

SAFE OPERATING PROCEDURE  
COMPANION ANIMAL HEALTH CENTRE

## LOCATION DETAILS

School/Branch: SCHOOL OF ANIMAL &amp; VETERINARY SCIENCES

## SAFE OPERATING PROCEDURE DETAILS

Task/activity:

Ethylene oxide gas sterilization machine (Anprolene gas steriliser)

Content Control

Date Prepared: 12 July 2011

Version: 2.2

PREPARED BY Name, Position and Signature (insert names of the supervisor, HSR, HSO and operator involved)

Name Matt Skeldon  
Peter HillPosition Vet technician  
Veterinary surgeonSignature  
P.B. Hill

## RISK ASSESSMENT

Has a risk assessment been completed and have all other environmental considerations been made?

Yes  No See Risk Assessment dated:  
1/07/2011

Risk Rating:

 Low Medium High Very High

## SAFE OPERATING PROCEDURE DETAILS

**Brief Description of Work**

The ethylene oxide steriliser is used to sterilise surgical equipment that cannot be put through the autoclave due to thermal liability.

**Hazard Identification**

Ethylene oxide is extremely hazardous. At room temperature, it is a flammable, carcinogenic, mutagenic, irritating, and anaesthetic gas with a misleadingly pleasant aroma. If the gas can be smelled, it is already at toxic concentrations. Ethylene oxide causes acute poisoning, accompanied by the following symptoms: a sweet taste in the mouth, sweating, flushing, strong throbbing headache, muscle twitching, diminished hearing, vomiting, dizziness, difficulty in speech and walking, pain in the legs, weakness, weak heartbeat, sleep disturbance, and transient loss of consciousness. It can also cause enlargement of the liver and acidosis. Ethylene oxide easily penetrates through clothing and footwear, causing skin irritation and dermatitis with the formation of blisters, fever and leukocytosis. Ethylene oxide irritates mucous membranes of the nose and throat and can cause damage to the trachea and bronchi, progressing to partial collapse of the lungs. High concentrations can cause pulmonary edema and damage to the cardiovascular system. The damaging effects of ethylene oxide may only occur 72 hours after exposure.

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### Control Measures

- The risks of ethylene oxide are mitigated by correct operation of the equipment. Detailed instructions for operating the equipment are shown below. Only staff that have received specific training and have signed off on the SOP are to use the machine.
- The ethylene oxide ampoules are kept in the locked cabinet in the X-ray room. Before use, the ampoules should be checked to ensure they are undamaged and in date.
- The external casing of the unit should be checked to ensure there is no damage
- The vent tubing at the rear of the machine should be checked for blockages or damage.
- Instruments containing batteries must be taken apart and the batteries removed and wrapped separately to protect against a spark occurring and igniting the ethylene oxide gas.
- Heat or hot air should never be used to dry an item prior to sterilizing it with ethylene oxide because it will dehydrate or desiccate bacterial spores making them more resistant to the ethylene oxide gas.
- Items should be dried by air or towel as any water left on items may react with the ethylene oxide.

### Safety and Preoperational Checks:

- Only staff that are trained and have signed off on the SOP are to use the machine.
- Check that ampoules are undamaged in date, {they are kept in the cupboard in central supplies }
- Check the external casing of the unit ensuring that there is no damage to the machine itself.
- Check the vent tubing at the rear of the machine. Ensure that it is not blocked or damaged.
- Instruments containing batteries must be taken apart and the batteries removed and wrapped separately to protect against a spark occurring and igniting the ethylene oxide gas.
- Heat or hot air should never be used to dry an item prior to sterilizing it with Ethylene oxide because it will dehydrate or desiccate bacteria spores making them more resistant to the ethylene oxide gas.
- Ensure that all instruments have been washed and air dried thoroughly. Any water left on items may react with ethylene oxide.

### Use and Maintenance of the Gas Sterilizer.

#### 1. Preparing the items for sterilization. Four basic steps must always be followed:

##### a) Disassemble

Items containing removable parts such as syringes must be taken apart before washing, drying, and wrapping to allow the Ethylene Oxide an unobstructed path.

##### **WARNING:**

Instruments which contain batteries should be taken apart and the batteries removed and wrapped separate packs to protect against a spark occurring and igniting the ethylene oxide gas.

##### b) Wash

Items must be washed surgically clean prior to sterilization using detergent and water.

##### c) Dry

Two accepted ways to dry any item prior to sterilization are:

1. Towel drying.
2. Drain drying (air drying)

##### **WARNING:**

Heat or hot air should never be used to dry an items prior to sterilizing with ethylene oxide because this will dehydrate or desiccate bacteria spores making them more resistant to the ethylene oxide gas.

##### **WARNING:**

Any water left on items may react with ethylene oxide. Please air dry instruments thoroughly.

##### d) Wrap

The following types of wrapping material are recommended for use with the Anprolene Gas Steriliser:

1. Andersen Seal and Peel Packaging. (This wrapping is airtight and waterproof and greatly extends the shelf life when heat sealed at both ends)
2. Cloth, like CSR wrap, has an estimated sterile shelf life of 30 days.
3. Paper / plastic and plastic pouches. The manufacturer's guidelines must be followed for optimal shelf life.

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**HINT:**

Exposure indicators such as the Andersen AN85 or AN86 are used to seal or label items. Indicators will change colour in the presence of ethylene oxide, helping to later identify items that have been sterilized. Exposure indicators **DO NOT** indicate sterility.

**2. Preparing the Sterilization Liner Bag**

1. Place prepared items in a new sterilization liner bag.

**WARNING:**

**Do not reuse sterilization liner bags. Even a tiny pinhole in a liner bag can allow gas to escape and cause cycle failure!**

2. Insert appropriate controls such as a Steritest (biological & chemical indicator) into the least accessible part of the sterilization liner bag.
3. Unroll the gas release bag containing the gas ampoule and, without opening it, gently move the ampoule to the centre of the gas release bag. Place it on top of items in the sterilization liner bag where it will be easy to break. In order to prevent liquid from coming into contact with the skin and prevent gas from escaping too quickly to achieve sterilization, never open the gas release bag.
4. Insert the purge probe into the sterilization liner bag with the bobbin and quick release fitting at the open end. Place the black Velcro® strap around the sterilization liner bag and the bobbin of the purge probe, and pull it snug through its loop to completely close the sterilization liner bag. The strap must secure the sterilization liner bag tightly around the purge probe in order to keep gas from escaping.
5. Connect the quick release connector to the purge probe, if it is not already connected.

**3. Starting the cycle**

1. Make sure the sterilizer power cord is connected. Press the power switch on the front panel. Wait to see the "(model #) ANPROLENE STERILIZER" and the "START" message to appear on the cabinet display.
2. Push the button to the right of START.
3. Wait for the SELF TEST and number of elapsed PUMP HOURS to appear.
4. Press the button next to the PURGE message on the right of the display and wait for 1 minute 30 seconds until the display reads '00:00:00'. The sterilization liner bag should vacuum down as excess air is removed.
5. When the display indicates "BREAK AMPOULE", carefully, so as not to puncture the sterilization liner bag, grasp the ampoule through the sterilization liner bag and activate it by snapping off the top.

**4. Selecting Cycle Length**

1. Close the door.
2. Lock the sterilizer and remove the key.
3. SELECT CYCLE LENGTH. (Right button = 12 Hour, Left button = 24 Hour).
4. If an electronic beep sounds, it is an alert that 5 seconds have elapsed and the sterilizer is awaiting a cycle time selection.
5. Log sterilization data if required.

**5. Unloading the Sterilizer and Determining Sterility**

1. Remove the sterilized items only after the sterilization cycle and 2-hour purge cycle have been completed and the display indicates "UNLOAD STERILIZER".
2. Discard the sterilization bag and spent ampoule with ordinary trash. Incubate Biological Indicator and record the results.
3. Press EXIT to end the cycle and return the sterilizer to standby state.

**WARNING:**

**Never remove items before the full 2-hour purge cycle has completed. The purge cycle is designed to aerate most products sufficiently to meet the OSHA short-term exposure level (STEL) of 5.0 ppm over 15 mins.**

4. The sterilizer can be used for extended aeration. After the regular cycle is finished, the sterilizer will continue to ventilate and purge the liner bag until the door is opened and the exit button is pressed, ending the cycle. A count-up timer will keep track of additional aeration since the standard 2 Hour Purge cycle was completed.

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Note: This Safe Operating Procedure must be reviewed :

- a) after any accident, incident or near miss;
- b) when training new staff;
- c) if adopted by new work group;
- d) if equipment, substances or processes change; or
- e) within 5 years of date of issue.

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**SAFE OPERATING PROCEDURE (Competency Sign-Off)**  
**(Also constitutes an authority to use the device for AVS Business)**

LOCATION DETAILS		
School/Branch: Animal and Veterinary Science / Faculty of Sciences.		
Section: SCHOOL OF ANIMAL & VETERINARY SCIENCES		
COMPETENCY SIGN-OFF FOR:		
Task/activity (including specify particular equipment, substance) Ethylene oxide gas sterilization machine (Anprolene gas steriliser)	Training Date:	
TRAINER:		
Name	Position	Signature
TRAINEE:		
Name	Position	Signature
COMPETANCY SIGN-OFF DETAILS:		
<p>The trainee has demonstrated a satisfactory level of competency in the following aspects:  <i>(Please tick the box if the trainee performs each aspect satisfactorily)</i></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Brief Description of Work</li> <li><input type="checkbox"/> Hazard Identification</li> <li><input type="checkbox"/> Control Measures</li> <li><input type="checkbox"/> Safety and Preoperational Checks</li> <li><input type="checkbox"/> Use and maintenance of the Gas Sterilizer               <ul style="list-style-type: none"> <li><input type="checkbox"/> Preparing the items for sterilisation</li> <li><input type="checkbox"/> Preparing the sterilization liner bag</li> <li><input type="checkbox"/> Starting the cycle</li> <li><input type="checkbox"/> Selecting Cycle Length</li> <li><input type="checkbox"/> Unloading the Sterilizer and Determining Sterility</li> </ul> </li> </ul>		
<p>Note: This Safe Operating Procedure (Competency Sig-off) must be reviewed :</p> <ul style="list-style-type: none"> <li>a) after any accident, incident or near miss;</li> <li>b) when training new staff;</li> <li>c) if adopted by new work group;</li> <li>d) if equipment, substances or processes change; or</li> <li>e) within 5 years of date of issue.</li> </ul>		

