

Smart Glove Donning Machine Hand Guards®



Xi'an Libang Medical Electronics Co., Ltd.
www.libang-me.com

Surgeons Reference

R&D Background

- For easy donning, sometimes surgeons choose bigger size gloves which does not fit very well, impacting protection and usability during surgery.
- The ill-fitting gloves can lead to infection for surgeons and patients.
- Double donning sterile gloves is the current trend of development.
- US FDA has forbidden powdered sterile medical gloves usage on Dec. 16th, 2016

Website Reference:

<https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm491778.htm>

The screenshot shows the top navigation bar of the FDA website with the logo and 'U.S. FOOD & DRUG ADMINISTRATION'. It includes a search bar and links for 'A to Z Index', 'Follow FDA', and 'En Español'. Below the navigation bar is a menu with categories like Home, Food, Drugs, Medical Devices, etc. The main content area features a breadcrumb trail: Home > About FDA > Reports, Manuals, & Forms > Reports > Economic Impact Analyses of FDA Regulations. A sidebar on the left contains a link to 'Economic Impact Analyses of FDA Regulations' and 'Examples of Previous Regulatory Impact Analyses'. The main heading is 'Summary: Banned Devices; Proposal To Ban Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove'. Below the heading are social sharing buttons for Facebook, Twitter, LinkedIn, Pinterest, Email, and Print. The introductory text states: 'The Food and Drug Administration has determined that Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove present an unreasonable and substantial risk of illness or injury and that the risk cannot be corrected or eliminated by labeling or a change in labeling. Consequently, FDA is proposing these devices be banned.'

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Economic Impact Analyses of FDA Regulations

Examples of Previous Regulatory Impact Analyses

Summary: Banned Devices; Proposal To Ban Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove

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The Food and Drug Administration has determined that Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove present an unreasonable and substantial risk of illness or injury and that the risk cannot be corrected or eliminated by labeling or a change in labeling. Consequently, FDA is proposing these devices be banned.

Clinical Situation

- Current difficulties exist of good fit donning sterile gloves (especially for double, triple donning)
- Sterile gloves breakage and tears is a hazard to doctors (especially pinhole tears which are not visible to the naked eye)

Objective:

To evaluate the effect of double layer gloves on protecting against HBV infection during surgery.

Results:

- 1) HBV infectivity of HBsAg positive was $10^0 \sim 10^9$ infective dose(ID)/ml
- 2) HBV infectivity of HBsAg negative was $10^0 \sim 10^4$ ID/ml.
- 3) Protective threshold value of single double layer gloves was 10^5 ID/ml
- 4) Protective threshold value of double layer gloves was 10^6 ID/ml

Conclusion:

Double layer gloves can prevent (23-33%) infections from HBV vector sources.

If the wearer have been immunized with HBV vaccine, the additional usage of double layered gloves can theoretically prevent HBV transmission completely through operation.

Gloves Leakage Investigation

Study	Sample size	Single-glove perforation	Double-gloves perforation (inner gloves)	Participants	Specialty
Caillot et al (2006)	n=638 DG=342 SG=296	18%	0%	Surgeons	Visceral surgery
Al-Maiya et al (2004)	n=250 Inner G =122 Outer G =128	21%	14.8%	All surgical team*	Hip arthroplasty
Lancaster et al (2007)	n=1000 DG=675 SG=325	10%	11%	All surgical team*	Obstetric and gynaecological
Thanni et al (2003)	n=596 DG=512 SG= 84	13%	16% Total perforation 86%	All surgical team*	Orthopaedic operation
Guo et al (2012)	n=218 DG=106 SG=112	8.93%	0%	Nurses	Different surgical department
Systematic review					
Tanner and Parkinson (2006)	n=8885 DG=4408 SG= 4477	9%	2%	All surgical team*	Different surgical department

Key: DG=double gloves, SG=single gloves, DG indicator=double gloves with indicator system

*All surgical team includes scribe nurses, first assistant and surgeon



Donning bigger size gloves

“HandGuards®” perfect
after donning



Hand Guards® Gloves Range

- Suitable for all types of medical gloves including: Latex, Nitrile (with or without powder), Sterile Exam Gloves, Vinyl Powder-Free Gloves.
- The size range is :
5.5,6,6.5,7,7.5,8,8.5,9,10,10.5 .



User Operation

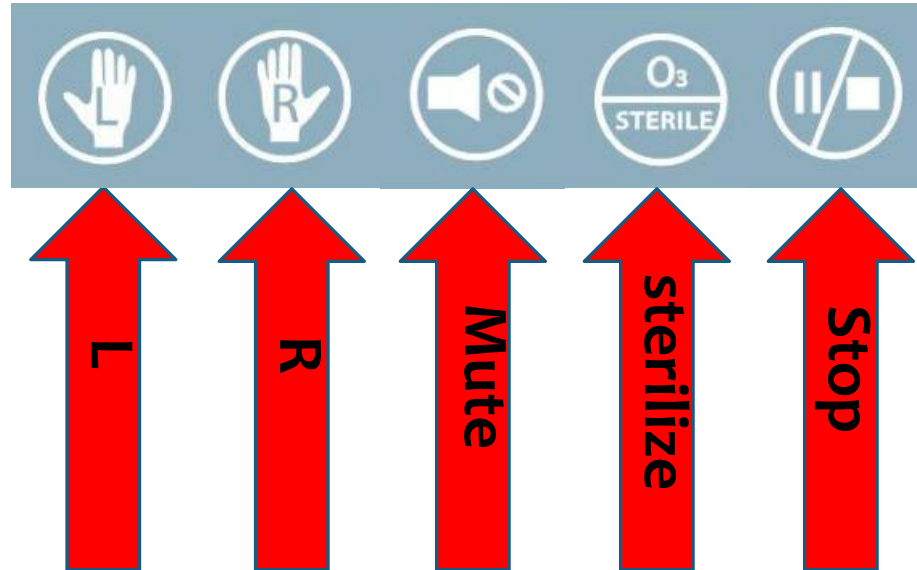
Infrared
sensing
area



- 1) The nurse choose the correct glove size to fit the doctor's hands.
- 2) Open the glove package and attach the gloves to the ring at the mouth of the glove donning machine.
- 3) The doctor place their hands over the infrared sensor area at no more than 10cm away.
- 4) After inflation of the gloves you will be Voice Prompted with the words “ Please donning”, at which time put your hands into the mouth of the machine within 1-3 seconds. The gloves will then smoothly shrink automatically around your hands. Donning is complete.

Keyboard Function

T-Touch



Highlights

- **Automatic Sterilization**
- **Leakage Detection**
- **Automatic Air Filtration**
- **Voice Prompt**



Safe & Fast Donning

- ★ Applies auto-sensing technology, non-contact operation to protect cleaned bare hands from all sources of contamination.
- ★ Suitable for powdered & powder-free sterile, excellent tensile strength gloves.
- ★ Improved fit and comfort, textured finger tips allows better grasp when used in both dry and damp environments

Automatic Sterilization

★ Uses automatic sterilization process to keep the inside of the machine completely sterile.

★ After the completion of sterilization, the equipment automatically stops.

Caution: After sterilization, it should be worked after O₃ decomposing conforms to the standards of environment.

Automatic Sterilization

- * The inside of the chamber housing the Ozone Generator, Humidifier, and De-Ozonizing Module.
- * With Automatic Humidification, Auto Sterilization, and quick Auto Ozone Degradation to keep the inside of the machine completely sterile, safe use & residue free.
- * Auto alarm notification upon completion of sterilization process.

Automatic Air Filtration

★ Uses automatic air filtration technology to maintain sterility inside the machine, so as to prevent contamination of the gloves.

Leakage Detection

Before donning, it can automatically detect leakage on gloves with voice safety alarm for breakage, pinholes, etc.

- ★ Takes 10 seconds, very fast at detecting leakage on gloves.
- ★ Voice Prompt: L(R) gloves has leakage, please change a new one.

Design Standard

★ The design complies with EU ROHS standard and China Health and Safety Standards for easy cleaning, sterilization and easy maintenance.

Intellectual Proprietary Rights(IPR)

- **Domestic Invention Patents**

The Patents No.: ZL201620319238.5

- **Overseas Invention Patents**

In the process of PCT alliance application to US, EU, Japan.

International Certificate

CE Certificate No.: AE 50385501 0001


TÜVRheinland®

CERTIFICATE
of Conformity
EC Council Directive 2014/30/EU
Electromagnetic Compatibility

Registration No.: AE 50385501 0001
Report No.: 50072613 001

Holder: Xi'an Libang Medical Electronics Co., Ltd.
5/F, Block D, Zone C, Pioneering R&D Park, No.69 Jinye Rd., High-Tech Zone, Xi'an, Shaanxi 710077 P. R. China

Product: Service machines
(Smart Glove Donning Machine)

Identification: Type Designation: SG180 (HAND GUARD)
Serial No.: SG1701001
Remark: Refer to test report 50072613 001 for details.

Tested acc. to: EN 55014-1:2006+A1+A2
EN 55014-2:1997+A1+A2
EN 61000-3-2:2014
EN 61000-3-3:2013

This certificate of conformity is based on an evaluation of a sample of the above mentioned product. Technical Report and documentation are at the Licence Holder's disposal. This is to certify that the tested sample is in conformity with all provisions of Annex III of Council Directive 2014/30/EU. This certificate does not imply assessment of the production of the product and does not permit the use of a TÜV Rheinland mark of conformity. The holder of the certificate is authorized to use this certificate in connection with the EC declaration of conformity according to the s.m. Directive.


Certification Body
Sun Lixun
Sun Lixun

Date 14.08.2017

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg


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Precisely Right.

TÜV Rheinland (China) Ltd.
Member of TÜV Rheinland Group

Xi'an Libang Medical Electronics Co., Ltd.
Mr. Xunshu He, Chief Engineer

Date : 15.08.2017
Our ref. : wangqan 01
Your ref.: H. X. S

5/F, Block D, Zone C, Pioneering R&D Park, No.69 Jinye Rd., High-Tech Zone, Xi'an, Shaanxi 710077

Ref : AE Certificate of Conformity EMC

Type of Equipment : Smart Glove Donning Machine
Model Designation : See Certificate
Certificate No. : AE 50385501 0001
Report No. : 50072613 001

Dear Mr. Xunshu He,

We herewith confirm that a sample of the above mentioned technical equipment has been tested and was found to be in accordance with the relevant requirements.

Enclosed please find your Certificate of Conformity.

We appreciate your kind support and would like to offer our assistance and continuous services in the future.

With kind regards,
Certification Body

Sun Lixun *Sun Lixun*

Enclosure

证书的详细资料请登陆www.tuvd.com.cn查询,或拨打客服电话800 999 3668 / 400 893 1300咨询

TÜV Rheinland (China) Ltd. Unit 707, AVIC Bldg., No. 108, Tel: (8610)6508 6660
Beijing Certification Center (China) Co., Ltd. Central Road, East 2nd Ring Fax: (8610)6508 6667
Road, Chaoyang District, 2nd Ring East Road, e-mail: service-gc@tuv.com
Beijing, 100022, P.R.China 邮编: 100022 Internet: http://www.chn.tuv.com

Application Theatre

Hospitals

Surgery, Obstetrics and Gynecology; Andrology; Infectious Diseases; Dermatology; Orthopedics surgery; Dentistry; Physical Examination; Emergency; Nursing; Laboratory.

Thanks for your time!!!

Safe and Easy Donning! Great protection to Health Workers and Patients!



Xi'an Libang Medical Electronics Co., Ltd.

Contact: Sarah Zeng

Marketing & Sales Director

Mobile/WeChat: +86-13279366998 Office Tel: +86 -29- 88346154 Skype: med_1247

E-mail: med@libang.com.cn Website: www.libang-me.com