Medical devices: from concept to creation

Zoe Pagett and Robert Morris

Abstract The design and production of a medical device (any device intended to be used for medical purposes) is a fascinating process, involving a multitude of extremely varied job roles, from the initial bioengineers creating the design of the devices all the way through to the regulatory compliance team making sure the device meets all the requirements of governing bodies. All the jobs have one thing in common: they are working to try to improve the lives of millions of people worldwide. This article provides an insight into the different stages involved in producing a medical device, specifically a joint replacement device, including detailed discussions of the different job roles involved. An interactive game has also been included to help visualise these different phases of producing a medical device.

The global medical device market was valued at an estimated $450 billion in 2019 and is still growing, covering everything from inhalers to pacemakers. An increasingly ageing population means new ideas and developments in the medical device and orthopaedics industry are continually needed to help preserve and improve the population's quality of life. This article aims to give you an insight into the five main stages involved in producing a medical device, specifically a joint replacement device. A wide variety of job roles are involved in these five stages; this article runs through a selection of these job roles, giving a broad overview and discussing some of the pros and cons as provided by real-world professionals working at DePuy Synthes, a medical device company specialising in joint replacement devices. An interactive game is also included to help visualise the different phases of producing a medical device.

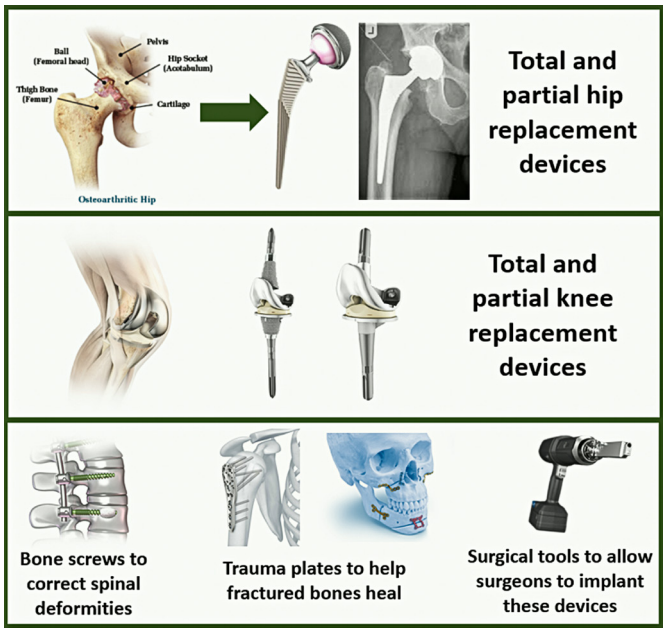

Figure 1 Medical devices produced by DePuy Synthes to solve conditions relating to orthopaedics

Medical engineering and orthopaedics

Medical engineering is the application of engineering principles to produce products to solve problems with the human body, ranging from advanced robotic prosthetic limbs to simple reading glasses. It has had a huge impact on human welfare and continues to design solutions to some of the biggest challenges facing human health. Orthopaedics is a sector of medical engineering involving the diagnosis and treatment of all problems involving the musculoskeletal system. This includes conditions relating to:

- bones – such as fractures and deformities;
- joints – such as arthritis and sports injuries.

Many of these conditions can be treated with medical devices such as those shown in Figure 1. This article focuses on joint replacement devices.

How are joint replacement devices produced?

Stage 1: Design phase

The population of the world is gradually increasing in age. With this age increase comes an increase in associated joint problems, such as arthritis, and a need for joint replacement devices. Arthritis is the swelling and tenderness of our joints; as we age, we wear down the protective cartilage within our joints, in particular the hip and knee. This wear causes the bones to rub against each other, causing pain and limited movement (Figure 2).

Joint replacement devices replace part or all of a joint. The first step in a joint replacement device's journey starts with doctors/surgeons working with bioengineers to discuss problems identified in patients for which solutions need designing.

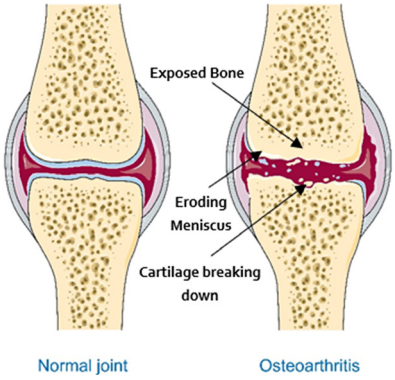

Figure 2 Comparison between a healthy and an arthritic knee joint; image provided by Laboratoires Servier, cc by SA 3.0

Once a problem has been identified, bioengineers work to come up with the solution. They do this by using patient X-ray data, computer-aided-design packages and knowledge of human anatomy to produce 3D models of potential solutions. Computer simulations of the models are run to gain an insight into how they will perform in physical testing. The requirements of patients vary greatly and so the devices must be easily adapted to fit the specific needs of patients.

Bioengineers must carefully consider which materials to use to construct their devices to ensure the highest level of comfort for the patient, as well as to ensure that the device has a sufficient lifespan, to minimise the risk of a revision of the implant being required. Particular focus is brought upon the bearing surfaces of the device, which are the surfaces that interact and glide against each other during activity and movement. There are three main bearing combinations for joint replacement devices: metal-on-metal bearings, metal-on-polyethylene bearings, and ceramic bearings. Each combination has its own advantages and disadvantages. Bioengineers will work with doctors and material science specialists to establish what combination of materials would be most suited for the device. This decision is based on a number of aspects, such as intended movement, potential friction (which may lead to wear of the device) and patient allergies.

Metal (typically titanium, cobalt-chromium or nickel) on polyethylene is one of the most commonly used bearing combinations. The metal part provides strength and stability, mimicking the mechanical properties of natural bone, while the polyethylene part provides a smooth surface with minimal risk of wear. The metal selected may vary as some patients may have an allergy to nickel, cobalt or chromium – in these cases titanium will be the metal of choice.

Stage 2: Testing phase

Once a design is finalised, it needs to be tested. Testing rigs are set up where devices are placed under a variety of different loads to test the effects friction has on the wear and tear on the device's surface; this process is called tribology. Testing can run for thousands of cycles, simulating different movements such as walking, sitting down or climbing stairs to understand how the device will perform throughout a patient's lifetime. Biomechanics testing is also performed, where devices are placed under varying loads to find information such as the device's breaking points and what exactly happens when the device fractures.

Stage 3: Sterility assurance and manufacturing

Challenging features such as small holes, springs, hinges and so on, can make a device difficult to clean and sterilise. Sterility assurance scientists assess proposed designs to determine whether they pose a significant challenge in this regard. They work with engineers to reduce any cleaning challenges by altering the design. They may run the device through a full cleaning process before performing a number of cleanliness tests to ascertain the levels of harmful bacteria and manufacturing contaminants left on the surface of the device. This ensures that the device can be effectively cleaned and sterilised before being implanted, which is crucial for avoiding potentially life-threatening infections.

Once a device has passed all the above tests, production can begin. This involves the device being passed from machine to machine, each performing a very different step, from block cutting to high-precision drilling to laser marking. Once the device is produced, it is cleaned and transferred into a cleanroom for final vacuum packing and labelling. All devices come with a batch card for traceability purposes, which shows all the steps in the manufacturing of the device; each stage of the batch card will be signed off once complete to confirm that the stage has been carried out correctly according to the relevant instructions.

Stage 4: Regulatory compliance

In order to sell a device, evidence must be collected and put together showing that it is safe to be in contact with the body and that it performs exactly how it should. This evidence is collected by regulatory and medical affairs professionals, using the most up-to-date literature reviews, test data and clinical-study data. This evidence is put together into packages called tenders and presented to regulatory governing bodies for approval before it can be sold in the market. Once this has approval has been granted, the device is legally allowed to be sold. The evidence packages are then presented to potential buyers such as the NHS in the UK.

Stage 5: Post-market surveillance

Once the device has been made, released to the market and purchased/implanted, post-market surveillance begins. Post-market surveillance monitors the long-term

performance of devices and feeds this information back to the bioengineers to help them improve the devices. Joint replacement devices are intended to last the lifetime of the patient. However, despite all of the testing and quality checks, devices can sometimes fail, most commonly through improper surgical alignment and excessive loading, which leads to the device fracturing. When this occurs, the device is simply removed and a replacement device is implanted. The devices that are removed are studied by bioengineers to investigate why they failed and how to prevent this in the future. They are then either recycled (e.g. metal implants are melted down and repurposed) or disposed of.

Conclusion

This article has provided you with a broad overview of the five main stages involved in producing a joint replacement device. This is, however, very applicable to all medical devices. Figure 3 gives a visual representation of the process. Figure 4 provides an interactive game that will bring this information to life.

In Boxes 1 to 5, real-world working professionals from DePuy Synthes share more about what their jobs entail. There are countless varied job roles within the medical engineering industry with each role being equally vital to the production of devices that save lives. Medical engineering is an extremely fulfilling and rewarding

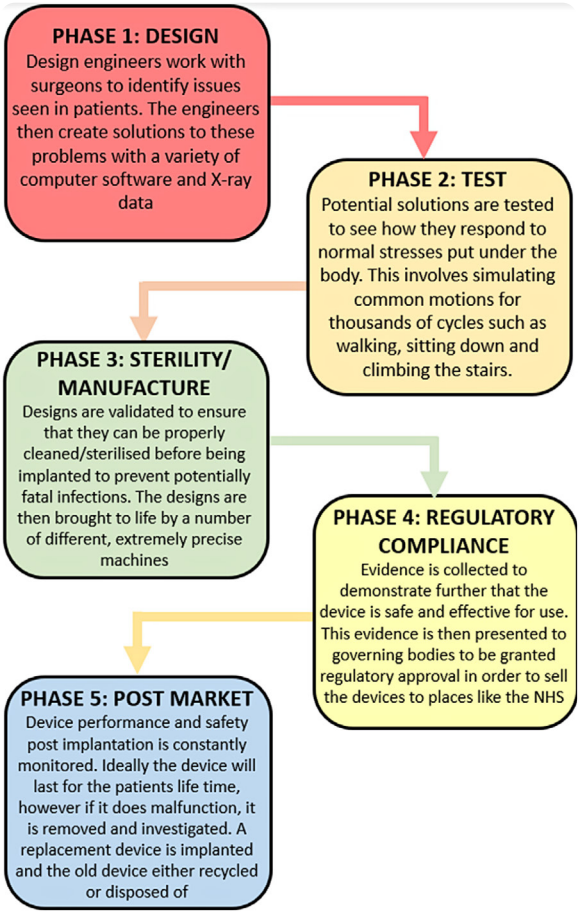

Figure 3 A visual representation of the life cycle of a joint replacement device

Box 1 Case studies: Design phase

Customs Design / Bioengineer

Customs Design Engineers use the latest technology and specialist knowledge of the human body to design custom-made, patient-specific implants and instruments. The specific needs of the patient are determined by analysing patient X-ray data and working closely with surgeons. CAD (computer aided design) is then used to create 2D and 3D models of the custom implant designs. Bioengineers do exactly the same; however, they produce new device designs as opposed to patient-specific devices. These models are then produced using CAM (computer aided manufacture). Once the custom implants have been fully inspected, they are sent to the surgeon who implants the custom device into the patient. Custom design engineering is a fast-paced department: engineers need to be able to design and manufacture custom implants quickly to prevent prolonged discomfort for the patient.

My favourite thing about my job is the fast pace that the team works at, as it means that there is never a slow or dull moment. I would recommend custom design engineering to someone else, as working with real patients is incredibly fulfilling and you know your designs have made a real difference to someone's life. Something that I find excites me about the future of medical engineering is probably the ever-decreasing size of electronics, soon allowing for lots of flexibility for them to be used in more wearables or medical devices.

Ben Schofield – Customs Design Engineer at DePuy Synthes

Design Quality Engineer

Design Quality Engineers are crucial in developing processes, testing procedures and implementing systems to ensure all activities performed throughout a company fulfil quality standards and meet the strict safety regulations set by governing bodies all across the world.

They work closely with Bioengineers and Custom Design Engineers to support them in a wide range of activities. These include helping to design devices to make them easier and more accurate to manufacture, or participating in risk-management activities for new devices and processes to identify potential risks and issues and tackle them to prevent future major incidents. They also monitor the transference of product and process designs to production, to ensure the design team thoroughly and effectively transfer their designs so that manufacturing can produce the device to the specified dimensions in order for it to perform its function once implanted.

Working in design quality engineering involves a load of different departments of DePuy which leads to projects involving both lab machines and equipment as well as implants/instruments. My favourite thing about my job is meeting and working with lots of different people, on different projects, and knowing that the work I am doing will make a difference to one or many people's lives. This makes working in medical engineering very rewarding and keeps me motivated.

Arya Nicum – Design Quality Engineer at DePuy Synthes

Box 2 Case studies: Testing phase

Tribologist

Tribology is the study of friction, wear and lubrication of interacting surfaces. Tribologists study how surgical implants will wear over the course of their lifetime and how they will behave in the body by using simulators that imitate movement such as walking, jogging or going up stairs, and then use surface texture scanners and various other machines to assess the wear of the implant. Tribologists also work alongside bioengineers and design teams to develop test protocols for the implants and then run them. After this the data are processed so that a report can be produced detailing the efficacy of the implant and instruments and hence informing the design team whether an implant or instrument will be effective and if not, how it could be improved.

The best thing about my job is being both desk based and hands on in the lab. It is great to know the work we do helps to make these implants the best they can be to accommodate the needs of the users. Working in tribology gives you a great insight into the testing and level of accuracy that needs to be upheld to get a medical device to market. It can be difficult though: you have to be really vigilant, whether it is writing in lab books or setting up a machine. I would recommend a career in medical engineering as the work you do in this field has a genuine impact on the quality of people's lives; you develop skills in engineering and appreciation of human anatomy. As technology advances the possibilities of applications of this to medical scenarios are endless.

Eleanor Cooke – Tribology Engineer at DePuy Synthes

Biomechanical Engineer

Biomechanical Engineers develop test protocols that represent, as accurately as possible, the conditions that an implant or instrument will be subjected to during surgery and across its lifetime. Testing can include heating up instruments to mimic cleaning or throwing instruments between buckets repeatedly to see the effect of impact or hitting an instrument many times. The test investigates new concepts and helps to inform the design teams which concepts will be most suitable for the implants and instruments. After the tests have been set up and completed the data are processed to produce a report that acts as an official record of the test results.

Biomechanical Engineers also carry out research such as finite element analysis on new device designs, which predicts how a product reacts to real-world forces, to help assist with the design of products.

I really enjoy the balance between practical work and 'at-desk' work, which keeps my role very interesting. Due to their application, medical devices must conform to very strict standards, which bring about challenges both in how they are designed and how they are tested. The relationship between testing and developing products is vital and seeing the results of my tests improving future designs is so rewarding; I am able to work on innovations that will help improve people's lives all over the world! Being on the cutting edge of medical devices and making a positive change globally makes medical engineering an extremely rewarding industry to work in.

Lucie Gale – Biomechanical Engineer at DePuy Synthes

Box 3 Case studies: Sterility assurance and manufacturing phase

Sterility Assurance

Once inside the body, implants will interact with the immune system and if there are any foreign substances present on the device, such as bacteria, this could cause severe infections around the implant leading to life-threatening complications. That is why all medical implants and instruments must be kept sterile. Sterility Assurance Scientists help to design implants and instruments to make them easier to clean and sterilise, and then test devices to demonstrate that they can be adequately cleaned and sterilised. They also write strict testing protocols to regularly check sterility levels of products, water systems, cleanroom environments, and many other aspects to ensure at every stage of the manufacturing process they are creating a clean and sterile product.

One of the best things about working in sterility assurance is the variety: my roles range from testing the water that parts are processed through to monitoring cleanrooms, coordinating parts for external microbiological testing and summarising our results in reports. I would recommend this job, especially if you enjoy a combination of microbiology and engineering. Medical engineering is an exciting and rewarding field to work in as you get to improve the lives of real patients. The increasing age of the population gives lots of scope for future development and progress within the field.

Zoe Pagett – Sterility Assurance Scientist at DePuy Synthes

Manufacturing Engineer

Once a device has passed all required tests, it can begin production. Manufacturing Engineers are responsible for the design and operation of all machines and processes involved in the manufacture of the device. The manufacturing route of a medical device is extremely complicated, involving multiple, very different stages. In general, there are two main routes:

- Additive manufacturing – this is where a device is built by adding material layer by layer from the ground up, for example by 3D printing.
- Subtractive manufacturing – this is where a device is made my removing material from a larger object, for example by cutting, drilling, grinding, laser marking, etc.

The role of a Manufacturing Engineer involves planning and prioritising device production to meet business demands, validating new machines, responding to incidents and much more.

I love my role as a Manufacturing Engineer because I get to work with so many different, incredibly intricate and fascinating machines. Being able to coordinate, control and finally watch all these machines come together to produce a device that is going to help improve someone's life is extremely fulfilling and I couldn't recommend it more. There are challenges: it can be very busy and pressured, especially when there are strict targets to be met, but we always come together as a team.

John Boston – Manufacturing Engineer at DePuy Synthes

Box 4 Case studies: Regulatory compliance

Regulatory Affairs

In order to sell medical devices in a specific country, a company must meet that country's specific regulatory requirements to effectively demonstrate that the device is safe to use and will perform its intended role. Regulatory Affairs is crucial in accomplishing that, effectively allowing a company to sell its products all over the world and allow the health benefits of the product to reach millions of people. Every country has its own very specific product requirements that vary greatly, and it is the role of Regulatory Affairs to show a product complies with all of them. This can include putting together evidence packages demonstrating the safety and efficacy of a product, finding certificates, renewing licences, legalising or notarising documents, and much more.

My favourite thing about my job is that no two days are the same. Every request is unique, each with its own requirements, challenges, and learning points. It can get very complicated and difficult to navigate at times due to the number of different share points and databases; however, it usually only takes a bit of communication with the right contacts for these issues to get solved. I would definitely recommend a career in medical engineering. It is so interesting, the industry has the capability of improving quality of life for people all over the world. A day's work enables you to exercise a wide-ranging skillset and engage with a range of people.

Freya Hedley – Regulatory Affairs Specialist at DePuy Synthes

Medical Affairs

When selling medical devices to buyers such as the NHS, tender evidence packages must be created and presented. These evidence package includes clinical evidence, literature searches, test results and complaint data that support the safe and effective use of a company's products. The Medical Affairs department is responsible for putting together these packages to convince buyers that the company's products are the best on the market. They must ensure their publications are kept as up to date as possible by constantly reviewing literature and clinical-trial data. The department is also responsible for tracking the number of products sold and used worldwide and any issues identified with them, which is extremely importance as it is one of the main ways in which devices can be improved to prevent the issue recurring. In summary, the Medical Affairs department works to aid the selling and tracking of medical devices.

My favourite thing about the job is the connections I get to make across the globe and understanding communication on a deeper level. I like working in the medical device industry as it is an innovative industry that offers me the opportunity to make an impact on improving people's quality of life. I would recommend my job to others, as it is a friendly company with plenty of perks, in which to build your professional portfolio. The most difficult thing about my job is learning to use Excel more thoroughly!

Abbie Hayes – Medical Affairs Specialist at DePuy Synthes

Box 5 Post-market phase

Customer Service and Complaint Management

The Customer Service department is responsible for the journey of a medical device from warehouse to customer. This involves taking calls from sales reps and customers, coordinating with the warehouse team and ensuring delivery is accurate and on time to hospitals and customers. The customer service experience is constantly being updated and improved through, for example, automation and digitalization, which provide a much smoother, quicker more efficient service that benefits both the company as a whole and customers.

The Complaint Management team review all sorts of complaints regarding the company's products and it is their job to investigate these complaints and gather as much information as possible to feed back to the engineering team so that they can modify their designs to ensure the issues don't happen again.

For me, the best part of working in Customer Services is the variety of tasks and knowing that I am helping to improve the process of dealing with customers as well as helping to improve customers' experience with the company. There is constant innovation within the company, which gives you the opportunity to grow and develop while working alongside a great team. It can be difficult to know how to communicate with hospitals appropriately to understand their needs as a customer, but this is a skill you develop over time as you gain experience.

Charlotte Alpar – Customer Service department at DePuy Synthes

career where you are able to work to improve the lives of millions of people all around the world.

If you would like any more information about the work we do at DePuy or about medical engineering in general then please get in touch using the emails below. Furthermore, we have multiple virtual work experience sessions at DePuy Synthes running throughout the year for students aged 16+; please contact us for more information.

Instructions for the game (Figure 4, overleaf)

To play this game, print off the game board. You need a die, and a counter for each player. The aim of the game is to simulate bringing a medical device to market. Players take it in turns to roll the die and move along the board following the numbers in the squares, moving through the different stages of producing a medical device. Every time you land at the base of a green implant, you go up to the top of the implant while checking out the closest green box around the outside of the game to see what has gone well with your project. Every time you land at the top of a red fractured bone, you must go down to the base of the bone, looking at the closest red box to see what has set you back. The winner is the person who reaches square 56 first, getting their medical device on the market fastest.

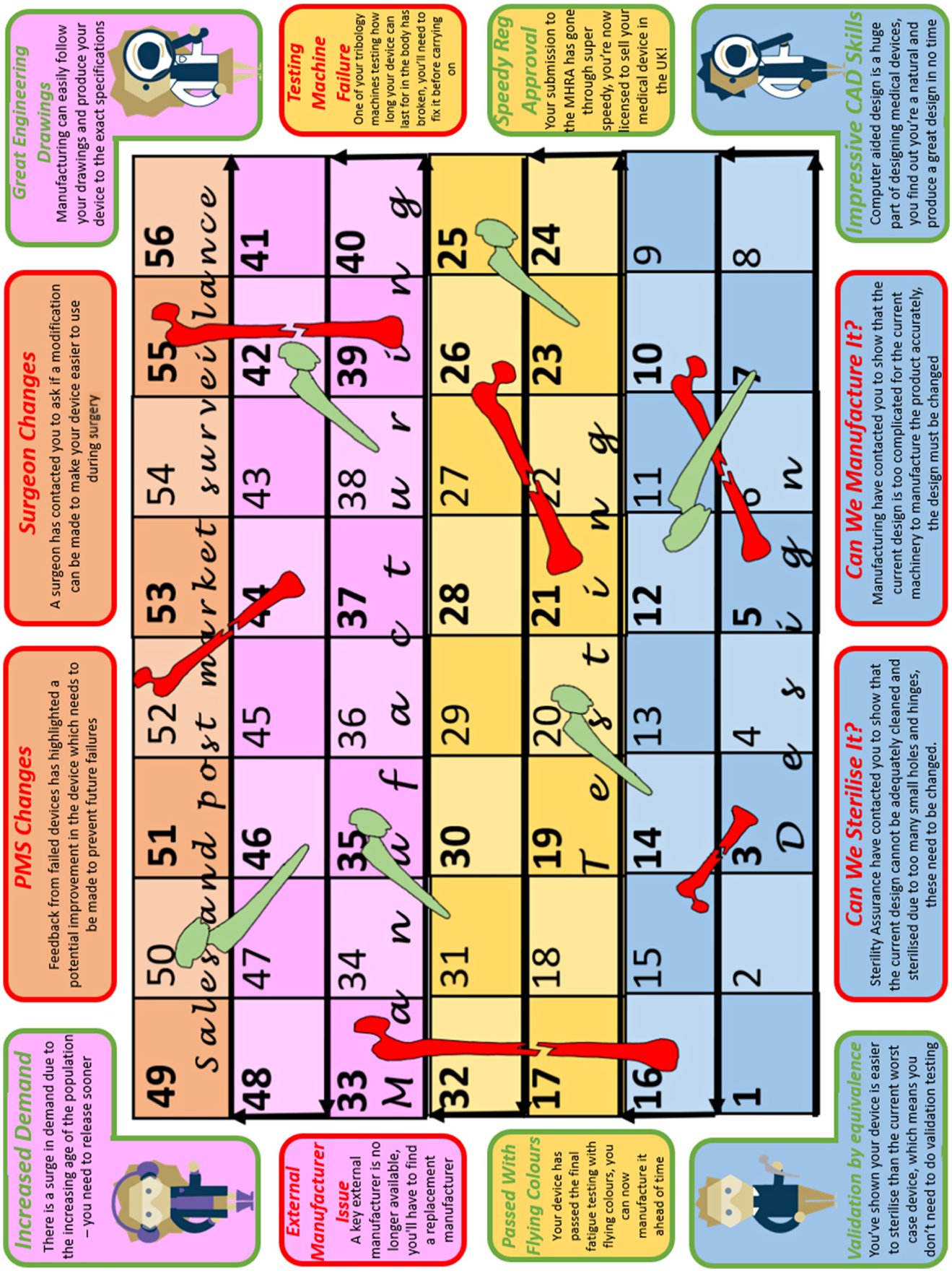

Figure 4 An interactive game to bring the development process of a joint replacement device to life

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