HOW SUPPLIED
Liquefied phenol is supplied in a single use applicator containing 0.3ml of liquefied phenol.

STORAGE
Room temperature. Protect from light and heat.

Symbol Reference Key

	Consult instructions for use
NON STERILE	Non-Sterile
	Quantity
Latex	Latex Free
!USA	For US audiences only
REF	Catalog Number
LOT	Lot Number
	Use By
	Date of Manufacture

Distributed by
Anthony Products, Inc.
7740 Records Street • Indianapolis, IN 46226
800-428-1610 • (317) 545-6196 • Fax (317) 543-3289
www.anthonyproducts.com

PhenolPro™
Safety Applicator

Instructions for Use

NON-STERILE

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.

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PhenolPro™ Safety Applicator

Before using, read the following information:

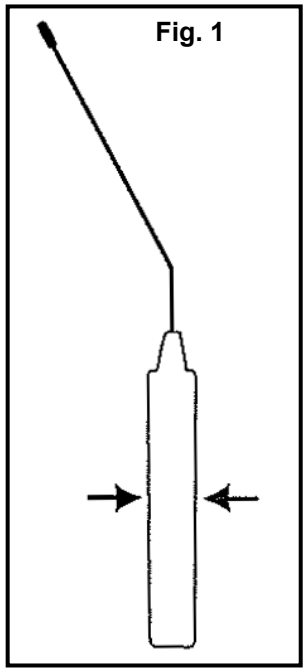
NON-STERILE

DESCRIPTION

The PhenolPro Safety Applicator is a single use applicator used to safely deliver phenol to the ear drum for myringotomy surgery. The liquefied phenol is a caustic liquid containing <11% water and >89% phenol.

INDICATIONS FOR USE

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



Hold upright and squeeze both sides

INSTRUCTIONS FOR USE

1. Open the pouch and remove the applicator.
2. Squeeze the plastic tube to break the ampule inside the tube (Fig. 1).
3. The phenol is delivered into the hypo tube and onto the applicator tip by squeezing the plastic tube.
4. Insert ear speculum into ear canal of patient.
5. Insert wet applicator tip through the ear speculum and swipe the applicator top against the tympanic membrane over the desired site of incision.
6. Remove the applicator.
7. The applicator tip can be used on the same patient, both ears if applicable.
8. Dispose of applicator in medical waste disposal.

CONTRAINDICATIONS

Liquefied phenol used as a topical anesthetic for the tympanic membrane prior to myringotomy is contraindicated in the per-existing tympanic membrane perforation, known allergy or hypersensitivity to phenol and in individuals such as young children or mentally impaired whose ability to remain still during its application is unreliable.

WARNINGS

Local inflammation may occur in individuals with hypersensitivity to phenol. Phenol applied topically to the tympanic membrane has been reported to cause necrosis of the tympanic membrane. Liquefied phenol instilled into the middle ear has caused nerve deafness and my cause facial paralysis with dehiscence of the bone over the fallopian canal. 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

Liquefied phenol should be applied to the tympanic membrane only with enclosed applicator design for this purpose. Prior to myringotomy any excess phenol should be removed from the surface of the tympanic membrane and the ear canal by suction as the excess phenol may be drawn into the middle ear during myringotomy (see warnings). In the presence of an atrophic tympanic membrane phenol may erode through the middle ear. Incision during myringotomy following topical anesthetic with liquefied phenol should be confined to the blanched area of the tympanic membrane which corresponds to the area anesthetized. During myringotomy following topical anesthesia with liquefied phenol care should be taken to avoid the medial wall of the middle ear as it will not be anesthetized.

Contact of liquefied phenol with the skin should be avoided as it my cause sever 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, convulsion, 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 fulmination central nervous system depression with coma, hypothermia, loss of vasoconstrictor tone, cardiac depression, cerebral edema and respiratory arrest are common manifestations of systemic poisoning in man. However, stridorous breathing, mucus rates, froth at the moth and nose eventually occur. Liver, kidney and bladder damage occur.

ADVERSE REACTIONS

Following application of liquefied phenol to the tympanic nerve deafness has occurred as well as necrosis of the tympanic membrane. Applied to the skin phenol causes blanching and corrosion.

CLINICAL PHARMACOLOGY

Liquefied phenol is both an anesthetic and an antiseptic. It penetrates squamous epithelium and may denature protein causing a depolarizing local anesthesia. Liquefied phenol is also bactericidal and fungicidal 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 catchol and quinol which are 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 effect area with soap and 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 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 seek 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 remove. Follow castor oil by giving 30-60ml 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.