

PROFORMA

**Title of document:**

(Delete / Add document types as appropriate)

**Author:**

(Name & Position)

**Search Engine Keywords:**

(Words you think staff will use to search for this document)

**Related links:**

(E.G. Websites, SUHTranet pages, other documents)

**Description:**

**Single Use Equipment**

Infection Control Team

**Key Contact:**

Consultant Nurse Infection Control

Single-use equipment

Single patient-use equipment

Risk assessment

Other infection control policies

Medical devices policies

Medical devices are either classified as single-use, single patient-use or reusable.

This policy sets out clear guidance on the difference between these classifications.

It also provides a framework for risk assessment, to enable staff to clearly identify when purchase of single-use items is appropriate.

**Final Validation Committee:**

Strategic Infection Control Group

**Date agreed:**

(can be manually added when document validated)

**Date sent to Policy**

**Administrator:**

(can be manually added when document validated)

**Accountable Officer:**

(Name & Position)

Director of Nursing and

Director of Infection Prevention and Control

**Responsible Officer:**

(Name & Position)

Consultant Nurse Infection Control

**Directorates who use the document:**

All directorates and departments

**Highlighted to:**

(Key staff, Departments, Directorates)

All staff via directorate and departmental leads

**Date doc. implemented in**

**SUHT:**

**Date of next review:**

**Date doc. loaded on SUHTranet:**

**Date(s) Reviewed** (if applicable):

**Details of most recent review:**(Outline main changes made to document)

**Signature of Chairman of Validation Committee:** .....

**Print Name:** .....

**Post Held:** .....

## 1 INTRODUCTION / PURPOSE

- 1.1 Medical devices are either classified as single-use, single patient-use or reusable. This policy sets out clear guidance on the difference between these classifications. It also provides a framework for risk assessment, to enable staff to clearly identify when purchase of single-use items is appropriate.
- 1.2 The Policy is based on the advice published by the Medicines and Healthcare Products Regulatory Agency.
- 1.3 The Policy applies to all groups of staff.
- 1.4 Employees of the Trust who breach the Policy may be liable to disciplinary action, up to dismissal.

## 2 ACTION REQUIRED

- 2.1 All staff should ensure they are familiar with this policy, and should use devices in accordance with their classification. Managers should use the risk assessment tool as part of reviews of medical devices in use, and when they are planning new purchases, to identify whether purchase of single-use items is required.

## 3 QUERIES

- 3.1 Any queries regarding this policy should be addressed to the Infection Control Team,

## 4 REVIEW

- 4.1 This Policy will be reviewed no later than April 2007.

## 5 PRINCIPLES

- 5.1 Selection of single-use medical devices must be made following consideration of:
  - 5.1.1 National decontamination guidance, and the level of risk of the device.
  - 5.1.2 The facilities available to decontaminate reusable items.
  - 5.1.3 The ease or difficulty with which the item can be decontaminated (complexity of the device).

## 6 THE DECONTAMINATION PROCESS

- 6.1 Decontamination is the total process used to remove organic matter and micro-organisms from an item and render it safe for use. There are three levels of decontamination: cleaning, disinfection and sterilization.

## 7 CLEANING

- 7.1 Cleaning is a process which physically removes infectious agents and the organic matter on which they thrive but does not necessarily destroy infectious agents. The reduction of microbial contamination depends upon many factors, including the effectiveness of the cleaning process and the initial bioburden.

## 7.2 **Cleaning is an essential pre-requisite to ensure safe effective disinfection or sterilisation.**

## 8 Disinfection:

- 8.1 Disinfection is a process used to reduce the number of viable infectious agents but which may not necessarily inactivate some microbial agents, such as certain viruses and bacterial spores. Disinfection does not achieve the same reduction in microbial contamination levels as sterilisation.

## 9 STERILIZATION

9.1 Sterilisation is a process used to render an object free from viable infectious agents including viruses and bacterial spores.

## 10 SELECTION OF DECONTAMINATION METHOD

10.1 The level of decontamination required for an item is dependant upon the anticipated use of that item. The MHRA provides the following guidance:

Level of risk	Use of Item	Decontamination Process Required
Low risk	<ul style="list-style-type: none"><li>• In contact with intact skin</li><li>• Not in contact with the patient</li></ul>	Cleaning
Medium Risk	<ul style="list-style-type: none"><li>• In contact with broken skin</li><li>• In contact with mucous membranes</li><li>• Used on immunocompromised patients</li><li>• In contact with pathogenic micro-organism that is easily transmitted</li></ul>	Cleaning  FOLLOWED BY  Disinfection or Sterilization
High Risk	<ul style="list-style-type: none"><li>• In contact with broken mucous membranes</li><li>• Entering sterile body cavity</li></ul>	Cleaning FOLLOWED BY Sterilization

## 11 Single-Use, Single Patient-Use and Reusable Items

11.1 All medical devices, including endoscopes and their accessories, are designated either as single-use, single patient-use or reusable devices. The following definitions apply:

11.1.1 **Single-use:** A device that is used once, on a single patient, and then disposed of.

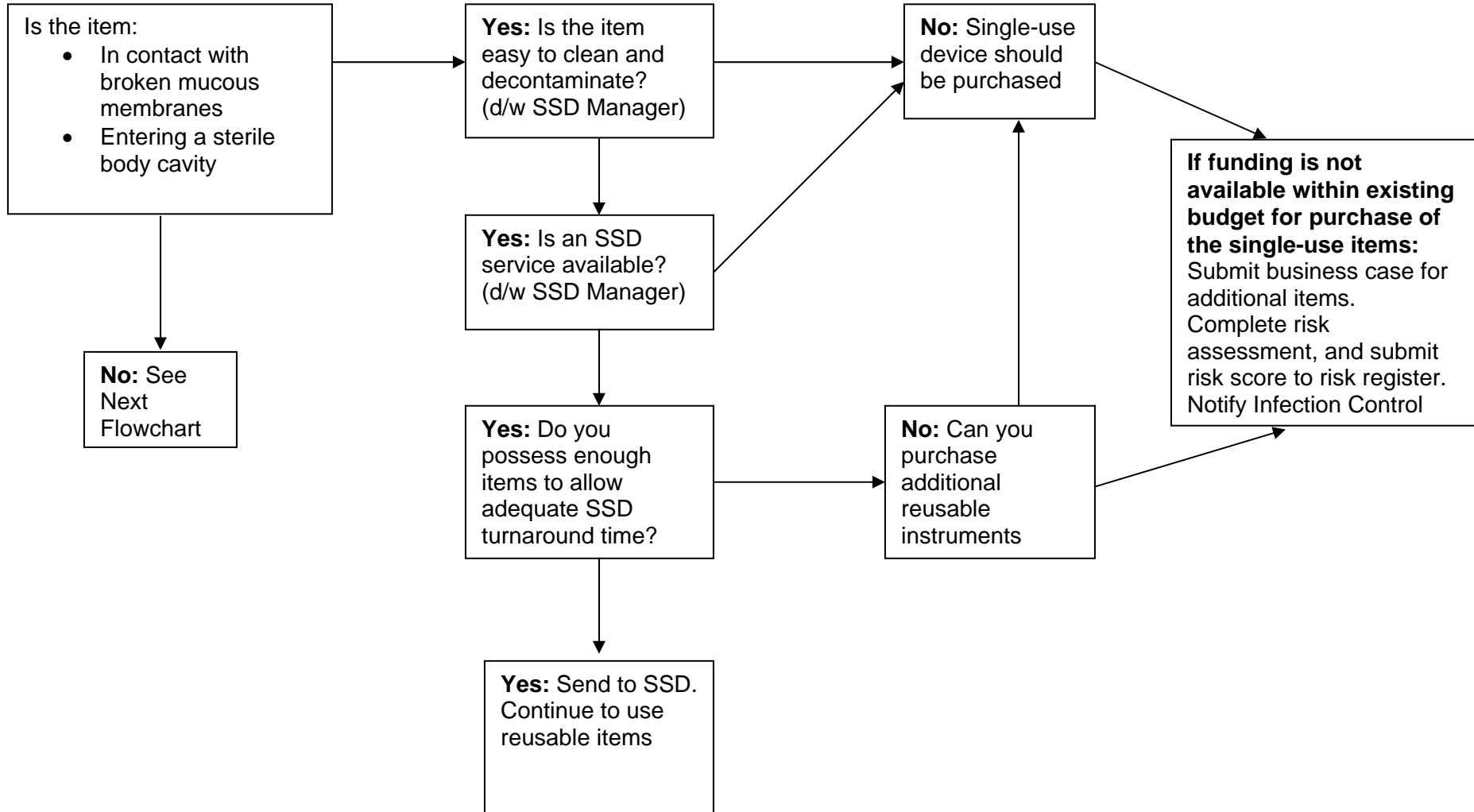
11.1.2 **Single Patient-Use:** A device that can be used more than once on a single patient.

11.1.3 **Reusable:** A device that can be reused on multiple patients, provided it is adequately decontaminated between uses.

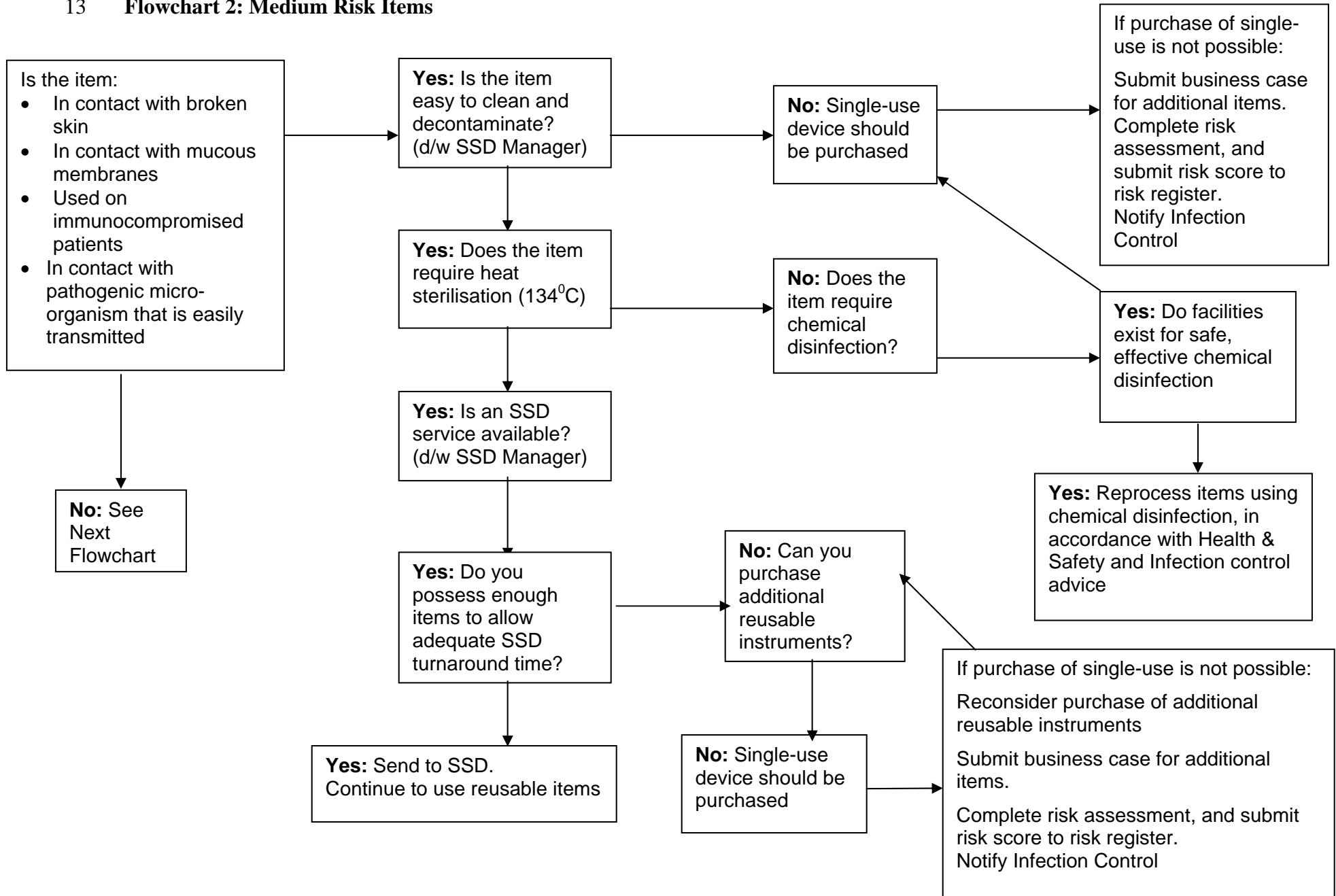
11.2 All medical devices are marked on their packaging. Items for single use will be marked with the following symbol:



12 Flowchart 1: High Risk Items



13 Flowchart 2: Medium Risk Items



14 **Flowchart 3: Low risk Items**



- 14.1 Single-use low risk items are not justified, except in exceptional circumstances such as severe trauma or massive haematemesis. In these circumstances items such as blood pressure cuffs may become heavily contaminated with blood, and single-use is justified.
- 14.2 Certain severe communicable diseases may require use of single-use low risk items, on the advice of the Infection Control Team, or on-call Microbiologist.

15 **SPECIFIC NATIONAL GUIDANCE**

- 15.1 Laryngoscope Blades should be cleaned and sterilised between patients. They must therefore be sent to SSD if single-use blades are not used. Alternatively, use of transparent blade covers followed by thorough cleaning of the blade and handle with detergent and water is acceptable.
- 15.2 Endoscope Biopsy Forceps, Guidewires and Cytology Brushes should be single-use, as they are too difficult to decontaminate.

16 **DOCUMENTATION OF RISK ASSESSMENT**

- 16.1 When a risk assessment is performed for high or medium risk items, it must be documented. The proforma on the following page should be used for this, and a copy of the appropriate flowchart completed and appended to the proforma.
- 16.2 If the need for an SSD Service is identified this must be discussed with the SSD Manager, and the outcome of this recorded.
- 16.3 This risk assessment should be appended to any business case for the equipment or used in support of a purchase requisition. If it is not needed as evidence for either of these purposes it should be filed in the department as evidence that risk assessment has been performed.

**SOUTHAMPTON UNIVERSITY HOSPITALS NHS TRUST**

**PROFORMA**

**INFECTION CONTROL RISK ASSESSMENT FOR USE OF SINGLE-USE  
AND SINGLE PATIENT-USE EQUIPMENT**

Directorate:	Department:
--------------	-------------

Item	
------	--

Risk category of item (See section 10)	HIGH	MEDIUM	LOW
---	------	--------	-----

Does flowchart indicate SSD Service should be considered	YES	NO
If yes, date discussed with SSD Manager		
Outcome of discussion	SSD Service POSSIBLE SSD Service NOT possible	

Final Outcome	
---------------	--

If issue cannot be resolved:

Date Infection Control Team notified of continuing risk	
Date placed on risk register	

Print name of person completing form	
Signature	
Date completed	

**REFERENCES**

Health Service circular: HSC 1999/178. Variant Creutzfeldt-Jakob diseases (vCJD): Minimising the risk of transmission

Health Service circular: HSC 1999/179. Controls assurance in infection control: decontamination of medical devices

Medical Devices Agency (2000) Device Bulletin DB 2000(04). Single-Use Medical Devices: Implications and consequences of reuse.

SOUTHAMPTON UNIVERSITY HOSPITALS NHS TRUST

APPROVED

POLICY

PROFORMA

**Title of document:**

(Delete / Add document types as appropriate)

**Author:**

(Name & Position)

**Search Engine Keywords:**

(Words you think staff will use to search for this document)

**Related links:**

(E.G. Websites, SUHTranet pages, other documents)

**Description:**

**Single Use Equipment**

Infection Control Team

**Key Contact:**

Consultant Nurse Infection Control

Single-use equipment

Single patient-use equipment

Risk assessment

Other infection control policies

Medical devices policies

Medical devices are either classified as single-use, single patient-use or reusable. This policy sets out clear guidance on the difference between these classifications.

It also provides a framework for risk assessment, to enable staff to clearly identify when purchase of single-use items is appropriate.

**Final Validation Committee:**

Strategic Infection Control Group

**Date agreed:**

(can be manually added when document validated)

**Date sent to Policy Administrator:**

(can be manually added when document validated)

**Accountable Officer:**

(Name & Position)

Director of Nursing and

Director of Infection Prevention and Control

**Responsible Officer:**

(Name & Position)

Consultant Nurse Infection Control

**Directorates who use the document:**

All directorates and departments

**Highlighted to:**

(Key staff, Departments, Directorates)

All staff via directorate and departmental leads

**Date doc. implemented in SUHT:**

**Date of next review:**

**Date doc. loaded on SUHTranet:**

**Date(s) Reviewed** (if applicable):

**Details of most recent review:**

(Outline main changes made to document)

**Signature of Chairman of Validation Committee:** .....

**Print Name:** .....

**Post Held:** .....