

Instructions for Use (Professional use only)		PDP89B Podonics Dispense Applicator Phenol Blue 89%	
Device item codes	REF: PDP89B-12 pack of 12	UDI	5070002441403
	REF: PDP89B-30 pack of 30	UDI	5070002441410
Intended Use	A non-sterile solution of phenol intended to be applied directly to the nail bed as part of a Matrixectomy procedure as described in the National Nail Surgery Guidelines. After application, this device cannot be reused.		
Intended User	Intended to be used and administered by suitably qualified medical professionals such as Chiropodists, Podiatrists and Orthopaedic surgeons in a clinical environment for performing Matrixectomy procedure on patients diagnosed with Onychocryptosis. Please refer to National Nail Surgery Guidelines. Please refer to National Nail Surgery Guidelines.		
Intended Patient	Intended to be used by the above medical professionals on patients diagnosed with Onychocryptosis (Ingrown toenail). Should not be used on diabetic patients susceptible to infection, foot ulcers, circulatory issues, or pregnant women. Should not be used on diabetic patients susceptible to infection, foot ulcers, circulatory issues, pregnant women, newborns or children under the age of 6		
Directions for Use	<p style="text-align: center;">Instructions For Use</p> <p style="text-align: center;"> Do NOT attempt to break glass ampule, other than at marked ends. Do NOT attempt to break in the middle or remove glass from plastic outer tube. Apply appropriate (PPE): Medical gown, medical gloves, goggles and/or visor before activation and use.</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 30%;"> <p>1. Snap – using both hands to hold the SafeTPen, gently snap the top ampule tip</p> <p>2. Snap – repeat the same process with the bottom ampule tip</p> <p>3. Squeeze – using your fingertips, lightly squeeze the device to load the SafeTPen</p> </div> <div style="width: 60%;"> </div> </div>		
Warnings & Precautions	<ul style="list-style-type: none"> Phenol is classified as ‘Hazardous’ and should be handled with care. Do NOT attempt to break glass ampoule anywhere other than at the marked break points Do NOT attempt to break glass in the middle of the ampoule or remove the ampoule from the plastic outer tube. Do NOT attempt to remove applicator tip at any time for any reason. Do NOT use if there are signs the integrity of the ampoule or sleeve tube has been compromised prior to opening. 		
Contraindications	<ul style="list-style-type: none"> Diminished vascular supply to the digit is a relative contraindication to nail surgery. Overt bacterial infection of the operative site is a relative contraindication to chemical cauterisation. Use caution with people who have a bleeding disorder or who are taking anticoagulant therapy. 		
Adverse effects	<ul style="list-style-type: none"> Pain is the most common complication following nail surgery and is more likely to occur when infection is present before the procedure. Even with meticulous patient preparation and technique, postoperative infection may occur. 		
Reporting	In accordance with Medical Devices Regulation 2017/745 all adverse events that occur in relation to the device should be reported to the manufacturer, and/or the manufacturers authorised representative, and the competent authority of the Member State in which the user and/or patient is established.		
	Caution should always be used when using this product. Take necessary precautions including the wearing of appropriate personal protective equipment		Do not use the product if the packaging has been damaged or if there are signs that the solution has leaked from the vial on opening.
	Treat all used applicators as medical waste and dispose of according to local laws and regulations for such waste. Return used applicators to original grip seal pouch prior to disposal		Avoid all unnecessary contact with skin by wearing protective clothing as serious burns may result. Avoid contact with eyes by wearing appropriate eye protection
	Keep away from heat, sparks or open flame. Combustible		May be fatal if swallowed, inhaled, or absorbed through skin. Can severely irritate eyes, skin, and mucous membranes. May affect liver, kidneys, respiratory tract and central nervous system.
	May cause possible allergy or asthma symptoms or breathing difficulties if inhaled for prolonged periods. Ensure application is conducted in well ventilated environments and avoid confined spaces		
First Aid Measures	<p>In the event of contact, immediately flush eyes, or skin with plenty of water for at least 30 minutes while removing any potentially contaminated clothing. seek medical attention immediately.</p> <p>If ingested, do not induce vomiting without specified instructions from a medical professional. 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 difficulty breathing, administer oxygen and seek immediate medical attention.</p>		
	Manufactured by: Podonics Ltd, 70 Bounces Road, London. N9 8JS www.podonics.com		
	European Healthcare & Device Solutions (Ireland) Ltd. Stratton House. Bishopstown Road. Cork. T12 Y9TC. Ireland Phone: +353 (86) 228 0846 email: info@europeandevicesolutions.co.uk		