

# Learn about cell salvage: everything you want to know but are afraid to ask.....or..... 10 years of the UKCSAG

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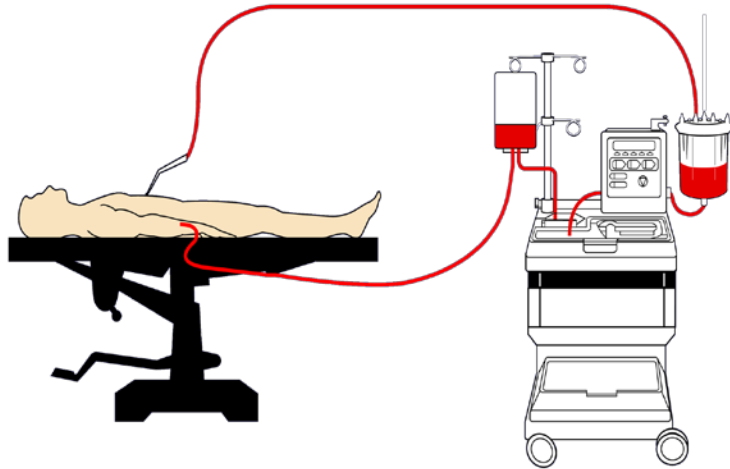
# Stuff you probably should know about me.....but daren't ask

- PhD in Biochemistry/Cell Biology – Tissue Engineering
- 20 years (nearly) experience of running cell salvage devices in theatres
- Founder & Director of SwabTech Ltd  
(NHS spin-out company)
- No other commercial interests

# Cell Salvage

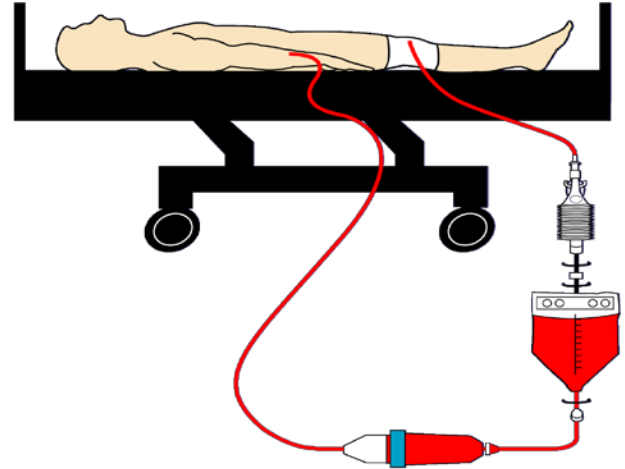
## Intra-operative (ICS)

Collected blood is anticoagulated, filtered, concentrated, washed with saline, and returned to the patient



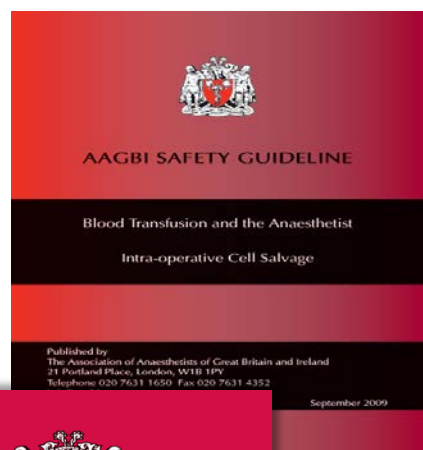
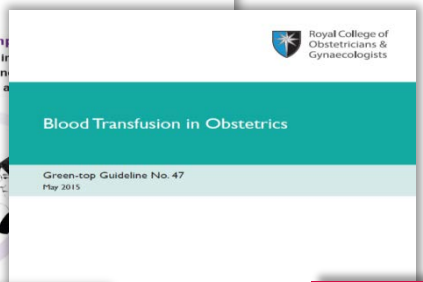
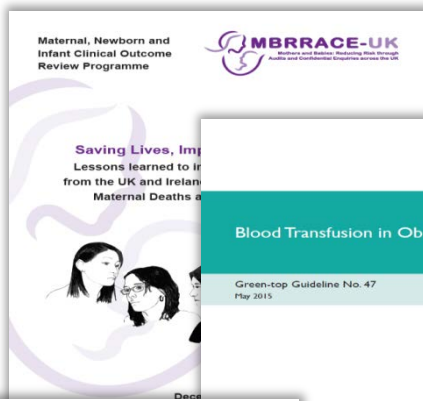
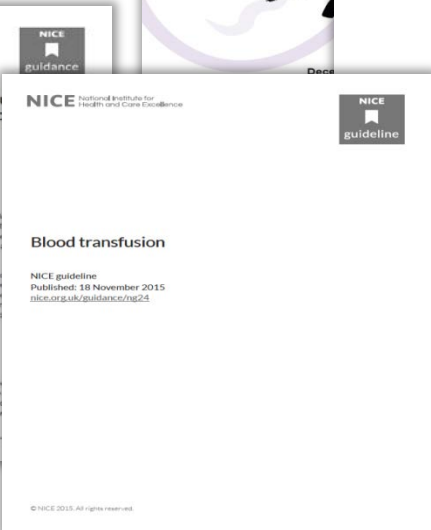
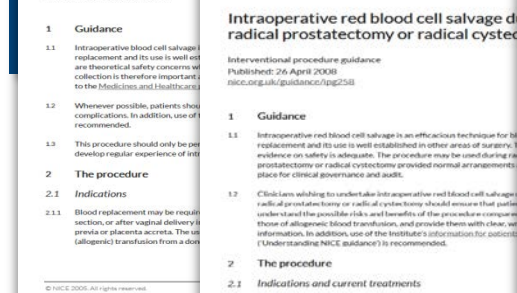
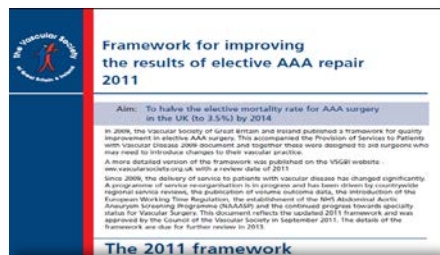
## Post-operative (PCS)

Defibrinated 'whole blood' collected from an autologous wound drain is filtered prior to reinfusion



Efficacy and quality are directly dependent on the skill of the operator and the established processes in place

# Cell salvage guidelines



# Allogeneic blood transfusion regulation (legislation) and guidance

J PAC Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee

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Guidelines for the Blood Transfusion Services

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5. Collection of a blood or component donation
6. Evaluation and manufacture of blood components
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11. Reagent manufacture
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13. Patient testing (red cell immunohaematology)
14. Guidelines for the use of DNA/PCR techniques in Blood Establishments
15. Molecular typing for red

## Guidelines for the Blood Transfusion Services

### 8th Edition

The 'Red Book' (as the printed version of these guidelines are known) materials produced by the United Kingdom Blood Transfusion Service. The guidelines reflect an expert view of current best practice, and describe technical details of processes. Every effort has been made to ensure the legally binding requirements of the Blood Safety (and Quality) Regulations 2005 No. 50.

The publication of the Red Book and its appearance on the website practices outlined are brought into use in the Services simultaneously. Implementation dates may be decided separately by the 4 UK Service (England, Northern Ireland, Scotland or Wales) for details of

The printed book can be purchased from:

The Stationery Office ([www.tsoshop.co.uk](http://www.tsoshop.co.uk))

Direct link: (<http://www.tsoshop.co.uk/bookstore.asp?FO=1160007&Action=Book&ProductID=9780117051673&From=Search>)

### Publication history

1990	1st edition	Published by TSO
1993	2nd edition	Published by TSO
1994	3rd edition	Published by TSO
1999	Amendments	Published by TSO
2000	4th edition	Published by TSO
Nov 2001	5th edition	Published by TSO
Nov 2002	6th edition	Published by TSO
Oct 2005	7th edition	Published by TSO
Mar 2013	8th edition	Published by TSO



## Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2015



Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee

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Transfusion Handbook

Transfusion Practice

Regulations & Implementation

Systematic Review Initiative

UK Transfusion Committees

Management Systems

## Quality Management Systems

Documents for download

- Technical Agreement for the Provision of Blood and Blood Components (doc)
- Method Validation Procedure (pdf)
- Process Validation in Blood Transfusion (pdf)
- Implementation - Local Survey (pdf)
- Quality assurance specification (pdf)
- Validation (OCD user group) (pdf)
- IB Electronic Issue validation (pdf)
- IB AutoVue LIS link validation (pdf)
- IB AutoVue LIS link validation results sheet (xls)
- IB AutoVue Serology validation (pdf)
- Validation (OCD user group) (pdf)

Standard Operating Procedures (SOP)

- Calibration (pdf)
- Change control (pdf)
- Quality audit (pdf)
- Recall (pdf)


- Transfer of components (pdf)
- SLA for the transportation of blood/blood components by taxi/courier
  - Appendix 1 to the SLA for transporting blood/blood components
- User Requirement Specification (URS)
  - Blood Bank
  - Temperature Monitoring System

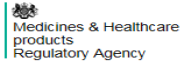
# Cell salvage regulation





# Cell salvage regulation



  
Medicines & Healthcare  
products  
Regulatory Agency

[See more information about this Guidance](#)

## Guidance

### How MHRA ensures the safety and quality of medical devices

Published 18 December 2014

**Contents**

- Report a medical device that does not comply with the regulations
- Enforcement policy
- Inspections
- Enforcement duties
- Exceptional use of non-complying devices
- Complaints
- Appeals procedure
- More information

The MHRA administers the law on medical devices to ensure their safety and quality.

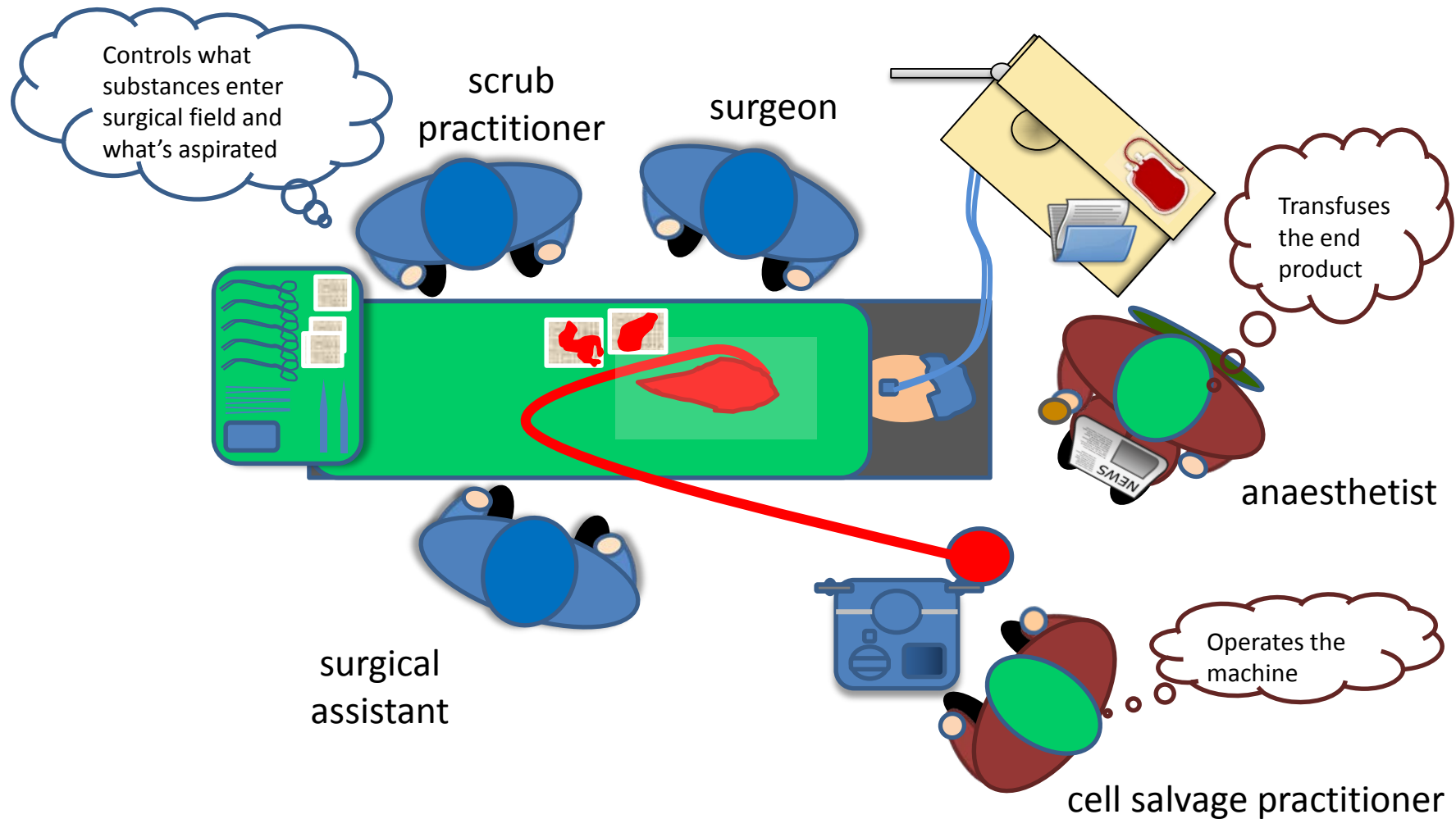
The legislation that underpins MHRA's enforcement work is:

- the Medical Devices Regulations 2002 (SI 2002 No 618, as amended)
- the General Product Safety Regulations 2005 (SI 2005 No 1803)

These safety regulations fall under the Consumer Protection Act 1987.

## Your duties as a registrant

- promote and protect the interests of service users and carers;
- communicate appropriately and effectively;
- **work within the limits of their knowledge and skills;**
- delegate appropriately;
- respect confidentiality;
- manage risk;
- report concerns about safety;
- be open when things go wrong;
- be honest and trustworthy; and
- keep records of their work.



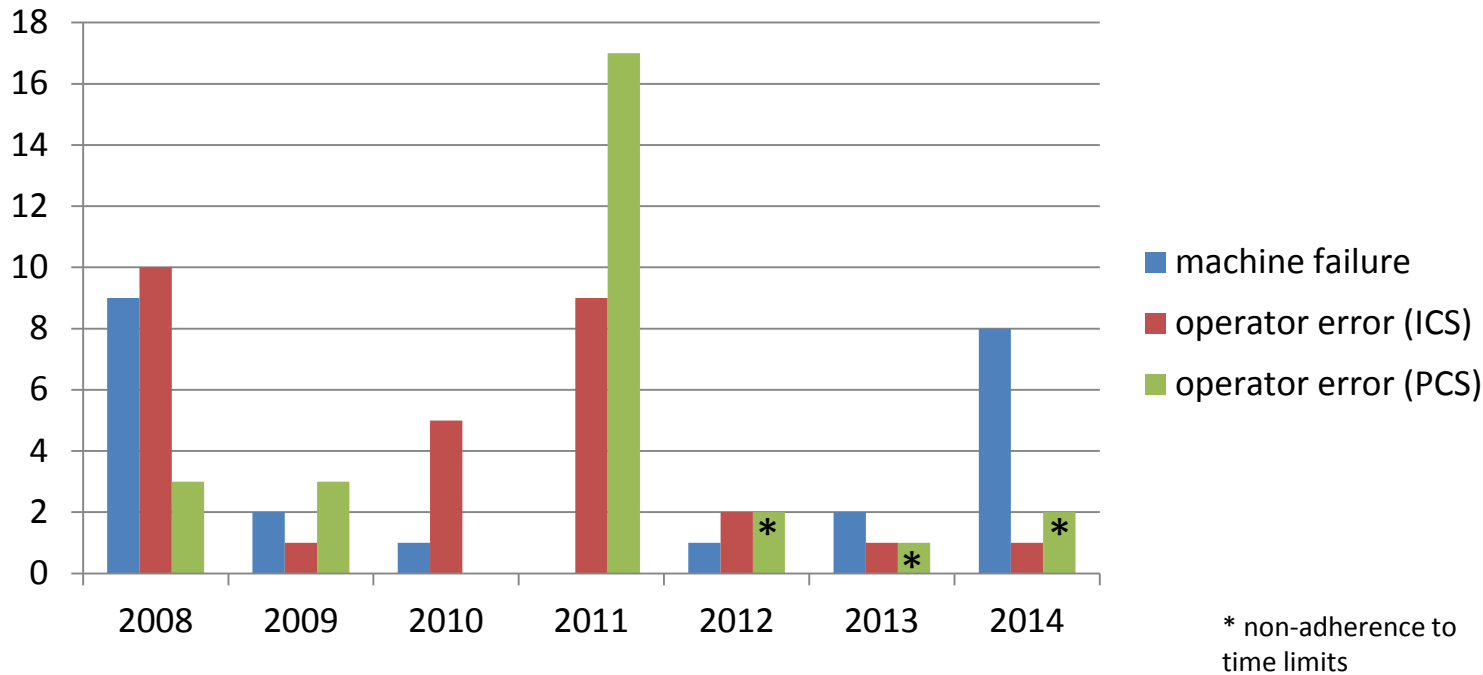




- Founded in 2006
- Determine standards and promote best practice
- Facilitate education and practice development
- Facilitate professional support networks
- Provide a forum for partnership with industry

# Cell salvage SHOT reports

## Adverse events



# Competency assessment

**Post-operative Cell Salvage Competency Assessment Workbook**

**Assessment**

**Hospital:**

**Trainee:**

**Hospital:**

**Trainer/Supervisor:**

**Date commenced:**

**Date completed:**

**PCS19 Prepare equipment for intra-operative blood salvage collection**

**OVERVIEW**

This standard is about preparing equipment necessary for intra-operative blood salvage collection.

Users of this standard will need to ensure that practice reflects up to date information and policies.

Version No 1

**KNOWLEDGE AND UNDERSTANDING**

You will need to know and understand:

1. the current European and National legislation, national guidelines and protocols in relation to intra-operative blood salvage collection
2. your responsibilities and accountability in relation to the current European and National legislation, national guidelines and protocols, code of conduct and Clinical Governance
3. the importance of working within your own sphere of competence and accountability in relation to the collection of salvaged blood
4. infection prevention and control in the preparation of salvaged blood and potential consequences
5. the rationale behind the use of autologous blood
6. the role of the facility equipment in relation to the collection of salvaged blood
7. the purpose of the collection set equipment
8. the dangers of using equipment designed for single use
9. the importance of labelling the collection equipment as blood saving
10. the need for an appropriate anticoagulant
11. the reason for setting up the collection unit
12. the importance of intra-operative cell salvage equipment being used in relation to other blood products
13. the rationale for expiry time on the set up

**PCS20 Operate equipment for intra-operative blood salvage collection**

**OVERVIEW**

This standard is about operating equipment necessary for intra-operative blood salvage collection.

Users of this standard will need to ensure that practice reflects up to date information and policies.

Version No 1

**KNOWLEDGE AND UNDERSTANDING**

You will need to know and understand:

1. the current European and National legislation, national guidelines and protocols in relation to intra-operative blood salvage collection
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10. the need for an appropriate anticoagulant
11. the reason for setting up the collection unit
12. the importance of intra-operative cell salvage equipment being used in relation to other blood products
13. the rationale for expiry time on the set up

**PCS21 Prepare equipment for processing intra-operative salvaged blood**

**OVERVIEW**

This standard is about preparing equipment for processing intra-operative salvaged blood.

Users of this standard will need to ensure that practice reflects up to date information and policies.

Version No 1

**KNOWLEDGE AND UNDERSTANDING**

You will need to know and understand:

1. the current European and National legislation, national guidelines and protocols in relation to intra-operative blood salvage collection
2. your responsibilities and accountability in relation to the current European and National legislation, national guidelines and protocols, code of conduct and Clinical Governance
3. the importance of working within your own sphere of competence and accountability in relation to the collection of salvaged blood
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7. the purpose of the collection set equipment
8. the dangers of using equipment designed for single use
9. the importance of labelling the collection equipment as blood saving
10. the need for an appropriate anticoagulant
11. the reason for setting up the collection unit
12. the importance of intra-operative cell salvage equipment being used in relation to other blood products
13. the rationale for expiry time on the set up

**PCS22 Operate and monitor equipment for processing intra-operative salvaged blood and complete salvaged blood processing**

**OVERVIEW**

This standard is about operating processing equipment, monitoring the equipment during salvaged blood processing and completing the salvaged blood process.

Users of this standard will need to ensure that practice reflects up to date information and policies.

Version No 1

**KNOWLEDGE AND UNDERSTANDING**

You will need to know and understand:

1. the current European and National legislation, national guidelines, organisational policies and protocols in relation to intra-operative blood salvage collection
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## INTRAOPERATIVE CELL SALVAGE FOR LAPAROSCOPIC SURGERY

### AREA of APPLICATION

Intraoperative cell salvage (ICS) is safe to use in laparoscopic surgery. Current evidence shows its effectiveness in laparoscopic surgery for ectopic pregnancy, splenic and abdominal trauma.

Clinical teams and ICS operators should assess any risks associated with the options below on a case by case basis.

### STAFF

All staff involved in the cell salvage process and the theatre practitioner for the procedure.

### PROCEDURE:

As with all ICS procedures it is essential that anticoagulant is used and flushed through the line, and the reservoir primed before commencing cell salvage. Additionally, all fluid used for irrigation must be suitable for intravenous use.

There is no specific laparoscopic set that is designed for ICS. There are many different configurations of laparoscopic sets but most will have 2 tubes, one for irrigation (often marked in a colour) and one for suction (which is clear). There are 2 options to set up for ICS in laparoscopic surgery.

1. The laparoscopic set suction tubing is connected directly to the ICS reservoir; this should be primed with anticoagulant. The advantage of this set up is that it is easy to perform, but the disadvantage is that anticoagulant is only mixed with the blood in the reservoir, not the tubing.
2. The laparoscopic set suction tubing is replaced by the double lumen aspiration and anticoagulation suction tubing that attaches to the ICS reservoir. The laparoscopic set suction tubing must be removed close to the hand piece and replaced with the ICS double lumen tubing. This has the advantage of mixing the blood with the anticoagulant much earlier and so reduces the chance of clotting.

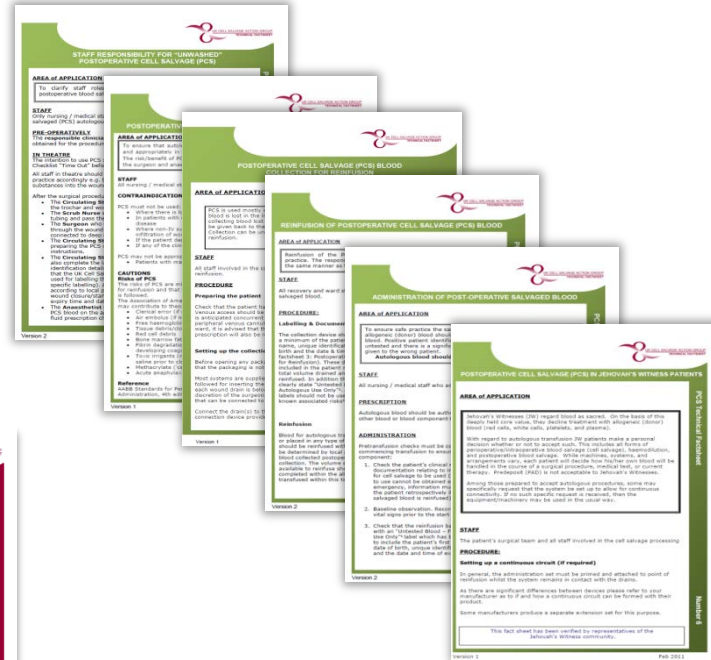
The following image shows set up 2

ICS Technical Factsheet

Number 11

# ctsheets

## PCS



# ICS Education Workbook



**Winner of the 2009 UK Allied Health  
Professionals and Healthcare Scientists  
Award for *Achieving Excellence in  
Learning, Teaching, Development or  
Mentorship***

UK Awards for


Allied Health Professionals  
and Healthcare Scientists

**AHP  
HS**  
UK Awards  
2009

# www.learnbloodtransfusion.co.uk

- Learn cell salvage e-learning
- Register via learnPro NHS or e-learning for Health (e-lfh.org.uk)

[Glossary](#) | [Learning Outcomes](#) | [Resources](#) | [Accessible Version](#)



## Safe Transfusion Practice

### Learn Cell Salvage

[Introduction](#) | [Unit One](#) | **[Unit Two](#)** | [Unit Three](#) | [Unit Four](#) | [Scenarios](#) | [Assessment](#)

### Overview

This unit will give you an understanding of the need for a blood conservation strategy for surgical patients.

By the end of this unit you will be able to:

- Identify the principles of blood conservation
- Identify the areas where blood conservation can be undertaken in surgical patients
- Describe the main methods of blood conservation.

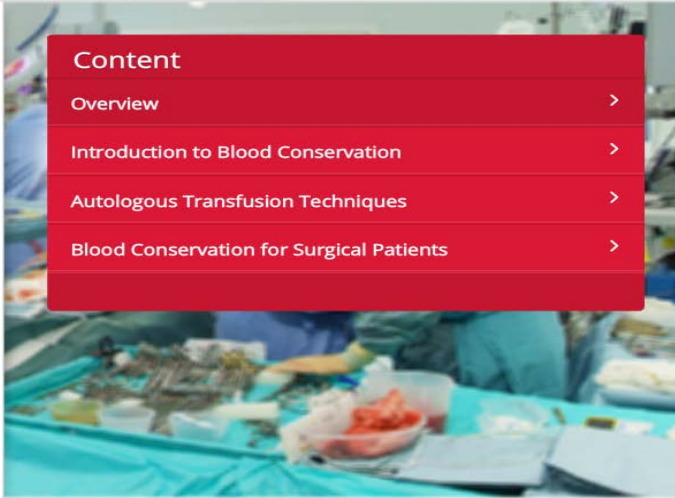
Click on the next button to continue

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- [Introduction to Blood Conservation](#) >
- [Autologous Transfusion Techniques](#) >
- [Blood Conservation for Surgical Patients](#) >

Unit Two: Part 1 of 4

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# UK Cell salvage action group

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[Framework for Service Provision](#)

[Intraoperative Cell Salvage Education](#)

[Cell Salvage Competency Workbooks](#)

[Practicalities of Service Provision](#)

[Patient Factsheet](#)

[Technical Factsheets and Frequently Asked Questions \(FAQ\)](#)

[Adverse Event Reporting](#)

[Newsletters](#)

[National Guidance](#)

[UKCSAG Intraoperative Cell Salvage Survey](#)




# Frequently asked questions (FAQ)

- In which procedures is ICS indicated?
- Can ICS be utilised with the pulse lavage in orthopaedics?
- Does it matter whether plastic or metal suckers are used in ICS?
- Can sump suckers be used with ICS?
- What filters should be used for reinfusing ICS blood?
- Does ICS require a dedicated operator?
- Is ICS considered safe to use in HIV/Hepatitis C positive patients?
- Does a patient have to consent to having cell salvage?

# Infrequently asked questions (IFAQ)

- Can cell salvage be used for a patient who has Rh Null disease?
- Can cell salvage be used for a patient with cold agglutinin antibodies?
- Can cell salvage be used for a patient undergoing C-section with a twin pregnancy with a hydatidiform mole and co-existent healthy fetus?

# What's new?



UK CELL SALVAGE ACTION GROUP  
TECHNICAL FACTSHEET

## METALLOSIS AND INTRAOPERATIVE CELL SALVAGE

### AREA of APPLICATION

Metallosis is the medical condition involving the accumulation and deposition of metal debris in the soft tissues of the body.


The risk of using intraoperative cell salvage (ICS) with metallosis in situ should be carefully considered by the clinical team on an individual case basis and balanced with the benefits of using ICS.

### STAFF

All staff involved in the cell salvage process, the surgeon, anaesthetist and the theatre practitioner for the procedure.

### BACKGROUND:

**Metallosis** most commonly occurs when metal implants grind on each other causing fragments to shed. It is associated in particular with hip resurfacing or replacements with a 'metal on metal' bearing, but can also be seen with any worn or damaged joint replacement where metal parts have come into contact with each other.




Metallosis is **rare**, with an incidence quoted at around 5% for metal on metal joint implants. Typically the metals involved are cobalt, chromium and titanium. Particles of metal and soluble metal ions are released. The immune system identifies the debris as foreign bodies, which can lead to adverse inflammatory reactions including fluid collections, tissue necrosis and occasionally a rash (Adverse Reaction to Metal Debris – ARMDs).

Symptoms include pain, swelling and implant loosening secondary to the necrosis.

ICS Technical Factsheet

Number 12

Version 1 June 2016




UK CELL SALVAGE ACTION GROUP  
EDUCATION WORKBOOK

## Intraoperative Cell Salvage

(Cell washing devices)

## Education Workbook



Edition 2  
xx 2016

# Future developments

## BBTS Education Hub

Specialised educational resources tailored to the needs of cell salvage operators

### Short-term

Updated education and assessment workbooks (available via the e-Portal)

Downloadable material

On-line record of progress

On-line record of assessment

On-line case log

Access to BBTS CPD tool

### Mid/Long-term

Educational videos, e.g. swab washing, QC sampling

Company specific videos and knowledge assessments

Presentations

Forum



<http://www.transfusionguidelines.org.uk/transfusion-practice/uk-cell-salvage-action-group>