

Patient Information and Consent application for Freezepen Cryotherapy Procedure

This consent form provides necessary information about the cryotherapy procedure.

The Freezpen is a non-invasive, non-sterile, reusable medical device for the cryogenic treatment of the following benign skin lesions. Lesions are treated by applying an extremely precise flow of nitrous oxide directly on the lesion.

The FreezPen procedure uses -89 ° C liquid nitrogen at 55 bars.

Treatment results are individual, and no definite guarantee can be given to the final outcome. In general, treatment-related changes are noted after 1 month of treatment.

Contraindications:

- Unstable diabetes
- Skin conditions, e.g. skin tumours, exanthema,
- Open wounds
- Solar hyperkeratosis
- Unexplained, suspicious liver spots and moles
- Cancer tissues and malignant tumours

Contraindications related to temporary conditions:

- Infections accompanied by fever
- Acute chemotherapy or radiotherapy from four weeks before beginning the therapy to four weeks after finishing the therapy
- Cold intolerance
- Vascular insufficiency

Possible side effects:

Although cryotherapy is a relatively low-risk procedure, some side effects may occur as a result of the treatment.

They include:

- Permanent changes in pigmentation
- Sensory impairment. Though rare, damage to nerves is possible, particularly in areas where these are positioned closer to the surface of the skin, such as in the fingers, the wrist, and the area behind the ear.
- Hair loss. Hair follicles are easily damaged by cryosurgery and permanent hair loss is not uncommon.
- Pigmented spots. It is common use to not treat pigmented spots in sunny seasons

I confirm that I am familiar with the consent form and understand the content of the procedure to be performed on me.

PATIENT NAME _____

DATE _____ SIGNATURE: _____