EVEXAR Medical Ltd

Environmental Impact and Disposal of EVEXAR Illuminated Rigid Endoscopes (Proctoscope etc)

This paper outlines the EVEXAR position with respect to the use of batteries in disposable product.

In the European Union – a directive on the recycling of batteries exists which states that batteries, cells and accumulators must be recycled. At first glance, it would appear that this directive applies to the EVEXAR illuminator.

However, sitting above this directive is a directive on the disposal of hazardous waste. Clinical Waste is defined within this directive as special waste. – see below for more formal definitions

Clinical waste is defined as 'waste contaminated with infectious or potentially infectious materials' and the Illuminator/Endoscope combination obviously falls into this category.

The directive states how clinical waste must be processed – principally through incineration and possibly through autoclaving or irradiation.

There is therefore no conflict between the disposal of the EVEXAR Illuminator/Proctoscope as clinical waste and the need to recycle batteries – note that the process of recycling of batteries comes from the disposal of general 'municipal' waste.

EVEXAR has chosen the batteries for these Illuminators to be as small as is reasonable commensurate with both an effective illumination period, acceptable shelf life and environmental disposal.

The technology of the battery is 'alkaline' – see below for how the cell works. Note that the ingredient materials are

- Nickel Plated Steel
- Zinc
- Potassium Hydroxide
- Manganese Dioxide
- Nylon
- Brass
- Water

The LR44 supplier is chosen to ensure that the cells are lead, cadmium and mercury free in order to minimise as much as possible, any environmental impact.
On incineration, the non-volatile materials are non-toxic and environmentally compatible and indeed the processors process the residual ash to extract metals for reprocessing.

It is useful to compare the disposable incineration process against the potential for reusable equipment. The key differentiator in the discussion is what must we do to a re-useable instrument to enable it to be re-used. In most cases, the answer is to clean it. This has obvious implications.

How do we know that we have cleaned the device sufficiently to prevent cross infection – the answer is simply –we don't – and the use of many reusable instruments is being contraindicated for this very reason.

If we have re-useable devices – what is the environmental impact of the cleaning and sanitising chemicals used over the lifetime of the device – it can be argued that these fluids and cleaning agents have an equal or perhaps even greater environmental impact.

Concern is sometimes expressed regarding possible explosions from incinerating cells. The EVEXAR product does not represent an explosion hazard on incineration for several reasons.

- The volume of the cell is very small..

- The construction of the LR44 cell is of a metal can (the positive terminal) crimped around a metal disc (the lid) forming the negative terminal. Separating these two parts electrically, to prevent a short circuit, is a nylon disc. The nylon disc melts and distorts at low temperature releasing any possible pressure build up. Also – the force of the crimping is relatively weak and this will yield at forces well below those which could be experienced in incineration.

- The incineration is carried out in an industrial scale enclosed incinerator – even if the cells did explode, it would represent no hazards to incinerator operators and the amount of energy released from an LR44 cell weighing only a few grams is small.

Clinical Waste incinerator operators were consulted in the design and development of these devices and they expressed no concerns regarding the incineration of these Illuminators/Proctoscope as clinical waste

Definition of Clinical Waste

Clinical waste

Clinical waste is defined in the Controlled Waste Regulations 1992. It means any waste which consists wholly or partly of:

- human or animal tissue;
- blood or bodily fluids;
- excretions;
- drugs or other pharmaceutical products;
- swabs or dressings; or;
- syringes, needles or other sharp instruments;

which unless rendered safe may prove hazardous to any person coming into contact with it. And:

- any other waste arising from medical, nursing, dental, veterinary, pharmaceutical or similar practice, investigation, treatment, care teaching or research, or the collection of blood for transfusion, being waste which may cause infection to any person coming into contact with it.

What controls are there on the disposal of clinical waste?

Clinical wastes are healthcare wastes that may prove hazardous to those that come into contact with them. There are stringent controls in place to ensure that clinical waste is managed safely and is recovered or disposed of without harming the environment or human health. Under the Environmental Protection Act 1990 it is unlawful to deposit, recover or dispose of controlled (including clinical) waste without a waste management licence, contrary to the conditions of a licence or the terms of an exemption, or in a way which causes pollution of the environment or harm to human health. Contravention of waste controls is a criminal offence. Section 34 of the Act, places people concerned with controlled (including clinical) waste under a duty of care to ensure that the waste is managed properly, recovered or disposed of safely and is only transferred to someone who is authorised to keep it. Householders are exempt for their own household waste.

This is the definition of ‘clinical waste’ from DEFRA - EVEXAR Illuminated Endoscopes (Proctoscopes, Sigmoid scopes etc) must therefore be classified as clinical waste according to the highlighted points

It is evident that the EVEXAR products must be disposed of as clinical waste and moreover, disposed of by a licensed organisation.

Within the hospital environment, clinical waste is removed and processed by such licensed operators.

This is the position on Clinical Waste in Scotland

Clinical wastes

The regulatory and legislative requirements surrounding the management of clinical waste can be confusing at times. In this section of the website we aim to provide access to guidance and best practice for those involved in the management of clinical wastes.

What is clinical waste?

Clinical waste is the term used to describe waste produced from healthcare and similar activities that may pose a risk of infection or may prove hazardous. It has different meanings to different people and can be defined in different ways. The most commonly used definition can be found in the Controlled Waste Regulations 1992.

In practice, clinical waste can be divided into two categories of materials:

- waste which poses a risk of infection
- medicinal waste

Clinical waste should be segregated from other types of waste and be treated/disposed of appropriately in suitably permitted, licensed or exempt facilities on the basis of the hazard it poses.

Assessing and classifying your clinical waste

Healthcare wastes can be found in sub chapters *18 01* (wastes from natal care, diagnosis, treatment or prevention of disease in humans) and *18 02* (wastes from natal care, diagnosis, treatment or prevention of disease in animals) of the European Waste Catalogue (EWC).

Clinical waste may be hazardous or non-hazardous and like all wastes it must be classified and assessed appropriately. Guidance on the classification and assessment of clinical waste as special (hazardous) waste can be found in the guidance document 'Hazardous Waste: Interpretation of the definition and classification of hazardous waste (WM2)'.

The Scotland and Northern Ireland Forum for Environmental Research (SNIFFER) has produced a guidance document which provides assistance to those managing hygiene waste produced as a direct result of healthcare and non-healthcare activities.

SEPA's position

Unless it can be satisfactorily demonstrated that 'healthcare wastes', i.e. those described by Chapter 18 of the EWC and EWC 20 01 31*, have been adequately segregated and categorised then **SEPA's default position is that healthcare waste should be assumed to be special (hazardous) waste until and unless proved otherwise**.

This is an NHS guidance document on waste definition and its handling

Waste Definition & Classification

DOH (2006) Health Technical Memorandum 07-01: Safe management of health care waste

1. INTRODUCTION

Waste regulation requires the classification of health care waste, produced as aconsequence of health care activities in hospitals and community settings, on the basis of its hazardous characteristics and point of production. There are two types of healthcare waste – hazardous and non-hazardous.

Hazardous waste	**Non-hazardous waste**
Infectious waste (e.g. anatomical waste, sharps)	Offensive/hygiene waste (e.g. incontinence and other human hygiene, sanitary waste, nappies)
Cytotoxic & cytostatic medicines	Non-cytotoxic and cytostatic medicines
Health care chemicals and hazardous properties	Domestic waste
	Packaging Waste
Batteries	Recyclable materials
X-ray photochemicals	Food waste
Radioactive waste	

2. WASTE DEFINITION & CLASSIFICATION

All clinical waste needs to be segregated so it can be disposed of appropriately, on the basis of the hazard it poses. The *Safe Management of health care waste* memorandum introduces a new single classification system that enables a unified approach to assessing, at the source of production, whether waste is:

Infectious clinical waste
Medicinal waste
Offensive/hygiene waste

The Hazardous Waste Regulations (2005) place a duty on waste producers to segregate hazardous and non-hazardous waste at source. The unified approach outlined by the SMHCW memorandum is recommended to ensure compliance with all regulatory requirements – from production through to transport and finally to disposal.

2.1 Clinical Waste Definitions

Clinical waste is divided into two categories of materials:
Waste that poses a risk of infection
Medicinal waste

Infectious Waste

Infectious waste is defined as waste that poses a known or potential risk of infection.
Even minor infections are included in the definition of infectious.
Any implanted medical device that has been in contact with infectious bodily fluids should also be classified and treated as infected waste.

All health care waste – whether produced in a hospital or a community setting – is assumed to be infectious waste until it's assessed. This assessment is based on an item and patient-specific clinical assessment, which is undertaken by the health care practitioner.
Any failure to segregate infectious waste from non-infectious waste will mean the entire waste stream has to be classified as infectious waste, and consigned for appropriate treatment and recovery, or disposal.

Medicinal Waste

Medicinal waste includes expired, unused, spilt and contaminated pharmaceutical products, drugs, vaccines, and sera that need to be disposed of appropriate. It also includes discarded items contaminated from use in the handling of pharmaceuticals, such as bottles or boxes with residues, masks, connecting tubing, syringe bodies and drug vials.

Only cytotoxic and cytostatic medicines are classified as hazardous waste and must be segregated from other medicines. Failure to segregate cyto medicines will mean the entire medicinal waste stream must be disposed of at a waste incinerator.
Other non-cyto medicines may have harmful properties (e.g. controlled drugs) and should be referred to the appropriately authorised personnel for disposal and destruction.

2.2 Non-Clinical Waste Definitions

Offensive/hygiene waste

This is a new term to describe waste which is both non-infectious and non-hazardous (and therefore, does not require specialist treatment or disposal) but which may cause offence to those coming into contact with it. The category includes waste previously described as human hygiene waste and 'sanpro' waste.

Examples of offensive/hygiene waste include:

Incontinence and other waste produced from human hygiene
Sanitary waste
Nappies

2.3 Waste Classification

As a result of recent regulatory changes including the Landfill Regulations, the *Hazardous Waste Regulations* and the *List of Wastes Regulations*, all health care waste must now be classified using European Waste Catalogue (EWC) codes. In Scotland the *List of Wastes Regulations* do not apply, and 'hazardous waste' is defined as 'special waste' under the *Special Waste Regulations.*

3. REFERENCES

Department of Health (2006) *Health technical memorandum 07-01: Safe management of health care waste*, London: The Stationery office. Available at

http://www.dh.gov.uk

Statutory Instrument (2005) The hazardous waste (England and Wales) regulations,
London: The Stationery office. Available at

http://www.opsi.gov.uk/si/si2005/20050894.htm

This section (from Wikipedia) identifies the construction of the alkaline (LR44) cell

Construction of Alkaline Cells

> ***Alkaline batteries*** *are a type of power cell dependent upon the reaction between zinc and manganese dioxide (Zn/MnO_2). Compared with traditional carbon/zinc batteries, while both produce approximately 1.5 volts per cell, alkaline batteries have a higher energy density and longer shelf-life. Compared with silver-oxide batteries, which alkalines commonly compete against in button cells, they have lower energy density and shorter lifetimes.*

A cell consists of a steel can, nickel-plated at both ends, the negative, flat terminal being electrically isolated with a nylon seal. Inside the can is the manganese dioxide cathode, a separator membrane, the powdered zinc anode in a potassium hydroxide water electrolyte. Finally, at the axis is a brass pin electrically connected to the negative terminal.