













SYMBOL REFERENCE KEY	
	Consult instructions for use
	Quantity
	Catalogue Number
	Lot Number/Batch Code
	Use-by-date
	Non-sterile
	Do not reuse
	Do not use if package is damaged and consult instructions for use
	Manufacturer
	Caution
	Caution: US Federal law restricts this device to sale by or on the order of a physician
	Keep away from sunlight



IFU-26707 | RevB | FEB2023



Summit Medical LLC
815 Vikings Parkway, Suite 100
St. Paul, MN 55121 | USA

P: 1-888-229-2875 | +1 651-789-3939
F: 1-888-229-1941 | +1 651-789-3979
www.summitmedicalusa.com



APDYNE PHENOL APPLICATOR KIT

Instructions for Use





Before using, read the following information



NON-STERILE

Description

The Apdyne Phenol Applicator Kit is a single use kit used to apply phenol. The liquefied phenol is a caustic liquid containing <11% water and >89% phenol.

Indications and Usage

Liquefied phenol is a useful topical anesthetic for the tympanic membrane. It simultaneously coagulates, sterilizes and anesthetizes the epithelium of the tympanic membrane prior to myringotomy.

For Professional Use Only.

Contents

- Screw top vial containing 0.2mL of liquefied phenol
- Applicator with absorbent tip

Storage

Room temperature. Protect from light and heat.

Instructions for Use

1. Wear gloves when handling.
2. Open tray.

Note: Do not open tray if packaging appears wet.

3. Place vial of phenol upright in circular depression in tray and open the vial.

Note: Light exposure discolors phenol. Liquefied phenol should be colorless or have a slight shade of yellow/pink.

4. Dip foam tip of applicator in phenol, draining excess by touching tip to side of vial, leaving tip soaked but not dripping.

Note: Ensure there is no damage to the foam tip before dipping it in phenol. Do not use device if the foam tip is damaged.

5. Apply phenol to desired application site.
6. After use, close vial and place contents back in tray. Dispose of in medical waste.



Warnings

Local inflammation may occur in individuals with hypersensitivity to phenol. Liquefied phenol is absorbed directly through the skin and prolonged contact may cause chemical burns. Contact over large areas may cause systemic toxicity. (See Precautions)

Precautions

Contact of liquefied phenol with the skin should be avoided as it may cause severe irritation with second to third degree burns; areas usually turn white and later yellowish-brown and may be deeply eroded and scarred.

Solutions are readily absorbed through the skin and may cause profuse perspiration, intense thirst, nausea and vomiting, diarrhea, cyanosis from methemoglobinemia, hyperactivity, stupor, hypotension, hyperpnea, abdominal pain, hemolysis, convulsions, coma, and pulmonary edema followed by pneumonia. If death from respiratory failure is not immediate, jaundice and oliguria or anuria may occur. Skin sensitization occurs occasionally. A profound fulminating central nervous system depression with coma, hypothermia, loss of vasoconstrictor tone, cardiac depression, cerebral edema and respiratory arrest are common manifestations of systemic poisoning. However, stridorous breathing, mucus rales, froth at the mouth and nose eventually occur. Liver, kidney and bladder damage occur.

Adverse Reactions

Phenol causes blanching and corrosion.

Clinical Pharmacology

Liquefied phenol is both an anesthetic and an antiseptic. Liquefied phenol is also bactericidal and fungicidal with some sporicidal and virucidal activity.

Phenol is absorbed through the gastrointestinal tract and directly through the skin and mucous membranes. It is metabolized to phenyl-glucuronide and phenyl sulfate and small amounts are oxidized to catechol and hydroquinone which are mainly conjugated. The metabolites are excreted in the urine and when oxidized to quinines may tint the urine green.

Overdosage

Topically applied liquefied phenol can be absorbed in sufficient amounts to provide systemic effects. (See Precautions)

For treatment of skin contact remove contaminated clothing and shoes immediately. Wash affected area with soap or mild detergent in large amounts of water until no evidence of chemical remains (at least 15-20 minutes). In case of chemical burns, cover areas with sterile, dry dressings. Bandage securely but not too tightly and seek medical attention immediately. For eye contact wash eyes immediately with large amounts of water, occasionally lifting upper and lower lids until no evidence of chemical remains (at least 15 - 20 minutes). In case of burns apply sterile bandages loosely without medication and see medical attention immediately.

In case of ingestion, if the victim is conscious, and if corrosive injury is absent, remove poison by gastric lavage or emesis. Activated charcoal is useful. Follow with 60ml of castor oil which dissolves phenol, retards its absorption and hastens its removal. Follow castor oil by giving 30 - 60 ml of Fleet's phosphor-soda diluted 1:4 in water. Gastric lavage and emesis are not to be used in the presence of esophageal injury. Gastric lavage or emesis should not be performed on an unconscious person. Gastric lavage should be performed by qualified medical personnel. Medical attention should be sought immediately.

No specific antidote is available. Treat symptomatically and supportively.



Single-use, one-patient device will degrade if reprocessed. No effective cleaning process has been developed to prevent cross contamination. Contamination of a reprocessed device may lead to injury, illness or death of the patient.