



# New Device Clearance

## Wartner Wart Removal System - K011708

**Product Name:** Wartner Wart Removal System

**Manufacturer:** Wartner Medical Products

**Address:** c/o N. Wilson Consulting, Inc., 25 Bellini Avenue, Brampton, Ontario CANADA L6T 3Z8

**Clearance Date:** February 20, 2002

**510(k) Statement:** <http://www.fda.gov/cdrh/pdf/K011708.pdf>

**What is it and when is it used?** This system is used to remove common, harmless warts. These are skin-colored growths that resemble the head of cauliflower, and are caused by a virus. They usually appear on the hands and feet.

The system has two main parts. One is a pressurized spray can that contains two chemicals, dimethyl ether and propane. The other is a foam applicator that fits into the end of the spray can. This system can be bought without a prescription.

**How does it work?** You push the foam applicator into the end of the spray can. The chemicals from the can enter the foam applicator and become very cold-about -50 degrees Celsius. You then remove the foam applicator and hold it on the wart for no more than 20 seconds. The cold from the applicator kills the virus and the infected skin of the wart.

**What will it accomplish?** This system will usually kill common, harmless warts so they disappear in about two weeks. If a wart or part of it is still there two weeks after you treat it, you may need to treat it again.

**When should it not be used?** Do not use this system to remove any skin growths other than common, harmless warts. If you are not sure what type of growth you have, contact your doctor before using this system. Do not use this system to remove:

- warts on irritated skin,
- moles or birthmarks, because these may be signs or more dangerous problems
- warts with hair growing from them,
- genital warts, which are warts on the penis or vagina,
- warts on mucous membranes, such as inside the mouth or near the anus,
- warts on the face, nose, lips, or ears or near the eyes,
- warts on thin skin, such as armpits, breasts, buttocks or genitals,

- warts in places that you can't see well, such as on your back,
- warts on children younger than 4 years old,
- warts on women who are pregnant or breast-feeding,
- warts on diabetic patients,
- warts on patients who have poor blood circulation.

Do **not** allow children to use this system, and do not use it if you cannot see clearly. Be sure to follow the instructions on the container and the information leaflet, which has detailed instructions.

**Additional information:** 510(k) Statement will be available at:

<http://www.fda.gov/cdrh/pdf/K011708.pdf>

Other:

- Medical Encyclopedia--Warts--MedlinePlus Health Information  
<http://www.nlm.nih.gov/medlineplus/ency/article/000885.htm>
- Medical Encyclopedia--Cryosurgery--MedlinePlus Health Information  
<http://www.nlm.nih.gov/medlineplus/ency/article/002322.htm>
- Medical Encyclopedia--Genital Warts--MedlinePlus Health Information  
<http://www.nlm.nih.gov/medlineplus/ency/article/000886.htm>

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*(Updated 06/03/02)*