

## National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines

### Evaluation of label adherence to single use and reusable hollowware containers used in the operating room – Report 1

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This paper is available on the ACSQHC web site at [www.safetyandquality.gov.au](http://www.safetyandquality.gov.au).

# National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines

## Evaluation of label adherence to reusable hollowware containers used in the operating room

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### 1. Introduction

The Australian Commission on Safety and Quality in Health Care (ACSQHC) is responsible for maintaining the *National Recommendations for User-applied Labelling of Medicines, Fluids and Lines* (the *Labelling Recommendations*) described at <http://www.safetyandquality.gov.au/our-work/medication-safety/user-applied-labelling/>. ACSQHC also identify and reduce national barriers to implementation.

Implementation is an evolving process and *Labelling Recommendations* issues referred to ACSQHC's advisory groups are recorded in the *Labelling Recommendations Issues Register* on the ACSQHC web site at <http://www.safetyandquality.gov.au/our-work/medication-safety/user-applied-labelling/>

IR8 from the *Labelling Recommendations Issues Register* considers the labelling of containers on the perioperative sterile field.

Labels may be difficult to remove from stainless steel and other reusable hollowware containers used in operating rooms. This would render such containers unsuitable for reuse.

Jurisdictions advise ACSQHC that stainless steel and other reusable containers are used in preference to disposable containers in a high proportion of health facilities in Australia. Thus, it is a requirement that labels may be removed entirely after use.

The *Labelling Recommendations* specify 'peel off' labels are used for container labels on the perioperative sterile field. Moreover, ACSQHC engaged health services to evaluate sterile labels and adherence to reusable containers in the perioperative area to establish viability of container reissue.

The evaluation looked specifically at the performance of labels from 3 suppliers to establish the potential for these labels to be removed from reusable plastic or stainless steel containers after exposure to 3 fluids frequently used in the perioperative sterile field.

Identification of medicines in containers on the sterile field is mandatory. Therefore, the ability to remove 'peel off' labels from reusable containers used on the perioperative sterile field supports the continued use of reusable hollowware containers.

## 2. Aims

To evaluate the performance of sterile labels with regards to: a) label adherence; and b) label residue on the surface of hollowware containers over time.

## 3. Methodology

St Vincent's Hospital, Sydney conducted the evaluation in February 2012 following a request from ACSQHC using labels sterilised at the Prince of Wales Hospital, Randwick.

The evaluation was conducted in empty operating room with recommended ranges for air temperature and humidity and with standard air flows (Figure 1).

**Figure 1: Procedure for evaluation of sterile labels:** Four tables (Control, Contrast, Sodium Chloride, Water). Three containers (stainless steel, plastic reusable, plastic disposable)



The following were evaluated:

### A) Sterile labels from three companies

Pre-printed labels

1. [Defries] Sterile stock currently in use in the evaluation site sterilised by ethylene oxide (ETO);

Abbreviated container labels

2. [Baypac]
  - a. 1 set sterilised by Steam
  - b. 1 set sterilised by ETO; and
3. [Stirling Fildes] sterilised by ETO

### B) Materials - Hollowware containers made from one of three materials

- stainless steel;
- reusable plastic; and
- disposable plastic containers

### C) Surfaces - Hollowware container surfaces dampened with one of three fluids

- water;

- sodium chloride; and
- contrast medium with a strong concentration (Iopromide 76.9 gm / Ultravist 370)

#### D) Three time periods

- 2 hrs;
- 4 hrs; and
- >16hrs

#### E) Solvents for removal of residue (Figure 2)

- Alcohol wipes
- Eucalyptus oil

**Figure 2. Solvents:** Alcohol wipes, Eucalyptus Oil



#### F) Control

A control was established and evaluated to ensure the labels were capable of remaining adhered to dry hollowware surfaces and to evaluate the amount of residue remaining on these dry surfaces. The control was a complete set of labels and hollowware containers evaluated over the same time periods (as above) with the exception that all surfaces were dry.

## 4. Results

### 4.1 Label adherence

All labels remained adequately adhered to the Control (dry surface: stainless steel, reusable plastic and disposable plastic) for all three time periods (2 hrs, 4 hrs, > 16 hrs).

### 4.2 Label residue

#### **Label 1**

- The top layer of this label separated untidily from the Control at all time periods, leaving uneven amounts of fibrous and tacky residue on the surfaces for all time periods. Neither of the solvents removed this residue adequately, either in isolation or combination. Firm, persistent scraping followed by solvent might be effective however, this would be slow, impractical and likely to damage the surface of the hollowware.

### Label 2a

- This label was easily removed from the Control at all time periods, leaving no residue after 2 hours. On both plastics, there was no residue after 4 hours or > 16 hours.
- On stainless steel alone, there was minimal residue after 4 hours which was easily removed with alcohol wipes.
- On stainless steel alone, there was minimal residue after > 16 hours, which was easily removed with alcohol wipes and eucalyptus oil.

### Label 2b

- This label was easily removed from the Control at all time periods, leaving no residue after 2 hours. On both plastics, there was no residue after 4 hours or > 16 hours.
- On stainless steel alone, there was minimal residue after 4 hours and > 16 hours which was easily removed with alcohol wipes.

### Label 3

- This label was easily removed from the Control at all time periods, leaving no residue after 2 hours. On both plastics, there was no residue after 4 hours or > 16 hours.
- On stainless steel alone, there was minimal residue after 4 hours and > 16 hours which was easily removed with alcohol wipes.

## 5. Evaluations

### 5.1 Label adherence

All labels remained adequately adhered to all container materials (stainless steel, reusable plastic and disposable plastic), and all dampened surfaces (water, sodium chloride, contrast medium) for all three time periods (2 hrs, 4 hrs, > 16 hrs).

### 5.2 Label residue

Figure 3 and Tables 1 to 4 follow

**Figure 3. Label residue on stainless steel dampened with water at 2 hours:** Left Kidney Dish: Label 1 and Label 2a – Too much residue to remove with solvents: Right Kidney Dish: Label 2b and Label 3 – No residue



**Table 1: Removal of label 1 and any associated residue on hollowware following exposure to fluids for varying times**

Materials, dampened surfaces and Time Periods			Label remained attached		Label removal			Comments	
			YES	NO	No residue	With Residue			
						Minimal residue easily removed	Removed with solvent		Too much residue
<b>Stainless Steel</b>	Water	2 hours	X				X	See Figure 3	
		4 hours	X				X		
		> 16 hours	X				X		
	Sodium Chloride	2 hours	X					X	
		4 hours	X					X	
		> 16 hours	X					X	
	Contrast	2 hours	X					X	
		4 hours	X					X	
		> 16 hours	X					X	
<b>Plastic (reusable)</b>	Water	2 hours	X				X	Removed with alcohol wipes and eucalyptus oil	
		4 hours	X				X		
		> 16 hours	X				X		
	Sodium Chloride	2 hours	X				X	X	Removed with alcohol wipes and eucalyptus oil
		4 hours	X					X	
		> 16 hours	X					X	
	Contrast	2 hours	X			X			
		4 hours	X				X		Removed with alcohol wipes
		> 16 hours	X				X		Removed with alcohol wipes and eucalyptus oil
<b>Plastic (disposable)</b>	Water	2 hours	X				X	Removed with alcohol wipes and eucalyptus oil	
		4 hours	X				X		
		> 16 hours	X				X		
	Sodium Chloride	2 hours	X				X	X	Removed with alcohol wipes and eucalyptus oil
		4 hours	X					X	
		> 16 hours	X					X	
	Contrast	2 hours	X			X			
		4 hours	X			X			
		> 16 hours	X				X		Removed with alcohol wipes

**Table 2: Removal of label 2a and any associated residue on hollowware following exposure to fluids for varying times**

Materials, dampened surfaces and Time Periods			Label remained attached		Label removal			Comments	
			YES	NO	No residue	With Residue			
						Minimal residue easily removed	Removed with solvent		Too much residue
<b>Stainless Steel</b>	Water	2 hours	X				X	See Figure 3	
		4 hours	X				X		
		> 16 hours	X				X		
	Sodium Chloride	2 hours	X				X	Removed with alcohol wipes and eucalyptus oil	
		4 hours	X			X			
		> 16 hours	X		X				
	Contrast	2 hours	X				X	Removed with alcohol wipes	
		4 hours	X				X	Removed with alcohol wipes	
		> 16 hours	X					X	
<b>Plastic (reusable)</b>	Water	2 hours	X		X				
		4 hours	X		X				
		> 16 hours	X		X				
	Sodium Chloride	2 hours	X				X	Removed with alcohol wipes and eucalyptus oil	
		4 hours	X			X			
		> 16 hours	X				X		
	Contrast	2 hours	X				X	Removed with alcohol wipes and eucalyptus oil	
		4 hours	X				X	Removed with alcohol wipes	
		> 16 hours	X			X			
<b>Plastic (disposable)</b>	Water	2 hours	X		X				
		4 hours	X		X				
		> 16 hours	X		X				
	Sodium Chloride	2 hours	X				X	Removed with alcohol wipes and eucalyptus oil	
		4 hours	X		X				
		> 16 hours	X		X				
	Contrast	2 hours	X				X	Removed with alcohol wipes	
		4 hours	X		X				
		> 16 hours	X				X	Removed with alcohol wipes	



**Table 3: Removal of label 2b and any associated residue on hollowware following exposure to fluids for varying times**

Materials, dampened surfaces and Time Periods			Label remained attached		Label removal			Comments		
			YES	NO	No residue	With Residue				
						Minimal residue easily removed	Removed with solvent		Too much residue	
<b>Stainless Steel</b>	Water	2 hours	X				X		Removed with alcohol wipes and eucalyptus oil	
		4 hours	X					X		
		> 16 hours	X				X			
	Sodium Chloride	2 hours	X					X		Removed with alcohol wipes
		4 hours	X		X					
		> 16 hours	X			X				
	Contrast	2 hours	X					X		Removed with alcohol wipes
		4 hours	X		X					
		> 16 hours	X					X		
<b>Plastic (reusable)</b>	Water	2 hours	X		X					
		4 hours	X		X					
		> 16 hours	X				X			
	Sodium Chloride	2 hours	X					X		Removed with alcohol wipes and eucalyptus oil
		4 hours	X		X					
		> 16 hours	X			X				
	Contrast	2 hours	X					X		Removed with alcohol wipes
		4 hours	X		X					
		> 16 hours	X		X					
<b>Plastic (disposable)</b>	Water	2 hours	X		X					
		4 hours	X		X					
		> 16 hours	X				X			
	Sodium Chloride	2 hours	X					X		Removed with alcohol wipes
		4 hours	X		X					
		> 16 hours	X		X					
	Contrast	2 hours	X					X		Removed with alcohol wipes
		4 hours	X		X					
		> 16 hours	X		X					

**Table 4: Removal of label 3 and any associated residue on hollowware following exposure to fluids for varying times**

Materials, dampened surfaces and Time Periods			Label remained attached		Label removal			Comments		
			YES	NO	No residue	With Residue				
						Minimal residue easily removed	Removed with solvent		Too much residue	
<b>Stainless Steel</b>	Water	2 hours	X				X		Removed with alcohol wipes	
		4 hours	X			X				
		> 16 hours	X			X				
	Sodium Chloride	2 hours	X		X					
		4 hours	X			X				
		> 16 hours	X				X		Removed with alcohol wipes	
	Contrast	2 hours	X					X		Removed with alcohol wipes
		4 hours	X					X		Removed with alcohol wipes
		> 16 hours	X			X				
<b>Plastic (reusable)</b>	Water	2 hours	X		X					
		4 hours	X		X					
		> 16 hours	X				X			Removed with alcohol wipes
	Sodium Chloride	2 hours	X		X					
		4 hours	X		X					
		> 16 hours	X			X				
	Contrast	2 hours	X					X		Removed with alcohol wipes
		4 hours	X			X				
		> 16 hours	X			X				
<b>Plastic (disposable)</b>	Water	2 hours	X		X					
		4 hours	X		X					
		> 16 hours	X				X			Removed with alcohol wipes
	Sodium Chloride	2 hours	X		X					
		4 hours	X		X					
		> 16 hours	X			X				
	Contrast	2 hours	X					X		Removed with alcohol wipes
		4 hours	X			X				
		> 16 hours	X			X				

## 6. General observations and comments

All labels remained adequately adhered to all materials (stainless steel, reusable plastic and disposable plastic) and all surface conditions (dampened surface: water, sodium chloride and contrast) for all three time periods (2 hrs, 4 hrs, > 16 hrs).

The labels adhered to stainless steel were generally more difficult to remove and left most residue, though there was not much difference between time periods, with label removal at 2 hours and > 16hrs equally difficult (See Image 3).

In many instances, the label residue on stainless steel was too difficult to remove with either or both of the solvents (alcohol wipes and eucalyptus oil).

Firm, persistent scraping followed by solvents might be effective. However, this would be slow, impractical and likely to damage the surface of the hollowware.

The labels on reusable plastic hollowware containers were generally removed with little residue, or came off with solvents (alcohol wipes or alcohol wipes followed by eucalyptus oil).

The labels adhered to a dampened surface were generally removed with less resistance and residue, particularly the contrast agent, which appeared to act as a thin layer between the hollowware surface and the label.

Whilst the ease of removal of labels was the key focus, the adherence of the label for periods intended to reflect practice, was also established. Results indicate that labels from 2 of the three manufacturers could be removed either with or without application of alcohol wipes and/or eucalyptus oil. The following limitations are noted:

- a. Only 3 fluids were tested and labels appeared to perform differently with exposure to different fluids; and
- b. Fluids were tested by adding a 'wipe' of fluid not by making the label very wet or immersing the label for any time.