



# Safe Use of Insulin Pens

**IMB Safety Notice: SN2010(16)**

**Circulation Date: 21 December 2010**

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**NOTICE**

## **MANUFACTURER/SUPPLIER**

Various

## **TARGET GROUPS**

All Hospital staff  
All Nursing Home staff  
Risk Managers  
Nursing Managers  
Hospital Pharmacists  
Diabetic Clinics/ outpatients  
Diabetic nurse specialists  
Diabetic departments  
Endocrinology units  
Endocrinology Consultants  
Paediatric wards  
Laboratory Managers  
Chief Medical Scientists  
Purchasing / Material Managers

## **ISSUE**

The risk of bloodborne pathogen transmission when insulin injection pens are used on more than one patient.

## **BACKGROUND**

Insulin pens are designed to administer accurate doses of insulin. The insulin pen is an injection device with a cartridge or reservoir containing several doses of insulin. Pens are available as pre-filled, disposable units or as re-usable pens, requiring replacement insulin cartridges. A sterile, disposable needle is attached to the pen for each use.

Insulin pens are placed on the market with the “intended purpose” for “**single-patient**” use and are labelled accordingly.

Using an Insulin pen on more than one patient is contrary to the guidance outlined in the device labelling / Summary of Product Characteristics (SPC). The use of these devices on multiple patients could result, possibly, in the transmission of pathogens (such as Hepatitis B or C or Human Immunodeficiency Virus (HIV) to patients who use the same pen, even when the needles are changed between patients.

# S A F E T Y

## NOTICE

### **ACTION OR RECOMMENDATIONS**

1. Ensure that this notice is communicated to the appropriate personnel within your organisation.
2. Ensure that procedures are in place to ensure that
  - a. single use devices are only used once.
  - b. single patient use devices are not used on multiple patients
3. Examine the guidance produced by Manufacturers in the “instructions for use” or the SPC before use.
4. Ensure that facilities are in place to ensure the safe disposal of these devices.

### **IMB REFERENCES**

SN2004(04) The “intended purpose” of a Medical Device  
SN2004(06) Instructions for Use provided by the Medical Device Manufacturer  
SN2010(14) Single Use & Single Patient Use Medical Devices

### **ENQUIRIES**

All adverse incidents relating to a medical device or any adverse events or medication errors associated with the use of insulin pens or cartridges should be reported to IMB:

Irish Medicines Board  
Kevin O’Malley House  
Earlsfort Centre  
Earlsfort Terrace  
Dublin 2

Telephone: +353-1-6764971  
Fax: +353-1-6344033  
E-mail: [vigilance@imb.ie](mailto:vigilance@imb.ie)  
Website: [www.imb.ie](http://www.imb.ie)