

Swab-it

LICENSED PHENOL IMPREGNATED SWABS WITH 89% PHENOL LIQUID USP

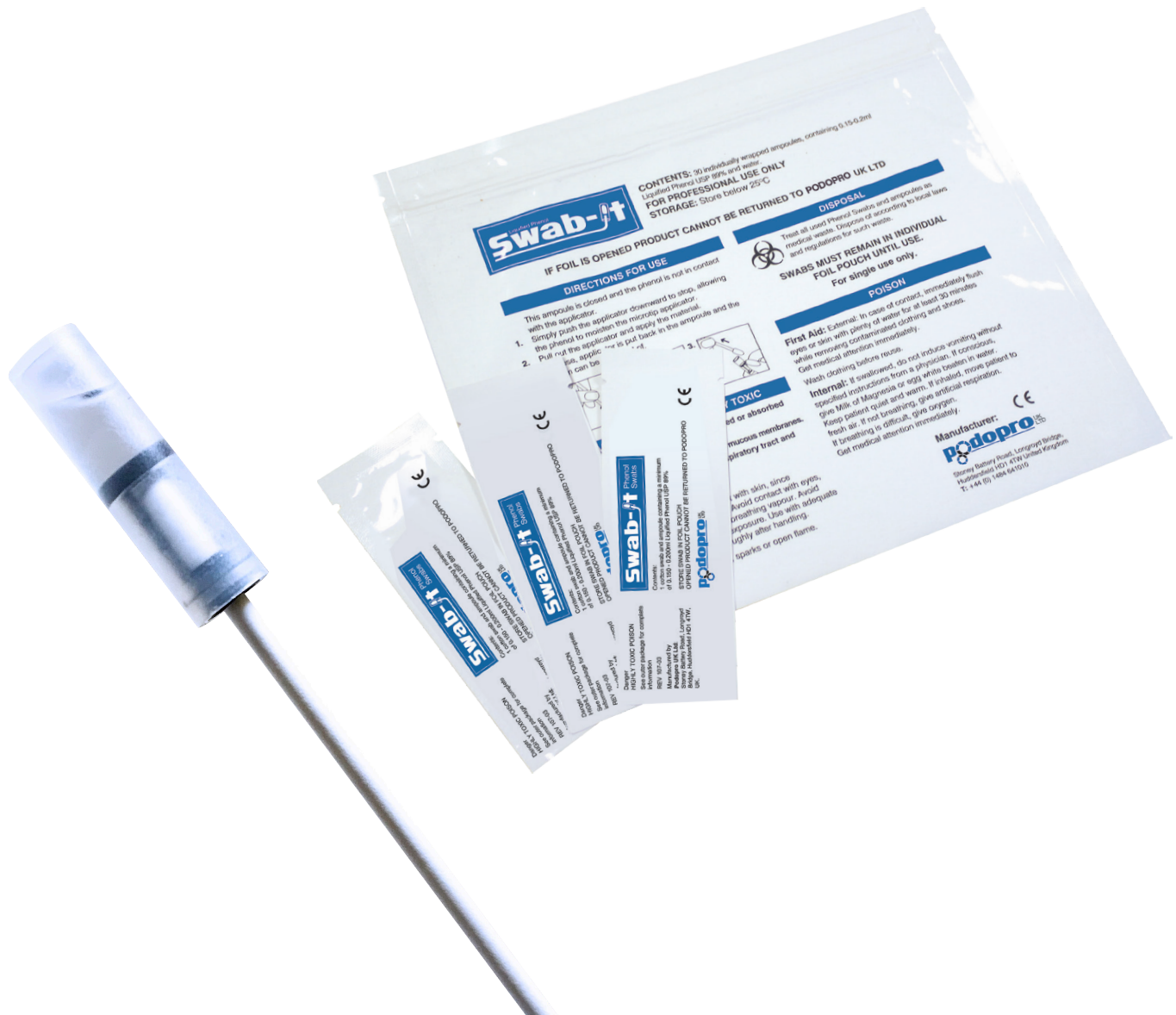
- CLASS IIA MEDICAL DEVICE
- SEALED AMPOULES WITH INTEGRATED SWAB APPLICATOR
- INDIVIDUALLY WRAPPED IN POUCHES AND SUPPLIED IN A RESEALABLE OUTER PACK
- PROVIDES A SAFER ALTERNATIVE TO BOTTLED PHENOL LIQUID

Swab-it

PHENOL SWAB-IT

The Phenol Swab-it was developed in the UK in 2004 to offer a safer alternative to Bottled Liquid Phenol. The Swab-it consists of a controlled dose of phenol contained in a small, sealed ampoule with an integrated cotton bud applicator. The ampoule is activated using the cotton bud applicator, which is used to absorb the phenol liquid. Individual ampoules are heat-sealed within single foil pouches which are then packed in a releasable outer foil package.

- 17 YEARS OF SAFE AND EFFECTIVE USE ACROSS THE WORLD.
- CONTROLLED PHENOL DOSE REDUCES THE RISK OF EXCESSIVE APPLICATION OF PHENOL.
- 1 SWAB PER APPLICATION IS AN EASY TO REPLICATE PROCEDURE AND REDUCES THE RISK OF CROSS INFECTION.



NAIL MATRIXECTOMY USING PHENOL SWAB-IT

Phenol is used to create a controlled burn designed to destroy tissue and is therefore not considered to be a hazard during the conduct of nail matrixectomy surgery. Fumes and leakage are reduced by containing the phenol in individual ampoules within single foil pouches which are placed in a resealable outer foil package. Each ampoule contains between 0.175ml & 0.20ml of phenol liquid 89% USP and includes an integrated cotton bud applicator.

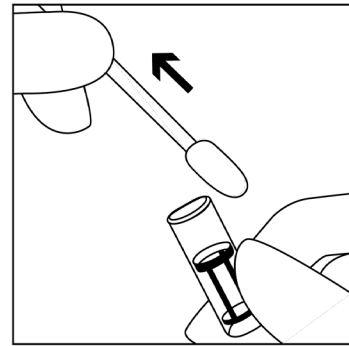
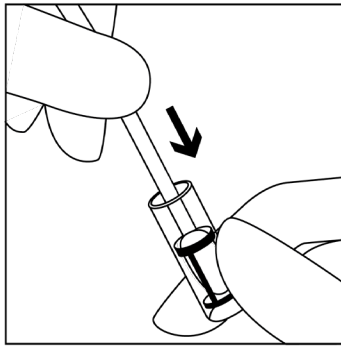
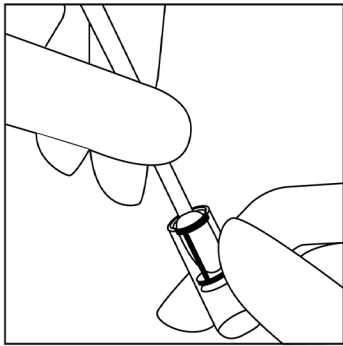
- **Toxicity:** Phenol is used to create a controlled burn designed to destroy tissue and is therefore not considered to be a hazard during the conduct of nail matrixectomy surgery. This is a well-established method for which there is no approved and licensed alternative.
- **Spillage:** Phenol Swab-It provides small, single-use aliquots of phenol in a disposable ampoule which is activated by inserting the integrated cotton bud applicator. This offers a vast improvement when compared to using bottles of phenol, where the risks of spillage are significantly greater.
- **Excessive contact:** The phenol dose in the ampoule is controlled within 0.175ml to 0.20ml. Inclusion of the swab within the ampoule ensures that the risk of excessive application of phenol is significantly reduced. Manufacturing to an ISO 13485 based quality system ensures consistency of output.
- **Fumes:** Fumes are reduced significantly due to the single ampoule product design. The packaging materials are also capable of preventing any fumes from escaping whilst the product is in storage.
- **Leakage:** Risk of leakage is reduced by containing the phenol in individual polyethylene ampoules within single foil pouches. 30 single swabs are then packed in a resealable outer foil pouch for further protection. The ampoule material specification and construction ensure that it is resistant to mechanical destruction. Manufacturing processes have been designed to ensure that a reliable seal is created after the ampoules are filled.



DIRECTIONS FOR USE

The Phenol Swab-It device enables the safe application of 89% USP phenol used to prevent regrowth following the removal of an ingrowing toenail (nail matrixectomy). The phenol is applied once the procedure to remove the toenail has been completed and works by stripping away the top levels of skin within the nail bed.

1. To activate simply push the applicator downward to stop, allowing the phenol to moisten the cotton bud.
2. Carefully remove the applicator and apply the phenol.
3. After use place the applicator back in the ampoule and the device can be safely disposed.



ACTIVATION OF PHENOL SWAB-IT

Holding the applicator securely (ideally placed on a flat surface) and no more than 5mm away from the ampoule, push the cotton bud into the phenol liquid. Do not push the swab from the end of the applicator as this may cause it to bend or break and could cause spillage. The ampoule should always be activated using the pre-inserted swab. The additional swabs provided in the pack are of a smaller diameter than those in the ampoule and should be used in a situation where the standard swab is too big. The smaller swabs should only be inserted after the pre-inserted swab has been used to activate the ampoule.

SAFETY INFORMATION

WARNING DANGER! HIGHLY TOXIC



May be fatal if swallowed, inhaled or absorbed through skin. Severely irritates eyes, skin and mucous membranes. May affect liver, kidneys, respiratory tract and central nervous system.



FIRST AID:
Eyes or skin with plenty of water for at least 30 minutes while removing contaminated clothing and shoes.
Get medical attention immediately.
Wash clothing before re-use.



Avoid unnecessary contact with skin, since serious burns may result.
Avoid contact with eyes, skin and clothing.
Avoid breathing vapour.
Avoid prolonged or repeated exposure.
Use with adequate ventilation.
Wash thoroughly after handling.



INTERNAL:
If swallowed, do not induce vomiting without specified instructions from a physician. If conscious, give milk of magnesia or egg white beaten in water. Keep patient quiet and warm. If inhaled, move patient to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.



Combustible.
Keep away from heat, sparks or open flame.

Get medical attention immediately.

STORAGE: Store below 25°C. Swabs must remain in the individual foil pouch until use. For single use only.
DISPOSAL: Treat all used Phenol Swabs and ampoules as medical waste.

FREQUENTLY ASKED QUESTIONS

HOW MANY PHENOL SWAB-IT SHOULD I USE DURING TREATMENT?

The number of Phenol Swab-It required will be dependent on the surface area of the nail bed requiring ablation and will be different for partial, full or bi-lateral nail avulsion. A study was undertaken by Judith Brown at the Durham School of Podiatric Medicine in 2002 on the use of phenol swabs. The findings were that two 1 minute applications using 2 swabs (1 swab per application) for a PNA resulted in no regrowth issues and allowed for a faster recovery time for the patient.

Using the appropriate amount of phenol is a matter of judgement and an experienced clinician will observe factors such as the blanching of the skin to determine whether more swabs are needed.

WHAT IS THE APPLICATION TIME FOR THE PHENOL SWAB-IT?

Application times should be determined by your own clinical judgement and made on a patient-by-patient basis. Phenol Swab-It is a delivery system for liquid phenol, so there is no necessity for clinicians with a good success rate using phenolisation during nail matrixectomy surgery to alter their procedure. We can provide information from studies carried out by podiatry professionals, offering guidance on this subject.

WHAT IS THE AVERAGE REGROWTH RATE?

Phenol Swab-It is a licensed CE marked medical device for the delivery of the phenol liquid. You should expect to achieve similar results compared to using bottled phenol. Studies relating to the use of phenol in nail matrixectomy indicate a success rate in approximately 98% of cases (regrowth may occur in approximately 2% of cases).

ARE PHENOL SWAB-IT AVAILABLE IN DIFFERENT SIZES?

Phenol Swab-It are supplied with a standard size swab sealed within the ampoule and this swab must be used to puncture the ampoule. Additional swabs are provided in the pack of a smaller diameter, these may be inserted after the ampoule has been punctured and used to apply the phenol where the standard swab is considered too big, for example when treating a smaller area.

HOW SHOULD I DISPOSE OF THE PHENOL SWAB-IT?

The used swab and ampoule will contain no more phenol than any gauze dressings used during nail surgery performed with bottled liquid phenol. Disposal of the product should be aligned with your existing protocol for this type of medical waste.



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