

DATE: 24 June 2024

PRODUCT: Histofreezer FLEX or Histofreezer STAT

SUBJECT: Recommended Cleaning of Adapter and Why

The Histofreezer FLEX may be used with either buds or its uniquely designed two-part cone system. As per the Instructions for Use (IFU), both buds and cone tips are discarded after use since they have touched the patient being treated.

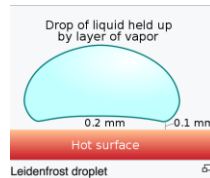


The question has arisen about the cone adapter and how best to clean it after use? This Bulletin was written to help direct clinicians on how to approach this question and the supporting information.

The Leidenfrost Effect: When using cones to treat a topical lesion, the Histofreezer FLEX dispenses a small amount of liquid gas into the cone tip. The liquid will appear to bubble in the cone tip and adapter and eventually evaporate freezing the targeted area.

It is important to understand how this process is working. In practice, the gas does not touch the surface of the skin. The difference in temperature between the warm skin and the cold gas creates a vapor layer at the surface of the skin. Heat from the skin is transferred through the vapor layer to the gas which then slowly evaporates.

This is known as the Leidenfrost Effect and is the reason the gas only acts to take heat from the skin but never actually touches it. See Image below:



DeWitt; Bergman; Lavine (2006). Fundamentals of Heat and Mass Transfer (6th ed.). pp. 325–330.

Cleaning of Histofreezer FLEX:

The Histofreezer FLEX is designed to treat a variety of topical lesions. The canister of gas and handle cannot be heated to clean and therefore may be wiped with any water-based biocide or 70% alcohol (see Instructions for Use).

As mentioned above the applicators or cone tips must be discarded after each patient. Four cone adapters are supplied in each kit. These should also be treated with a water-based biocide cleaner or 70% alcohol.

Summary:

Each clinical site will have protocols for cleaning and use of equipment and kits. The Histofreezer FLEX instructions provides guidance that is compatible with the product component materials and intended use. Please contact CryoConcepts at CustomerCareMed@cryoconcepts.com or call 1-855-355-CRYO if there are specific questions about this topic.