



Personalised surgical process for joint replacements

**A joint statement of demand for innovation in the joint
replacement care pathway to improve patient outcomes**

A JOINT STATEMENT OF DEMAND FOR INNOVATION IN THE JOINT REPLACEMENT CARE PATHWAY TO IMPROVE PATIENT OUTCOMES

Corporació Sanitària Parc Taulí (CSPT) has identified an unmet need for solutions to enable the personalisation of the joint replacement surgical pathway.

This joint statement of demand describes the current situation and its limitations, why innovation is needed, and the outcomes required of new and alternative solutions.

In order to demonstrate a credible market demand for a solution that can deliver these outcomes, we have been reaching out to other hospitals that may have a similar need and may, in the future, be interested in buying such a solution and / or collaborating in this initiative.

The following organisations have confirmed that they support this initiative and share this unmet need:

*Biodonostia Health Research Institute (Spain)
Vall d'Hebron Barcelona Hospital Campus (Spain)
Hospital Clínic de Barcelona (Spain)
Vilnius University Hospital Santaros Klinikos (Lithuania)
Sant Joan de Deu Hospital (Spain)
Italian Society of Architecture and Engineering in Health (Italy)*

Via this document we are continuing to reach out to other healthcare providers who may be interested in new and innovative solutions to improve the joint replacement pathway. We therefore invite you to read this statement of demand and provide your feedback via a short survey. Alternatively get in touch with us via email. You can find the link to the survey and email contacts at the end of the document.

Please pass this document onto anyone you think would be interested.

Personalised surgical process for joint replacements

Our aim is the **personalisation of joint replacement**, shifting from a 'best fit' scenario to tailor-made joints for each patient.

Personalised medicine is becoming more and more common in clinical practice. It has been proven to provide both patients and physicians with considerable benefits, such as increased satisfaction, as well as the possibility of enhancing the efficiency of the health system, reducing costs and avoiding post-operative complications. [1]

Why innovation is needed

A joint replacement is a surgical procedure in which parts of a damaged joint are removed and replaced with a metal, plastic, or ceramic prosthesis, which is designed to replicate the movement of a healthy joint.

In 2019, 595 joint replacements were performed in CSPT, with 120,000 in Spain and more than 3 million across Europe. Moreover, as the general population ages, the number of joint replacements is expected to increase every year.

Success factors in joint replacement

Joint replacement is a complex operation and the most important determining factors for success are the fit of the implant to the patient's body, and the suitability of the implant for the specific characteristics of the patient including gender, height, weight, and age.

"It is essential for the surgical outcome that the surgeon has all the possible options at their disposal in order to select the best possible fit for the patient during the operation."

Alex Berenguer, MD, PhD Orthopedic Hand Surgeon
Hospital Universitari Parc Taulí Sabadell

In this scenario, the surgeon has to make important surgical choices that have consequences in terms of patient outcomes, cost, and use of resources during the operation based on professional judgement and experience. These 'in situ' choices include the material to be used, the optimal positioning and the size of the implant.

Consequently, the surgeon needs to have a sufficient range of trial implants and instrumentation available to them during the operation, and each of these needs to be selected and sterilised in advance of the surgery.

An additional complication for the surgical team is that the most appropriate size might not be available. The manufacture of implants and instrumentation is based on a supplier's prediction of how many of each size will be needed in any given year. As a consequence, the supply of minority sizes can become limited. In Spain, this problem is exacerbated by the population's characteristics meaning that a greater number of minority sizes are required than in other countries such as the US. [2]

Another important aspect of the surgical process is the pre-operative assessment of the patient to enable the surgeon to narrow down the number of trial implants that have to be prepared. Currently this includes a CT scan, which is limited to the joint in question due to concerns about excessive radiation exposure. Increased precision and interpretation of the measurement, and moreover a whole-body comprehensive biomechanical and medical assessment scan would enable optimisation of the design of a patient-specific solution.

Tailor-made solutions would remove the resource-intensive preparation for surgery and optimise the joint replacement process. By 'tailor-made' we mean bespoke implants and patient-specific instrumentation enabled by precision measurement taking into account variables such as height, weight, age, derived during the pre-operative examination process that can be processed to enable on-demand, personalised manufacture of implants and patient-specific instrumentation.

*"We find that in some cases the positioning and fit of new joints are less than ideal, which may cause post-operative and functional complications, resulting in periodic revisions and in some cases revision surgeries. **With a tailor-made solution, this issue would be eliminated and now technology can make this possible".***

Ferran Fillat, PhD Orthopedic Surgeon and 3D Surgical Planner Specialist,
Hospital Universitari Parc Taulí Sabadell

The traceability of the whole surgical process from the point when the responsible surgeon indicates a surgery until it is carried out is necessary to monitor the whole process. This is essential for compliance with European regulations on custom-made medical devices. [3]



The requirement

The unmet need that we have identified can be summarised as follows:

Personalised surgical process for joint replacements, incorporating:

- The **design** and on-demand **manufacture** of tailor-made joint replacements and patient specific instrumentation
- Pre-operative precision **measurement** incorporating whole body assessment to optimise the personalised biomechanical performance
- The **monitoring** and **full traceability** of both the manufacturing and surgical process

The solution should:

- Deliver **demonstrable** clinical, cost and resource benefits
- Have the potential to be **applied** to other areas of elective surgery
- Meet all necessary **standards** in relation to quality, approvals, ethics and data protection, inter-operability etc.

What can you do next?

Thank you for taking the time to read this Statement of Demand. CSPT is keen to identify and engage with other surgeons, hospitals, and healthcare providers that have the same or similar needs before we start communicating with potential solution providers. At this stage, we have the flexibility to adapt the Statement of Demand to include particular needs that would increase its relevance for other interested healthcare providers.

Demonstrating that there is a wider potential market will better encourage potential suppliers to invest in developing innovative solutions that meet the unmet needs identified.

Your voice is vital to encourage suppliers to innovate to provide solutions. If you also believe that this subject is an unresolved issue or unmet need or would like to provide feedback, then please express interest by clicking the link below. This will take you to a short survey where we ask a few simple questions.

[**Click here to complete the survey.**](#)

About the buyer

This Statement of Demand has been developed by the following partnership in the context of the EcoQUIP+ project:

Corporació Sanitària Parc Taulí (CSPT) is a healthcare centre, which provides high-quality health care to a population of 420.000 inhabitants in the eastern Catalan region of Spain. As an indicator of its activity, CSPT is equipped with a total of 744 beds, including Intensive Care Units (ICU) beds, rehabilitative care beds and long-term care beds.

Fundació Parc Taulí (FPT) is an organisation that supports biomedical teaching, training, and research in collaboration with CSPT. FPT provides researchers with facilities for basic research, assistance in search of funds for scientific and medical research.

Agència de Qualitat i Avaluació Sanitàries de Catalunya (Agency for Health Quality and Assessment of Catalonia, AQuAS) is a public entity of the Catalan Department of Health whose mission is to generate scientific and relevant knowledge to contribute to the improvement of the quality, safety, and sustainability of the healthcare system.



References

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3. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EE [Internet]. 2017 [cited 2020 May 6]. Available from: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745>

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About EcoQUIP+

EcoQUIP Plus (www.ecoquip.eu) is a collaborative innovation procurement project in the healthcare sector. EcoQUIP Plus aims to demonstrate how pro-innovation procurement methods can improve the efficiency, quality and sustainability of healthcare and to increase the take up of much needed innovative solutions through collaborative actions.

If you would like to find out more about EcoQUIP+ please visit:



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