

Hydrozid: Application Process

Hydrozid is ready for use by licensed medical professional after unpacking. Prior to using product, read Instructions for Use.

01 Hydrozid[®] is ready for use after unpacking. Do not remove the tip of the application tube. It must remain in place during treatment.

02 Release the locking mechanism under the activation arm, from left to right. The canister is now ready to use.

03 Select the appropriate application template based on the size and location of the skin lesion you are treating. The application template should be slightly larger than the skin lesion being treated.

Position the application template over the treatment area with your non-dominant hand.

04 Hold the Hydrozid[®] canister in the other hand and spray at a distance of 1 inch or two finger width from the lesion. Treatment times vary based on the lesion. A film of white ice crystals will now form on the lesion. After the area is no longer white, indicating that the thawing period has ended, repeat another freeze-thaw cycle. See the recommended treatment times in the Hydrozid[®] instructions for use which will vary based on the type of lesion being treated. The clinician must always adjust the treatment to the individual patient.



Lesion	Recommended Freeze Thaw Times
Verruca plantaris	6 seconds, 4-6 cycles
Verruca vulgaris	6 seconds, 4-6 cycles
Verruca plana	3 seconds, 6 cycles
Seborrheic keratosis	6 seconds, 2-3 cycles
Lentigo (facial)	3 seconds, 2 cycles
Lentigo (non-facial)	3 seconds, 2 cycles
Acrochordon	3-6 seconds, 2 cycles
Actinic keratosis (facial)	4-5 seconds, 2 cycles
Actinic keratosis (non-facial)	4-5 seconds, 2 cycles
Molluscum contagiosum	3-6 seconds, 2 cycles

**Freeze times provided above are recommendations. Providers should always assess the individual patient and lesion to determine the correct treatment. Ice crystals MUST thaw before freezing again.*

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CONTRAINDICATIONS

Hydrozid® is to be used only on benign lesions and/or pre-malignant lesions (actinic keratosis). Do not treat a lesion that cannot be diagnosed with certainty or cancer is suspected. If there is doubt that a lesion is benign or pre-malignant, a biopsy is recommended. Do not use on healthy skin. Improper use may lead to unwanted damage to the skin and underlying tissues, including nerves. Do not use on irritated, eczematous, or infected skin. Do not use on open, bleeding, or bleached skin. Do not use on mucus membrane areas. Not for use in treatment of children under the age of 5 years. Cryosurgery is reported to be safe in pregnancy(3). As no clear guidelines are available(5) caution and physician's discretion are advised for the patient and treatment selection.

CAUTIONS

Pressurized container; may burst if heated. Protect from sunlight. Do not expose to temperatures exceeding 50°C/122°F. Keep away from the heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking. Do not pierce or burn, even after use. Hydrozid® can be disposed in normal household. Do not attempt to refill an empty canister. Federal law prohibits transportation if refilled and a penalty of up to \$500,000 fine and 5 years imprisonment (49 USC 5124). If the canister is dropped, inspect for damage or leakage. Damage may not be visible, and the practitioner may not know if the canister was dropped since it was last used. DO NOT USE. Contact BIBAWO Medical A/S for further support or replacement. Always use gentle pressure when activating the trigger nozzle. This will reduce the cryogen waste and prevent splatter. Reducing waste means more treatments per canister. Always place the disk in lock position after use (see directions for use) to avoid inadvertent spraying in the next use. Do not attempt to remove the tip mounted into the distal end of the tube. The narrow aperture of the tip makes it easier to target the damaged tissue mitigating the risk of damaging the surrounding healthy skin. The tip also comprises a conical inner shape that prevents condensation and dripping during the treatment. For thin skin or sensitive areas, it is recommended to under-treat the patient. Do not touch the lesion until the ice formation disappears. Allow the lesions to thaw naturally. Early thawing will reduce the effectiveness of the freeze and lesion destruction. If a lesion persists following treatment, re-inspect the lesion and re-confirm the diagnosis.

WARNINGS

Read all instructions prior to using Hydrozid®. Hydrozid® is non-flammable, non-toxic and a non-oxidizer. Neither protective equipment nor well-ventilated areas are required. The application templates must only be used with Hydrozid®. Due to the risk of infection, the application templates are for single use. Do not attempt to clean Hydrozid®/the application templates. All application templates are disposable. Application templates may be used multiple times on the same patient with similar lesions in the same anatomical location but should be disposed between patients or treatment of different lesions to avoid spreading potential bacteria, diseases, or viruses. The application templates are used to protect the surrounding healthy tissue. Do not make any attempt to treat without the application templates until you have substantial experience and are familiar with the device and recommended treatment times. It is solely at the healthcare professional's discretion to ensure it is safe and suitable to treat without the use of the application templates. Failure to use an application template and attempt an open spray could result in damage of the surrounding healthy tissue. Do not treat lesions that cannot be diagnosed with certainty. If there is doubt that a lesion is benign or pre-malignant, a biopsy is recommended to determine classification and if cryosurgery with Hydrozid® is an option. Do not attempt facial treatments until you have substantial experience and are familiar with the device, application templates, and recommended treatment times. Incorrect use could cause damage to the skin. When treating sensitive areas of the body such as around the eyes and ears, be sure to shield or protect the areas so that the cryogen does not come into contact with healthy tissue. Avoid contact with eyes. Keep out of reach of children. Never freeze scrotum tissue with a testicle directly beneath. Always gently separate scrotum tissue that is being treated away from the testicle, then perform the procedure. Special attention and caution are needed in the treatment of patients who have sensitive skin, heavily pigmented skin, sensory loss, poor blood supply, children and/or the elderly. Not for use in treatment of children under the age of 5 years. Those with collagen vascular disease, cryoglobulinemia, Raynaud's disease, cold urticaria, blood dyscrasias, diabetes, stasis problems, pyoderma gangrenosum, neuropathy, impaired immune system, and ulcerative bowel disorders may present special complications including, but not limited to, slower healing time. Physician's discretion should be used for patient and treatment selection.

POTENTIAL COMPLICATIONS AND SIDE EFFECTS OF CRYOSURGERY

The most common complications and side effects related with cryosurgery are described below (4):

Acute complications: Local pain, Edema especially facial use and when used in infants/children and elderly, Cryoblisters formation, Syncope in anxious patients, Headache after treatment of head and neck, Hemorrhagic necrosis, Wound infection and delayed wound healing, Temporary scar hypertrophy, Subcutaneous emphysema

Long-term complications: Hypopigmentation, Local hypoesthesia due to nerve damage, Milia formation, Cicatricial, Alopecia

Common side effects: Skin may turn white temporarily, Overexposure may cause damage to the top layers of the skin resulting in scars and/or nerve damage, Exposure of healthy skin may cause local tissue death, Formation of large blisters which may cause pain, Hypopigmentation and scars, Post-inflammatory hyperpigmentation