

Innovation Across Borders – Forum VBO-FEB

Innovation Case Preparation Form

WHO

- Welke onderneming(en) werd(en) hierbij betrokken? (grootte, bedrijfssector,...)?
- Met welke partner(s) (clusters, O&O-centrum, spin-offs, hubs,...)?

3D-Side S.A. is a Belgian spinoff company that develops, manufactures and sells patient-specific products for complex bone surgeries. The company was founded in 2015 as a result of two PhD projects in tumour surgery (Laurent Paul (2009), *Computer-assisted resection and reconstruction of pelvic tumor sarcoma*, Université catholique de Louvain, Brussels) and neurosurgery (Khanh Tran Duy (2008), *Design and analysis of an assistance device for orthognathic surgery*, Université catholique de Louvain, Louvain la Neuve). After completing his thesis, Khanh Tran Duy single-handedly launched CENTIS to integrate 3D technology into the medical field. Following an R&D phase, he developed a patient-specific mould for cranial implants. Once regulatory analysis and certification were complete, CENTIS began selling this product in Belgium. Laurent Paul founded Visyos to aid surgeons in the treatment of bone tumours. While developing this concept, Paul shifted from navigation-based assistance (a GPS-like system for bone surgery) to patient-specific instruments. Visyos was the only company in the world to market such instruments for bone tumour surgery, with development predominantly focused in Belgium and France.

CENTIS and Visyos first teamed up in 2011, sharing regulations, certification, technical needs and opportunities. In July 2014, after several years of strong and fruitful cooperation, Laurent Paul and Khanh Tran Duy decided to merge their activities with a view to certifying the technology and tapping into European markets. After a quick and successful fund-raising campaign led to the creation of 3D-Side in February 2015, they hired four people and purchased an in-house 3D printer. Although the company has only been in existence for just over a year, behind it lies almost 15 years of research and over 120 surgical cases sold in Belgium, France and Spain so far.

3D-Side assists surgeons by introducing 3D technologies to operating theatres, from medical images to operating theatres. The company combines engineering accuracy with medical expertise to tailor surgical treatment to each respective patient. Using 3D software, additive manufacturing technologies and extensive knowledge of the surgical field, the product portfolio has now expanded into advanced 3D planning, bone models, surgical guides and dedicated implants. The instruments reliably shift preoperative planning into the operating room, increasing the quality of healthcare while cutting operating times.

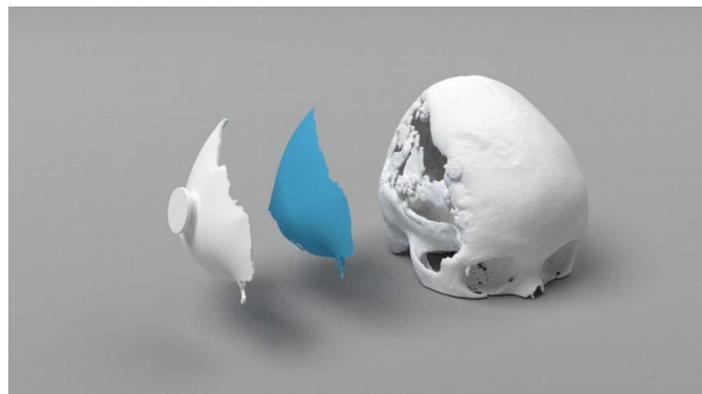
WHAT

- Wat was de doelstelling van de innovatie?
- Waarin bestaat precies de innovatie (toepassing, soort innovatie – product/procedé/businessmodel/support diensten/management,...)?

3D-Side proposes a new concept to repair skull defects: a surgical tool that surgeons use to intraoperatively create a patient-specific cranial implant and adapt its final contours to the real patient.

There are currently two main ways to repair skull defects, namely by manually manufacturing the implant intraoperatively or by using 3D technologies to preoperatively create patient-specific implants. However, hand-moulded implants (in bone cement) only offer poor-quality implants and are time-consuming in the operating theatre. Preoperatively-made implants (e.g. in titanium, ceramic) are expensive, cannot be modified during surgery (leading to inaccurate results if there is any discrepancy between the CT scan and the patient's reality), and have a long lead time. Moreover, these two methods do not provide for an accurate reconstruction in the case of one-stage resection and reconstruction procedures. Even coupled with a surgical guide or navigation system to assist the resection, the contouring is never accurate enough to obtain a perfect implant fit in the skull defect. A second surgery is then needed to resolve this issue.

This newly patented 3D-Side product overcomes the drawbacks of the current methods by providing a very accurate reconstruction while shortening surgery times and cutting costs and lead time, even for one-stage resection and reconstruction surgery.



Using 3D technologies, an implant is designed based on a patient's medical images. 3D printing is then used to create the guide for shaping this patient-specific implant intraoperatively. A specific coating is applied on this guide to maintain the perfect implant shape during intraoperative handling.

During surgery, the surgeon manufactures the implant by placing bone cement on the guide and adapting its shape to the patient's skull defect. Within just a few minutes, the implant is ready to be fixed into the patient by any means.

IMPACT

- Voor de business/ de onderneming (verwerving van een nieuwe markt, groei, kostenvermindering,...)
- Op de markt (eindafnemers, tussenpersonen)
- Over het geheel genomen, ten aanzien van de maatschappelijke thematiek

Our new concept enables surgeons to manufacture accurate patient-specific implants intraoperatively. Using dedicated instrumentation, the product enables highly precise skull reconstruction within a very limited amount of time using a material typically used for these surgeries, which drastically reduces costs. This solution also gives surgeons the freedom to tailor implants to the actual patient (and not just to medical images) and to avoid second surgeries in the case of a resection and reconstruction procedure.

As such, our technological solution has established an innovative surgical procedure that is adaptable and cost-effective as well as being very accurate and time-saving. 3D-Side has effectively taken the best of both current methods (hand-moulded implants and preoperatively-made implants) to respond to real market needs. Our solution will therefore drastically change the market due to the cost-effectiveness of our product (half of the market price) and the flexibility it offers to the real consumers, the surgeons.



Our innovation has already been successfully used in Belgium (90% of the market in Wallonia) and is currently being introduced abroad. Surgeons are really happy with the method and the final result: it gives them the freedom to manufacture and adapt their implants during surgery while offering patients a perfect aesthetic result.

Thanks to this innovative product, we won the Medtec Europe Start-Up Academy 2016 award, a contest giving numerous European start-ups the opportunity to present their innovations to the medical device industry!

KATALYSATOREN & OBSTAKELS

- Hoe verloopt / verliep de ontwikkeling van het project (duur, algemene indruk)?
- Wat vergemakelijkt / vergemakelijkte het verloop van het project (katalysatoren)?
- Wat zijn / waren de moeilijkheden en uitdagingen waaraan het hoofd moet /moest worden geboden (hinderpalen)

Our innovation consists of a medical device for the manufacturing of cranial implants (class III). The main challenge then involved developing the product in order to guarantee the safest medical solution possible.

A range of tests and risk analyses were performed to this end. The product's design was iterated until the requirements were met: a safe, accurate, flexible innovation that cuts both costs and time.

Thanks to this development in medical devices, we have gained experience in the different aspects of a medical device's life cycle, from initial ideas up to market access. This innovative product has been patented and we are now starting to address the market access problem. The complicated process of reaching the real consumers (neurosurgeons) costs a lot of time and money.