temperature, Hopps made an unexpected discovery: if a heart stopped beating due to cooling, it could be started again by artificial stimulation using mechanical or electric means. This lead to Hopps' invention of the world's first cardiac pacemaker **in 1950**. It was an external pacemaker which consisted of placing an electrode on the heart. Along with it, he placed another electrode on the patient's body surface. This design, though fully functional, had its drawbacks due to the immobility of the patient and the constant power blackouts that occurred. His device was also far too large to be implanted inside the human body [**11**].

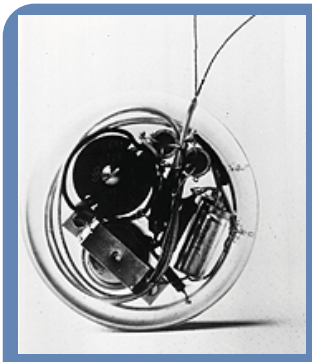


1950 - first pacemaker developed by John Hopps

To view the video interview of John Hopps speaking about his research, please click **here**.

After 7 years of research and tests by doctors, surgeons, engineers and clinicians, the first clinical implantation of a pacemaker into a human was made **in 1958** in Sweden. The device was designed by Rune Elmqvist and surgeon Åke Senning. However, the device failed after three hours.

In February 1960, an improved version of the Swedish Elmqvist design was implanted in Uruguay by doctors Fiandra and Rubio. That device lasted until the patient died of other ailments, 9 months later. The early Swedish-designed devices used rechargeable batteries, which were charged by an induction coil from the outside.



1960 - pacemaker developed by Wilson Greatbatch

In 1960, a second improved version of the Elmqvist design was constructed by engineer Wilson Greatbatch who used a mercury battery as the energy source. The first patient lived for a further 18 months. Also **in the 1960s**, it was found that the electrical leads could be connected to the heart through veins, which eliminated the need to open the chest cavity and attach the lead to the heart wall.

This newer generation of pacemakers gave patients freedom of mobility and peace of mind because of the implementation of a battery.

As the mercury battery appeared to be unreliable, the introduction of the lithium-iodide battery **in 1975** prolonged the battery life of a pacemaker from 10-12 months to almost 10+ years. Developments and refinements of the material of the device itself were also made. **Since the 1970s**, the pacemaker generator is sealed in a metal case using titanium and has become the standard since then. Over time, the size of the device could also be reduced by using smaller components. Additionally, the range of pacemakers available has grown to allow patients to have the best treatment possible for their condition [**12**].

Today - pacemaker (size of a EUR 2 coin)

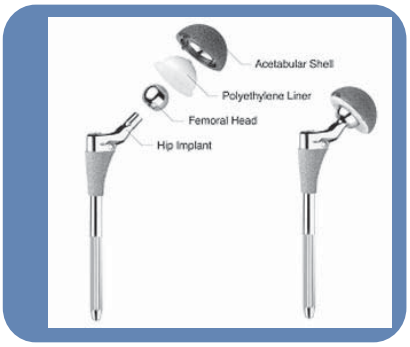
Currently, pacemakers have become so advanced that they are like mini-computers, the size of a EUR 2 coin. They can keep data of the patients heart beat patterns, may be controlled by radio frequency through the use of telemedicine or telemonitoring solutions, and even adjust the beat rate according to the person's activity level.

Many doctors, surgeons, engineers and researches have contributed to the pacemaker that patients can benefit from today. As research never stops, scientists and doctors hope to develop the future generation of pacemakers with infinitely lasting battery lives and even the ability to learn the patients' lifestyle and adjust the heart rate to what it thinks is best. Moreover, recent research in neuro-stimulation will allow for the creation of a "brain" pacemaker that can help reduce the symptoms of patients suffering from Parkinson's disease by stimulating the brain.

History of the hip implant

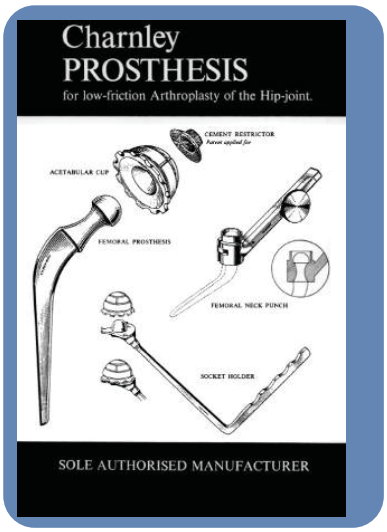
Osteoarthritis, factures/dislocation, rheumatoid arthritis and bone necrosis are diseases that cause damage to the bone joints. Once a bone joint is partially or fully damaged, pain can be felt and make movement difficult. A damaged joint can not be cured but can be replaced by an artificial joint that will act as the real one.

Hip replacement is a medical procedure in which the hip joint is replaced by a synthetic implant called prosthesis. The prosthesis consists of steel components: a socket, ball, and stem. When the metal ball is joined with the socket, the new hip can allow for smooth, nearly frictionless movement. Hip replacement surgery is today's most successful and safest form of joint replacement. In 2005 in Europe, more than 600,000 procedures were performed [**13**]. In Germany in 2008, more than 220,000 procedures were performed [**14**]. The American Academy of Orthopeadic Surgeons (AAOS) predicts that by 2015 in the US the number of first time hip implants will increase from 285,000 to 572,000 a year (175%) [**15**]. Around 19 million people in Europe are considered to suffer from osteoporosis and the incidence of fractures is estimated to increase exponentially with age. Today, the average total hip replacement patient is between 65-70 years old. However, recent improvements in implant material and design now allow younger, more active patients to receive a total hip replacement and achieve good long-term functional outcomes.



Due to the crippling nature of arthritis, surgeons have been trying for well over a century to successfully treat this disease. It was clear that many people required surgery to relieve the pain and keep their joints mobile. Surgeons realised soon enough that the calcium deposit or the irregular cartilage which causes the pain needed to be removed to smoothen the surface of the joint. A lot of research was done to find the best materials to resurface or remove the hip that would be biocompatible with the body and strong enough to withstand the forces placed on the hip: muscles, fat, gold, magnesium, etc. were thought of but all failed into trials.

In 1925, an American surgeon moulded a piece of glass into the shape of a hollow hemisphere which could fit over the ball of the hip joint and provide a new smooth surface for movement. Even though biocompatible, the glass could not withstand the stress of walking and quickly failed. For more than 18 years, doctors and surgeons tried to find the right material to replace the hip, without any real success.



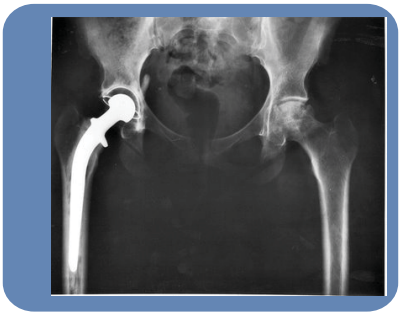
It is only **in 1958** in England that John Charnley decided to put his efforts in hip replacement research and surgery. The same year, he introduced a new material for the implant: Teflon, as he believed that it would allow for a smooth joint surface to articulate with the metal ball component. Unfortunately, Teflon was not as promising as he thought and decided to go for polyethylene. Polyethylene is today's most popular plastic in the world, used for the production of grocery bags, shampoo bottles, children's toys, and even bullet proof vests. This new material worked extremely well and he even decided to introduce a new substance used to firmly secure the artificial joint to the bone: the bone cement. John Charnley is considered the father of the modern hip prosthesis.

By 1961, Charnley was performing the surgery regularly with good results. He further improved the techniques and component designs. Thousands of people were successfully relieved of their hip pain and the long term results became very predictable [**16**].

Since that time, many skilled surgeons have improved upon the concepts which started in central England. Methods of fixation and actual cementing techniques significantly improved. Refinements in the design of the prosthesis have evolved to more clearly mirror the normal hip joint.

In the last ten years there has been considerable effort and research in trying to improve even more the methods of fixation. Occasionally, it has been found that cement fixation breaks down over time. If a living type of bone could be created, this would theoretically be longer lasting and possibly stronger. To this end, implants with textured surfaces which allow bone to grow into them have been developed. These have been used experimentally in animals and are now being used in humans. The results of these cementless joints look very promising when utilised under the correct circumstances.

Kim Bertin, an American surgeon based in Utah (US), has helped design and develop new total hip implants and instruments which are used by surgeons worldwide [**17**]. **In 2002**, he has begun performing outpatient hip replacement surgery. This is one of the most significant advancements in total hip replacement with less invasive techniques which allow the patient to recover faster. The procedure has even progressed to the point that some patients are able to have their surgery accomplished as an outpatient procedure. In the orthopaedic field, other types of implants exist, from foot and knee to shoulder and hand implants, which are also specifically developed to meet patients' needs.



History of Tension-Free Vaginal Tape (TVT)

In our previous issue, we wrote about the Tension Vaginal Tape (TVT) procedure which has already helped and improved the quality of life of one million women in the world suffering from stress urinary incontinence (SUI). Stress urinary incontinence is loss of urine when coughing, laughing, sneezing or exercising. Damage to the muscles that hold up the bladder, and injuries to the nerves during childbirth may be causes. Internationally **launched on the market in 1998** after more than **22 years** of research, product developments and tests, the TVT is available in 75 countries. More than

80% of the women who went through this surgery are cured and more than 10% have noticed a significant improvement of their symptoms [18].

"Sling" procedures such as the TVT have been used for the treatment of stress urinary incontinence **since the early 1900s**, with the first surgery performed by Von Giordano **in 1907**. **In 1947**, three doctors developed a procedure which became the standard for new procedures, the "Marshall-Marchetti-Krantz procedure". Patients undergoing the MMK procedure were placed under general anaesthesia and required two to six days of hospitalisation. It was also considered an invasive surgery and, as such, carried risks of infection, internal bleeding, and haemorrhage. Additionally, the possibility of permanent damage to the bladder or urethra could not be ruled out.

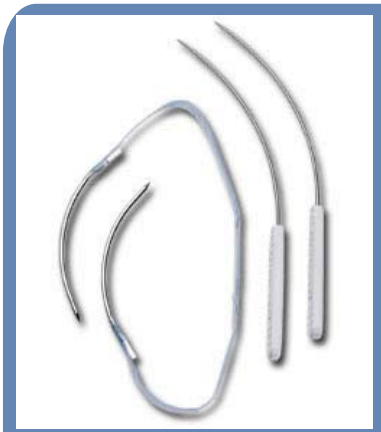
In 1961, Dr John Burch reported a modification of the MMK operation which involved placing the surgical sutures at the bladder neck and tying them to the Cooper ligament.

In 1978, McGuire and Lytton reintroduced the sling procedure to the urologic community. The procedure was only advocated for complicated cases, patients who had failed multiple procedures.

A bit later, Prof Carl Gustav Nilsson and some of his Finnish colleagues who were practicing the sling and the MMK procedures were not happy with their results. They believed that the procedures available were too invasive and techniques used by surgeons to perform the surgeries too different. Their clinical benefits were also too difficult to predict, with patients having to wait for weeks or months before their health condition had improved or was cured. Back then, new theories on urologic dynamics were developed and new ways of approaching the bladder and the urethra were searched for. The "Mid-urethra theory" came to life and set a new angle of approaching the issue: the middle part of the urethra is more important to cure incontinence than the bladder neck.

Today - TVT procedure
(minimally-invasive and minimal pain)

With this new theory, Professor Nilsson and his colleagues worked on designing a surgical procedure that would allow such a practical approach. At the time, their goal was to create a procedure that would be minimally-invasive and become a standardised procedure which could be easily thaught and performed. The first efforts were put **in 1990** and the first devices were ready to be tested on patients **in 1994**. For four years, the procedure was tested and further improved. These trials allowed for the TVT procedure to become what it is today: a minimally-invasive surgery which can be performed under local, regional or general anaesthesia, which does not require any stitches to hold the tape in place and which causes minimal pain, discomfort and little interference with daily activities.



Today - Tension-free Vaginal Tape
used for TVT procedure

Simultaneously, a survey was conducted **in 2008** which followed 90 women treated with the TVT. This survey wanted to analyse data from an 11-year follow up study on the safety and effectiveness of tension-free vaginal tape as a treatment for stress urinary incontinence in women. It was found that after 11 years, 90% of the patients were objectively cured and 97% considered themselves subjectively cured or improved. The study also found that none of the patients complained of difficulties urinating during the long-term follow-up visit. Preoperative assessment included a 24-hour pad test, a stress test, physical examination and a visual analogue scale for assessing how bothersome the condition was to each patient [19].

Those results substantiate the evidence showing that the TVT procedure is a safe, effective solution that offers excellent long-term cure rates for women suffering from SUI.

To listen to Prof Carl Gustav Nilsson's podcast on his research, please click **here**.

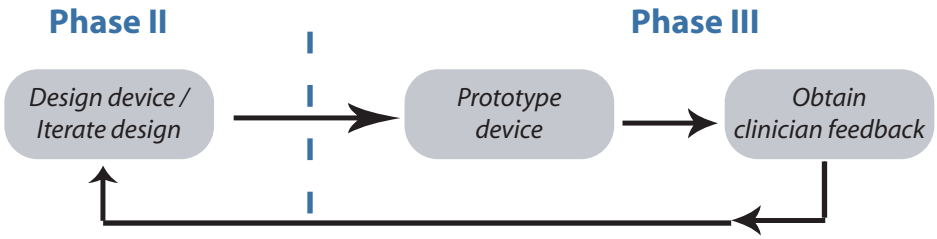
Development process of a medical device

The table below [**20**] is a simplified version of the development process of a medical device. While developing a device, many elements must be taken into consideration. Typically, the design & development and verification & validation phases of a new device takes place from phase II to IV.

DEVELOPMENT PROCESS

Phase I	Phase II	Phase III	Phase IV	Phase V
Initiation Opportunity and Risks Analysis	Formulation/ Concept and Feasibility	Design & Development/ Verification & Validation	Final Validation/ Product Launch Preparation	Product Launch and Post-Launch Assessment
Initial evaluation of possible development of commercial product	*Definifition of design input based on customer needs and technical requirements*	*Development of product design and of manufac-turing process; verification and validation*	*Definifition of design input based on customer needs and technical requirements*	*Market introduction of new product; continuous improvement of the device*

It is also during those phases that clinician feedbacks and the performance testings take place. Due to the many challenges and complexities associated with medical design and development, a smooth development path rarely occurs. A device concept is always prototyped to be presented to device users such as physicians and nurses. The protype is then tested. If the tests are bad, the model is re-evaluated and the design device re-designed and a new prototpye is created. As read in the history of the pacemaker, the hip implant and the TVT, those two phases can be very long and involve the work of many researchers, engineers, professors and doctors to develop the best devices.



Thinking ahead to meet future patients' needs

For some devices, the history can be long and implicate many actors but it is only by trying, testing and hearing what patients have experienced that you can achieve the best results.

Research and development in the medical device industry never stops; it is always about thinking ahead of time, predicting the health challenges of tomorrow and designing the new generation of devices which will meet those challenges and foster good health in Europe. The needs and expectations of Europe's future population will continue to increase in areas such as cardiovascular, orthopaedics, home and diabetes care to name just a few.

In the future, the industry will emphasise research into:

- Less invasive procedures
- Miniaturisation of devices and procedures with nanotechnologies
- Continued material development and drug/biologics device combinations
- Opportunities for cell therapy and regenerative medicine
- Integration of computer technology for patient-driven homecare and home monitoring
- Healthcare Information Technology to increase the number of installations of electronic medical records
- The occupational safety and efficiency of healthcare staff

Innovate in a global economic downturn

The current economic downturn is compromising the capability of the medical technology industry to find the necessary resources to innovate. While in Europe there seems to be no decline in innovation potential, some short-term clouds on the horizon are visible in terms of who is funding that innovation.

Due to the economic crisis, it has become almost impossible for early-stage companies to raise capital in the market. If SMEs are not able to access funding to start and run their activities, it is more than likely that these companies will not start up at all. The same holds true for younger companies which, up to three years ago, were viable and on track to generate good profits and which will also fail as they will be not able to get new funding. In the years to come, however, Europe will need exactly these companies. Additionally, investment in research and development at a corporate level in established companies will decrease, which in turn will lead to a reduction in their capacity to innovate.

Europe has the opportunity to leverage investment in medical research and development and develop products and services that can benefit trade and employment in Europe. If this does not happen in Europe, countries elsewhere in the world will seize the opportunity, and other parts of the world will benefit from European medical research and development spending.

Urgent actions from the European Institutions and member states are therefore required to support SMEs and to promote their growth and potential for innovation by implementing new policy measures especially tailored to their needs. Innovation as a whole should also be promoted and its development facilitated to continue to close the gap with the US and Japan, and to avoid seeing European innovations migrate to those areas.

Promotion of innovation at EU level

Public consultation on the effectiveness of Innovation Support in Europe

On 6 March 2009, the European Commission launched a public consultation in order to get insights on how to best improve the effectiveness of public innovation support mechanisms in the EU, against the background of constantly evolving innovation patterns in enterprises. Two questionnaires are available. The first one for the beneficiaries of innovation support measures, the companies, and the second one for key institutional stakeholders active in the design, funding, implementation, and evaluation of innovation support measures at regional, national and European level to give their opinion on the key issues of better innovation support in Europe.

The consultation is closed for comments on 4 May 2009. Its results will be summarised in a Commission Staff Working Document scheduled for publication in June 2009 [21].

2009 , The European Year of Creativity and Innovation (EYCI) [22]

2009 is the year of creativity and innovation in Europe. Throughout the year, the European Commission aims to raise awareness of the importance of creativity and innovation for personal, social and economic development; to disseminate good practices; to stimulate education and research, and to promote policy debate on related issues. For this occasion, the Commission created a website which serves as a platform for access to projects, and explains how to participate in the Year and to provide news on events taking place during the 2009.

EYCI 2009 takes place within the overall framework of several EU policy initiatives fostering Creativity and Innovation. These include amongst others the following:

- Recommendation of the European Parliament and of the Council on key competences for lifelong learning
- Council Resolution on new skills for new jobs
- Broad- based innovation strategy for the EU
- European policy cooperation in Education and Training
- European agenda for culture in a globalizing world

Pro Inno Europe – European Innovation 2008 Scoreboard

The European Commission Directorate General Enterprise & Industry, under its initiative "Pro Inno Europe", also published in January 2009 the "European Innovation 2008 Scoreboard" which provides a comparative assessment of the innovation performance of EU Member States, under the EU Lisbon Strategy.

The 2008 Scoreboard uses measures for a range of innovation dimensions:

- Availability of human resources, and public and private finance – 'enablers', outside individual firms;
- Investments by firms, collaboration between firms and between firms and public sector organisations, entrepreneurial effort, intellectual property rights generated through innovation – 'firm activities', or the direct efforts of firms to innovate;
- Firms which have brought innovations to market, or introduced them to their own processes, and the economic effects of innovation – 'outputs' of firms' innovation.

Based on data covering the years 2006 and 2007, the effects of the current economic crisis on innovation performance do not yet show up in the indicators. Consequently, it will be interesting to analyse next year's report and see how the economic downturn affected innovation in Europe. The complete document is available on the **Pro Inno Europe website** [**23**].

Sources

[1] **"Looking to the future - The Healthcare Century"**
Presentation of Martin Dewhurst , McKinsey & Company (16 October 2008 - Ecomed MedTech Forum)
Available upton request.

[2] **Eucomed Activity report 2007-2008**
http://www.eucomed.be/press/publications.aspx

[3] **BVMed Annual Report 2007/2008**
http://www.bvmed.de/stepone/data/downloads/16/c7/00/annrep0809.pdf

[4] **Facts and figures - SMEs in Europe**
http://ec.europa.eu/enterprise/entrepreneurship/facts_figures.htm

[5] **Communication from he Commission on the European Competitivness Report 2008**
http://ec.europa.eu/enterprise/enterprise_policy/competitiveness/doc/compet_rep_2008/com_2008_0774.pdf

[6] **The Changing Economics of Medical Technology**
Institute of Medicine (IOM), 1991

[7] **"Small Business Act" for Europe**
http://ec.europa.eu/enterprise/entrepreneurship/sba_en.htm

[8] **First European SME Week**
http://ec.europa.eu/enterprise/policies/entrepreneurship/sme-week/index_en.htm

[9] **SME Case study**
Text kindly provided by IMDA, t he Irish Medical Device Association
http://www.imda.ie

[10] **Pacemaker Implant Rates per Million Inhabitants**
http://www.eucomed.be/press/~/media/2D4C2A1B97814750812095C618665F84.ashx

[11] **Invention of the cardiac pacemaker**
http://inventors.about.com/library/inventors/blcardiac.htm

[12] **Artificial Pacemaker**
http://en.wikipedia.org/wiki/Artificial_pacemaker

[13] **Treatment of Osteoarthritic Change in the Hip Joint Preservation or Joint Replacement?**
http://www.springerlink.com/content/g2r27vx66137h41r/

[14] **Hintergrundinformationen zum Stand des künstlichen Gelenkersatzes in Deutschland**
BVMed-Medienservice 2009

[15] **The new hip trend**
http://articles.latimes.com/2006/jun/05/health/he-joints5

[16] **Profession John Charnley**
http://rheumatology.oxfordjournals.org/cgi/content/full/41/7/824

[17] **Kim C. Bertin, M.D.**
http://www.utahboneandjoint.com/html/kim_c__bertin__m_d_.html

[18] **Eucomed Focus on the Value of Medical Technology**
http://www.eucomed.org/press/focus_on.aspx

[19] **Study Supports Minimally-Invasive Surgery for Stress Urinary Incontinence in Women**
http://nursing.advanceweb.com/editorial/content/editorial.aspx?cc=121707

[20] **Study on Medical Device Development Models**
http://medicaldesign.com/mag/model_device_development_0908/

[21] **Public Consultation on the effectiveness of Innovation Support in Europe**
http://ec.europa.eu/enterprise/newsroom/cf/itemlongdetail.cfm?item_id=2490

[22] **2009, the European Year of Creativity and Innovation**
http://create2009.europa.eu/

[23] **Pro-Inno Europe**
http://www.proinno-europe.eu/index.cfm?fuseaction=page.display&topicID=437&parentID=51