G VIR®

TECHNICAL FILE

"Active" hand protection against
Aids, Hepatitis C...*

Manufacturer's details

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HUTCHINSON® healthcare

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Contents:

Introduction:

Health care professionals have major concerns about occupational exposure to blood from viruses-infected patients. Currently, hepatitis B virus (HBV) can be prevented by vaccination whereas only post-exposure prophylaxis is available for human immunodeficiency virus (HIV) and no immediate prophylaxis is available for hepatitis C virus (HCV).

Among all blood exposure accidents reported, sharp (needlestick) injuries are associated with the highest contamination risk which is estimated at 0.5-3% for HCV and 0.3% for HIV (Jagger J, JAMA 2002;288:1469 ; Gerberding JL. N Engl J Med 2003;348:826-833).

Hand protection is recommended to prevent exposure to blood and bodily fluids, but the safety offered by single or even double gloving systems in case of needlestick injuries has been often questioned.

The G-VIR® glove was designed to improve the protection level in case of such accidents.

Company profile:

Hutchinson Santé is a subsidiary of Hutchinson, one of the world leaders in the transformation of elastomers (25,800 employees).

Hutchinson is engaged in a variety of industrial, aeronautic or consumer product groups and offers the strength of its innovation and work ethic in three main activity sectors: Automobile, Aerospace and Industry, and Consumer Goods.

Hutchinson is committed to a strategy of innovation, by conducting major research and development activities.

Hutchinson Santé was established in 2003 as a part of to the “Consumer Goods” activity. Its mission is to design, manufacture and provide health care workers with unique added value medical devices in the field of protection.

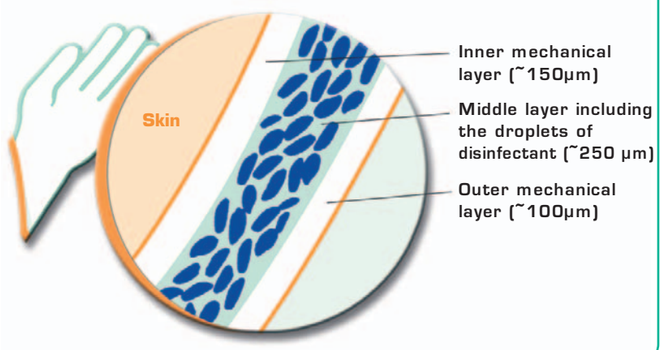
With a staff of 30 professionals located near Paris, France, Hutchinson Santé ambitions to manufacture and market gloves derived from G-VIR® technology, whilst pursuing research for the development of other unique “protective devices”.

Product Description:

G-VIR® is a new concept for an "active" surgical glove, designed to provide health care workers with high protection against the risks of contamination caused by viruses such as HIV and HCV.

The glove is made of two boundary layers between which a large quantity (about 8mL per glove) of disinfecting liquid in drop-like compartments is sandwiched.

Cross-sectional drawing of the G-VIR® glove

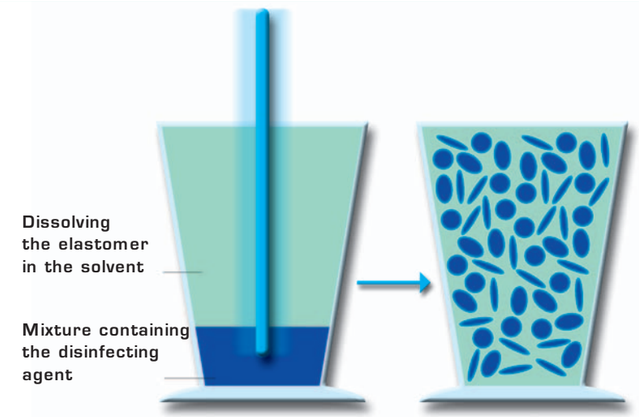


The G-VIR® glove consists of (see illustration):

- an outer mechanical layer, in direct contact with patients, products and surgical instruments;
- a middle biological layer, containing a disinfecting liquid (mixture of quaternary ammoniums salts and chlorhexidine digluconate) evenly distributed in the form of microdroplets;
- an inner mechanical layer, coated with an inert substance to facilitate donning.

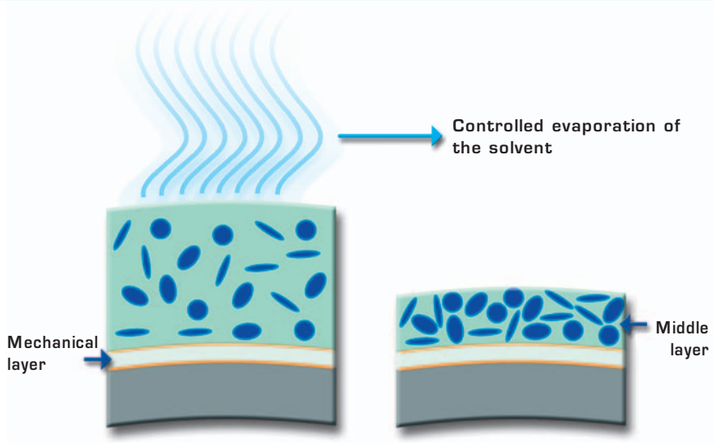
The total thickness of the G-VIR® glove, at the back of the hand, is 500µm+ /- 50µm, which is equivalent of a double glove thickness.

Producing of the emulsion



The disinfecting liquid is incorporated using a highly innovative technology. This patented technology consists in the processing of a non-aqueous emulsion of the disinfecting agent in a continuous phase obtained by dissolution of a thermoplastic elastomer in a solvent.

Formation of the film



Then, the emulsion is dip coated on a mechanical layer. The controlled evaporation of the solvent provides a thin film of thermoplastic elastomer filled with close-packed microdroplets.

A third elastomeric layer is deposited to complete the final "sandwich" structure of G-VIR®.

It should be noted that the "dissolving" method provides a non porous film after the evaporation of the solvent.

In short :

2 mechanical layers, (inner and outer) both made up of thermoplastic elastomer
1 biological layer, made up of a thermoplastic elastomer matrix filled with disinfecting liquid droplets
The disinfectant is a mixture of quaternary ammoniums salts and chlorhexidine digluconate
Absence of natural rubber latex and powder

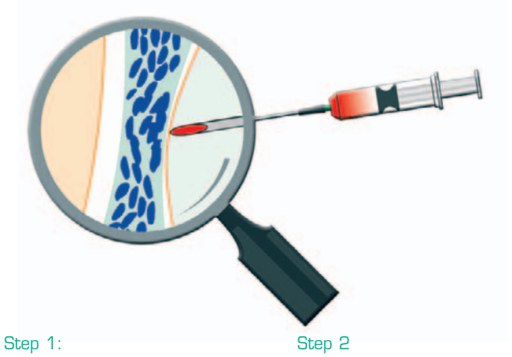
Efficacy of the G-VIR® glove:

The efficacy of the G-VIR® glove in case of accidental perforation relies on two main contributions. The first one is based on a very specific "action mechanism" that occurs when the film is broken. The second one is related to the biological performance on enveloped viruses, such as HIV and HCV.

Action Mechanism

The action mechanism of the G-VIR® glove maximises the quantity of disinfecting liquid available at the breaking point.
It is based on an observation from daily life: when an orange is peeled, the pores in the skin produce a liquid under pressure that may be sprayed over several metres. The elastic energy of deformation is converted into pressure exerted on the fluid. This allows the liquid to be projected.
As a result, the properties of each layer of the glove were adjusted (viscoelastic properties, rate of filling, size of the microdroplets…) in order to resemble the structure of an orange peel and to obtain the effect: expulsion of the disinfecting liquid under pressure on the instrument piercing the outer layer. In May 2004, this unique mechanism was published in the Nature Materials journal (P.Sonntag et al., Biocide squirting from an elastomeric film, 2004, 3, N°5, 311-315).

The mechanism can be broken down in three steps, illustrated below, in case of an injury with a hollow bore needle.

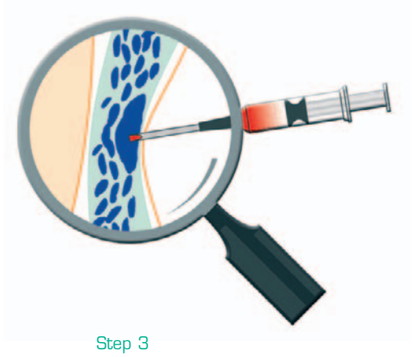


Step 1:

Immobilisation:
the needle deforms the outer layer without piercing it, leading to an increasing pressure in the middle layer.

Step 2

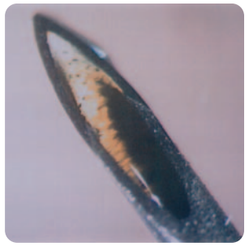
Concentration:
under the effect of the pressure, the walls between the microdroplets break and the liquid concentrates at the point of contact.



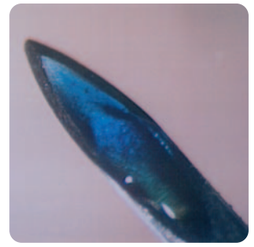
Step 3

Expulsion:
by advancing, the needle finally pierces the outer layer. The liquid disinfectant is then expelled under the effect of pressure.

A simple colorimetric test illustrates the expulsion of the disinfectant inside and around wounding objects. This test consists in placing a colouring agent sensitive to the disinfectant in the hollow needle tip and observing the immediate colour change after the passage of the needle through the glove, as illustrated below.



Before



After

Biological Performance

G-VIR® biological efficacy has been assessed in vitro and in vivo in comparison with single or double gloving systems.

To better understand the efficacy of the glove, the very specific conditions gathered during a percutaneous injury have to be considered. The basic transmission risk factor is the quantity of inoculated viruses, directly linked to the patient viral load and to the volume accidentally inoculated (Cardo DM, N Engl J Med 1997;337:1485-1490).

The volume of blood that may be inoculated is extremely low (about 1/10 of a microlitre in the case of a puncture with a 22-gauge hollow bore needle). In addition, even if the patient presents a high viral load (several million copies per millilitre), the number of potentially transmissible viruses would remain relatively low (about a hundred or, at the most, a few hundred).

It is also important to consider that HIV and HCV are enveloped viruses, known to be highly sensitive to surface active agents (detergents) such as quaternary ammoniums salts (the main ingredients in the disinfecting liquid). The action kinetics of detergents on the phospholipidic bilayer of these viruses is known to be extremely fast (Lasch, J, Biophys. Acta, 1995, 1241, 269).

In the absence of relevant standards in the literature, Hutchinson Santé designed specific tests to assess the G-VIR® biological performance during a simulated percutaneous injury. An automatic puncture apparatus was designed to ensure accurate control of puncture parameters such as the puncture speed, depth and angle, etc.

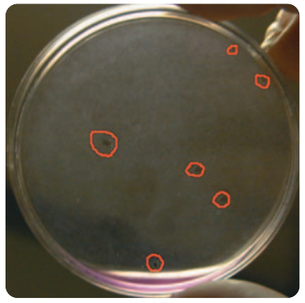
Severe experimental conditions were set for these tests: model viruses (Feline Immunodeficiency Virus, Bovine Viral Diarrhea Virus or Herpes

Efficacy of the G-VIR® glove:

Simplex Virus type 1) with a high viral load (10^6 viruses/ml) in blood were used to contaminate needles. Punctures were made with hollow bore needles leading to a much higher blood inoculum and therefore to a much higher number of viruses to inactivate. Indeed, the "wiping effect" of a puncturing device by any glove results from a mechanical constriction process which is mainly influenced by the glove viscoelastic characteristics, failure mechanism and geometry of the puncturing device. If suture needles can be partly cleansed by a single, or better a double, glove, other sharp objects (scalpel blades, bone fragments,…) with more complex geometries are not subject to the same mechanical cleaning process because of hidden, sometimes porous, less accessible surfaces. As a result, the use of hollow-bore needle could be considered as a relevant model (worst case scenario) to simulate accidents caused by such objects.

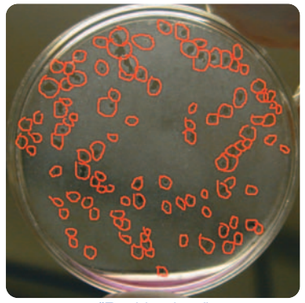
Step 1
Contamination of a 22G hollow needle
Attachement of the needle on the puncture apparatus

Step 2
Perforation of no glove, simple glove, double glove or G-VIR® glove and recovery of the inoculum transmitted in collecting medium. Then sampling of the collecting medium



G-VIR®

Step 3
After incubation, viruses are counted thanks to a plaque assay technique



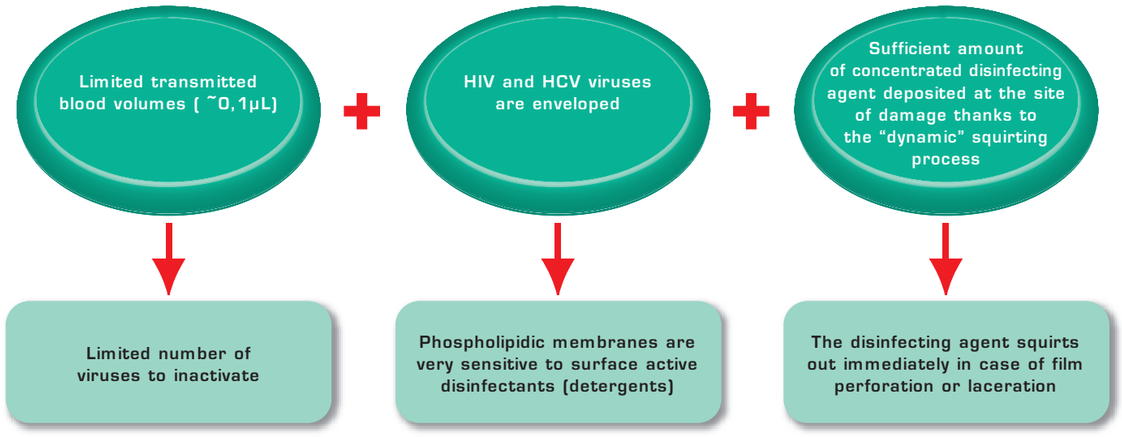
"Double glove"

	Without any glove	Simple gloving	Double gloving	G-VIR® Glove
Quantity of liquid transfered in case of hollow-bore needle puncture (22G)	0,4 µL	0,2 µL	0,2 µL	0,2 µL
Quantity of viruses transfered if the viral laod is 10^6 viruses/mL	400 viruses	200 viruses	200 viruses	40 viruses
% of reduction		-50%	0%	-80%

In these experimental conditions, the G-VIR® glove elicited in average an **80 % reduction in the number of transmitted viruses as compared to a double latex glove.** (R.Krikorian and al, Standardization of needlestick injury and evaluation of a novel virus-inhibiting protective glove, J. Hosp Inf., 2007,Vol.66, 339-345)

As a summary:

The efficacy of the G-VIR® glove results from three combined factors :



Clinical Data:

A new product, such as the G-VIR® glove with an original construction and composition, had to be assessed in clinical conditions in order to check several criteria:

- satisfactory ergonomics,
- good mechanical resistance compatible with surgical use,
- the absence of side effects.

In June 2006, over 600 health care workers from over 100 French hospitals tested and assessed the G-VIR® glove during surgical procedures by filling out the grid of criteria:

Assessment of the glove by speciality

SURGICAL FIELDS	Orthopedists (125 pers.)	General, visceral, urology surrgery (119 pers.)	Gyneco-Obstetrics (57 pers.)	Chest & Heart surgery (14 pers.)	Other (ORL, Plastic…) (135 pers.)	Operating Room nurses (168 pers.)	Overall average (618 pers.)
GENERAL PRESENTATION							
○ Packaging/Labelling	3,3	3,8	3,4	3,6	3,1	3,1	**3,4**
○ General appearance (material/ odour/ colour…)	3,4	3,4	3,5	3,1	3,4	3,4	**3,3**
COMFORT & ERGONOMY							
○ Dry hand donning	3,1	3,0	3,4	3,3	2,9	3,3	**3,2**
○ Cuff length	3,7	3,6	3,7	3,5	3,6	3,7	**3,6**
○ Cuff tightness	3,6	3,5	3,5	3,3	3,5	3,5	**3,5**
○ Shape / Hand fitting	3,4	3,4	3,5	2,9	3,3	3,5	**3,3**
○ Elasticity / Easiness of movements	3,3	3,2	3,5	3,0	3,3	3,3	**3,3**
○ Dexterity / Tactile feeling	3,1	2,9	3,2	2,5	3,0	3,1	**3,0**
○ Grip quality	3,5	3,2	3,4	2,8	3,4	3,3	**3,3**
BARRIER & SAFETY							
○ Mechanical resistance	4,1	4,1	4,2	4,5	4,1	4,1	**4,2**
○ Liquid tightness	4,1	4,1	4,3	4,5	4,1	4,1	**4,2**
○ Feeling of safety	4,1	4,1	4,2	4,6	4,1	4,2	**4,2**
SIDE EFFECTS							
○ Moist hands	3,4	3,3	3,6	2,7	3,3	3,6	**3,3**
○ Skin reactivity	3,8	3,6	3,8	3,2	3,7	3,7	**3,6**
AVERAGE	**3,6**	**3,5**	**3,7**	**3,4**	**3,5**	**3,5**	**3,5**

Rating compared with the gloves usually used ranging from 1 (unacceptable) to 5 (much higher than the average)

The results of this study demonstrate that the G-VIR® glove, with a thickness eqivalent to that of the double glove, satisfies the dexterity, comfort and resistance required in surgical practice.

Recommendations for Use:

G-VIR® is a protective medical device which has to be used during precise procedures: high risk surgical procedures.

N.B.: The accidental viral transmission from a patient to a health care worker is subject to three conditions:

- that the patient is infected by the virus (probability P1),
- that a Blood Exposure Accident occurs (probability P2 equal, to simplify matters, to the probably of a percutaneous accident),
- that the viral load transmitted is sufficient to infect the health care worker (probability P3).

To our knowledge, G-VIR® is the only medical device that effectively reduces the P3 probability. Considering the additional cost of this glove G-VIR® is recommended whenever P1 and P2 probabilities are high, in other words, in situations presenting a much increased risk of contamination.

In conclusion, the use of G-VIR® gloves falls within a total approach regarding the discipline and control of procedural risks in operating rooms. It must be considered as the gold standard of protection in high risk situations.

Company and Product Identification:

1. THE COMPANY

1.1	**Name:** Hutchinson Santé S.N.C.	
1.2	**Address:** Headquarters: 2, rue Balzac 75008 Paris - France Customer Service: Rue Marret et Paturel 60140 Liancourt - France	**Tel:** + 33 1 72 87 48 08 **Fax:** + 33 3 44 73 87 09 **e-mail :** info.gvir@gvir.com **Web site:** www.g-vir.com
1.3	**Status:**	Manufacturer
1.4	**Hutchinson Santé Quality System certified in conformity with the following standards:**	ISO 13485 2003, ISO 9001:2000, and Appendix II of Directive 93/42/EEC
	Notified Body:	SGS United kingdom Ltd Systems & Services Certification (0120)
	Date of certifications:	June 2003 (ISO 13485 et Directive 93/42/EEC) November 2005 (ISO 9001)
1.5	**Responsible for Medical Devices Vigilance/Post Market Surveillance :**	Tel: + 33 1 72 87 48 08 Fax: + 33 3 44 73 87 09

Company and Product Identification:

2. THE MEDICAL DEVICE

2.1 **Name:** G-VIR®

Description: Synthetic, powder-free surgical glove incorporating a disinfecting liquid

2.2 **CE Mark:** Obtained in June 2003

European Directive applicable: 93/42/EEC "Medical devices"
According to Appendix no.: Appendix II (section 4 excluded)

Medical device class: IIa (Rules 6 and/or 15 of Appendix IX of Directive 93/42/EEC)

Notified Body and number: SGS United Kingdom Ltd Systems & Services Certification (0120)

Date of the first European marketing: 28 October 2003

2.3 **Basic material:** thermoplastic elastomer (no natural latex)
Donning layer: no powder

2.4 **Shelf-life:** 3 years from date of manufacture.

2.5 **Sterilisation:** gamma irradiation

2.6 **Catalogue references:**

Reference	Size	Description
5412	6	Boxes of 20 pairs of gloves
5413	6 ½	Boxes of 20 pairs of gloves
5414	7	Boxes of 20 pairs of gloves
5415	7 ½	Boxes of 20 pairs of gloves
5416	8	Boxes of 20 pairs of gloves
5417	8 ½	Boxes of 20 pairs of gloves
5418	9	Boxes of 20 pairs of gloves
5421	Multi-sizes*	Boxes of 20 pairs of gloves

*Including an assortment consisting of 4 pairs of sizes 6 ½, 7, 7 ½, 8, 8 ½

2.7 **Packaging:**
Boxes of 20 pairs of gloves, each pair packed in a sterile individual pouch

2.8 **Labelling:**
A traceability label on the box and print on the individual pouch of pairs of gloves indicates the following:
- shelf-life, batch no., size of the device

The following information is also provided in the form of a bar code (standard EAN 128) found on the traceability label:
- GTIN product, batch no., shelf-life

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