

WARNINGS

External use only

- Do not** use if unsealed or damaged.
- Do not** apply over open wounds or infections.
- Do not** use on patients allergic to silicone adhesive strip that secures the device.
- Do not** use on extremely delicate or thin skin.
- Do not** freeze.

A. Intended Purpose

NeedleCalm is a single use device intended to be used as a diversional adjunct therapy for discomfort and anxiety associated with needle procedures.

This is inclusive of hypodermic needles and intravenous cannulae inserted via the intramuscular (IM), intravenous (IV), and subcutaneous (SC) routes.

NeedleCalm is intended to be used by individuals who are trained to perform injection and venous access procedures e.g. healthcare practitioners or patients that have been trained to self administer injections.










B. Storage Information

 **Keep box in refrigerator** at 2° to 8°C for at least 4 hours before use.

Keep out of direct sunlight and humid conditions. Store at room temperature.

Do not use if the box or any of the contained pouches have been damaged or unintentionally opened.

C. Glossary of symbols

	Do not use if package is opened or damaged		Single use only
	Date of manufacture		Manufacturer
	Catalogue number		Lot number
	Expiry date		Consult instructions for use
	Keep product out of sunlight		

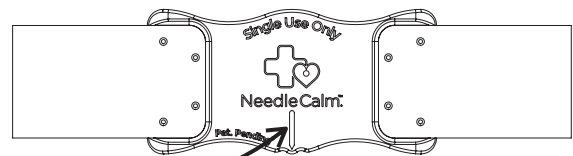
D. Device Description

NeedleCalm is a single use device.

The NeedleCalm device has thermoplastic properties that can allow it to retain a cool temperature. The reverse side of the device includes stimulation points to stimulate the skin and silicone adhesion tape to gently secure the device to the patient.

NeedleCalm should be applied after refrigeration, on the skin 2 - 5 cm above the procedure site to provide a light pressure and cooling sensation to help distract the patient from the pain associated with needle insertion.

NeedleCalm is applied in conjunction with Standard Practice for needle procedures.



Indicator
to point towards
chosen procedure site

Figure 1: Device showing indicator strip

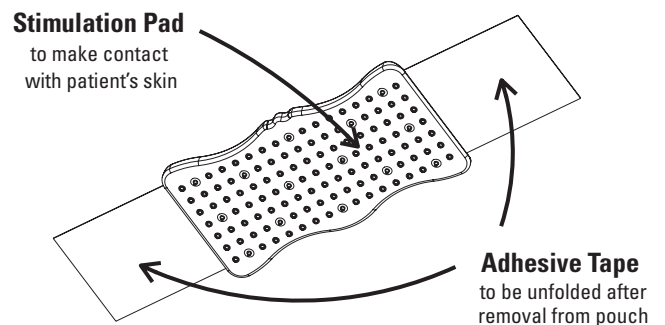


Figure 2: Reverse of the device

Instructions overleaf

F. Instructions

STEP 1 REFRIGERATION

Refrigerate NeedleCalm at 2° to 8°C for at least 4 hours before use so that the device is cold to touch before use. It is recommended that the device remain cold for maximum effectiveness. Use within 2 minutes upon removal from refrigeration.

STEP 2 CHOOSE PROCEDURE SITE

NeedleCalm can be used on multiple sites for needle procedures and is suitable for use on children and adults with a minimum arm circumference of 13cm.

Ensure patient is comfortable and select one of the following sites for procedure:

1. **Deltoid**
2. **Antecubital fossa**
3. **Hip**
4. **Buttocks** (dorsogluteal muscles)
5. **Abdomen**
6. **Upper thigh** (vasterus lateralis)

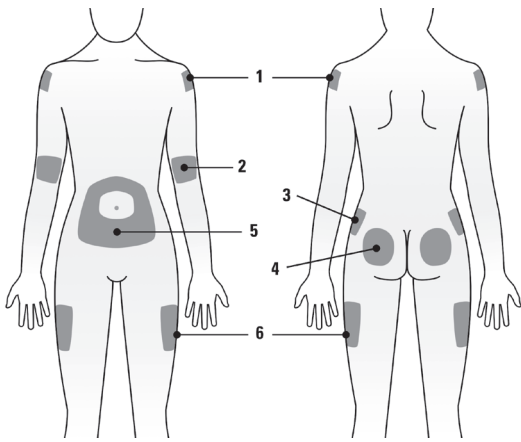


Figure 3: Front of body procedure sites

Figure 4: Rear of body procedure sites

Allow space above procedure site to apply device. We recommend placing the device **2 – 5 cm superior to procedure site** (when using a tourniquet ensure the device is placed **between the tourniquet and the procedure site**).

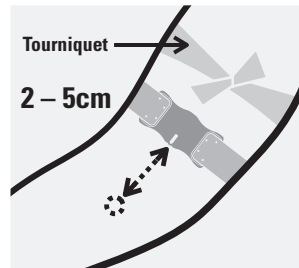


Figure 5: Antecubital fossa (elbow pit)

STEP 3 PREPARE PROCEDURE SITE

Perform hand hygiene and prepare all equipment for procedure, as per the health facility protocol.

STEP 4 APPLY NEEDLECALM DEVICE

Use device **within 2 minutes** of removing from fridge (recommended).

Ensure patient is ready to commence the procedure.

Remove pouch containing the NeedleCalm device from refrigerator.

Open pouch and remove device.

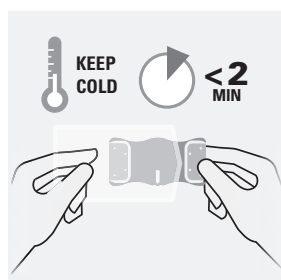


Figure 6: Unwrapping the device

Holding the smooth surface, **pre-bend** the device by folding one side inwards towards the middle and hold for three seconds (See Figure 7).

Repeat for the other side.

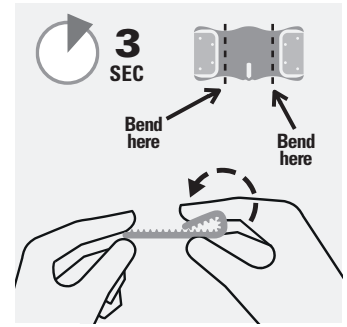


Figure 7: Pre-bending of the device

The device will be curved as shown in Figure 8.



Figure 8: Device curvature after bending

Locate the indicator on the device. Position between **2 – 5cm above** the chosen procedure site.

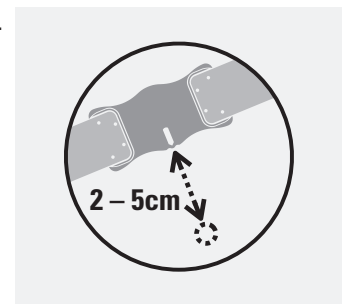


Figure 9: Positioning of the device

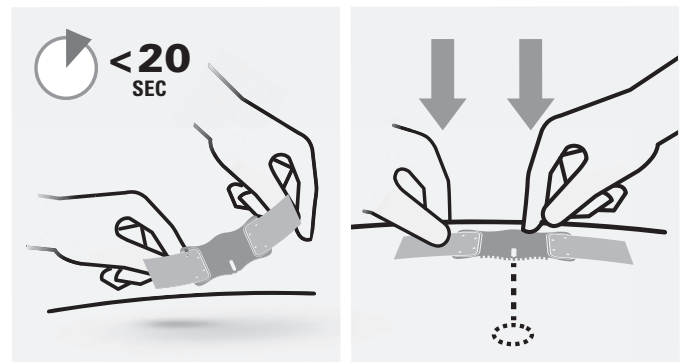


Figure 10: Application of the device

Remove protective backing from either side of the device ensuring adequate skin adhesion with the spikes contacting the patients skin.

Apply the NeedleCalm device only moments before needle insertion and press firmly during needle insertion.

Do not move or remove NeedleCalm until the needle has been removed from the patient.

If more than 20 seconds elapse between placement and the needle insertion, remove NeedleCalm from the skin and repeat the process.

STEP 5 COMPLETE PROCEDURE & DISPOSE NEEDLECALM

Once procedure is completed and needle is removed from patient, remove the NeedleCalm device from site by gently peeling back silicone tape from patient's skin.

Dispose of used NeedleCalm device directly into general waste immediately after use (if contact with bodily fluids occurs, dispose as per facility protocol). Indentation of the skin is normal and usually will resolve within an hour.