Contract No. IP 026599-2

Custom IMD

"SME Supply Chain Integration for Enhanced Fully Customisable Medical Implants, using New Biomaterials and Rapid Manufacturing Technologies, to Enhance the Quality of Life for EU Citizens"

Instrument: Integrated Project dedicated to SMEs

Thematic Priority: Priority 3 – NMP: Nanotechnologies and nano-sciences, knowledge-based multifunctional materials and new production processes and devices

Publishable Final Activity Report

Period covered: from 1-02-2007 to 31-01-2011 **Date:** 07-04-2011

Start Date of Project 1-02-2007 **Duration:** 48 months

Project coordinator name: Mr. Manuel León - Dr. Esther Hurtós

Project coordinator organisation name: ASCAMM **Revision:** 01

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Publishable Executive Summary

1.- Project Execution

1.1.- Summary description of project objectives

The year 2010 will be remembered by a new paradigm that the physicians will be able to plan and execute surgeries making use of fully customised implants, thoroughly designed according to the clinical needs of the patient. The CustomIMD project made it possible thanks to the development of new biomaterials, technology and processes for the manufacture of innovative fully customised medical implants through rapid manufacturing. From now on, implant design, manufacture, sterilisation, regulatory approval and delivery to the surgeon will be achieved within a 48 hour time frame.

The project directly addresses the needs of European high-tech SMEs implementing a result driven approach in order to achieve breakthroughs and innovations throughout the implant supply chain.

The core objectives of the project were:

- The development of innovative biomaterials fulfilling the requirements of Rapid Manufacturing techniques.
- To generate a strong toxicological and biocompatibility knowledge base for the new biomaterials.
- To achieve innovations within five Rapid Manufacturing techniques enabling the processing of the selected biomaterials.
- To achieve integration of the medically certified e-supply chain enabling customised implants to be supplied to the surgeon within 48 hours.
- The design, manufacture and test of three fully customisable implant products: craniofacial bone plate, lumbar spinal disc replacement, and dental restoration.
- To demonstrate the direct economic savings to the European healthcare services by implementing customisable implants and to quantify its wider economic and societal ‘added value’.

Industrial Transformation Breakthroughs:

- A faster supply chain of customised implants within 48 hours.
- The development of new European biomaterials with new characteristics (bio-mimic properties).
- Development and Implementation of five ‘Rapid Manufacturing’ (RM) techniques into industry for the newly developed biomaterials (from resource-based to knowledge-based manufacturing).
- Move from mass produced identical products to new concepts of custom made, ecoefficient and sustainable products, achieving higher economic added value and greater competitiveness.
- Achievement of the critical mass of data for key biomaterials to provide support and confidence to industry to seek product regulatory approval / certification for implants manufactured using the new biomaterials.

Main Scientific Breakthroughs:

- New biomaterials with bio-mimic properties (e.g. anisotropic, bio-active) demonstrated for dental, craniofacial and spinal applications.

- Management integration of customised implant e-supply chain (confidential patient data, material supply, implant design and manufacture, sterilisation and regulatory compliance).
- Innovations within Rapid Manufacturing techniques enabling the processing of the new biomaterials materials resulting in new concepts of product design achieving higher 'added value' (e.g. drug delivery, porosity, coatings, biocompatible and bioactive properties).
- Enhanced material properties for polymers, enabling minimally invasive spinal implants.

Societal Breakthroughs:

- Patient healthcare provision of fully customised implants within 48 hours, achieving patient added value (quality of life, less patient discomfort, better functionality, and patient rehabilitation).
- A 20% overall reduction in European Implant Healthcare Costs (hospitalisation and patient productivity; healthcare insurance; surgery effectiveness; and patient rehabilitation).

1.2.- Contractors involved

The consortium comprises 22 partners from seven European countries, 14 of them small and medium enterprises (64% of the project consortium). SMEs are prominent throughout the management structure and work programme. The manufacturing technologies, materials, implant devices and e-collaboration technologies developed in the project framework are primarily those of the SME partners.

About 60% of the budget is addressed to the SME members, ensuring their strong involvement in all areas of the project. The project is coordinated by Ascamm Foundation and it clearly demonstrates the leading role of SMEs: the Board of Directors is vice-chaired by an SME (Neos) and primarily comprises SMEs (five of eight).

Furthermore, SMEs have been encouraged to assume the position of WP's leaders, with the support of the RTD partners.

Fig. 1 CustomIMD consortium at the Final Meeting in Ascamm (ES), 20th January 2011.

List of Partners

Role	Nº	Full Name	Short Name	Country	Date enter project	Date exit project
CO	1	Ascamm	Ascamm	ES	M1	M48
CR	2	NeoSurgery	Neos	ES	M1	M48
CR	3	Xpand Biotechnology	Xpand	NL	M1	M48
CR	5	Icotec	Icotec	CH	M1	M48
CR	6	Aimplas	Aimplas	ES	M1	M48
CR	7	IBV	IBV	ES	M1	M48
CR	8	Materialise	Material	BE	M1	M48
CR	9	Degradable Solutions	DS	CH	M1	M48
CR	10	BEGO	BEGO	DE	M1	M48
CR	11	Suprapolix	Supra	NL	M1	M48
CR	12	Innalox	Innalox	NL	M1	M48
CR	13	EOS	EOS	DE	M1	M48
CR	14	PlastiaSite	Plastia	ES	M1	M48
CR	15	ENTE	ENTE	PL	M1	M48
CR	16	SPMC	SPMC	NL	M1	M24
CR	17	Smithers Rapra Technology	Rapra	UK	M1	M48
CR	18	TNO	TNO	NL	M1	M48
CR	19	ILT	ILT	DE	M1	M48
CR	20	UDIAT	Udiat	ES	M1	M48
CR	21	AZM	AZM	NL	M1	M48
CR	22	Sant Pau	Sant Pau	ES	M1	M48
CR	23	Laser Med	LasMed	PL	M1	M48
CR	24	Fundación INASMET	Tecnalia-INAS	ES	M13	M48

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1.3.- Work performed and results achieved

The level of progress achieved by **CustomIMD** project is highly satisfactory. New biomaterials, additive manufacturing technologies, medical devices, protocols for customisation together with ICT tools to support customised collaborative design and supply chain management have been obtained, completely fulfilling the project objectives.

Many results will be further developed beyond CustomIMD calendar, showing the real interest of the partners involved in the final exploitation of the CustomIMD outputs.

All results are in a precompetitive development phase. Further steps are needed to get to next phases: further development, testing, industrialisation and investments. Demo parts are available and they are considered key for attracting interest and investments for the further steps.

At the Plan for Use and Dissemination of Knowledge (PUDK) the Consortium has identified over 30 project results.

Examples of the end results are as follows:

- Innovative biomaterials development
- New advanced manufacturing technologies or new processing techniques for existing materials
- New medical devices: medical implants and dental restorations
- New biomechanical test procedures
- New software products
- Knowhow on data communication and protection

Most of these results can be grouped in four demonstrators: the cranial implant, the dental restoration, the lumbar disc replacement and the e-supply chain. Additionally, a summary of the conclusions from the socio-economic and environmental evaluation of CustomIMD developments is provided, together with some examples showing how the knowledge generated has been transferred to different target groups by dissemination and training actions.

Cranial Implant

A new concept in cranial bone plate has been obtained by integrating the materials developed, manufacturing technologies and a specific design that optimizes the performance of the new polymeric implant for a fast osteointegration and a minimum amount of foreign material left implanted in the long term:

1. The material combines laser sintered PEEK and a new composite consisting of osteoinductive HA ceramic powders in a matrix of biodegradable SupraB polymer.
2. The manufacturing technologies include two steps: a) Laser sintering with a newly developed system developed in CustomIMD that allows single parts and scaffold manufacturing with PEEK material and b) the polymeric composite intrusion within the PEEK scaffold, for which a process has also been developed.
3. The design of key concepts encompass the load bearing PEEK scaffold structure and the implant border design, which allows direct contact of the osteoinductive composite with the natural bone without hindering the required mechanical resistance.
4. An alternative numerical model has been developed for non-destructive biomechanical validation of scaffold geometries (homogenization method), reducing computational simulation time and using a standard computer.

5. Improved cranial implant fixation and CT scan accuracy methods to minimized irradiation have been developed.
6. Results of sterilisation test (optimal sterilisation method) and biotesting, that is in vitro (for biocompatibility), indicated that the Custom IMD cranial implant is biocompatible. Results of animal implantation testing, using pig model, were very positive
7. The Cranial implant results (design, fabrication and testings) will be published in peer reviewed scientific journals.

The Custom IMD concept of hybrid cranial opens new ways in the reconstruction of skull defects.

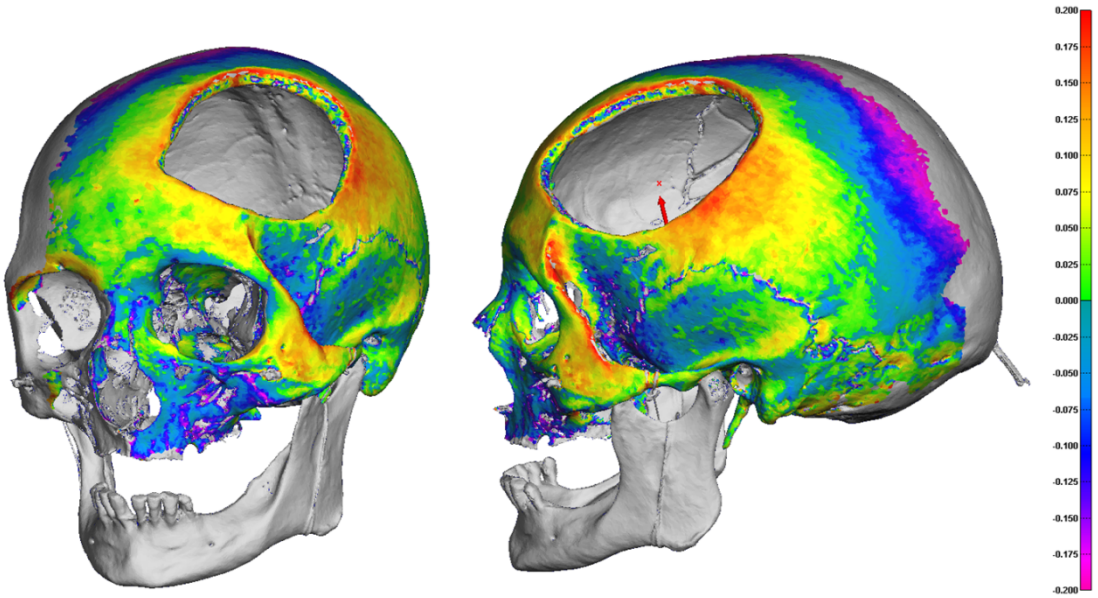

Fig. 2. CT Scan accuracy research in the cranial implant design protocol. AZM-IDEE (NL).

Fig. 3. New PEEK laser sintering machine used for the cranial implant scaffold manufacturing. EOS (DE).

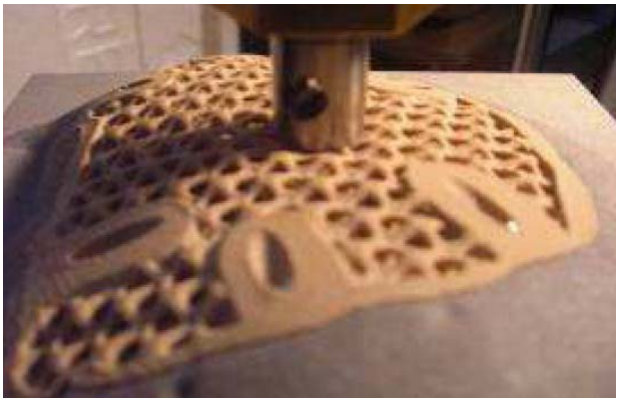

Fig. 4 PEEK scaffold testing: to validate the load-bearing resistance of the cranial implant. Ascamm (ES).

Fig. 5. Cylindrical PEEK meshes infiltrated with HA/SupraB-composite.used for animal testing of the cranial implant solution. AZM (NL), EOS (DE), Suprapolix (NL), Xpand (NL).

a)

b)

Fig. 6. Cranial implant design: a) Permanent PEEK scaffold guaranteeing the load bearing resistance. b) Implant ready for the surgery: PEEK scaffold + biodegradable osteoinductive composite. AZM (NL), EOS (DE), Suprapolix (NL), Xpand (NL), Ascamm (ES).

Dental Restorations

Conventional manufacturing methods for all types of ceramic dental restorations are costly as they require a great amount of manual work. Also up to 95% of the starting material is discarded in the process. To sort this problem, CustomIMD project has developed a new production method for dental restorations by Selective Laser Melting (an Additive Manufacturing technology) of pure

ceramic powder. SLM technology yields a density of almost 100% without any post-processing and it is based on direct and complete melting of ceramic powder by a laser beam.

High customised dental restorations are manufactured based on digital data, collected directly from patients. This procedure extends the freedom in design while producing parts by continuous deposition of melted ceramic layers with no geometric limitations, or the typical shrinkage observed in other sintering methods.

Ceramic samples were produced by laser melting for the first time in a pilot production line in industrial settings. The dental parts had the following characteristics: Density nearly 100%, no glassy phase and a bending strength up to 550 MPa.

The CustomIMD bridges obtained by laser melting have not yet reached the high standard of the milled bridges in terms of breaking load and geometrical fit. Further development is still necessary in order to produce dental restorations by the laser melting process with optimum quality.

The transfer of this technology to an industrial application is already in progress. It is expected to improve the quality of the parts while reducing costs for the manufacturing of single dental restorations.

Fig. 7 Micrographic view of ceramic powder for dental restorations. Perfect spherical grain shape. Innalox (NL).

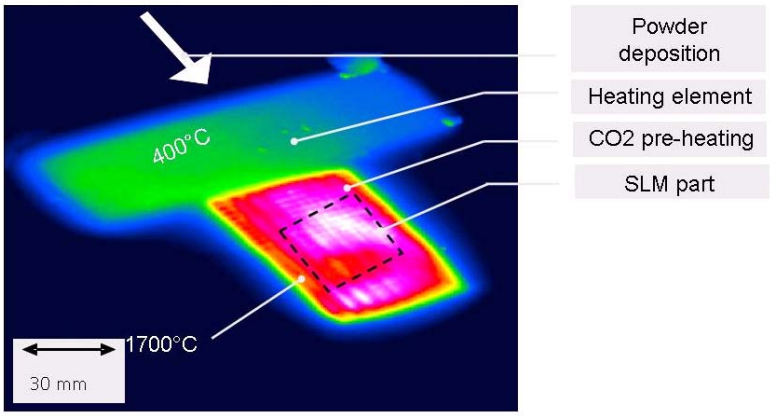

Fig. 8 Additive manufacturing of ceramic powder for dental restorations. Thermal camera image of powder pre-heating (400°C) and laser pre-heating (1700°C) during the Selective Laser Melting (SLM) process. Fraunhoffer-ILT (DE).

Fig. 9 Ceramic bridges produced by milling (top) in a commercial process, and laser melting (bottom) with the CustomIMD developed process. Bego (DE)

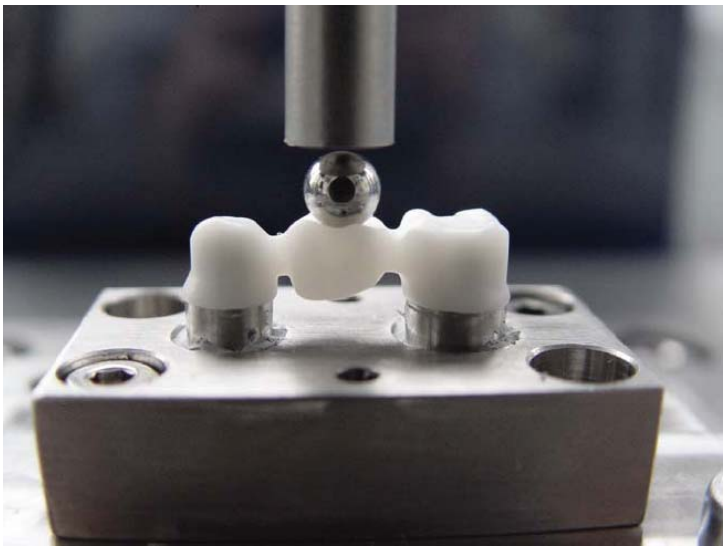

Fig. 10 Mechanical testing of a dental bridge. Bego (DE).

Lumbar Spinal Disc Implant

Around 80% of the population will suffer lumbar back pain at least once in their life. There are many causes for back pain, among them the degeneration of the intervertebral disc. Until now, there were not widespread solutions to total or partial lumbar disc replacement in the market.

CustomIMD has developed a lumbar disc replacement with the following benefits:

• The implant is customised: it is made to fit the patients' anatomy and needs.

• Minimally invasive insertion: posterior or lateral approach.

• The implant respects the biomechanical balance of the patient, maintaining physiological kinematic behaviour.

- It maintains the height of the disc.
- Absorbs shocks similarly to the natural nucleus.
- Excellent wear characteristics.
- Designed to minimise the risk of implant migration.

The conclusions of CustomIMD achievements regarding the design, manufacture and testing of a fully customisable lumbar spinal disc replacement are:

1. The Nucleus Replacement solution has been selected, manufactured and sterilized.
2. The final design and material proposed for the customized nucleus replacement implant shows an excellent mechanical strength. Selected material confers high flexibility and compliance to the implant, minimizing the risk of breakage under high compression and shear loading conditions.
3. The new spinal implant has demonstrated a good mechanical endurance under dynamic loading conditions. It has a good response to axial compression fatigue loading, without functional failure after long-term testing. Moreover, the implant shows excellent wear behaviour, with a very low wear rate under multi-axial loading conditions typical of wear testing.
4. The customization process has been established: image acquisition and treatment protocol, design protocol and manufacturing process. Moreover, biomechanical and biological tests reflect excellent device performance. All these results demonstrate that the design selected represent an innovative and really promising approach to solve the disc degeneration disease and disc hernia.
5. Moreover, a preliminary instrumentation which will follow the implant has also been designed and manufactured. Cadaveric implant trials demonstrate that the device can be implanted with minimal invasive procedures.

Finally, the device requirements established during the first months of the Custom IMD project has been analyzed and mostly accomplished.

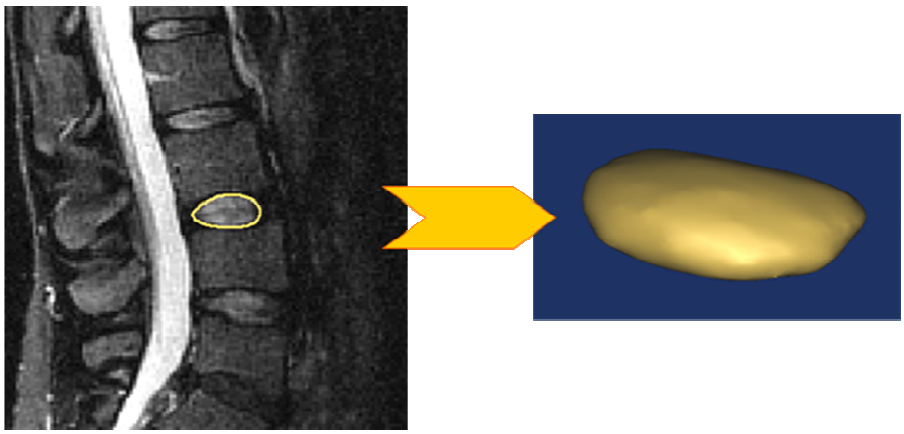

Fig. 11. Customised nucleus design based on the 3D reconstruction of the patient Magnetic Resonance Image (MRI). NEOS (ES), Sant Pau (ES)

a) b)

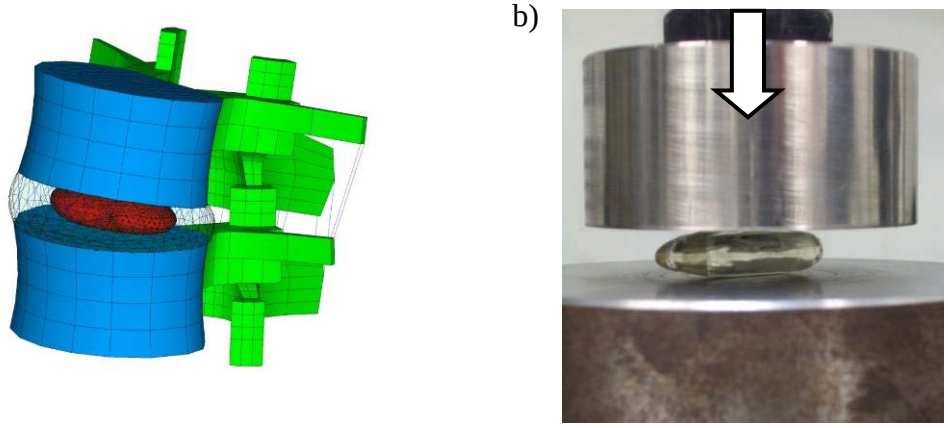

Fig 12. Customised nucleus implant biomechanical validation: a) FEM virtual testing using a parametric model of the lumbar spine and b) Experimental mechanical testing. IBV (ES)

E-Supply chain

The CustomIMD consortium has developed a platform for managing on-line the whole production process, from patients' data collection, to part design and delivery of the implant sterilised and ready for surgery. Following the latest trend in e-medicine, the platform, developed by the consortium, includes a special protocol to ensure the confidentiality of patients' personal information throughout the process.

The tool is an e-collaborative platform, enabling integration between healthcare centres and industry. In other words, it provides industry with design requirements obtained from the patient data acquisition process.

This ensures manufacturing fully customized medical devices according to patients' physical characteristics. The system also encompasses a final logistic step, responsible for delivering the spinal or cranial implant or dental restoration in a short timeframe.

The communication is performed through a secure webpage. All clients (e-collaborators) can access it through any type of internet connection, at any time, allowing integration and communication throughout the whole chain. In order to comply with the data protection regulations, the system uses an encryption protocol, ensuring patient's privacy. Moreover, only strictly necessary data is transmitted to those partners within the supply chain whose work depends on it.

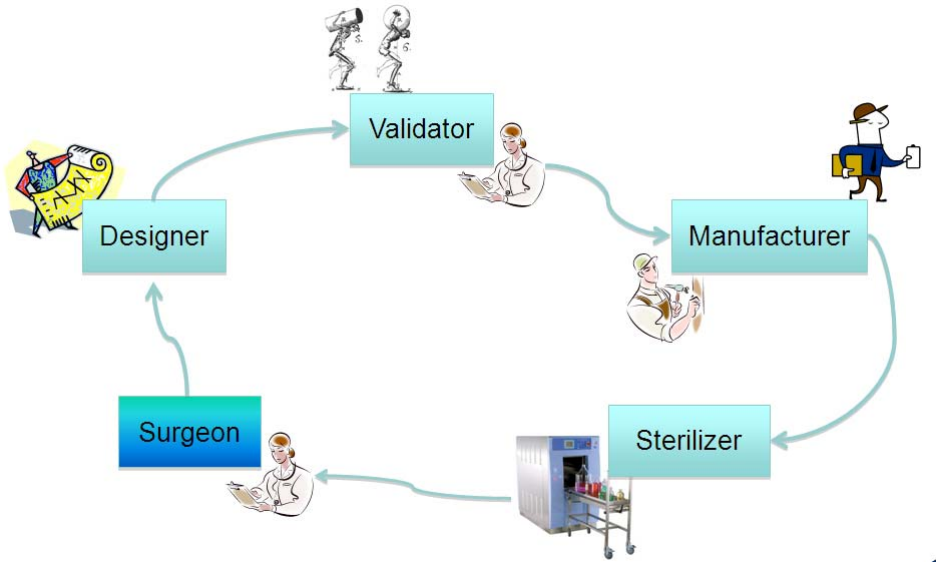

Fig. 13. E-supply chain workflow, Plastia (ES).

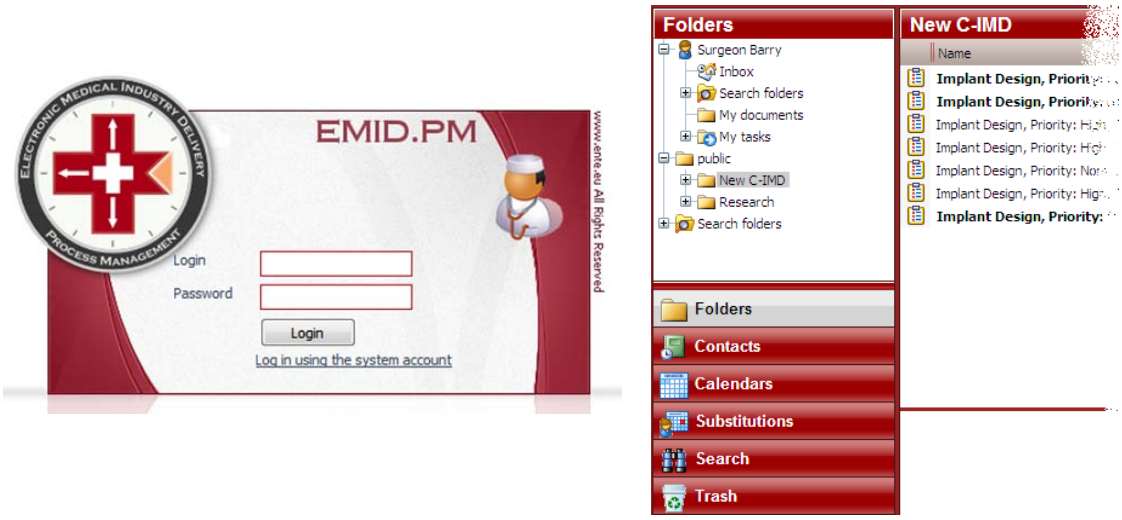

Fig. 14. E-supply chain platform. Ente (PL)

Socio-economic evaluation

Full economic and societal evaluations for the different implants developed in CustomIMD have been done.

The major **economic advantages** that have been analyzed are:

-Custom IMD the cheapest among all treatment options.

-Custom IMD is the cheapest of all treatment options, from the perspective of each stakeholder involved (hospital, specialist, patient, etc.).

-Custom IMD is the most cost-effective treatment option.

-Custom IMD is the most cost-effective treatment option from the perspective of each stakeholder (hospital, specialist, patient, etc.).

In order Custom IMD solution to take up its expected position in the market, hospital and patients will need to be convinced that it represents a good cost-effective relation. That basically means health improve and cost reductions. However, in case it may slightly increase overall costs, the process would still present an interesting cost-effectiveness if the benefits for health are high.

That said, the CustomIMD consortium had to ensure that the increased implant price keeps in line with the increase in effectiveness since an excessively high market price together with a moderate improvement in effectiveness would make the custom IMD implant unattractive.

In terms of social benefits, we could highlight the following::

- Custom IMD produces the greatest health gain of all alternative treatments of its field.

- Patient satisfaction is higher among patients who have received a Custom IMD implant.

- All stakeholders prefer the custom IMD solution above all available treatment options.

In summary, the most important stakeholder is the one who will need to pay for the implant (e.g., hospital, health insurer). If the CustomIMD has the potential to be the cheapest treatment, this will make the solution more attractive for them.

However, other stakeholders are less interested in costs and more interested in difference in quality and health impact; satisfaction can depend on a variety of criteria, including health gain, time of hospitalization, risk of infections, costs etc.

Anyway, dominant indicator of the societal value of a medical intervention is the degree of health gain that it can achieve in comparison with other alternatives. Health gain is measured in terms of improvement in survival and/or quality of life and is often quantified in terms of quality-adjusted life-years.

All in all, there is good reason to expect that stakeholders such as family members, hospitals and medical specialists would prefer a CustomIMD implant as long as it fulfills their expectations.

In summary, compared to current solutions, a CustomIMD implant has the potential to:

- Improve health gain: by a potentially faster recovery and reduced risk of failure or side-effects.
- Increase patient satisfaction: health gain, customised treatment, minimally invasive surgery and faster production.
- Reduce costs: maybe a higher cost, but possibly a reduction in other healthcare expenses e.g., surgery.
- Be more cost-effective: possibly reducing the total costs and improving effectiveness.
- Become the preferred treatment: due to a combination of factors, health gain, lower costs, cost effectiveness, perceived quality and service.

Environmental Evaluation

The environmental evaluation fulfils the sustainability and eco-efficiency objectives of the Custom IMD Project. The purpose of such evaluation is to compare the environmental impacts of the current implants to the new customised implant devices for the three different cases (cranial, spinal and dental).

It was concluded that the CustomIMD cases have a better environmental performance than the current cases for all three studies:

- For spinal and cranial cases, the environmental impacts of patient care were reduced for the custom cases as a result of faster surgery and shorter hospitalization.
- The impact of the implant manufacture varied from case to case. For dental case, the custom implant results in slightly lower impact than current case. The custom spinal implant has a slightly higher impact due to the material type and amount required for manufacture. For craniofacial case, the custom implant had a far lower impact than the current implant.

Although the manufacture of implants is an important aspect in total environmental impact, the transport to and from the hospital/dental clinic by patient and visitors contributes for the greatest proportion of the environmental impact.

Dissemination, training and demonstration actions:

The results have been demonstrated to target audiences. The consortium has performed multiple dissemination actions towards the scientific community, specialists and the general public. This is a selection of some of these activities:

Bioforum 2009

Central European Forum of Biotechnology and Innovative BioEconomy

The CustomIMD eSupply chain was demonstrated to representatives of the R&D medical industry.

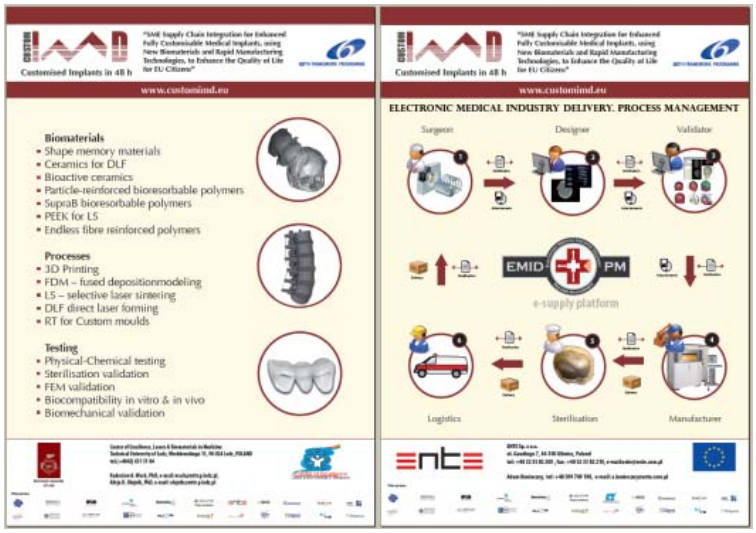

Fig. 15. Poster presented at Bioforum 2009, Poland.

1st April 2009 CSIOZ E-ZDROWIE Conference, Poland

Medical conference about Health Information Systems and E-Health

Power point presentation, poster and e-supply chain was demonstrated by Ente to representatives of ggovernment institutions, directors of the main hospitals and health medical institutions.

21st January 2010: Escolab activity with Secondary School students

Fig. 16. Attendees to the Escolab dissemination activity held at Ascamm (ES). A student had his hand 3D digitalised and several steps of the CustomIMD supply chain were demonstrated.

28th September 2010: 'Medical Rapid Prototyping and Additive Manufacturing in Cranio-Maxillofacial Surgery' one-day training seminar and workshop organized by AZM, Ascamm Materialise and Sant Pau. This workshop, held at Sant Pau hospital, Barcelona, involved both lectures and a more hands-on virtual implant planning session, focusing on the work undertaken within the Craniofacial Bone Plate case study. Partners who presented work undertaken within Custom IMD include: Suprapolix, EOS, Ascamm, LasMed and Materialise.

Fig. 17. Attendees to the 'Medical Rapid Prototyping & Additive Manufacturing in Cranio-Maxillofacial Surgery' seminar held at Sant Pau Hospital (ES).

20th October 2010: Telford Polymer Association Meeting: Custom IMD 'Developments in Polymer-Based Biomaterials for Customised Medical Implants' training presentation was given at this event to educate members of the polymer industry local to Rapra about the work of the project.

Fig. 18. Attendees to the Telford Polymer Association Meeting held on 20th October 2010, which focused on the polymer-based biomaterials developed within Custom IMD (UK)

November 2010: CONTROL PROCESS SEMINAR

Presentation of the capabilities to manufacturers of the eSupply chain platform and its advantages for manufacturing processes of medical devices.

Fig. 19. Attendees to the Control Process Seminar, from the manufacturing industry of plastics goods, at Aimplas (ES).

21st January 2011 Final Public Event CustomIMD. Ascamm, ES.

A Final Public event with the participation of all CustomIMD partners was organised in which the project results were disseminated and demonstrated. Presentations and a fair show of several results allowed the direct contact between the attendants with the partners.

Fig. 20. Attendees to the Final Public Event, during the results presentation, at Ascamm (ES).

8-10 February 2011 MD&M West, Anaheim, CA, USA

EOS presented the potential of PEEK for use in Laser-Sintered Craniofacial Implants at the Pacific Design & Manufacturing/MD&M West shows at the Anaheim, California Convention Center.

A technical paper was presented and the implants displayed at EOS booth.

To conclude the summary of CustomIMD achievements, the following is a selection of **on-line public contents on CustomIMD activities and results**:

- A video has been produced to explain CustomIMD concept through the e-supply chain of the Spinal Implant. It is publicly available at Youtube link.

  http://www.youtube.com/watch?v=kkQjW-HPQ5E

- Extended Services Platform

CustomIMD Extended Services platform has been developed in support of the Custom IMD e-supply chain platform to connect researchers, end-users, service providers, industry associations, investors and other key actor of the process.

It provides a range of information and support services such as training materials, legal & regulatory support, news, links and other services.

Training courses provide detailed information on the key objectives of the project and the technical developments which have been made. They are available to the general public on the Extended Services platform in flash format. The flash format allows users to click a button if they wish to view additional notes to support the information provided in the slides.

Everybody can access the Extended Services platform upon registration as a user at: http://www.customimd.com/CustomIMDES/ and after receiving an email confirming that the user's account has been activated.

- Custom-IMD web-site also reports on the project results through the presentations of the Final Public Event organised on 21st January 2011 at Ascamm (ES). http://www.customimd.eu/

2.- Dissemination and use

Each project partner has developed their own 'Exploitation Plan' that demonstrates how the project results will be integrated into their own forward business plan and research actions. Throughout the life of the project, all project partners have been updating the project 'Exploitation and Dissemination Plan'.

Based on the project results achieved so far, five patents have already been filed, 16 scientific publications appeared as papers or in congresses, a new manufacturing machine is in the market and some join exploitation agreements have been discussed.

Exploitation activities include: Protection and management of IPR and project results; gathering of reliable market intelligence and forecasts; feasibility studies for the creation of spinoff activities; evaluation of the project results for application within new markets; and the development of effective support structures to reinforce supply chain.

The following is a list of publishable results of the final Plan for Using and Disseminating the Knowledge (PUDK) identified by the consortium of CustomIMD project:

Result nº	**5**
Result name	**Bio-resorbable materials combining SupraB chemistry and bioactive ceramics for Fused Deposition Modelling for implants.**
Result abstract (brief)	**A range of innovative bioactive polymer-ceramic composite materials have been developed suitable for use in the rapid manufacture of medical implants. More specifically implants for craniofacial applications. The materials are biocompatible and biodegradable, while their mechanical integrity takes care of the protection of the deeper tissues. Moreover, the bioactivity can be used in the tissue engineering of bone. The beneficial processing conditions of the SupraB–polymers allow rapid manufacturing of customized implants tailored to the patients need via fused deposition manufacturing (FDM) techniques.**
Result development stage (proof-of-concept, laboratory prototype, working prototype-demonstrator, pre-industrial, industrial product...)	**Laboratory prototype**
Collaboration sought or offered (manufacturing agreement, financial support or investment, information exchange, training, consultancy, other…)	**Bio-active and resorbable materials are offered applicable with FDM-production technology**
Collaborator details (type of partner sought and task to be performed)	**Implant manufacturer**
Intellectual property rights (granted or published)	
Contact details: (City, Contact name, Contact Organisation, Country, e-mail)	**Eindhoven, T. Bosman, SupraPolix BV, Netherlands, info@suprapolix.com**

Custom-IMD Publishable Results	
Result nº	**11**
Result name	**Laser Sintering system to enable the sintering of PEEK powders**
Result abstract (brief)	**New High Temperature Laser-Sintering system (Additive Manufacturing) enabling the processing of high performance polymers with a melting point of up to 400 °C, such as Polyaryletherketons.**
Result development stage (proof-of-concept, laboratory prototype, working prototype-demonstrator, pre-industrial, industrial product...)	**Process optimised for capability and rate using production equipment. Capability and rate confirmed via economic run lengths on production parts.**
Collaboration sought or offered (manufacturing agreement, financial support or investment, information exchange, training, consultancy, other…)	**Business opportunities using Laser-Sintering for the production of medical devices (implants, prosthesis, tools, certification process.**
Collaborator details (type of partner sought and task to be performed)	**Manufacturers of medical devices**
Intellectual property rights (granted or published)	**Not addressed at this moment**
Contact details: (City, Contact name, Contact Organisation, Country, e-mail)	**Krailling/Munich, Germany** **EOS GmbH Electro Optical Systems** **Martin Bullemer** **Martin.bullemer@eos.info**

Result nº	**12**
Result name	**Selective Laser Melting Technique for ceramic material**
Result abstract (brief)	**Demonstration objects and test samples for pilot tests have been built and validated. Measured mechanical strength was sufficient. Testing of a statistically meaningful batch is still open. Work will proceed after project termination.**
Result development stage (proof-of-concept, laboratory prototype, working prototype-demonstrator, pre-industrial, industrial product...)	**Process validated in laboratory level using representative development equipment.**
Collaboration sought or offered (manufacturing agreement, financial support or investment, information exchange, training, consultancy, other…)	**Information exchange, training and consultancy**
Collaborator details (type of partner sought and task to be performed)	
Intellectual property rights (granted or published)	**Patent pending (ILT, Innalox, TNO, BEGO)**
Contact details: (City, Contact name, Contact Organisation, Country, e-mail)	**Yves Hagedorn** **Fraunhofer Institute for Laser Technology (ILT)** **52074 Aachen** **Germany** **Hagedorn@ilt.fraunhofer.de**

Result nº	14b
Result name	E-collaboration process dedicated for implant manufacture and deliveries
Result abstract (brief)	The use of the EMID.PM platform allows creating an e-supply chain for the register of activities and flow of documents and files, from the moment the surgeon files the prescription with the specifications until the implant is delivered. The use of a 3D TOOL to visualize the design of the implant and the images, as well as an INTELLIGENT LAYER to control and analyze the process, are integrated in the BPM. Moreover, an ANONYMISATION ALGORITHM tool is integrated to remove the patient identity from the images meeting medical standards established by the European regulations. The full platform implements a DATA PROTECTION SYSTEM to protect the application and the patient sensitive information. EMID.PM allows to create any other workflow case if there will be needed. http://emidpm.ente.com.pl
Result development stage (proof-of-concept, laboratory prototype, working prototype-demonstrator, pre-industrial, industrial product...)	Working prototype-demonstrator, pre-industrial product
Collaboration sought or offered (manufacturing agreement, financial support or investment, information exchange, training, consultancy, other…)	Manufacturing, Training, Consultancy
Collaborator details (type of partner sought and task to be performed)	Industrial partners,
Intellectual property rights (granted or published)	Granted
Contact details: (City, Contact name, Contact Organisation, Country, e-mail)	Adam Konieczny, ENTE Sp. z o.o. +48 509 709 108 Ul Gaudiego 7; 44-100 Gliwice a.konieczny@ente.com.pl

Result nº	16
Result name	Intelligent planning layer
Result abstract (brief)	An application to perform the monitoring, control and analysis for the process to create a customized human implant process. The main innovations are: - Interaction with a BPM engine. - Customization of the necessary times per activity and per participant to finish the process in 48 hours (knowing how much time each activity has to last). - Generation of alerts when an activity is not fulfilled in the established time. - Data mining to detect bottle necks and analyze the performance of the process.
Result development stage (proof-of-concept, laboratory prototype, working prototype-demonstrator, pre-industrial, industrial product...)	Experimental proof of concept completed
Collaboration sought or offered (manufacturing agreement, financial support or investment, information exchange, training, consultancy, other…)	Training, Consultancy
Collaborator details (type of partner sought and task to be performed)	ICTs, Industrial partners, medical centers, technological centers
Intellectual property rights (granted or published)	Granted
Contact details: (City, Contact name, Contact Organisation, Country, e-mail)	Isaac Pinyol, PlastiaSite S.A. +34 935 944 739 Cerdanyola del Vallès, Barcelona, Spain ipinyol@plastia.com

Result nº	**19**
Result name	**Craniofacial Bone Plate implant**
Result abstract (brief)	**New way of design and manufacturing of hybrid cranio-facial implant for reconstruction of skull defect. The research focused on 3D printed PEEK in combination with use of resorbable polymer-bone substitute mixture.**
Result development stage (proof-of-concept, laboratory prototype, working prototype-demonstrator, pre-industrial, industrial product...)	**Basic capability was proved by validation in vitro and by small scale animal study.**
Collaboration sought or offered (manufacturing agreement, financial support or investment, information exchange, training, consultancy, other…)	**Not addressed at this moment**
Collaborator details (type of partner sought and task to be performed)	**Other medical departments in order to test the new process in large scale animal studies and first clinical trials.**
Intellectual property rights (granted or published)	**Not applicable**
Contact details: (City, Contact name, Contact Organisation, Country, e-mail)	**Maastricht,** **Prof. dr. Jules Poukens,** **Medical University Center Maastricht,** **The Netherlands** **jules.poukens@scarlet.be**

Result nº	**20**
Result name	**Fixation system for craniofacial plates**
Result abstract (brief)	**New methods for fixation of cranial reconstruction plates.**
Result development stage (proof-of-concept, laboratory prototype, working prototype-demonstrator, pre-industrial, industrial product...)	**Part of new developments is in laboratory testing fase, some techniques are already applied clinically.**
Collaboration sought or offered (manufacturing agreement, financial support or investment, information exchange, training, consultancy, other…)	**Licensing to other companies**
Collaborator details (type of partner sought and task to be performed)	**Implant manufactures**
Intellectual property rights (granted or published)	**Partly protected by filled patents**
Contact details: (City, Contact name, Contact Organisation, Country, e-mail)	**Maastricht,** **Prof. dr. Jules Poukens,** **Medical University Center Maastricht,** **The Netherlands** **jules.poukens@scarlet.be**

Result nº	**21B**
Result name	Protocol for the validation of craniofacial plates.
Result abstract (brief)	Protocol development for numerical simulation of scaffold structures allowing a significant computer time and cost reduction with respect to conventional Finite Element Analysis (FEA). The protocol is based on the asymptotic expansion homogenization, technique that allows the substitution of the heterogeneous medium for an equivalent homogenous medium.
Result development stage (proof-of-concept, laboratory prototype, working prototype-demonstrator, pre-industrial, industrial product...)	Procedure validated by both experimental and theoretical studies.
Collaboration sought or offered (manufacturing agreement, financial support or investment, information exchange, training, consultancy, other…)	Consultancy, training and engineering services are offered.
Collaborator details (type of partner sought and task to be performed	Engineers interested in alternatives to FEA for heterogeneous media.
Intellectual property rights (granted or published)	
Contact details: (City, Contact name, Contact Organisation, Country, e-mail)	**Esther Hurtos.** ehurtos@ascamm.com ASCAMM FUNDATION. Av. Universitat Autónoma, 23 08290, Cerdanyola del Vallés, Barcelona- (Spain) http://www.ascamm.com/.

Result nº	**26**
Result name	**Training Materials and Support Infrastructure**
Result abstract (brief)	**Training and educational resources have been developed covering key subject areas of the project, such as:** - **Biomaterials development** - **Customised medical device case studies** - **Rapid manufacturing technologies** - **Custom IMD E-supply chain** - **Legislation and Regulation** **These materials are available in a range of formats such as presentations, leaflets, guides, technical posters, reports and review documents. They provide both background information on topics relevant to Custom IMD and also provide information on the work completed within the project, highlighting the benefits and potential areas of application for the materials and technologies developed.** **Please register at: http://www.customimd.eu/CustomIMDES/ to access the full range of Custom IMD educational resources.**
Result development stage (proof-of-concept, laboratory prototype, working prototype-demonstrator, pre-industrial, industrial product...)	**Training resources have been developed and finalised and are currently available online via the Custom IMD Extended Services website.**
Collaboration sought or offered (manufacturing agreement, financial support or investment, information exchange, training, consultancy, other…)	**In order to ensure long-term transfer of the knowledge developed within Custom IMD, training providers who run courses on topics relevant to the project (eg. materials for medical devices, polymer-based medical materials, rapid manufacturing of customised medical devices, development of an e-supply chain for the manufacture of medical devices, regulations for customised medical devices) could incorporate aspects of the Custom IMD training material and information into their own training provision, providing a prior agreement from Custom IMD partner is obtained clarifying the terms of use, and the project and originating partner are properly acknowledged.**

Collaborator details (type of partner sought and task to be performed)	
Intellectual property rights (granted or published)	
Contact details: (City, Contact name, Contact Organisation, Country, e-mail)	**Steve Rowlands** **Smithers Rapra Technology Ltd.** **Shawbury, Shrewsbury, Shropshire UK SY4 4NR** srowlands@rapra.net