PROJECT NO: FP6-508225

DISBLADE

A New Concept For The Hardening Of Polymers Allowing The Production Of Disposable Surgical Blades Preventing The Need For Sterilisation

Co-operative Research (Craft)

Horizontal Research Activities Involving SMEs

Final Activity Report
Date of issue of this report: November 2006

Start Date: 1st March 2004 Duration: 27 Months

Lead Contractor: Pera Innovation Ltd

Version 01

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PROJECT INFORMATION

PROJECT NO: FP6-508225

CONTRACT NO: COOP-CT-2003-508225

TITLE OF PROJECT*:* DISBLADE – *A New Concept For The Hardening Of Polymers Allowing The Production Of Disposable Surgical Blades Preventing The Need For Sterilisation*

COORDINATOR: Pera Innovation Ltd

SME EXPLOITATION MANAGER: Clinipart Ltd

***SME CONTRACTORS*:**
2 A/S Kenneth Winther-Varektojsfarik
3 Mapro Spol s.r.o.
4 Clinipart Ltd
5 Fedegari Autoclavi Spa
10 Charpak Ltd

***OTHER ENTERPRISE / END USER CONTRACTORS*:**
6 Rosti AS

RTD PERFORMER CONTRACTORS:
8 Pera Innovation Ltd
9 The National Institute of Technology

PUBLISHABLE EXECUTIVE SUMMARY

This report covers the work carried out during the whole 27 month period of the project.

The main body of this report is a précised overview. However more detailed results can be found in the Deliverable Reports, which are confidential at this time.

The Disblade project proposed to develop a manufacturing process to produce high performance all-plastic disposable surgical instruments at low cost through innovations in component design, micro-moulding techniques and polymer surface hardening treatments.

The tasks of the project cover pressure vessel design and construction, surface treatment, sharp edge moulding, blade sharpening and disposal, system optimisation and integration, validation and protection of the intellectual property.

Progress has been very good, with significant effort being assigned to the initial scientific tasks, and this in-depth research has resulted in a patent application. The planned schedule was adapted to better reflect the predicted timescales of the tasks based on the new knowledge as it was gained during the earlier stages of the project.

All meetings have been well attended and the partners have been actively involved in the research, management and exploitation work.

The project has created a web site for the combined use of an on-line administrative tool for the partners (password protected) and web presence. The web site can be seen via www.disblade.com which currently redirects to www.pera.com/rndprojects . The public project page can be viewed by selecting DISBLADE from the list on the left.

The majority of the project technical objectives have been met and the project has resulted in a patent application, providing a strong base for the expected rapid commercialisation across a range of markets.

SECTION 1 - PROJECT OBJECTIVES AND MAJOR ACHIEVEMENTS DURING THE LIFE OF THE PROJECT

1.1 Overview of General Project Objectives

Overall Project Objective:

The overall objective of our work was to produce a process for the manufacture of disposable polymer surgical blades. This relies on greatly enhancing the scientific understanding of super critical carbon dioxide in combination with Sol-Gel chemistry to enable the development of a polymer surface treatment that can dramatically increase the surface hardness of polymers to a value of at least 7 Mohs'.

To meet this we had a number of technological objectives, these were

- Produce a polymer blade with a surface hardness of at least 7 Mohs', 40% greater than existing grades of stainless steel used for surgical blades.
- Produce a blade surface hardness of at least 5 Mohs' to a depth of at least 15 microns.
- Achieve blade stiffness comparable to existing stainless steel blades.
- Achieve a flatness tolerance of ±5 microns over the length of the polymer blade.
- Have the ability to produce a blade that can cost effectively be sharpened to a level of sharpness (edge radius of less 150 nano metres) comparable to existing stainless steel blades and conform to the relevant sections in BS 2982:1992.
- Achieve a level of wear resistance to enable the blade to retain its sharpness for at least as long as stainless steel blades
- To design a manufacturing cell with the ability to run 24 hours per day, 365 days per year with no more than 5% down time (including routine maintenance).
- Achieve a manufacturing cost of less than €0.25 for a surgical scalpel, complete with handle and sterile packaging.
- Achieve a hot plate disposal route that renders the blade sharp safe (blade edge radius is greater than 0.5mm) in less than one second.

Relation to State of the Art

Disposable surgical instruments have already been introduced to many hospitals, in a bid to prevent patients being infected with CJD & other viruses. However many of the single use instruments are being re-used due to high cost associated with replacing them. The average price for a single use scalpel is €1.31. For this price, the scalpel is made of a pre-assembled stainless steel blade mounted on an injection moulded plastic handle. However the UK Government has been forced into a u-turn on single use surgical instruments in tonsil & adenoid surgery as the quality of the instruments is so poor that doctors have been told that they can go back to re-usable instruments. The reason behind the poor quality of the instruments is that the designs for traditional metal instruments were replicated in polymer materials. The mechanical properties of metal & polymers are different, therefore different design techniques have to be used.

- Reusable Instruments: The scalpel is a typical example of a widely used re-usable instrument. The handles are made from either stainless steel or nickel alloy & the surgical blades are made sterile in stainless steel or made either sterile or non-sterile in carbon steel. Once it has been used the blades are

removed from the handle & disposed. The handles are sterilised for re-use. The biggest cause of injuries & resulting infections is the installation and removal of the blade.

- Single Use Instruments: In an attempt to address concerns over risks of injury, a disposable scalpel with retractable stainless steel scalpel blade has been produced. Once used the scalpel blade can be fully retracted into the handle, enabling safe passing & disposal. This is produced in the USA. Attempts have been made at producing single use scissors & forceps but it was discovered that they are not fit to use, as the scissor blades go blunt very quickly and the forceps are only stiff enough for a small number of tasks.

- Silicon Wafer Blades: Development is being carried out on a surgical blade etched from the wafers of silicon, in a process similar to that to make integrated circuits. It is thought that this could be used in procedures such as cataract surgery or neurosurgery, that are precision reliant. As this is in the early stages, the potential costs are expected to be far greater than the costs of stainless steel blades, making them only suitable for use in specialist operations.

- Sol-Gel: These technologies have been developed considerably over the past 10 years in laboratories world wide. The physical properties that they bring, such as the increase in the surface hardness, durability, stiffness & wear resistance of materials, may widen the use of polymers in industry. However the use of environmentally harmful wet chemicals may limit their uptake.

- Grinding of Polymers: It is not currently feasible to grind the edge of a polymer part to a level of sharpness that is comparable with the existing stainless steel blades due to machining process melting and burring the parts being machined.

1.2 Summary of Recommendations from Previous Reviews

A number of questions and comments were made following the submission of reports at the end of the first reporting period. These were all addressed at the time, and are summarised below:

- Financial Summary Report – Wrong Calculation
- Missing Audit Certificates – It has been subsequently agreed that audit certificates for all participants will only be provided to accompany these Final Reports
- Clare Form C wrong addition
- Winther Form C wrong % of indirect costs
- Amendment request and documents required for change of co-ordinator.

There are no actions pending as a result of these recommendations.

1.3 Summary of Project Objectives & Major Achievements for Life of Project

The specific objectives for the fifteen-month period of 1st March 2005 to 31st May 2006 of the project are summarised in the table below.

Deliverable No	Task	Partners Involved	Objective	Achievements During Reporting Period
1.1	1.1	Fedegari Pera	FEA model of pressure vessel, engineering drawings for vessel and valve arrangement with associated circuit diagrams.	Completed
1.2	1.2	Fedegari Pera	A proof tested pressure vessel fitted with precise valves and a control system.	Completed
1.3	1.3	TI	Table of results highlighted the highest performing pressure vessel parameters to plasticize LCP.	Completed
1.4	1.4	TI	Table of results highlighting the exact amounts of reagents and corresponding pressures to achieve the polymer plaques with the greatest surface hardness to the greatest depth.	Completed
2.1	2.1	Pera CPD Rosti	Detailed scalpel design with associated FEA data on blade stiffness. Up to 3 scalpel models produced by rapid prototyping techniques.	Completed
2.2	2.2	Winther Clare Pera	Prototype two shot injection mould tool.	Completed
2.3	2.3	Clare Winther CPD Pera	Up to 200 polymer scalpels and associated moulding parameters.	Completed
3.1	3.1	TI Pera CPD	An optimized surface modification treatment verified on case study polymer scalpels. Test results stating blade stiffness and hardness. Test results stating scalpel handle stiffness and “feel”.	Completed
3.2	3.2	Pera	Demonstration of the blade sharpening and polishing system. Sharpened polymer blades and associated comparative test results	Completed
3.3	3.3	Pera	Demonstration of sharp safe blade disposal system	Completed

4.1	4.1	Pera Mapro	Functional operation of the integrated system to meet the process performance specified in the industrial objectives	Completed
4.2	4.2	CPD Rosti	Test results and product approval	Completed
4.3	4.3	Mapro Rosti CPD	Successful demonstration to the project partners of the case study part. Validation of the commercial viability of the technology application, including feature benefits and cost implications by representatives of the primary and secondary market sectors.	Completed
5.1	5.1	CPD Winther Mapro Charpak Fedegari Rosti	A report on potentially competitive patents and a plan for patent applications if required with exploitation agreements between the partners	Completed
5.2	5.2	Charpak Winther Mapro CPD Fedegari Rosti Pera TI	Production of support material for transfer of the knowledge to the partners through case studies and generic design guide	Completed
5.3	5.3	Charpak Winther Mapro CPD Fedegari ROSTI	2 papers presented at conferences and major exhibitions and production of 2 publications in the form of editorials, technical papers and trade press	Completed
5.4	5.4	Charpak Winther Mapro CPD Fedegari Rosti	A report on the standards, ethical and regulatory aspects of the exploitation of the results	Completed
5.5	5.5	Charpak Winther Mapro CPD Fedegari Rosti	Over 200 companies contacted directly to promote the project results	Completed
6.1	6.1	Pera Winther Mapro CPD Fedegari Rosti Charpak TI	Delivery of a technology implementation plan	Completed

6.2	6.2	Charpak Winther Mapro CPD Fedegari Rosti Pera TI	Delivery of 6 month progress reports, mid term review report and final report. Submission of the cost statements at midterm and end of project. Organise Kick Off, midterm and Final meetings.	Completed
6.3	6.3	Charpak Winther Mapro CPD Fedegari Rosti Pera TI	Provision of audit certificates and bank guarantees and amended consortium agreement (if applicable)	Not yet completed
6.4	6.4	Charpak Winther Mapro CPD Fedegari Rosti Pera TI	Report on gender, societal and ethical issues of exploitation	Completed

1.45.3 Problems/Issues During Project

It became apparent during the first period that Clare-Pak wanted to withdraw from their roles of Co-ordinator and Exploitation Manager and from the consortium. As such, Clinipart (CPD) took on the role of Exploitation Manager, and Pera took over the role of Co-ordinator. Rosti had already proven their injection moulding skills, and took over the injection moulder technical role in the project. In addition, the consortium expanded to incorporate Charpak as an additional partner with the complementary skills of in-process packaging.

SECTION 2 - WORK PACKAGE PROGRESS REVIEW FOR PROJECT LIFETIME

2.1 Work Package Objectives

The work package objectives for the project are summarised in the table below.

Work Package No.	Work Package Title	Lead Contractor Short Name	Person Months	Start Month	End Month
WP1	The Enhancement of Scientific Understanding of $ScCO_2$ and Alkoxide Reagents	TI	**22.5**	1	9
WP2	Creation of a New Technological Capability to Injection Mould Sharp Features	Winther	**28.0**	2	10
WP3	Validation of the novel surface modification treatment	Pera	**15.5**	10	17
WP4	Integration & Clinical Trials	Mapro	**16.0**	13	23
WP5	Innovation Related Activities	Clinipart	**9.4**	1	27
WP6	Consortium Management	Pera	**3.6**	1	27

2.2. Overview of Work Package Technical Progress

Work Package 1 – The Enhancement of Scientific Understanding of $ScCO_2$ and Alkoxide Reagents

Task 1.1: Design of Pressure Vessel & Valve Arrangement
Task Leader: Fedegari
Partners Involved: Fedegari & Pera

Objectives:

To design a pressure vessel to accommodate at least 50 scalpels, withstand pressures exceeding 20 bar and temperatures exceeding 120^{o}C. To design a valve arrangement to allow the introduction of $ScCO_2$ to a mass flow rate accuracy of 0.02g/s. To design a valve arrangement to utilize $ScCO_2$ as a carrier medium to introduce the other reagents at a pressure greater than vessel pressure to a mass flow rate accuracy of 0.02g/s.

Progress:

The vessel has been designed to withstand 55 bar and 120C. It is fabricated from stainless steel with carbon content lower than 0.03% which is predicted will withstand the reagents to be used in the solgel process. It contains a complex arrangement of valves and controls which will allow CO_2 to be heated and pressurised, and reagents to be added to this pressurised fluid stream before it enters the vessel. The controls are initially manual, to allow for experimentation, but can be automated once precise process conditions are specified. The monitors allow the process conditions to be recorded.

Deliverable Report 1.1 contains the detailed results.

Task 1.2: Manufacture of Pressure Vessel & Valve Arrangement
Task Leader: Fedegari
Partners Involved: Fedegari & Pera

Objectives:

To manufacture a pressure vessel and valve arrangement to carry out the polymer surface modification treatment.

Progress:

The pressure vessel which was designed in Task 1.1 has been built on site at Fedegari, and the surrounding systems are being ordered and assembled. It has been found to take longer than originally anticipated in the contract to purchase and assemble the associated control and monitoring devices surrounding the pressure vessel. At the beginning of the 6th month, the purchasing activity was completed, and the bench scale apparatus was ready to be used in the first half of October 2004.

This delay in the completion of this task has also delayed Tasks 1.3 and 1.4 and on to delay elements of WP3.

This task is complete and a Deliverable Report 1.2 contains the detailed results.

Task 1.3: Characterisation of $ScCO_2$ as a Solvent Replacement
Task Leader: TI
Partners Involved: TI, Pera, Fedegari

Objectives:

To scientifically characterise the performance of $ScCO_2$ in combination with methanol as a replacement for conventional solvents to plasticize the outer layers of LCP.

Progress:

This task was delayed due to the unexpected delay in assembling the pressure vessel and initial research was performed using the equipment available to TI in Italy. Small sections of LCP and glass filled LCP plaques were exposed to CO_2 and examined for signs of swelling or crystallisation, as is common when semi-crystalline polymers that have been treated. In-vessel weighing demonstrates a small effect. Optimisation of the plasticisation was conducted in conjunction with the optimisation of the Alkoxide reagent treatment by varying the temperature, time, and pressure conditions.

This task is complete and Deliverable Report 1.3 contains the detailed results.

Task 1.4: Characterisation of alkoxide reagents to produce a nanostructure
Task Leader: TI
Partners Involved: TI, Pera, Fedegari

Objectives:

To scientifically characterize the specific amounts of metal alkoxide reagent and water/HCL required to produce a nanostructured co-continuous phase of silica on the surface of LCP.

Progress:

This task was delayed due to the unexpected delay in assembling the pressure vessel and initial research was performed using the equipment available to TI in Italy, but the exact reaction conditions were not available until the Fedegari vessel was completed. Optimisation of the treatment through the control of the reagents and conditions was considered in conjunction with the optimisation of the plasticisation. Temperature, time, acidity and pressure conditions were varied. The moulding parameters have also been found to affect the efficacy of the treatment.

This task is complete and Deliverable Report 1.4 contains the detailed results.

Work Package 2 – Creation of a New Technological Capability to Injection Mould Sharp Features

Task 2.1: Creation of Polymer Scalpel

Task Leader: Pera

Partners Involved: Pera, CPD, Rosti

Objectives:

To design a polymer scalpel utilising two shot injection moulding technology with equivalent stiffness to existing stainless steel blades.

Progress:

A novel polymer scalpel has been designed specifically for the first skin cuts of an operation. The blade is shaped like a boat hull, and protrudes from the bottom of the handle, allowing pressure to be put on the top of the blade. The handle is square in cross-section, reducing the risk of the knife rolling in the surgeon's hand. This design removes the risk of handle reuse, as the conventional disposable blades are incompatible.

SLA models of two versions of the novel scalpel have been produced. Samples are available for ergonomic trials, although at this stage the blades are not sharpened.

This task has been completed and Deliverable Report 2.1 contains the detailed results.

Task 2.2: Creation of an Innovative Prototype Two Shot Moulding Tool

Task Leader: Winther

Partners Involved: Winther, Clare, Pera

Objectives:

To design and manufacture a two shot injection mould tool with an injection compression mechanism on the blade cavity of the tool.

Progress:

A novel scalpel was designed in Task 2.1 However, this design will involve complex robot controlled grinding to achieve the rounded sharp edge. As such, a conventional shape straight bladed scalpel blade is also being moulded for initial functional trials of the technology.

The tooling for the straight blade has been designed, built and moulded. This will also allow a sliding compression cam to be used to assist the moulding of the sharp blade edge.

This task is complete and Deliverable Report 2.2 contains the detailed results.

Task 2.3: Validation Trials
Task Leader: Winther
Partners Involved: Winther, Pera, Clare, CPD

Objectives:

To produce injection moulded scalpels with the sharpest possible polymer blade

Progress:

The straight edge blade tool has been successfully moulded to produce blades. The moulding parameters have been shown to affect the efficacy of the solgel treatment process and the optimisation of the orientation of the polymer was made in conjunction with Task 3.1. Injection compression trials were performed to further enhance the blade edge.

This task is complete and Deliverable Report 2.3 contains the detailed results.

Work Package 3 – Validation of the novel surface modification treatment

Task 3.1: Validation of novel surface modification treatment on polymer scalpels
Task Leader: TI
Partners Involved: TI, Pera,CPD

Objectives:

To validate the performance of the novel surface modification treatment on the case study polymer scalpel.

Progress:

Optimisation trials including the plasticisation, alkoxide treatment and moulding conditions were performed to produce blades with optimum properties. Blades were assessed by scanning electron microscopy, microhardness, nanohardness, flexural and cutting tests.

This task is complete and Deliverable Report 3.1 contains the detailed results.

Task 3.2: Creation of blade sharpening and polishing system
Task Leader: Pera
Partners Involved: Pera

Objectives

To create a grinding and polishing system to sharpen the modified polymer blade to a level of sharpness comparable to existing stainless steel blades.

Progress:

A conventional grinding machine was obtained and modified to reduce the movement and trials were performed on the treated blades. The sharpness was assessed using microscopy and cutting trials.

This task is complete and Deliverable Report 3.2 contains the detailed results.

Task 3.3 Creation of sharp safe blade disposal system
Task Leader: Pera
Partners Involved: Pera, TI

Objectives:

To create a sharp safe blade disposal system to render the blade blunt and safe within 1 second.

Progress:

A concept for the blade disposal equipment was developed and prototyped. Although the prototype was over-sized, it demonstrated the principle of blade blunting.

This task is complete and Deliverable Report 3.3 contains the detailed results.

Work Package 4 - Integration & Clinical Trials

Task 4.1: System Integration & Development
Task Leader: Mapro
Partners Involved: Mapro, Charpak & Pera

Objectives:

To develop schematic concept designs integrating the injection moulding, surface modification and blade sharpening system to form a fully automated prototype manufacturing cell.

Progress:

Schematic concept designs were developed to integrate the injection moulding, surface modification and blade sharpening system with in-process packaging to form a fully automated prototype manufacturing cell.

This task is complete and Deliverable Report 4.1 contains the detailed results.

Task 4.2: Clinical Trials
Task Leader: CPD
Partners Involved: CPD & Rosti

Objectives:
To carry out clinical trials on the resultant polymer scalpel to ensure that it is suitable for surgical operations and accepted by surgeons.

Progress:
The Disblade concept has been presented to surgeons and the wider industry for their feedback. Clinical trials were not performed on animals or humans.

This task is complete and Deliverable Report 4.2 contains the detailed results.

Task 4.3: Industrial Validation of Technical Capability
Task Leader: Rosti
Partners Involved: Rosti, Mapro

Objectives:
To validate that the technology created is capable of reaching a manufacturing performance to meet the specifications and cost models of the primary and secondary target sectors. To validate that the case study components are suitable for their designated application

Progress:
The Disblade technology has been validated to show that it is capable of reaching a manufacturing performance to meet the specifications and cost models of the primary and secondary target sectors.

This task is complete and Deliverable Report 4.3 contains the detailed results.

Work Package 5 – Innovation Related Activities

Task 5.1: Protection of IPR
Task Leader: Clinipart
Partners Involved: Clinipart, Winther, Mapro, Fedegari, Rosti, Charpak, Pera, TI

Objectives:
To ensure that all project results are formulated and compiled into a protectable form and all necessary patents are made.

Progress:
The Disblade technology has been patented in a UK application made on 30th May 2006. The official search results are not yet available. The assignment paperwork between the individual inventors and Clinpart and Rosti is in progress, and discussions are underway regarding the territories that will be protected.

This task is complete and Deliverable Report 5.1 contains the detailed results.

Task 5.2: Absorption of Results by Proposers
Task Leader: Clinipart
Partners Involved: Clinipart, Winther, Mapro, Fedegari, Rosti, Charpak, Pera, TI

Objectives:
To transfer specific knowledge from the RTD performers to the SME participants to enable them to rapidly apply and embed the technology onto specific products.

Progress:
Component specific samples are already being manufactured by the industrial participants (specifically Winther, Fedegari and Rosti) to meet the market interest that has been generated by the dissemination and press releases. Pera and TI do not have day to day involvement in the production of these samples, demonstrating that the technology has been effectively transferred into the proposers.

This task is complete and Deliverable Report 5.2 contains the detailed results.

Task 5.3: Dissemination of Knowledge
Task Leader: Clinipart
Partners Involved: Clinipart, Winther, Mapro, Fedegari, Rosti, Charpak, Pera, TI

Objectives:
To broadcast the benefits of the developed technology and knowledge beyond the consortium to potential industrial user communities

Progress:
The Disblade technology has been broadcast at a number of exhibitions and through the project website, press releases and the resulting press articles.

This task is complete and Deliverable Report 5.3 contains the detailed results.

Task 5.4: Socio-economic Aspects
Task Leader: Clinipart
Partners Involved: Clinipart, Winther, Mapro, Fedegari, Rosti, Charpak

Objectives:
To assess the socio-economic impact of the generated knowledge and technology

Progress:
The assessment has been made and Deliverable Report 5.4 contains the detailed results.

Task 5.5: Promotion of Exploitation
Task Leader: Clinipart
Partners Involved: Clinipart, Winther, Mapro, Fedegari, Rosti, Charpak

Objectives:
To create spin-offs from the participant organisations and promote the braod application of the results by organisations outside the consortium.

Progress:
A number of organisations from outside the consortium have expressed an interest in the technology, and component specific samples are being manufactured by the industrial participants (specifically Winther, Fedegari and Rosti) to demonstrate the technology for these applications. These applications are all spin-offs from the original surgical blade concept.

This task is complete and Deliverable Report 5.5 contains the detailed results.

2.3 Deviation From the Plan and Corrective Actions

The table below summarises the deviations from the work programme, and the corrective actions taken.

Work Package No.	Title	Deviations from Plan	Corrective Action
WP1	The Enhancement of Scientific Understanding of $ScCO_2$ and Alkoxide Reagents	Fedegari were very capable when it came to the vessel and control system design, although the design, manufacture and proof testing took more elapsed time than planned. Therefore the RTD resource at Pera was better applied to assisting TI with the characterisation of samples to speed up the testing and optimisation, reducing the hours necessary from TI. The final optimisation of the plasticisation and Alkoxide treatment needed to be performed in conjunction with moulding parameters, and was done in Task 3.1	Prioritised optimisation of solgel treatment and moulding conditions to allow other elements of project to progress.
WP2	Creation of a New Technological Capability to Injection Mould Sharp Features	Tasks 2.1 and 2.2 progressed well, although using different levels of partner resource to that originally planned (see Manpower Resource Table in Management Report). Task 2.3 progressed in parallel with Task 3.1, as moulding conditions have been found to affect the efficacy of the solgel treatment, in addition to affecting the moulded sharpness of the blade.	
WP3	Validation of the novel surface modification treatment	The treatment of samples in WP1 was delayed by the elapsed time taken to construct and prove the treatment equipment, delaying the start of WP3 as optimisation, sharpening and blunting trials could not properly proceed without full scientific understanding of the solgel process and optimised blade samples.	
WP4	Integration and Clinical Trials	Charpak have added to the consortium's knowledge of in-process packaging, contributing significantly to Task 4.1. Task 4.2 (clinical trials) was not completed due to the significant cost and time associated with these approvals.	Tests were performed on synthetic skin.
WP5	Innovation Related Activities	Rosti have better access to potential end users and markets than Clare-Pak and found themselves more able and eager to perform the feasibility and marketing trials for the project. Feasibility and marketing studies are progressing well and exploitation is likely to be rapid,	None

Work Package No.	Title	Deviations from Plan	Corrective Action
		based on the patented technology. Clinipart are representing the interests of the SME consortium and are ensuring that Rosti do not become too dominant.	
WP6	Consortium Management	Clare-Pak withdrew from their role as Exploitation Manager and Co-ordinator. High levels of contributions to project management have been seen from all partners, due to the excellent meeting attendance and communications	Clinipart and Pera agreed to take over the roles of Exploitation Manager and Co-ordinator respectively. Charpak were approached to join the consortium to add to the suite of industrial knowledge available

A copy of the work programme is included in Section 3.3 of this report. This Gantt work programme has been modified to reflect the progress achieved during the project.

2.4 Work Package Deliverables Update

Del. No.	Deliverable Name	Work Package No	Lead Participant	Date Due	Planned/Actual Delivery Date	% Complete	Estimated Indicative Persons Month	Used Indicative Person Months
1.1	FEA model of pressure vessel, engineering drawings for vessel and valve arrangement with associated circuit diagrams.	1	Fedegari	3	3	100	7.7	7.7
1.2	A proof tested pressure vessel fitted with precise valves and a control system.	1	Fedegari	4	7	100	7.7	7.7
1.3	Table of results highlighted the highest performing pressure vessel parameters to plasticize LCP.	1	TI	8	12	100	5.3	5.3
1.4	Table of results highlighting the exact amounts of reagents and corresponding pressures to achieve the polymer plaques with the greatest surface hardness to the greatest depth.	1	TI	9	12	100	5.9	5.9
2.1	Detailed scalpel design with associated FEA data on blade stiffness. Up to 3 scalpel models produced by rapid prototyping techniques.	2	Pera	5	5	100	10.7	10.7
2.2	Prototype two shot injection mould tool.	2	Winther	8	8	100	11.3	11.3
2.3	Up to 200 polymer scalpels and associated moulding parameters.	2	Winther	10	10	100	11.2	11.2
3.1	An optimized surface modification treatment verified on case study polymer scalpels. Test results stating blade stiffness and hardness. Test results stating scalpel handle stiffness and “feel”.	3	TI	12	12	100	8.4	8.4
3.2	Demonstration of blade sharpening and polishing system. Sharpened polymer blades and associated comparative test results.	3	Pera	17	17	100	4.1	4.1
3.3	Demonstration of sharp safe blade disposal system.	3	Pera	17	17	100	3.5	3.5
4.1	Functional operation of the integrated system to meet the process performance specified in the industrial objectives.	4	Mapro	18	18	100	7.1	7.1

Del. No.	Deliverable Name	Work Package No	Lead Participant	Date Due	Planned/Actual Delivery Date	% Complete	Estimated Indicative Persons Month	Used Indicative Person Months
4.2	Test results and product approval.	4	CPD	21	21	100	4.7	4.7
4.3	Successful demonstration, to the project partners of the case study part. Validation of the commercial viability of the technology application, including feature benefits and cost implications, by representatives of the primary and secondary target market sectors.	4	Rosti	23	23	100	7.1	7.1
5.1	A report on potentially competitive patents and a plan for patent application(s) if required with exploitation agreements between the partners.	5	CPD	27	27	100	1.3	1.3
5.2	Production of support material for transfer of the knowledge to the partners through case studies and a generic design guide.	5	CPD	27	27	100	3.1	3.1
5.3	2 papers presented at conferences and major exhibitions and production of 2 publications in the form of editorials, technical papers and trade press.	5	CPD	27	27	100	3.3	3.3
5.4	A report on the standards, ethical and regulatory aspects of the exploitation of the results	5	Pera	27	27	100	1.2	1.2
5.5	Deliverable: Over 200 companies contacted directly to promote the project results	5	Rosti	27	27	100	2.3	2.3
6.1	Delivery of a technology implementation plan	6	Pera	27	27	100	1.2	1.2
6.2	Delivery of six month progress reports, mid term review report and final report. Submission of the cost statements at mid term and end of projects. Organize kick-off, mid tem and final meetings.	6	Pera	27	27	100	1.2	1.2
6.3	Provision of audit certificates and bank guarantees and amended consortium agreement (if applicable)	6	Pera	27	27	100	0.9	0.9
6.4	Report on gender, societal and ethical issues of exploitation	6	Pera		27	100	0.9	0.9

2.5 Work Package Milestones Update

Milestone No	Milestone Name	WP No	Date Due	Actual or Forecast Delivery Date	Lead Contractor
M1	Prototype pressure vessel with reagent valves to control mass flow rate to 0.02g/s.	1	9	9	TI
M2	Surface modified LCP plaques	1	9	9	TI
M3	Prototype two shot injection mould tool with injection compression feature on blade cavity.	2	10	10	PERA
M4	Polymer scalpels with optimised blade sharpness	2	10	10	PERA
M5	Demonstration of blade grinding and polishing system.	3	17	17	PERA
M7	Sharp polymer scalpels	3	17	17	PERA
M8	Demonstration of sharp safe blade disposal system	3	17	17	PERA

SECTION 3 - Consortium Management

3.1 Consortium Management Tasks & Achievements

The consortium management tasks are listed below:

Task 6.1 - Delivery of a technology implementation plan (dissemination and use plan)

Task 6.2 - Delivery of six month progress reports, mid term review report and final report. Submission of the cost statements at mid term and end of projects. Organize kick-off, mid tem and final meetings.

Task 6.3 - Provision of audit certificates and bank guarantees and amended consortium agreement (if applicable)

Task 6.4 - Report on gender, societal and ethical issues of exploitation

This is in addition to the project management.

6 monthly reports have been written, circulated to the consortium and submitted to the EC. Regular meetings have been held and have been well attended.

3.2 Consortium Status Overview

The application of the research resource has changed slightly from the original plan. For WP1, Fedegari were very capable when it came to the vessel and control system design and manufacture, therefore the RTD resource at Pera was better applied to assisting TI with the characterisation of samples to speed up the testing and optimisation, reducing the hours necessary from TI. Technically, the modelling and injection compression moulding work has been taken on by Rosti and Pera reducing the contribution needed from Clare-Pak. Pera has also assisted Winther with initial tooling manufacture.

Clare-Pak made it clear that they wished to end their roles as Exploitation Manager and Co-ordinator. These roles were taken by Clinipart (CPD) and Pera respectively. Additional skills in the area of in-process packaging were incorporated into the consortium when Charpak joined.

3.3 Project Timetable & Status

3.3.1 Work Programme (Original)

#	TASK	WP/Task Leader	MONTHS 1	2	3	4	5	**6**	7	8	9	10	11	**12**	13	14	15	16	17	**18**	19	20	21	22	23	**24**
1.0	The Enhancement of Scientific Understanding of $ScCO_2$ and Alkoxide Reagents																									
1.1	Design of pressure vessel and valve arrangement	Fedegari																								
1.2	Manufacture of pressure vessel and valve arrangement	Fedegari																								
1.3	Characterisation of $ScCO_2$ as a solvent replacement	TI																								
1.4	Characterisation of alkoxide reagents to produce a nanostructure	TI																								
2.0	Creation of a New Technological Capability to Injection Mould Sharp Features																									
2.1	Design of polymer scalpel	Pera																								
2.2	Development of an innovative prototype two shot moulding tool	Winther																								
2.3	Validation trials	Clare																								
3.0	**Validation of the novel surface modification treatment**																									
3.1	Validation of novel surface modification treatment on polymer scalpels	Pera																								
3.2	Creation of blade sharpening and polishing system	Pera																								
3.3	Creation of sharp safe blade disposal system	Pera																								
4.0	**Inegration & clinical trials**																									
4.1	System integration and development	Mapro																								
4.2	Clinical trials	CPD																								
4.3	Industrial validation of technical capability	Clare																								
5.0	Innovation Related Activities																									
5.1	Protection of IPR																									
5.2	Absorption of results by proposers																									
5.3	Dissemination of knowledge																									
5.4	Socio-economic aspects																									
5.5	Promotion of exploitation																									
6.0	Consortium Management																									
6.1	Management of knowledge	Clare																								
6.2	Co-ordination of knowledge	Clare																								
6.3	Co- ordination of the technical activities at a consortium level	Clare																								
6.4	Co-ordination of the overall legal and financial aspects	Clare																								
6.5	Co-ordination of the gender equality, ethical and science aspects	Clare																								

3.3.2 Work Programme (As Updated) 27 Months

#	TASK	WP/Task Leader	MONTHS																										
			1	2	3	4	5	**6**	7	8	9	10	11	**12**	13	14	15	16	17	**18**	19	20	21	22	23	24	25	26	27
1	**The Enhancement of Scientific Understanding of $ScCO_2$ and Alkoxide Re**																												
1.1	Design of pressure vessel and valve arrangement	Fedegari																											
1.2	Manufacture of pressure vessel and valve arrangement	Fedegari																											
1.3	Characterisation of $ScCO_2$ as a solvent replacement	TI																											
1.4	Characterisation of alkoxide reagents…	TI																											
2	**Creation of a New Technological Capability to Injection Mould Sharp Features**																												
2.1	Design of polymer scalpel	Pera																											
2.2	Development of an innovative … moulding tool	Winther																											
2.3	Validation trials	Clare																											
3	**Validation of the novel surface modification treatment**																												
3.1	Validation of novel surface modification treatment on polymer scalpels	Pera																											
3.2	Creation of blade sharpening and polishing system	Pera																											
3.3	Creation of sharp safe blade disposal system	Pera																											
4	**Inegration & clinical trials**																												
4.1	System integration and development	Mapro																											
4.2	Clinical trials	CPD																											
4.3	Industrial validation of technical capability	Clare																											
5	**Innovation Related Activities**																												
5.1	Protection of IPR																												
5.2	Absorption of results by proposers																												
5.3	Dissemination of knowledge																												
5.4	Socio-economic aspects																												
5.5	Promotion of exploitation																												
6	**Consortium Management**																												
6.1	Management of knowledge																												
6.2	Co-ordination of knowledge																												
6.3	Co-ordination of the technical activities at a consortium level																												
6.4	Co-ordination of the overall legal and financial aspects																												
6.5	Co-ord' of the gender equality, ethical and science aspects																												

3.3.3 Clarification of Changes to Work Programme

A 3 month extension was requested and granted to enable the consortium to make a patent application and to allow us to produce a more robust Dissemination and Use Plan under the rules and security of the EC contract, ensuring confidentiality and that the ownership of the intellectual property is retained by the SMEs.

3.4 Meetings & Communication

There have been ten project review meetings since the start of the project. These have all combined technical, management and exploitation issues.

Project Review Meetings

	Date	Type of meeting	Location
1	30/03/2004	Kick-Off Meeting	Pera
3	25/06/2004	3 Month Technical	Fedegari
8	09/09/2004	6 Month Technical	Oslo/TI
16	02/12/2004	9 Month Technical	Fedegari
20	25/02/2005	Midterm Management	Pera
26	11/05/2005	15 Month Technical	Rosti
34	10/08/2005	18 Month Management	Pera
38	12/12/2005	21 Month Technical	Charpak
44	23/02/2006	24 Month Technical	Fedegari
49	16/05/2006	Final Management	Winther

Very constructive technical and commercial discussions have occurred at the project meetings, as described in the minutes and regular communication has taken place between the partners. The partners are working very well together.

In addition to the formal meetings a number of working party and specific exploitation meetings have occurred to discuss specific aspects of the project.

Project Working Party Meetings

No	**Date**	**Purpose**	**Location**
2	07/05/04	Working Party Meeting Solgel	Lboro/TI
4	30/06/04	Working Party Meeting Solgel	Lboro/TI
5	27/07/04	Working Party Meeting Solgel	Pera
6	16/08/04	Working Party Meeting Solgel	Lboro/TI
7	24/08/04	Working Party Meeting Solgel	Pera
9	13/09/04	Working Party Meeting Solgel	Lboro/TI
10	22/09/04	Working Party Meeting Solgel	Lboro/TI
11	15/10/04	Working Party Meeting Solgel	Lboro/TI
12	21/10/04	Working Party Meeting Solgel	Lboro/TI
13	29/10/04	Working Party Meeting Solgel	Lboro/TI
14	25/11/04	Working Party Meeting Solgel	Lboro/TI
15	01/12/04	Working Party Meeting Solgel	Lboro/TI

17	05/01/05	Working Party Meeting Solgel	Lboro/TI
18	19/01/05	Working Party Meeting Solgel	Lboro/TI
19	08/02/05	Working Party Meeting Solgel	Lboro/TI
21	18/03/05	Working Party Meeting Solgel	Lboro/TI
22	01/04/05	Working Party Meeting Solgel	Lboro/TI
23	05/04/05	Working Party Meeting Solgel	Pera
24	18/04/05	Working Party Meeting Solgel	Lboro/TI
25	04/05/05	Working Party Meeting Solgel	Lboro/TI
27	18/05/05	Working Party Meeting Solgel	Lboro/TI
28	27/05/05	Working Party Meeting Solgel	Lboro/TI
29	07/06/05	Working Party Meeting Solgel	Lboro/TI
30	08/06/05	Working Party Meeting Solgel	Pera
31	29/06/05	Working Party Meeting - Catch up briefing	Charpak
32	01/07/05	Working Party Meeting Solgel	Lboro/TI
33	05/08/05	Working Party Meeting Solgel	Lboro/TI
35	26/08/05	Working Party Meeting Solgel	Lboro/TI
36	27/10/05	Working Party Meeting Solgel	Lboro/TI
37	24/11/06	Working Party Meeting Solgel	Lboro/TI
39	18/01/06	Exploitation Meeting	Pera
40	31/01/06	Working Party Meeting Solgel Trials	Fedegari
41	01/02/06	Working Party Meeting Solgel Trials	Fedegari
42	02/02/06	Working Party Meeting Solgel Trials	Fedegari
43	09/02/06	Working Party Meeting Solgel	Lboro/TI
45	08/03/06	Working Party Meeting Solgel	Lboro/TI
46	13/04/06	Working Party Meeting Solgel	Lboro/TI
47	24/04/06	Patent Meeting	Lloyd Wise, London
48	09/05/06	Patent Meeting	Lloyd Wise, London

The venues for all project review meetings have been rotated at different partner-sites to give the consortium an opportunity to learn more about how the host partner operates, unless there has been a specific reason for visiting a particular location (for example the location of test equipment). A tour of the facilities has followed the meetings on the first visit. Meetings have continued to be held after the end of the project to allow exploitation discussions to continue.

A website has been created (www.disblade.com) which is an on-line administrative tool for the partners. The administrative element of the website is password protected.

SECTION 4 – OTHER INFORMATION

4.1 Dissemination

There have been a wide range of dissemination activities during the project. Once the patent was secured, articles based on our press releases have appeared in publications including:
Surface World & Product Finishing, September 2006, p52
British Plastics and Rubber, September 2006, p30

The Engineer 150 Years Special Edition
Materials World, October 2006, p15
European Plastics News, October 2006, p20

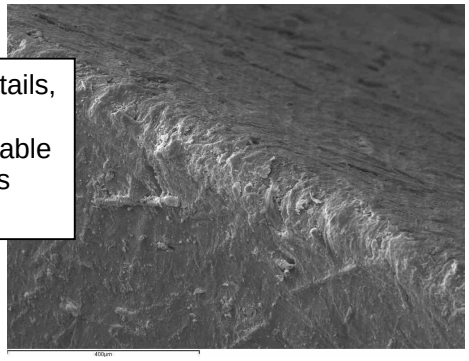
Presentations were also made at conferences and trade shows, including Medical Device Technology, February 2006, Birmingham. Full details are included in the Dissemination and Use Plan.

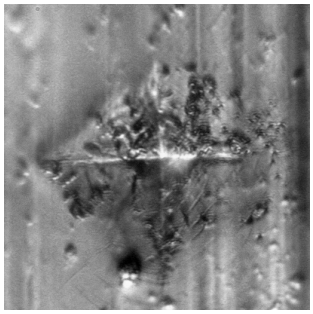
4.2 Overall Contributions of Consortium

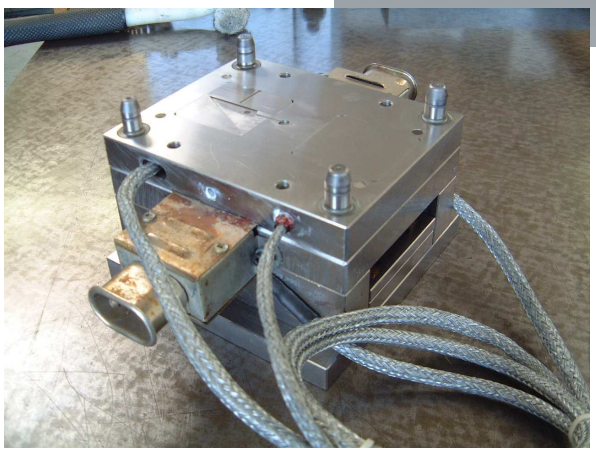
The SMEs have made valuable and real contributions to the project, in line with the project plan. Both RTD performers have made valuable contributions to the project, and have worked in close conjunction with each other and with the whole consortium. The work has been equally balanced between the SMEs and the RTD performers, with the RTDs providing the scientific background and research expertise, and the SMEs providing in-depth knowledge of markets and technologies.

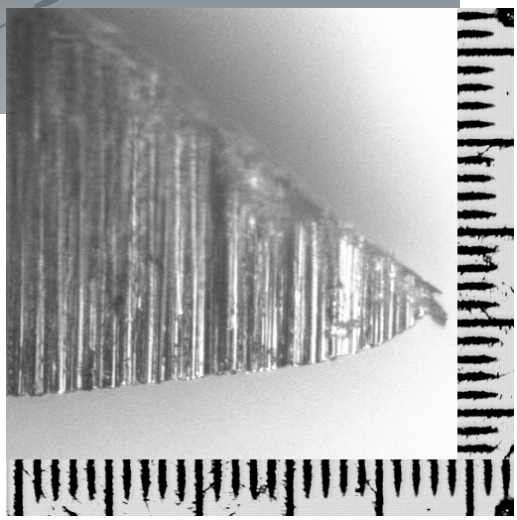
Project Images

For details, see Deliverable Reports









APPENDIX 1

Plan for Dissemination and Use

Dissemination and Use Plan

Project number: COOP-CT-2003-508225

Project acronym: Disblade

Project title: A New Concept For The Hardening Of Polymers Allowing The Production Of Disposable Surgical Blades Preventing The Need For Sterilisation.

Partner	Signature	Date
A/S Kenneth Winther-Vaerktojsfabrik		
Mapro Spol s.r.o.		
Clinipart Ltd		
Fedegari Autoclavi Spa		
Rosti AS		
Charpak Ltd		

SECTION 1 – EXPLOITABLE KNOWLEDGE AND ITS USE

Exploitable Results

Overview Table

Exploitable Knowledge	**Exploitable Product(s) or Measure(s)**	**Sector(s) of Application**	**Timetable for Commercial Use**	**Patents or Other IPR Protection**	**Owner** and Other Partners Involved
Method for hardening surface of polymers and blends	*Hardened LCP surfaces*	*1. Medical Devices* *2. Personal care products*	*2007 or soon afterwards*	*A treatment process **patent application** was made in May 2006.*	**Clinipart** Fedegari Mapro *Rosti* Winther Charpak Pera TI
All-polymer Scalpel Design	*Novel all-polymer scalpel and disposal system*	*Medical Device*	*Approx. 2010*	*A registered design application will be made prior to commercialisation.*	**Clinipart** Fedegari Mapro *Rosti* Winther Charpak
Treatment Equipment Design	*Polymer Treatment Equipment*	*Polymer Engineering*	*2007 or soon afterwards*	*Commercial secrecy.*	**Clinipart** Fedegari Mapro *Rosti* Winther *Charpak*

A: Method for Hardening Surface of Polymers and Blends

The carbon dioxide (CO_2) enabled solgel surface hardening technology for polymers and blends, for example Liquid Crystal Polymer (LCP) with 10% Polyamide 6 (PA6), developed during the project can produce a surface treatment on LCP that increases the surface hardness properties of the material. This could be exploited through the production and sale of all-polymer surgical scalpels and similar medical devices to health authorities and directly to health practitioners. Clinipart, the exploitation manager, own all Intellectual Property Rights (IPR) and manage the exploitation for the benefit of the consortium. It is planned that these medical devices will be marketed through Rosti with the consortium forming a commercial supply chain for the design and production equipment. It is anticipated that the conservative nature of the medical industry will need to be overcome before there is wide uptake of new instruments and suitable medical testing and approval will be required.

The technology that has been developed during the project can be exploited through the production and sale of other items, for example personal care products and engineering

components. Markets for these hardened surfaces in personal care products have already been investigated, and significant interest has been shown by some household name firms who can not be named at this time. The link to these companies has been through Rosti, and Rosti will continue to form the route to market where it fits with their business. For markets outside the interest of the consortium, the **patent protected intellectual property** can be licensed to interested third parties. The developed knowledge, now protected by a patent application, will also be widely disseminated, and a number of publications have also been made, based on 2 initial press releases and exhibition presentations. To date, an initial patent search has not identified any patents which this technology infringes, or any prior art that would prevent a patent being issued, although clarification of the claims and description of the patent will be part of the continuing patent application procedure once the official searches have been performed.

B: All-polymer Scalpel Design

The all-polymer disposable scalpel design and disposal system allows the scalpel blade to be destroyed in the operating theatre significantly reducing the risk of contaminated sharps injuries, and providing a significant social impact. This is enabled by the hardening treatment for LCP which allows a polymer blade to be produced. The scalpel design incorporates a non-removable blade and a curved blade design that would be unsuitable for conventional metal manufacturing techniques. The handle has also been ergonomically designed.

This design can be exploited through the production and sale of all-polymer surgical scalpels and similar medical devices to health authorities and directly to health practitioners. It is anticipated that these will be marketed through Rosti with the consortium forming a commercial supply chain for the design and production equipment for these and related devices. It is anticipated that the conservative nature of the medical industry will need to be overcome before there is wide uptake of new instruments and suitable medical testing and approval will be required.

The design and concept, once protected as a registered design, can also be disseminated. To date, a preliminary search of registered designs and patents has identified no areas of potential infringement.

C: Treatment Equipment Design

The pressure vessel equipment that has been designed for the treatment of plastics using CO_2 can be manufactured and sold by Fedegari to expand their pressure vessel output into new markets. Their new customers will be throughout the polymer industry, for treatment of plastics either under a technology licence from the consortium or for processes that are beyond the scope of the intellectual property of this project. Preliminary patent searches indicate that this will not infringe any existing IPR. The knowledge, once patent protected, can also be disseminated.

SECTION 2 – DISSEMINATION OF KNOWLEDGE

Overview table

Date	Type	Type of audience	Countries Addressed	Size of Audience	Partner Responsible
January 2005, March 2006,	Press release	Industry (polymers sector)	UK and worldwide	16000	Rosti
May 2006	Press article – The Engineer	Industry (polymers sector)	Worldwide	31000	Pera
November 2004 (Medica)	Exhibition	Industry (Medical sector)	Worldwide	5000	Clinipart
February 2006 (MDT)	Exhibition	Industry (medical sector)	UK	5000	Pera
March 2004 onwards	Project web-site	General Public	Worldwide	840 million	Pera
May 2006 onwards	Web-site	General Public	Worldwide	840 million	Rosti
May 2006	PhD presentation, Loughborough University	Academics and invited industrialists	UK	100	Pera
September 2006	Press Article - Surface World & Product Finishing, September 2006, p52	Industry (Surface Engineering sector)	UK	10000	Pera
September 2006	Press Article - British Plastics and Rubber, September 2006, p30	Industry (polymers sector	UK	10000	Pera
September 2006	Press Article - The Engineer 150 Years Special Edition	Industry (Engineering sector)	UK	31000	Pera
October 2006	Press Article - Materials World, October 2006, p15	Industry (polymers sector)	UK	21000	Pera
October 2006	Press Article - European Plastics News, October 2006, p20	Industry (polymers sector)	Europe	14000	Pera

The project website (www.disblade.com) has been set up at the start of the project and will continue until at least the end of the 2 year term. It is maintained by Pera and is a mirror of the Disblade public page at www.pera.com/rndprojects.

Regular press releases have been made to the polymer industry magazines, initially with very little technical content, and keeping all intellectual property confidential, to generate interest in the technology, and to start to identify potential licensees and spin-off applications. Now that patent protection is in place, further details have been released to the press to continue to stimulate market interest covering a wide variety of market sectors.

Exhibitions for the medical industry have started to generate a little interest in the scalpel product, and dissemination was informal and limited in scope. Further market stimulation and education will be required prior to product launch.

A. Stewart (Pera) and S. Bologna (TI) have been studying for PhDs at Loughborough University and Università di L'Aquila with their work linked to this project. At appropriate times for their studies, academic publications, conference presentations and theses will be given on their research. The consortium will be consulted before publication, where the work is directly linked to the project work, to ensure commercial secrecy is maintained as appropriate.

SECTION 3 – PUBLISHABLE RESULTS

Publishable summary of each exploitable result.

A: Method for Hardening Surface of LCP

A batch process for the surface hardening of polymers and polymer blends has been developed by the Disblade consortium, and a patent application has been filed. This technology produces an increase in surface hardness of moulded parts, giving improved scratch resistance and allowing a sharp edge to be polished.

The hardening method includes softening the polymer surface using carbon dioxide, then incorporating a ceramic pre-curser into the component. The pre-curser is then reacted to form a ceramic-polymer hybrid surface.

The process is performed in a specially designed pressure vessel to which carbon dioxide and tetra-ethoxy-silane (TEOS) are added at an elevated temperature and pressure. The use of water and acidic and basic conditions aids the reaction stages to form the hard polymer-ceramic hybrid.

The hardened polymers formed could be sharpened and used for a variety of applications, including scalpel blades and lancets, and will be taken to market initially through Rosti A/S.

B: All-polymer Scalpel Design

It is estimated that 1 in 10,000 people are infected with CJD at the time of their death, which equates to around 6 million people worldwide. As of 2004, CJD had caused over 100 human deaths in the UK alone. More seriously, however, the incubation period is as yet unproven, but is thought by some to be in the range of decades, suggesting that the scale of the new variant CJD and surgically acquired (iatrogenic) CJD problem could significantly increase in future years. At the time of writing, iatrogenic transmission of the CJD agent has been reported in over 250 patients worldwide.

One way to overcome this is to sterilise the surgical equipment. However, prions show resistance to all normal forms of sterilization, and the temperatures routinely used to sterilize surgical instruments actually help to spread CJD between humans. The only viable solutions are to use disposable surgical instruments, or to treat surfaces and instruments by flooding with or soaking in 2M NaOH or undiluted sodium hypochlorite for 1 hour and then rinse with water. Both of these options are cost prohibitive for routine operations, and the latter often results in the instruments being damaged. As a result, they are often only implemented when medical instruments have come into contact with high infectivity tissues of persons with suspected or diagnosed CJD. This poses a risk of infection from individuals with no symptoms or suspicion of CJD before, during or immediately after their procedure.
This has led to the need to provide a device which is economical to produce and can be disposed of after a single use.

The hardening process developed during the Disblade project, and protected by patent applications, allows a number of sharp polymer components to be considered, including a scalpel handle and blade, lancets and a number of other devices.

A design for a scalpel handle and blade set has been produced. This is optimised for the properties of the polymers and allows for the reduced flexural modulus, for example, in comparison to steel whilst being designed for final shape manufacture by injection moulding, ignoring the limitations traditionally imposed by the sheet nature of the steel blade material.

The designs have been prototyped to enable ergonomic feedback to be gathered from surgical and nursing personnel before European medical device directive and FDA approval is sought and scalpels are taken to market through Rosti A/S.

C: Treatment Equipment Design

A pressure vessel and control system has been designed, built and tested to allow the surface of polymers and polymer blend components to be hardened using the process developed during the Disblade project.

The vessel is fabricated from stainless steel with a composition chosen to withstand the reagents used in the hardening process. It contains a complex arrangement of valves and controls which allow carbon dioxide to be heated and pressurised, and other reagents to be added to the pressurised vessel. The controls are manual, to aid experimentation, but will be automated for full scale production. The temperature, pressure and flow monitors allow the process conditions to be recorded, assisting with product quality control.

Fedegari Autoclavi spa manufacture a wide variety of pressure vessels and autoclaves to order, and this vessel will be added to their product portfolio to service the polymer processors market demand.

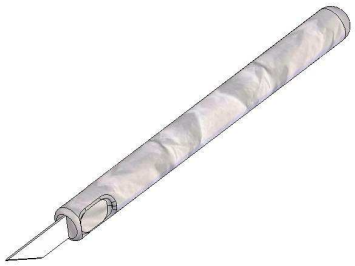
Appendix 2
Press Releases

Press Notice for Immediate Release –20th January 2005

Press Release Begins

EU project well on its way to all plastic scalpel

'Disblade' - a project funded by the EU involving 6 industrial partners and supported by Pera in the UK and The National Institute of Technology in Norway - began in March 2004 and is now well on the way to developing a product that could have a significant impact on the transference of infective prion particles between patients. Prions are small proteins found in the brain cell membrane and a distorted form of prion is responsible for "Mad Cow Disease" and causes Creutzfeldt-Jakob disease (CJD) in humans.



The project aims to develop a manufacturing process to produce high performance all-plastic disposable surgical instruments at low cost through innovations in component design, micro-moulding techniques and polymer surface hardening treatments, thereby developing a disposal route that renders the blade sharp safe in less than 1 second.

It is estimated that 1 in 10,000 people are infected with CJD at the time of their death, which equates to around 6 million people worldwide. As of 2004, CJD has caused over 100 human deaths in the UK alone. More seriously, however, the incubation period is as yet unproven, but is thought by some to be in the range of decades, suggesting that the scale of the new variant CJD and surgically acquired (iatrogenic) CJD problem could significantly increase in future years. At the time of writing, iatrogenic transmission of the CJD agent has been reported in over 250 patients worldwide.

One way to overcome this is to sterilise the surgical equipment. However, prions show resistance to all normal forms of sterilization, and the temperatures routinely used to sterilize surgical instruments actually help to spread CJD between humans. The only viable solutions are to use disposable surgical instruments, or to treat surfaces and instruments by flooding with or soaking in 2M NaOH or undiluted sodium hypochlorite for 1 hour and then rinse with water. Both of these options are cost prohibitive for routine operations, and the latter often results in the instruments being damaged. As a result, they are often only implemented when medical instruments have come into contact with high infectivity tissues of persons with suspected or diagnosed CJD. This poses a risk of infection from individuals with no symptoms or suspicion of CJD before, during or immediately after their procedure.

The project consortium, co-ordinated by Clare-Pak Ltd of Ireland, has already developed a polymer surface treatment, and further optimisation trials are now underway. Work is also continuing to perfect the moulding and shaping techniques used. Anyone interested in finding out more should contact Dr Jo Love at Pera Innovation on +44 (0) 1664 501501.

This press release represents the view of the project consortium, and the EC is not liable for any use that may be made of the information contained herein.

Press Release Ends.

NOTES FOR THE EDITORS

Disblade is a Co-operative Research Project funded under the European Community's Sixth Framework Programme. The project consortium consists of the following companies:
Clare-Pak Limited, Ireland
A/S Kenneth Winther-Vaerktojsfabrik, Denmark (http://www.winther.com/)
Mapro Spol S.R.O., Czech Republic
Clinipart Ltd, UK (http://www.clinipart.com)
Fedegari Autoclavi SPA, Italy (http://www.fedegari.com/)
Rosti AS, Denmark (http://www.rosti.com/)

These companies are supported by the research and development capabilities of Pera Innovation, UK (http://www.pera.com) and The National Institute of Technology, Norway (http://www.teknologisk.no).

For further details of the above project please contact:

Dr Jo Love (jo.love@pera.com)

Pera Innovation

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LE13 0PB
Tel: +44 (0) 1664 501501
Fax: +44 (0) 1664 501554
www.pera.com

Press Notice – for immediate release

Press Release Begins

Polymer Surface Hardening To Dramatically Reduce CJD Risk

'Disblade' - a project initially funded by the EU involving 6 industrial partners and supported by Pera in the UK and The National Institute of Technology in Norway started in March 2004 and has developed and patented a surface treatment technology that could have a significant impact on the transference of infective prion particles between patients. Prions are small proteins found in the brain cell membrane and a distorted form of prion is responsible for "Mad Cow Disease" and causes Creutzfeldt-Jakob disease (CJD) humans.

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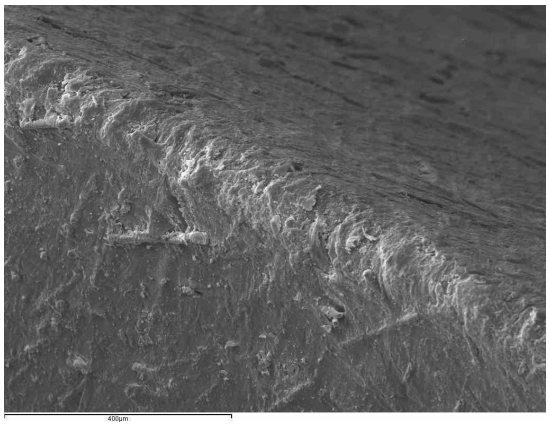
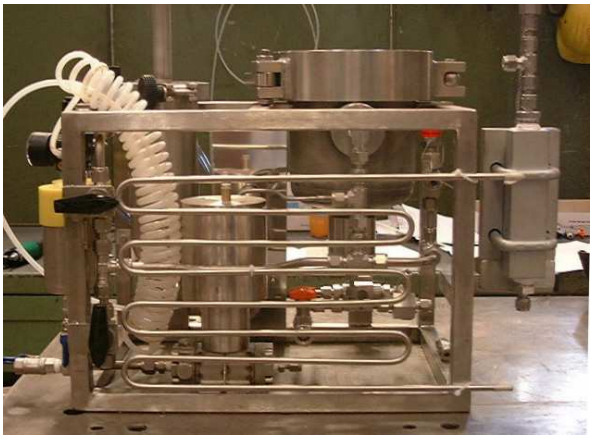
CJD has caused over 100 human deaths in the UK alone. More seriously, however, the incubation period is as yet unproven, but is thought by some to be in the range of decades, suggesting that the scale of the new variant CJD and surgically acquired (iatrogenic) CJD problem could significantly increase in future years. Sterilising surgical equipment does not always destroy the resistant prions and prevent iatrogenic transmission. High quality, low cost disposable instruments are therefore required for routine use to prevent transmission from patients who have not yet begun to show any symptoms of their CJD infection.

The project has developed a manufacturing process to produce high performance all-plastic disposable surgical instruments at low cost through innovations in component design, micro-moulding techniques and polymer surface hardening treatments and an associated disposal route that renders the blade sharp safe before it leaves the operating theatre.

The patented polymer hardening process developed by the consortium is based on a surface modification producing a organic-inorganic hybrid. In addition to a hard and sharp edge, this type of surface modification can offer high modulus and abrasion resistance, reduced gas permeability, low coefficient of thermal expansion and enhanced thermal oxidation resistance.





In contrast to other similar processes, this technique avoids the use of traditional organic wet solvents, profiting instead from the low toxicity, low cost, natural abundance, recoverability and recyclability of a pressurised gas.

When combined with the optimal polymer, this treatment can produce components with properties suitable for replacing metal in many applications, including surgical scalpels.

The project consortium, co-ordinated by Pera, is continuing with optimisation trials and is seeking additional commercialisation opportunities.

Anyone interested in finding out more should contact

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This press release represents the view of the project consortium, and the EC is not liable for any use that may be made of the information contained herein.

Press Release Ends.

NOTES FOR THE EDITORS

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A/S Kenneth Winther-Vaerktojsfabrik, Denmark (http://www.winther.com/)
Mapro Spol S.R.O., Czech Republic
Clinipart Ltd, UK (http://www.clinipart.com)
Fedegari Autoclavi SPA, Italy (http://www.fedegari.com/)
Charpak Ltd, UK (http://www.charpak.co.uk)
Rosti AS, Denmark (http://www.rosti.com/)

These companies are supported by the research and development capabilities of Pera, UK (http://www.pera.com) and The National Institute of Technology, Norway (http://www.teknologisk.no).

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