



***Eucomed Position Paper on
Access to Ostomy Supplies and Innovation***

Summary

The loss of continence individuals suffer as a result of ostomy surgery is often a life-changing experience. The impact on the quality of life of patients and their families can be profound. Access to ostomy supplies that are fitted and prescribed by a healthcare provider is critical to maintaining the health and well-being of the person with an ostomy. New innovations that provide enhanced skin protection and/or prosthetic functionality are also important for these individuals.

Policymakers must overcome a number of barriers to ensure adequate care is available to European Union citizens who have undergone ostomy surgery. Investment in innovation has delivered a wide range of sophisticated products with the potential to vastly improve quality of life. However, the reimbursement, procurement, and healthcare training systems have not kept pace. Payment classification systems take a one-size-fits-all approach to an area of considerable complexity, while limitations of monthly allowances restrict citizens' access to essential products and reduce the incentive for manufacturers to develop innovative new solutions for patients. The sophistication of ostomy products calls for increased support services, yet the lack of standardised ostomy nurse training programmes across Europe gives rise to major disparities in standards of care.

Continence is defined as the ability to retain urine and/or faeces until a proper time for their discharge.¹ For most of us, continence is such a basic, natural state that it is generally taken for granted. However, as a result of disease, genetics or trauma, approximately 700,000 Europeans have undergone life-saving ostomy surgery to remove diseased or damaged portions of their intestines or bladder. The surgery results in a loss of sphincter control and redirects the output from the intestinal or urinary system through a surgically created opening on the abdomen called a stoma. Patients have no control over the functioning of the stoma opening. While they are "cured" of their disease, people with an ostomy are incontinent and for the remainder of their lives wear an external collection device to collect the effluent (output from a stoma).

The purpose of this paper is to heighten awareness of ostomy surgery and the medical complications that can arise when those living with the effects of stoma surgery lack full access to the ostomy supplies they have been prescribed and continuously need. It identifies the access issues currently experienced by people with an ostomy within the European Union and lays out a set of guiding principles for government, payers and regulators to follow to ensure every person with an ostomy has access to these necessary medical devices.

¹Stedman's™ Medical Dictionary 2007 Edition.

What is an Ostomy?

An ostomy is simply defined as an artificial stoma or opening into the urinary or gastrointestinal canal, or the trachea². The term ostomy is used interchangeably with the term stoma, which is defined as a surgically created mouth or opening for the discharge of body wastes. Surgery to create an ostomy is required when there is a malfunction within the gastrointestinal or urinary systems.

There are numerous medical conditions that require surgery and the creation of a faecal stoma, such as a colostomy or ileostomy, including inflammatory bowel diseases (IBDs), colorectal cancer, diverticular disease, radiation enteritis, ischemic colitis, infectious enteritis, intestinal obstruction, gastrointestinal trauma, spinal cord injury, ovarian cancer and prostate cancer. A urinary stoma or urostomy is required when the bladder is bypassed or removed. Conditions that lead to a urostomy include bladder cancer, prostate cancer, interstitial cystitis, neurogenic bladder, and refractory radiation cystitis.

Over the years patients have benefited from improved stoma construction, which usually translates into better management. In addition to progress related to both faecal and urinary diversion, significant progress has been made in reducing the complications associated with radical pelvic surgery and in reducing the morbidity associated with any major surgical procedure. Significant advances include the improved ability to identify the autonomic nerves, while the increased use of the laparoscopic approach significantly reduces postoperative morbidity and recovery time. An article by Montorsi (2001) discusses a number of newer treatments.³

Stomas in the gastrointestinal tract can be permanent or temporary. The majority of stomas (56%) are permanent⁴. Clinicians usually tell their patients with a temporary ostomy that their stoma will be closed within nine weeks after the initial surgery.⁵ However literature reveals that 8% of faecal diversion patients never undergo closure of what was originally intended to be a temporary ostomy.⁶

² *Stedman's Medical Dictionary*. 24th ed, Baltimore, MD: Williams & Wilkins:1984.

³ Montorsi F et al: Counseling the patient with prostate cancer about treatment related erectile dysfunction. *Curr Opin Urol*. 11(6):611-617,2001.

⁴ Eucomed Ostomy Market Industry Survey, May 2011

⁵ Colostomy Association (2011) About Stoma Reversal. Available on-line at: http://www.colostomyassociation.org.uk/_assets/File/pdf/aboutstomareversal.pdf (Accessed 31 January 2012).

⁶ Colostomy Association (2011) About Stoma Reversal. Available on-line at: http://www.colostomyassociation.org.uk/_assets/File/pdf/aboutstomareversal.pdf (accessed 31 January 2012).

Who is affected?

Ostomy surgery impacts approximately 700,000 people (0.14% of the total population) in the EU, ranging from young women with ischemic colitis to older men with colorectal cancer. More than half of ostomy surgeries (55%) are considered permanent surgeries,⁷ meaning the patient will be permanently unable to control the output of effluent and will require a collection device attached to their abdomen. While patients' health generally improves significantly after surgery, psychological, social, work-related and sexual issues remain.⁸ The average lifespan of an ostomy patient after surgery ranges from 6.6 years for people with a colostomy to 11.3 years for those with an ileostomy.⁹

Overcoming barriers

According to Article 152 of the European Union Treaty¹⁰, the organisation and delivery of health services and medical care are the responsibility of the Members States. People with statutory health insurance and social long-term care insurance have the right to receive medical devices, instruction in their use, alteration, repair, and maintenance. However, barriers to optimal care remain:

- Generic payment classification systems take a one-size-fits-all approach, failing to take account of the breadth and complexity of ostomy care
- Increasing use of tenders which limit the number of suppliers and treat all ostomy products as interchangeable without taking into account the needs of the individual
- Monthly allowance restrictions limiting the quantity of essential supplies and accessories
- Failure to recognise medical (skin barrier) and prosthetic (pouch) nature of ostomy devices
- Lack of incentives to innovate because of closed reimbursement systems, capped monthly payments and evidence requirements inappropriate for prosthetic medical devices
- Need for increased support services – lack of standardisation of ostomy nurse training programmes across Europe

⁷Eucomed Ostomy Market Industry Survey, May 2011

⁸ Grant M, Ferrell B, Dean G, Uman G, Che D, Krouse R. Revision and psychometric testing of the City of Hope Quality of Life-Ostomy Questionnaire. *Qual Life Res.*2004;13(8):1445-57.

⁹ Eucomed Ostomy Market Industry Survey, May 2011.

¹⁰Europa Summaries of EU Legislation website,

http://europa.eu/legislation_summaries/institutional_affairs/treaties/amsterdam_treaty/a16000_en.htm, accessed 13 January 2012.

Ostomy surgery has both positive and negative consequences for patients. On the positive side, it results in removal of diseased portions of the intestines or bladder. As such, it is a cure that provides a new lease on life for those otherwise facing a dire future. On the other hand, ostomy surgery results in a loss of bodily control that is at the core of adulthood – the timing and location of defecation or voiding. Ostomy management products are single-use prosthetic devices that attempt to restore some of the lost functionality – storage and containment of stool or urine, albeit outside of the body. As prosthetics, ostomy products are different from other medical supplies such as tulle dressings and tapes. They provide both medical and functional benefits for patients.

Each person with an ostomy is a unique individual with specific medical and functional needs following surgery. Different medical conditions, skin types, body size and shape, and dietary patterns are among the factors that impact the fit and performance of an ostomy management system. Other considerations like the climate and body weight also impact the choice of ostomy system. For this reason, manufacturers market hundreds of different skin barriers and pouches to provide physicians and Stoma Care Nurses/Enterostomal Therapy Nurses (nurses specially trained in the selection and prescription of ostomy supplies) with a wide range of choices to meet their patients' needs.

It is essential that people with stomas maintain healthy peristomal skin.¹¹ Continual access to the prescribed products is important to avoid and manage medical complications which can result in costly medical care and hospitalisation.

What is the industry perspective?

Eucomed believes governments, payers and regulators of the EU should recognise the life-saving role of ostomy care, supplies and prosthetics in the daily lives of the 700,000 people with an ostomy in the European Union and the need for these individuals to have access to the prescribed ostomy supplies they need. This can support active and healthy ageing and reduce infection risks. Eucomed proposes the following **Guiding Principles for European Payer Access to Ostomy Supplies and Innovation**.

¹¹Herlufsen P, Olsen AG, Carlsen B, Nyback H, Karlsmark T, Laursen TN, Jemec GBE. Ostomy skin study: a study of peristomal skin disorders in patients with permanent stomas. *BJN*. 2006;15(16):854-862.

Governments, payers and policymakers must:

- 1) Recognise the life-saving role of ostomy care and prosthetics in the daily lives of hundreds of thousands of people in the European Union and the necessity of a specialised ostomy nurse to recommend and customise ostomy prosthesis for the individual;
- 2) Recognise that if a surgical procedure results in a patient needing a prosthetic which manages or restores intestinal or urinary system function – specifically the control of the elimination of the body's waste products – then such a patient should have access to individually prescribed, customised prosthetics and accessories in the needed quantities which the healthcare provider believes will best meet the patient's needs;
- 3) Encourage programmes, policies, and payment practices that facilitate, rather than discourage, innovation of and access to medical devices that restore or improve intestinal or urinary system function of individuals in the European Union with an ostomy.

About Eucomed

Eucomed represents the medical technology industry in Europe. Our mission is to make modern, innovative and reliable medical technology available to more people.

Eucomed members include both national and pan-European trade and product associations as well as medical technology manufacturers. We represent designers, manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and amelioration of disease and disability.

The industry we represent employs more than 500,000 highly skilled workers, turns over €95 billion per year, invests some €7.5 billion in R&D and encompasses of approximately 500,000 different medical technologies from sticking plasters and wheel chairs through to pacemakers and replacement joints.

Eucomed promotes a balanced policy environment that enables the medical technology industry to meet the growing healthcare needs and expectations of society. For more information visit www.eucomed.org