



COOP-CT-2005-018294

DUET

Development of a Disposable Endoscope

Horizontal Research Activities Involving SMEs

Co-operative Research (CRAFT)

Publishable Final Activity Report

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Project co-ordinator organisation: TWI Ltd

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Contents

1	Project Execution	1
1.1	Project objectives	1
1.2	List of contractors	2
1.3	Work performed	2
1.4	International state of the art	2
1.4.1	Current state of the art	2
1.4.2	Project's current relation to state of the art	3
1.5	Impact on the Endoscopy Industry	4
2	Dissemination and Use	4
2.1	The DUET endoscope	4
2.2	Optical system	4
2.3	Recycling plan	4
2.4	Steering and assembly	5

1 Project Execution

Endoscopes are miniature, elongated microscopes that physicians use to perform minimally invasive procedures on patients – in their hollow organs or invasive canals. Infection in patients can occur due to inadequate cleaning of endoscopes and instruments which pass through endoscopes. In this project, a team of SMEs developed single use endoscopy instruments which will eliminate the possibility of infection of the patient from this equipment. The technology developed in this programme will be applicable to other equipment developed by the SMEs. An additional aim is for the disposable endoscopy equipment to be constructed from materials which can be recycled after use.

1.1 Project objectives

The scientific and technical objectives

- To develop a low cost disposable endoscopic instrument giving the same patient experience as repeat-use devices.
- To eliminate infections to patients, and clinicians.
- By using low cost, high volume manufacturing technology and polymer materials, to produce colonic endoscopic equipment which is disposable.
- To develop endoscopic equipment whose material components can be recycled.

The economic objectives

- To develop single use endoscopic equipment costing less than 1% of the repeat use devices.
- To reduce the cost of endoscopy procedures making them accessible to more people, ie eliminating disinfecting costs.
- To reduce costs of litigation arising as a result of infection from endoscopy.

The social objectives

- To reduce health risks from exposure to contaminated re-useable endoscopic equipment.
- To improve flexibility and comfort to patients by offering them endoscopy quickly in more health centres and hospitals.

The environmental objectives

- To reduce the use of chemicals currently used in decontamination of endoscopic equipment.
- To provide a route for material recycling of the single use endoscopic equipment.

The main innovations

- 1 Disposable endoscopic equipment for less than 1% of the repeat use equipment.
- 2 Recyclable disposable endoscopic equipment.
- 3 A different business model for endoscopy allowing for much greater flexibility.
- 4 New, sterilised endoscopic equipment for each procedure.
- 5 High volume manufacturing technology for endoscopic equipment.

1.2 List of contractors

TWI	TWI Ltd – Project Co-ordinator (UK)
SUSL	Single Use Surgical Ltd (UK)
ENDO	Endomed GmbH (Germany)
ELD	Eldos Ltd (Poland)
VIST	Vistamed Ltd (Ireland)
FORG	Forge Europa (UK) left ther project in April 2007
OPT	Optoelectronica 2001 S.A. (Romania)
OMN	Omnivision (Cayman Islands) joined in April 2007
NHS	National Health Service (UK)
ISQ	Instituto de Soldadura e Qualidade (Portugal)

Co-ordinator Details

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1.3 Work performed

Prototype single use endoscopy tools were developed by the Partnership.

A plan for materials selection, recycling and disposal at the end of life of the tools has been formulated. The tools have been compared in their performance against the original specification for the device. A website for the project has been established www.duet-project.org.

1.4 International state of the art

1.4.1 Current state of the art

In the early 1900s the first attempts to view inside the body with lighted telescopes were made. These initial devices were often fully rigid. In the 1930s, semi-flexible endoscopes called gastroscopes were developed to view inside the stomach. South African born physician Basil Hirschowitz at the University of Michigan in 1957 pioneered fibre-optic endoscopy. Widespread use of the fibre optic endoscopes began in the 1960s. Until the last few decades, exploratory surgery was routinely performed when a patient was critically ill and the source of the illness was not known.

A typical modern endoscope has two fibre optic lines, a light fibre carries light into the body cavity and an "image fibre" carries the image of the body cavity back to the physician's viewing lens. There is also a separate port to allow for the administration of tissue excision (removal), sampling or other diagnostic and therapeutic work. Endoscopes may be used in conjunction with a camera or video recorder to document images of the inside of a body. New endoscopes may also have digital capabilities for manipulating and enhancing the video images and an internal system makes it possible for the physician to control bending of the instrument, referred to as distal-end angulation. Flexible endoscopes contain either an electronic video camera chip or glass fibres to produce or "return" images for the physician to view (Figure 1). Modern sterilisation methods place high demands on both

materials and their processing and are not fully functional in eliminating infections, disease and death from the re-use of these instruments.

Disposable capsule

Recently (2001), a new disposable capsule endoscope has received FDA approval for use in patients. Developed by Given Imaging, the M2A Capsule involves ingesting a small (the size of the large vitamin pill) capsule, which contains a colour camera, battery, light source and transmitter. The camera takes two pictures every second for eight hours, transmitting images to a data recorder about the size of a portable CD player that patients wear around the waist. Once swallowed the camera moves naturally through the digestive tract while patients carry out their normal activities. The Capsule endoscope is disposable and will be egested naturally.

(IEE Review, June 2004. www.iee.org/review). (A capsule camera to save stomachs – Japan- Article-@pan Inc Magazine)

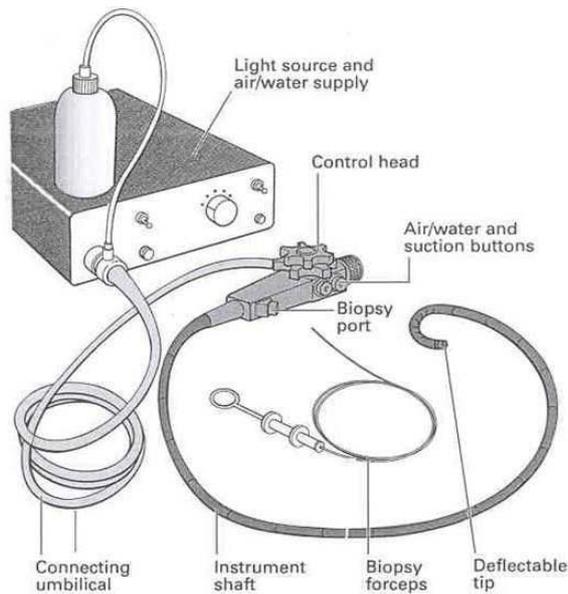


Figure 1 An endoscope machine.

Pulley system

Either a wire assembly or a chain drive can be used to articulate endoscopes. The wire pulley is the most commonly used on flexible endoscopes. A locking system allows these to be fixed in any position. The pulley system uses a pair of wire cables wound onto a two-slotted pulley and terminated with a solid stopper. Turning the control handles turns the pulleys that pull the wires as they wind themselves up. Tension is released by feeding out wire to give slack to the opposite side. A shaft in the control head connects the pulleys to the control handles. Endoscopes that have up and down as well as left and right angulation have two systems.

1.4.2 Project's current relation to state of the art

This project has demonstrated the feasibility of the use of disposable endoscopic tools. They can be cost effective, fit for purpose and suitable for safe disposal and, in due course, recycling.

1.5 Impact on the Endoscopy Industry

The demonstration of the feasibility of the single use equipment means that endoscopy can potentially be used much more flexibly than before. Currently, it is deployed in specialising hospitals due to the infra-structure required. Single use equipment has the potential to change this to a much more flexible approach where a concentration of equipment (endoscopes, monitors, cleaning equipment, etc), and specially trained people (cleaning technicians etc) is no longer necessary. This equipment may also in due course bring down the cost of endoscopy, making it more accessible.

2 Dissemination and Use

2.1 The DUET endoscope

Prototype single use endoscopy tools to assist in the inspection of the colon have been developed. Further work will be required to take these prototypes into production. The exploitation manager to whom all enquiries regarding the production and marketing should be addressed is:

Matthew Tulley
Single Use Surgical Ltd
BBIC
Innovation Way
Barnsley, S75 1JL
UK

e-mail: m.tulley@susl.co.ltd

2.2 Optical system

A design for prototype optics for the tools has been formulated during the project. This design originated at:

Mrs Alexandra Carmizoiu
S.C. Optoelectronica 2001 S.A.
Str. Atomistilor nr 409
077125
Magurele
Romania

e-mail: alex@optoel.ro

2.3 Recycling plan

The DUET disposable use endoscope tools require a plan for their end-of-life. This plan includes recommendations for the materials to be selected to aid disposal, incineration and recycling as required.

Interested parties should contact:

Pedro Cardoso
ISQ
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2740-120 Oeiras
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2.4 **Steering and assembly**

Mechanism to enable the simple and safe use of the endoscopy tools:
Interested parties should contact:

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