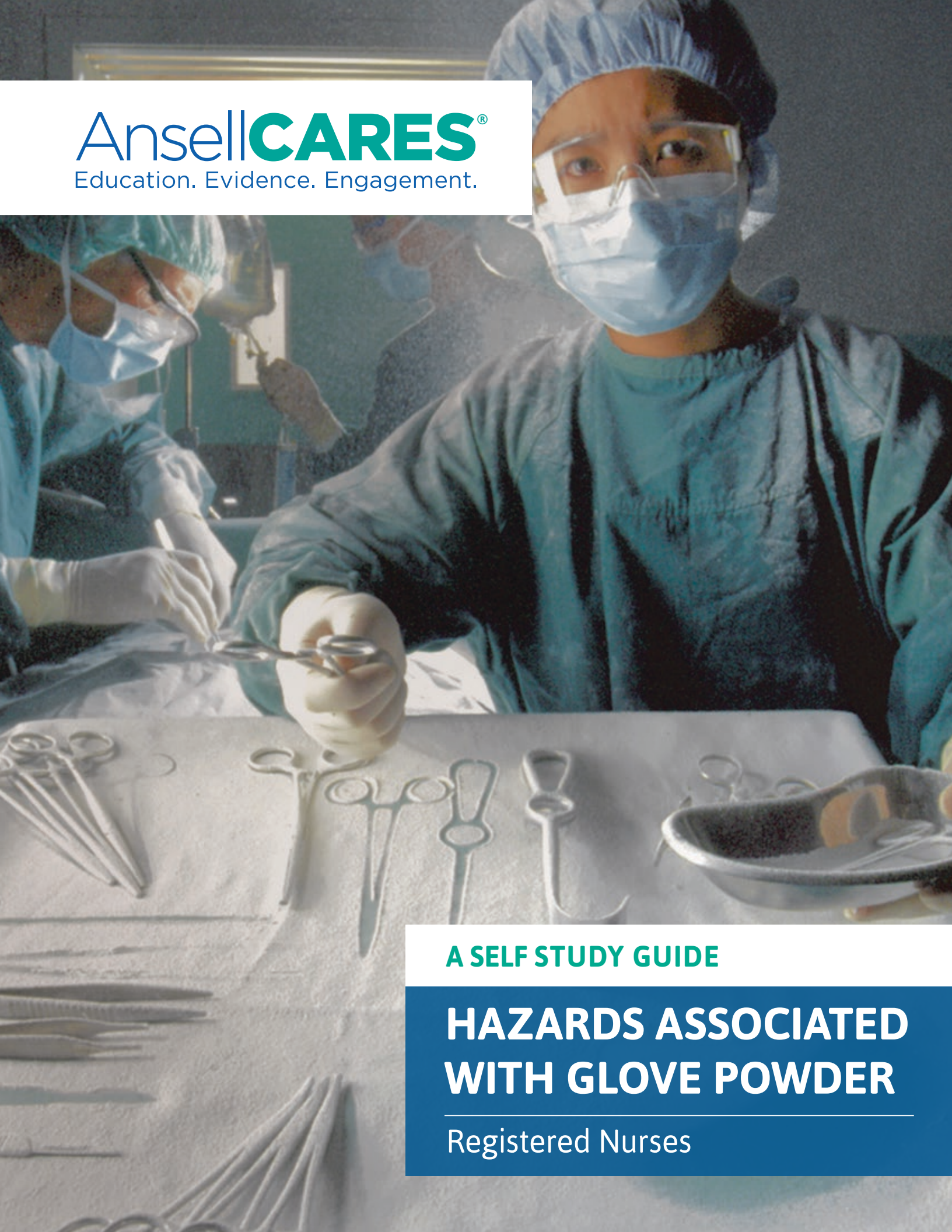

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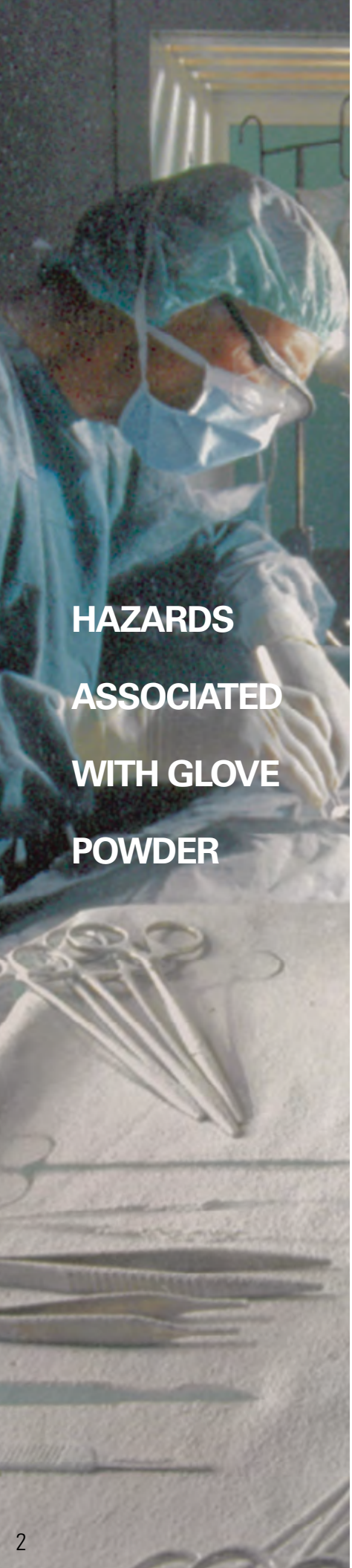
Education. Evidence. Engagement.

A SELF STUDY GUIDE

HAZARDS ASSOCIATED WITH GLOVE POWDER

Registered Nurses



HAZARDS ASSOCIATED WITH GLOVE POWDER

OVERVIEW

Glove powder includes dusting or donning powders, mold-release compounds, and manufacturing debris. Dry lubricants such as cornstarch, silicone etc., are used to make donning gloves easier and to prevent gloves from sticking together during the manufacturing process. Cornstarch, which meets the specification for absorbable dusting powder in the United States Pharmacopoeia (USP), is the most common lubricant for medical gloves. Only absorbable dusting powders that have an approved Premarket Approval Application (PMA) or New Drug Application (NDA) may be used for lubricating surgeon's gloves. There are no comprehensive studies of the amount of absorbable dusting powder used on powdered gloves. It is estimated that amounts of total particulates may range from 120 to 400 mg for a medium size powdered glove. (FDA Medical Glove Powder Report). Glove powder is composed of particles, thus, issues related to biologic responses to foreign bodies apply to both natural rubber latex (NRL) and synthetic gloves that are powdered.

LEARNING OBJECTIVES

Upon completion of this educational activity, the learner should be able to:

1. Discuss the history of medical gloves
2. Identify the donning agents used in medical gloves and their weaknesses
3. Explain the risks and complications associated with glove powder
4. Identify the costs associated with glove powder
5. Describe how powder-free gloves provide a solution to powder-related problems

INTENDED AUDIENCE

The information contained in this self-study guidebook is intended for use by healthcare professionals who are responsible for or involved in the following activities related to this topic:

- Educating healthcare personnel
- Establishing institutional or departmental policies and procedures
- Decision-making responsibilities for safety and infection prevention products
- Maintaining regulatory compliance
- Managing employee health and infection prevention services

INSTRUCTIONS

Ansell is a Recognized Provider of continuing education by the California Board of Registered Nursing, provider #CEP 15538 and the Australian College of Perioperative Nurses (ACORN). This course has been accredited for 2 (two) contact hours. Obtaining full credit for this offering depends on completion of the self-study materials on-line as directed below.

Approval refers to recognition of educational activities only and does not imply endorsement of any product or company displayed in any form during the educational activity.

To receive contact hours for this program, please go to the "Program Tests" area and complete the post-test. You will receive your certificate via email.

AN 85% PASSING SCORE IS REQUIRED FOR SUCCESSFUL COMPLETION

Any learner who does not successfully complete the post-test will be notified and given an opportunity to resubmit for certification.

For more information about our educational programs or hand-barrier-related topics, please contact Ansell Healthcare Educational Services by e-mail at edu@ansellhealthcare.com

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As employees of Ansell Mrs. Ouellet, Mrs. Richardson, Mrs. Taylor and Ms. Werner have declared an affiliation that could be perceived as posing a potential conflict of interest with development of this self-study module. This module will include discussion of commercial products referenced in generic terms only.

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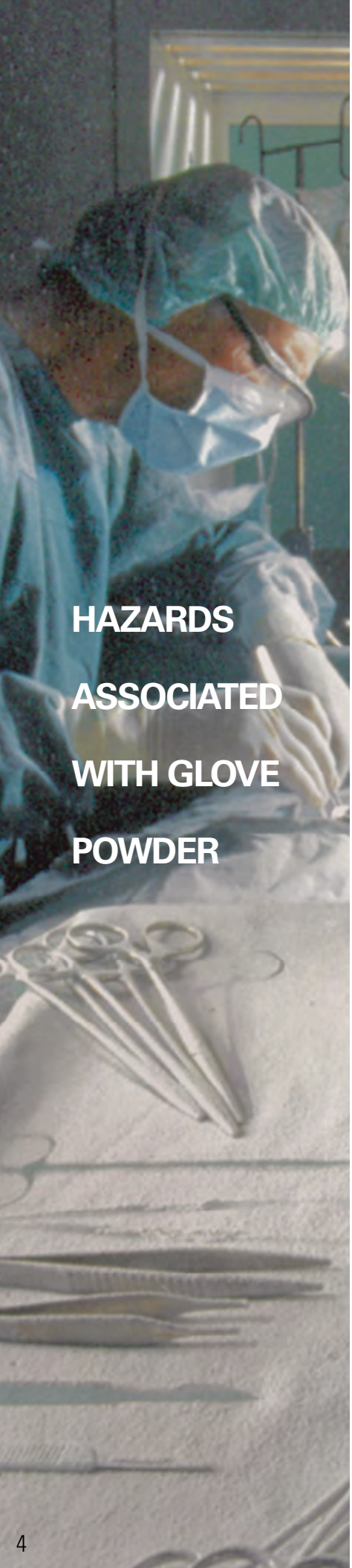
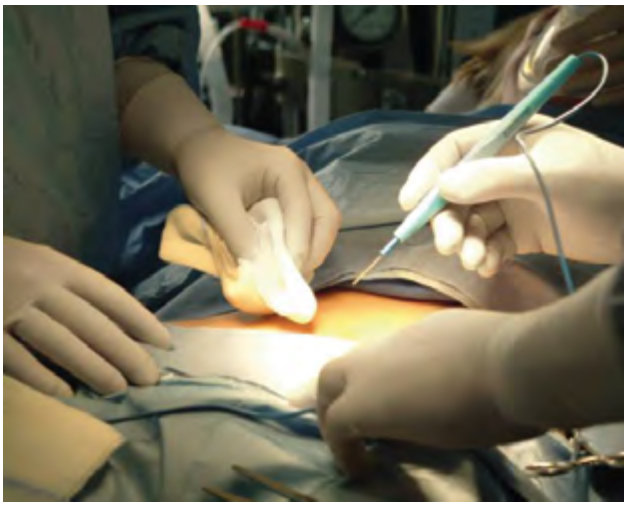


HAZARDS ASSOCIATED WITH GLOVE POWDER

INTRODUCTION

By the early 1900s the use of rubber gloves was common in the surgical suite in both Europe and the United States. Although the use of latex gloves in surgery became routine after World War I, gloves such as examination gloves, were not consistently used in other areas of patient care until the onset of the AIDS epidemic and the spread of hepatitis.

The increased incidence of hepatitis B, (HBV), hepatitis C (HCV) and AIDS (HIV) infections in the early to mid-1980s resulted in a tremendous increase of latex examination gloves although alternatives such as vinyl and technology for various synthetics existed. Latex examination gloves were proven to be one of the best methods of preventing transmission of HIV and hepatitis from infected patients to healthcare workers (HCWs).



By 1987, the US Centers for Disease Control and Prevention (CDC) instituted Universal Precautions (today called "standard precautions") recommending the use of personal protective equipment (PPE) such as gloves, masks, gowns, and eye shields to prevent transmission of bloodborne pathogens to save lives and prevent injury or illness in the workplace. This practice was quickly mandated in many countries by healthcare authorities

and professional healthcare associations around the world and may have accounted for this tremendous increase in glove usage. Between 1987 and 1996, the use of NRL gloves among medical professionals rose by more than 1000% (McCall, 2003; CDC).

- In 1986, about 1 billion disposable gloves were sold worldwide (http://www.glovegeeks.net/index.php Newsflash/the-gloving-of-america.html).

- In 2001, more than 30 billion pieces, including both latex and non-latex gloves, are manufactured every year. More than 20 billion of them, representing over $1 billion in purchases, are shipped to the United States. It is the single largest category of product sold by healthcare distributors. (Repertoire 2001).

- In 2008, more than 12 billion units of medical gloves were sold in the EMEA region.

Extraction of latex from *Hevea brasiliensis* tree (latex rubber tree)

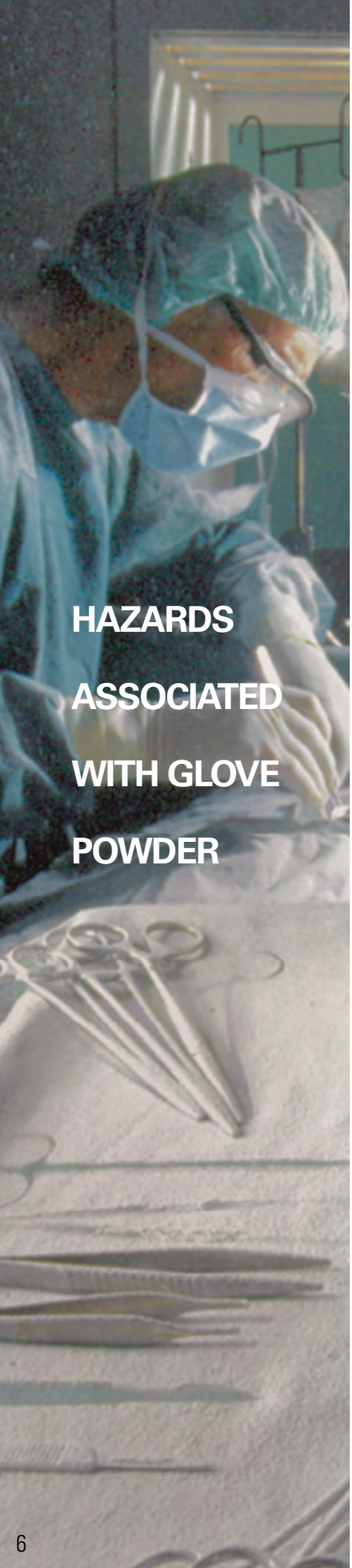
LATEX GLOVE HISTORY

William Halstead is the surgeon given credit for the introduction of surgical gloves in 1896. As chief of surgery at Johns Hopkins Hospital, his nurse, Caroline Hampton (later to become his wife), developed severe dermatitis from mercuric chloride, the disinfectant used to clean instruments and hands. As a result, he asked the Goodyear Rubber Company to make rubber gloves. These gloves were developed not to protect the patient but rather to protect the hands of those providing healthcare. Goodyear made two pairs of rubber gloves with gauntlets. They proved so effective in protecting Caroline Hampton's skin that they became a common item used in the operating room.

By chance Halstead's glove request coincided with early discoveries about the relationship between infection control and improved patient outcome. In 1847 in Paris, Semmelweis identified a link between infection and death in maternity patients cared for by physicians who were not washing their hands. Further, in 1843 in the United States, Oliver Wendell Holmes became an advocate for various medical reforms and notably posited the controversial idea that the hands of doctors were capable of carrying puerperal fever from patient to patient.

Those early gloves were not the thin barrier protection of today. They were thick and reusable, sterilized by boiling, and donned over wet hands. As sterilization techniques were refined, wet glove over wet hand donning was eventually abandoned and the use of powdered lubricants came into fashion. Gloves continued to be reused but were washed in mild soap, rinsed in distilled water, inspected for holes and tears, and then allowed to dry. They were then hand-powdered in a powder box before being wrapped and steam-sterilized. Extra powder packets were also available for the surgical team to apply to their hands just prior to donning.

Finally, in 1966, single-use powdered gloves became available, and these continue to set the standard of care today.



HAZARDS ASSOCIATED WITH GLOVE POWDER

PRODUCTION OF GLOVES ('000 PAIRS)

Year	Total Gloves (All types)
1989	3,186,794
1990	3,592,020
1991	4,439,018
1992	6,490,206
1993	9,726,772
1994	6,566,404
1995	6,991,781
1996	8,204,626
1997	9,010,261
1998	10,475,379
1999	10,916,612
2000	11,318,970
2001	12,082,387
2002	12,319,576
2003	15,051,026
2004	18,219,298
2005	19,146,849
2006	20,570,058
2007	20,570,666
2008	22,585,554
2009	23,132,708
2010	26,257,329
2011	30,897,840
2012	31,753,978
2013*	8,451,432

* Jan-March Source: Department of Statistics, Malaysia

POWDERED LUBRICANT HISTORY

The boiled wet glove over wet hand scenario described previously was not without its problems. It caused the skin to become macerated. As sterilization techniques were refined, wet glove over wet hand donning could be abandoned. A dry method that could withstand the rigors of the new steam autoclave (sterilization process) was needed in order to don gloves, and powdered lubricants began to be used.

Powder is used in the manufacturing process for the following three reasons:

1. Donning of Glove
Donning powder is applied to the inside of the finished glove so that the wearer is able to put the glove on smoothly. The powder also acts to absorb sweat from the hands of the wearer.

Glove formers on manufacturing line

2. Eliminate Glove Blocking
A powder may be used on the surface of the finished glove to keep the gloves from sticking to itself and to the glove package, also referred to as "blocking."

3. Mold Release
A powder used in slurry that coats the glove former at the beginning of production, so that the latex uniformly covers the former and the finished glove is able to be removed from the former.

Dipping of formers into latex

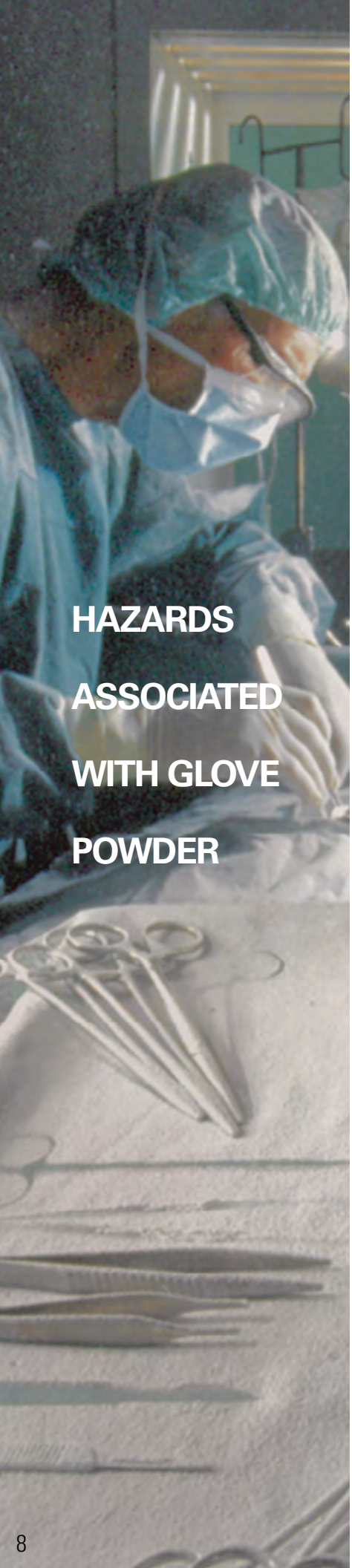
DONNING LUBRICANT AGENTS

A variety of powdered lubricants have been used since 1890:

Club moss
Lycopodium clavatum, or club moss, was one of the early glove lubricants in use by approximately 1890. Club moss was sometimes combined with talc to provide the powder necessary to ease the donning of latex gloves. With its use came early reports of complications, including tissue irritation, masses and adhesions.

Talcum powder
Following this revelation, many glove manufacturers switched to a talc-only lubricant. Talcum powder is a combination of magnesium silicate (chemically pure talc) with calcium magnesium carbonate, calcium magnesium silicate, and sometimes other substances. Early in its use, talc was also implicated in producing granuloma, adhesion, and inflammatory responses.

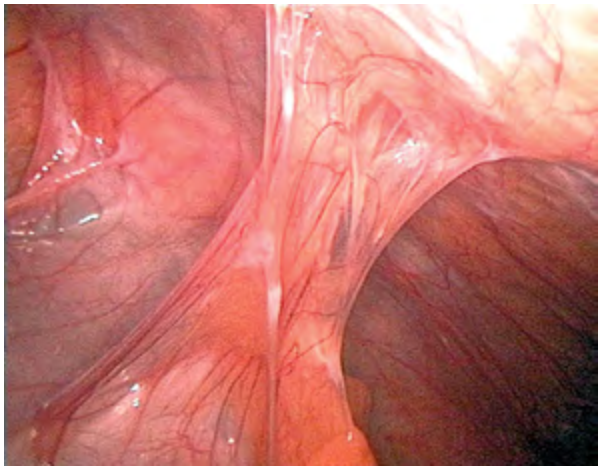
Search began in the early 1940s for a talc substitute. It took a while before a suitable alternative could be found. Various powders were experimented with, but they could not withstand the time and pressure in the autoclave without clumping. Additionally, the removal of glove powders was not a precaution practiced by the surgical team at that time.



HAZARDS ASSOCIATED WITH GLOVE POWDER

Cornstarch

In 1947 experiments by Lee and Lehman led to the discovery of a mixture of cornstarch, a powder treated with epichlorhydrin, and other ingredients. Cornstarch was able to withstand the autoclave and was acceptable to the wearer. Animal experiments established that cornstarch was absorbed with little or no reaction (Woods et al., 1997). As a result, early in the 1950s a corn starch derivative began replacing talc as the surgical glove powder of choice. Due to the continued reporting of talc complications, several national Pharmacopeia restricted the use of talc as an absorbable dusting powder for medical glove lubrication. Unfortunately cornstarch too was not without its problems, and further experiments by Lee demonstrated that even this compound produced inflammation and a foreign body-like reaction.



Adhesion development

Mold release agents

Talc and cornstarch have also been used in the glove manufacturing process in order to remove the finished product from the dipping mold. Cornstarch was trialed early on but could not be used because it would dissolve and disperse in the dipping solution. Today, a release agent such as calcium carbonate may be used. A powder-free coagulant is also available as a mold release substitute.

TODAY'S POWDERS

REGULATIONS

Today, most international standards do not accept the use of talc as a lubricant.

- European standard EN 455-part 3 (Medical gloves for single use – Part 3: requirements and testing for biological evaluation) specifies for instance that "Gloves shall not be dressed with talcum powder (magnesium silicate)."

- American standards ASTM D3577 – 06e1 "Standard Specification for Rubber Surgical Gloves" and ASTM D3578 – 05e1 "Standard Specification for Rubber Examination Gloves" specify that the outer surface and inner surface of these rubber gloves shall be free of talc.

- In APAC countries, ISO standards are predominantly used as the reference standards. Countries that have their own standards e.g. ANZ, Japan and China are usually based on ISO as well.

  - Australia Medical Device Regulations require for the safety of the device to be established – as do many others and this is where talc would not be deemed acceptable.

  - Where ISO does not exist for a certain method or specification, state of the art standards are acceptable as well. This means the ASTM and EN are covered for APAC.

In Europe, gloving powders used for medical gloves must be in compliance with several specifications defined in standards and must also comply as well with EN ISO 10993 – Biological evaluation of medical devices and EN ISO 14971, Medical devices – Application of risk management to medical devices (ISO 14971:2000).

They also have to comply with the European Pharmacopeia, while in the U.S. they have to meet the requirements of a specific monograph for absorbable dusting powder set out in the United States Pharmacopeia (USP). In most of the cases manufacturers use a cornstarch cross-linked with epichlorhydrin or phosphorus oxychloride and with no more than 2% magnesium oxide (to prevent caking or turning to paste).

WASHING POWDERED GLOVES

Since the early 1970s, many national and international standards have required manufacturers to label their sterile glove packages with a specific warning to remove the powder.

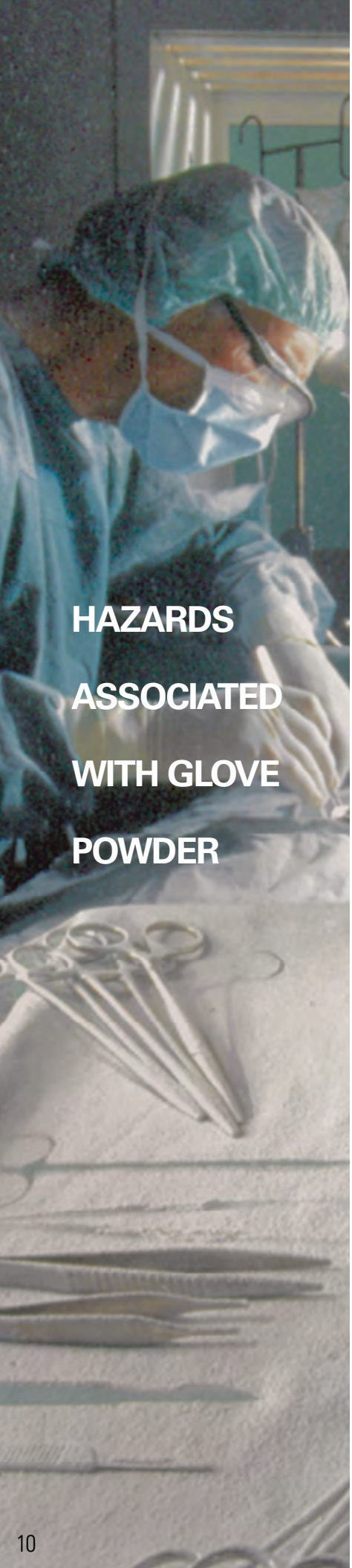
- In 1971 the FDA required manufacturers to label their glove packages with the following warning: "Caution: Powder should be removed from the gloves after donning by wiping gloves thoroughly with a sterile wet sponge, sterile wet towel, or other effective method."

- EN 455-3 today requires the following labeling: "CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions."

- In APAC most countries follow these guidelines above.
  - ISO is required in most APAC countries and states " in the case of gloves that have been treated with any surface-dusting material, a warning note to the effect that surface powder should be aseptically removed prior to undertaking operative procedures."

INEFFECTIVE

Studies have shown that this procedure of washing surgical gloves is not effective in removing cornstarch powder from gloves, and may in fact cause the cornstarch to clump together. Ellis pointed out in a publication that "conventional washing of the donned glove in saline solution was ineffective. It has been shown that careful washing of the gloves in two successive bowls of saline solution fails to remove all the starch." He also documents another technique that was shown to reduce the number of starch granules from 2,720 (with no attempt to remove starch) to zero when utilizing a "one minute cleansing with 10 ml of povidone-iodine, followed by a 30-second rinse under sterile water" (Ellis, 1990).



HAZARDS ASSOCIATED WITH GLOVE POWDER

Poor compliance with printed instructions has been cited in the literature, and washing powder off gloves prior to surgery is not completed consistently. Some of the reasons for poor compliance include awareness of required washing, cost of materials and time necessary to complete the activity. Additionally, powdered gloves are sometimes used in departments that cannot wash them properly as they do not have the sterile materials readily available to do so (e.g., ER, outpatient clinics, bedside, and interventional radiology).

COSTS

In a study by Fraser, the cost associated with washing procedures for cornstarch dusted gloves was determined by adding basin costs that contained the solution, solution cost, and unit wiping materials together and dividing by the number of team members. The direct cost of washing materials averaged $0.46 per glove with a range between $0.26 to $1.25 per glove, depending on the materials used and the level of washing required.

Estimated cost in Europe

*costs will vary by country, region, distributor, and contracts.

Process	Cost
Sterile basin or bowl (disposable)	€ 1.10
Sterile towel (ea.)	€ 0.75
10 ml povidone-iodine	€ 0.05
+ 500 cc sterile water or saline	€ 0.60

Glove washing set-up total: € 2.50* Also consider additional costs: 1.5 minutes of OR time x € 19 per minute = € 28.50 of OR cost Total additional OR expense due to glove washing = € 31

Estimated cost in Asia

	Process				Cost
	Washing Powdered Glove	Qty	Qty Per Cases	Powder	Powder Free
1	Glove	1 Pair	4 Pairs/ Cases	RM 1.30	RM 2.50
2	Sterile Water	500 ml	500 ml/ Cases	RM 2.50	No Cost
3	Sterile Basin (120" x 120")	1 unit	1 unit/ Cases	RM 8.00	No Cost
4	Sterile Gauze	1 sheet	1 sheet/ Cases	RM 0.50	No Cost

HEALTH AND SAFETY CONCERNS

Exposure to starch powder from both surgical and examination gloves can cause a number of undesirable reactions and complications for the patient and the healthcare provider. These vary from well-known allergy symptoms and upper respiratory-tract disorders to post-operative complications including adhesions and infections as well as laboratory misdiagnosis.

Glove powder can act not only as a vehicle for latex antigens but also for opportunistic and pathogenic micro-organisms, which increase the occupational risks to both HCWs and patients.

PATIENT EXPOSURE

Clinical reports, case studies, and further experimentation continue to report adverse reactions to gloving powders, including inflammation, granuloma formation, granulomatous peritonitis, adhesions, allergic responses, contribution to wound infection, and delayed wound healing. All of these contribute to longer hospital patient stays and increased healthcare costs.

Methicillin-resistant *Staphylocous aureus* (MRSA)

When glove powders are introduced during a surgical procedure; they play a role in excess scar tissue formation, inflammatory reactions in the eye and pericardia, as well as the peritoneal and pleural cavities, and other areas (Hunt, 1994). The longer the body is exposed to glove powders, the greater the chance for complications.

In addition to intra-operative complications from gloves, other reports have documented glove powder contamination of epidural catheters, leading to neurological complications, as well as being a potential cause for catheter occlusion (Truscott, 1997). Cardiac complications such as granulomatous endocarditis and thrombi have also been documented (Truscott, 1977). Glove powders have caused contamination of blood filters; granuloma formation from liposuction, facial sinus, and mastoiditis; and inflammation of joints following orthopaedic surgery. Uterine and fallopian tube adhesions, resulting from glove powder, are a significant risk of female infertility; the papers note that powder free gloves should be used even for routine vaginal examination.

In experiments conducted by Newsom and Shaw, it was demonstrated that Methicillin-resistant *Staphylocous aureus* (MRSA) and Vancomycin-resistant Enterococci (VRE) may be able to use glove powder as a vector and/or food source in a hospital environment (Newsom & Shaw, 1997).

The significance of these findings justifies the consideration of switching from powdered to powder-free gloves. The market has responded to this need with many choices and styles of powder-free gloves. HCWs should strive to eliminate any avenue of contamination that could impact positive patient outcomes and prolong a patient's hospital stay.

HEALTHCARE WORKER EXPOSURE

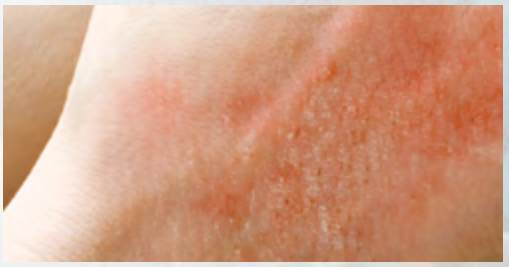
HCWs are exposed to glove powders when they wear gloves, work in areas where powdered gloves are used (such as the operating room, lab, and ER); or when they touch surfaces and items touched by others wearing powdered gloves.

Experts believe the repeated exposure to latex by direct contact, contact with mucous membrane, or inhalation plays a role in the following:

1. Irritant contact dermatitis

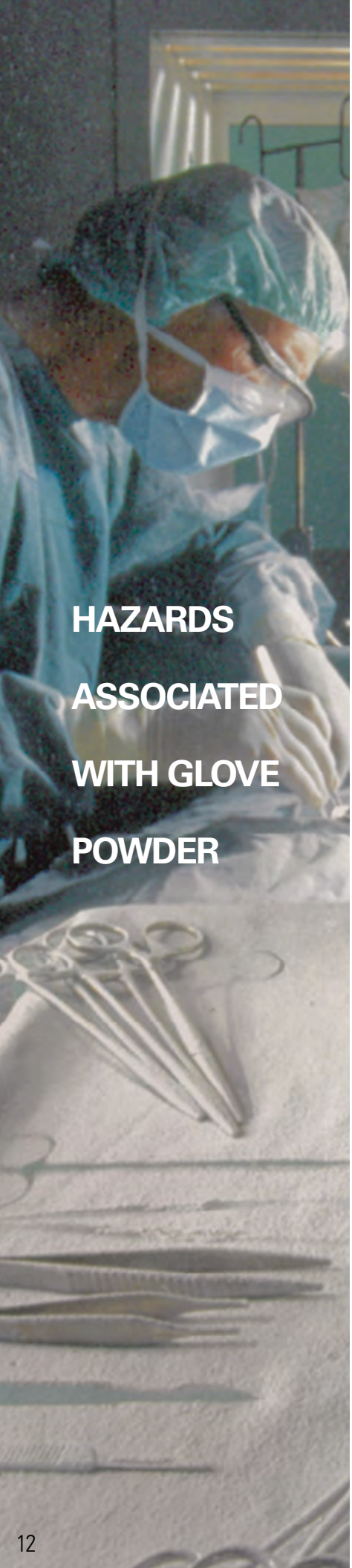
Irritant contact dermatitis is a non-immune reaction. It is a local reaction from damage to the skin from such things such as:

- detergents
- frequent hand washing
- inadequate drying
- climate extremes
- pre-existing dermatitis
- aggressive scrubbing techniques
- glove powders



Irritant contact cermatitis

This reaction is simply an irritation of the skin and should not be confused with an allergy. Symptoms can include redness, chapping, chafing, dryness, scaling, cracking, and subjective symptoms such as itching and burning.



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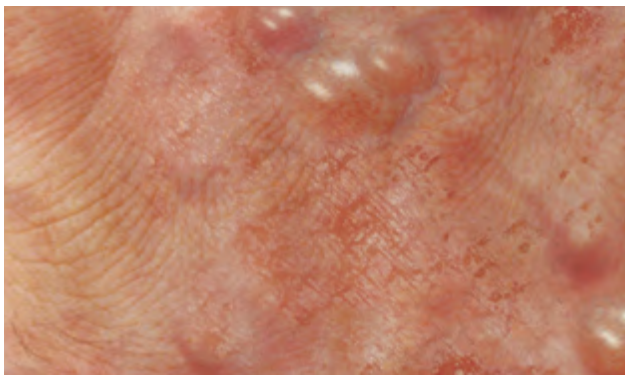
2. Immediate type I response (latex allergy)
Nutter first reported this immune reaction in 1979. It is not solely the result of exposure to gloves, but also to other natural rubber latex-based products such as condoms, balloons, rubber nipples, and other latex medical equipment. While much less common than delayed (chemical) reactions, the immediate allergic response has received more attention, both from researchers and in the literature, because of its potentially more serious outcome. In the majority of cases reported, the symptoms are a swelling and redness (commonly described as a "wheal and flare" reaction) local to the site of exposure, accompanied by non-specific symptoms such as such as itching and burning. A type I latex allergic response can elicit a more systemic symptomology such as conjunctivitis, rhinitis, and bronchial obstruction. More seriously and fortunately more rarely, symptoms of anaphylaxis, and in extreme cases anaphylactic shock, can occur.

Depending on the reference source, the incidence of latex allergy is approximately:

- 0% - 17% among healthcare workers
- 13% - 17% among the dental population
- 28% - 67% among the spina bifida population
- 1% - 6% among the general population

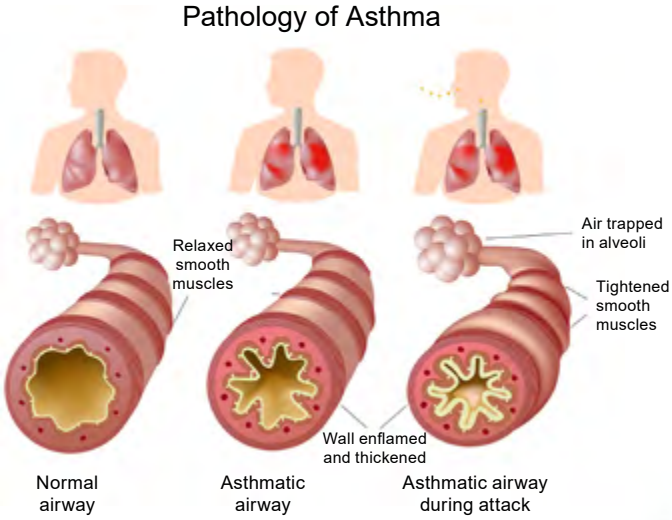


Latex allergy

A well-documented consequence of the use of starch powder in gloves is its capacity to bind with (NRL) protein antigens (Hesse, 1997). These allergen/protein-coated powder particles can be aerosolized when the gloves are donned or removed, thus contaminating the hospital environment. Inhalation or ingestion of these powders can lead to the sensitization and diverse allergic reactions to NRL (i.e., upper respiratory tract symptoms or eye irritation).

Solution – Powder-free gloves
Allmers et al reported a decrease in the number of HCWs with suspected NRL allergy including occupational asthma and contact urticaria when powdered gloves are substituted by powder-free gloves. Further, in a study conducted in Sweden, the investigators surveyed HCWs before and after implementation of powder-free glove use. They concluded there was a reduction in upper airway symptoms in the powder-free environment (Edelstam, 2002).

3. Occupational asthma
More and more HCWs are developing occupational asthma, a lung disease caused by inhaling workplace fumes, gases, or, in the healthcare environment, glove powder. In developed countries, it is the most common work-related lung disease. Although its exact prevalence is unknown, some researchers estimate it may account for 9% of asthma cases.



Occupational asthma can develop even if you have never had asthma before or had childhood asthma that previously cleared. It can worsen any pre-existing asthma. With treatment, occupational asthma is usually reversible. However, the only way to prevent its worst complication—permanent lung damage—is to completely avoid the substance causing the disease. It is possible to develop occupational asthma in almost any workplace, but the risk is highest in certain occupations. The Mayo Clinic in the U.S., listed the top 15 jobs at risk, and HCWs were part of that list. The asthma producing substance found in the hospital setting is the latex particles contained in aerosolized glove powder.

Signs and symptoms may include wheezing, coughing, shortness of breath, chest tightness, difficulty exercising, runny nose, and eye irritation.

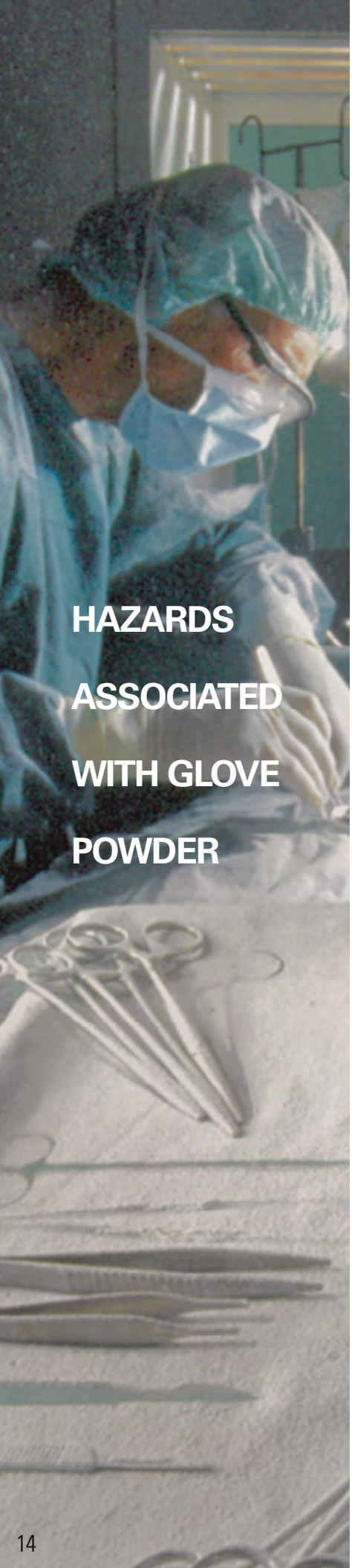
During the early stages of the disease, symptoms develop shortly after exposure, and up to 12 hours after exposure. Asthma may worsen as the workweek progresses, and subside during weekends and vacations, only to reoccur upon return to work.

In the later stages, symptoms may also develop away from work. Once the lungs have developed a pattern of overreacting to the offending substance, sensitivities to other substances may develop, such as house dust, cigarette smoke, and cold air.

The diagnosis for occupational asthma is made by an allergist on the basis of medical history and physical exam. The physician may perform pulmonary function tests, spirometer, and peak flow tests. The best treatment is to completely avoid the substance that causes symptoms. Asthma medications to help relieve symptoms may be prescribed. It might be necessary for HCWs to transfer to another job to prevent exposure to glove powder.

Solution – Powder-free gloves
A healthcare facility that removes powdered gloves from the environment is being proactive in ensuring the health and safety of employees and patients. Research has shown that the reduction of residual extractable proteins in latex gloves has a significant impact on reducing the incidence of allergic reactions to latex. Studies in the U.S., Canada, and Europe demonstrate that wearing low-protein, powder-free latex gloves greatly reduces the risk of allergic reactions and the likelihood of developing latex sensitivity. In addition, studies have shown that the use of low-protein, powder-free gloves allowed latex-sensitive individuals donning synthetic gloves to work safely alongside their colleagues.

ECRI, a non-profit international health services research agency and a Collaborating Center of the World Health Organization, confirmed that using lower-protein gloves—especially powder-free gloves—can help reduce the suffering and costs that result from NRL sensitivities. It also confirmed that, even though lower-protein NRL gloves sometimes cost more, they may be the most cost-effective choice.



HAZARDS ASSOCIATED WITH GLOVE POWDER

RESTRICTIONS AND BANS ON POWDERED GLOVES

The documented adverse effects caused by using powdered gloves are the reason for a global decrease in powdered gloves usage, and a shift towards powder-free gloves. Hospitals around the world, realizing the dangers of cornstarch on examination and surgical gloves, have started moving to powder-free gloving alternatives. Germany's regulations of personal protective equipment banned the use of powdered medical gloves in 1997. In 2000, the Purchasing and Supply agency for the United Kingdom ceased to purchase any gloves lubricated with cornstarch.

The US Food and Drug Administration (FDA) enacted a rule banning the use of powdered surgical gloves, powdered exam gloves, and absorbable powder for lubricating surgical gloves. The ban, first proposed in March 2016, was announced by the FDA on December 19, 2016 and became effective on January 18, 2017. FDA's rationale for the ban is based on the risk of illness or injury to patients and healthcare providers exposed to the powdered gloves, and when internal body tissue is exposed to the powder, this may include severe airway inflammation and hypersensitivity reactions. Powder particles may also trigger the body's immune response, which can lead to an array of conditions from allergic reactions to surgical complications. Alternatively, there are other medical gloves available that are powder free and provide the same degree of protection, hand dexterity, and performance without posing the same risks to individuals.

In addition, on January 8, 2017, the Saudi Food and Drug Authority (SFDA) banned the manufacture, import, sale and distribution of powdered surgical and patient examination gloves as well as the absorbable powder used to facilitate wearing of medical gloves. In a statement on its website www.sfda.gov.sa, the authority explained that the reason for the ban is the probable link of using such gloves with many health risks, including: acute respiratory infections, anaphylaxis, allergic asthma, inflammation and damage of lungs' airways (bronchial tubes), skin rash, and adhesions of abdominal membranes. The ban is to go into effect March 27, 2017.

On December 27, 2016, Japan announced their intention to enact a similar ban with a two-year transition through to December 2018. The Ministry of Food and Drug Safety of Korea, in a January 24, 2017 meeting, announced they too are considering a powdered-glove ban transition through to December 2018.

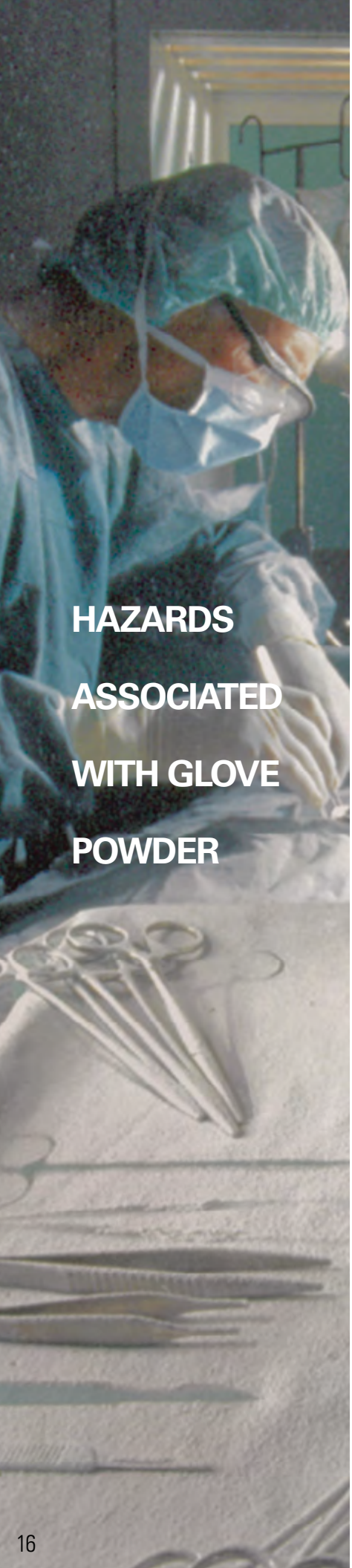
Hospital Authority (HA) of Hong Kong implemented a ban to local hospitals effective January 19, 2017, following the ruling of US FDA. This applies to government hospitals, which are under the responsibilities of HA. Private hospitals, which are not under control of HA, have also adopted the same stance.

CONCLUSION

The major adverse impact of glove powder appears to be its contributing role in undesirable reactions and complications for both the patient and healthcare provider. All of these contribute to increased healthcare costs:

- Powder can cause the development of adhesions and granulomas.
- Powder increases the risk factor for post-operative wound infections.
- Powdered gloves can increase latex allergens sensitization and provoke hypersensitivity type I reactions.
- Powder contaminates the hospital environment and increases occupational asthma and exposure to latex allergens through inhalation.
- Powder can increase the risk of cross contamination of microorganisms.
- Powder can interfere with laboratory testing causing false results.
- Powder has an abrasive action on the skin.
- Powder increases overall costs for healthcare facilities.

Governments, healthcare institutions, and accrediting agencies around the world are banning and/or restrictinng the use of powdered medical gloves. They recommend that those involved in health and safety policy decisions switch their organizations from powdered gloves to powder-free latex and/or synthetic gloves, as an effective method of reducing both patient complications associated with powdered gloves and the incidence of asthma and latex allergy in healthcare providers.



HAZARDS ASSOCIATED WITH GLOVE POWDER

ANSELL CARES

For years, Ansell has been raising industry's awareness of the fact that the level of proteins in natural rubber latex (NRL) contributes to the sensitivities and allergies experienced by healthcare staff who wear, or even work in the vicinity of, NRL gloves.

As the world leader and specialist in medical gloves, Ansell has also been very attentive to all possible risks related to the use of NRL gloves. For years it has educated consumers about such risks, while at the same time providing alternative gloving solutions that work. Its efforts have included early commitments to fundamental research, the creation of its Ansell Cares initiative, and ever increasing investments in innovative R&D and dedicated engineering. Ansell's position is to enable the healthcare community to make a responsible choice when choosing gloves to provide the best protection for HCWs and patients.

Ansell Cares was created in December 1991 in response to the FDA's Medical Alert on Latex Allergy to provide valuable support to the healthcare industry through a carefully structured program of education, research and awareness.

Ansell Cares was developed with three goals in mind:

- To research the cause, prevention and treatment of latex allergies.
- To educate patients and HCWs to recognize, prevent and treat these reactions.
- To create awareness of the issues of latex sensitization.

Today Ansell Cares:

- Remains a global, multifaceted education program guided and supported by leading scientists, physicians, educators and researchers from around the world.
- Creates education and awareness campaigns among healthcare professionals, industry experts and consumers, to help identify and prevent healthcare-associated infections,and preventable errors and injuries in the perioperative setting.
- Seeks to provide a safer working and living environment while promoting good health and well-being.

BIBLOGRAPHY

Allmers H, Brehler R, Chen Z, Raulf-Heimsoth M, Fels H, Bayr X. Reduction of latex aeroallergens and latex-specific IgE antibodies in sensitised workers after removal of powdered natural rubber latex gloves in a hospital. J Allerg Clin Immunol. 1998 Nov;102(5): 841-6

Allmers et al. Current state of the art in natural rubber latex allergy prevention. Hospital engineering and Facilities management. 2005. Business briefing.

Allmers H, Schmengler J, John SM. 2004 Decreasing incidence of occupational contact urticarial caused by natural rubber latex allergy in German healthcare workers. J Allergy Clin Immunol 114: 347-351

Allmers H, Schmengler J, Skudlik C. 2002 Primary prevention of natural rubber latex allergy in the German healthcare system through education and intervention. J Allergy Clin Immunol 110: 318-323

Beezhold D, Beck WC. Surgical Glove Powders Bind Latex Antigens. Arch Surg. 1992 Nov;127(11):1354-7

Bousquet J, Flahault A, Vandenplas O, et al. (2006). Natural rubber latex allergy among healthcare workers: a systematic review of the evidence. J Allerg Clin Immunol 118: 447-454

Charous BL, Blanco C, Tarlo S, Hamilton RG, Bayr X, Beezhold D, Sussman G, Yuninger JW. Natural Rubber Latex Allergy after 12 Years: Recommendations and Perspectives. J Allergy Clin Immunol. 2002 Jan;109(1):31-4

Chowdhury MM, Statham BN. 2003 Natural rubber latex allergy in a health-care population in Wales. Br J Dermatol 148: 737-740

Cuming R. Reducing the Hazard of Exposure to Cornstarch Glove Powder. AORN. 2002 Aug;76(2): 288-95

Cullinan P, Brown R, Field A, et al. 2003 Latex allergy. A position paper of the British Society of Allergy and Clinical Immunology. Clin Exp Allergy 33: 1484-1499

Dave et al. Glove powder: Implications for Infection Control. J Hosp Inf. 1999; vol 42:283-285.

Duron, J.J. et al. Post-operative peritoneal adhesions and foreign bodies. Eur. J. Surg. Suppl. 1997; vol. 579: 15-16.

Dyck R. Historical Development of Latex Allergy. AORN. 2000 July

Edelstam G, Arvanius L, Karlsson G. Glove Powder in the Hospital Environment–Consequences for Healthcare Workers. Intl. Arch Occup Environ Health. 2002 Apr;75(4):267-71

Edlich RF. A Plea for Powder-free Surgical Gloves. J Emerg Med. 1994 Jan-Feb;12(1):69-71

Ellis HE. Pathological Changes Produced by Surgical Dusting Powders. Ann R Coll Surg Engl. 1994 Jan;76(1):5-8

Ellis H. The Hazards of Surgical Glove Dusting Powders.Surgery, Gyn and Obstetrics. 1990 Dec; 171:521-527

Emerson, M. Chairman's conclusions. Eur J Surg. 1997.

Fay MF, Dooher DT. Surgical Gloves: Measuring Cost and Barrier Effectiveness. AORN. 1992 June; 55:1500-19

Fischer MD, Reddy VR, Williams FM, Lin KY, Thacker JG, Edlich RF. Biomechanical Performance of Powder-Free Examination Gloves. J Emerg Med. 1999 Nov-Dec;17(6):1011-8

FDA Web site, Medical Glove Guidance Manual. Draft, July 30, 1999:37-47.

Fraser I. Simple and effective method of removing starch powder from surgical gloves. Br Med J 1982; 284:1835.

Field, E.A. The use of powdered gloves in dental practice: a cause for concern? J. Dent. 1997; vol. 25: 209-214.

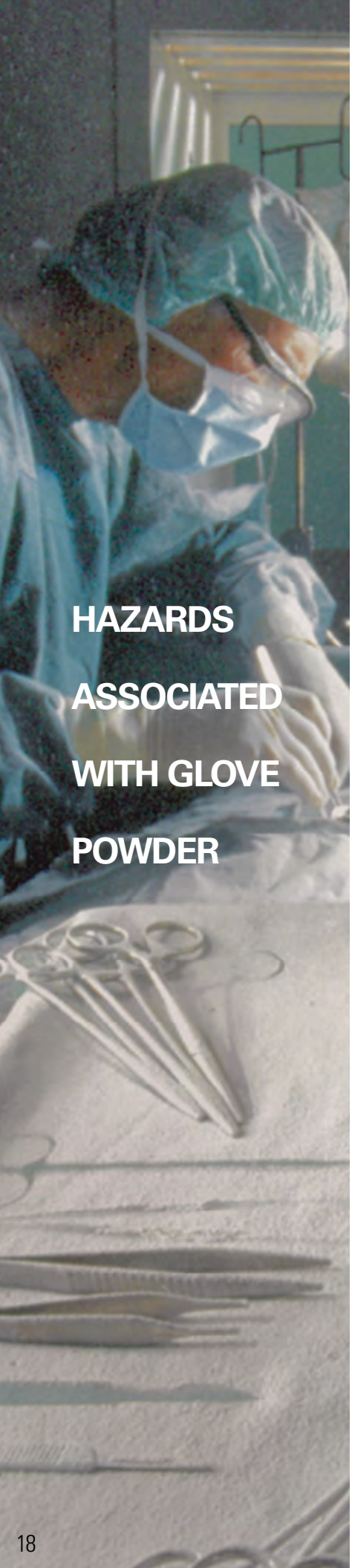
Fry D. The Economic Costs of Surgical Site Infection. Surg Infec. 2002 Vol. 3 Supplement 1:37-43

Giercksky, K.E. Misdiagnosis of cancer due to multiple glove powder granulomas. Eur. J. Surg. Suppl. 1997; vol. 579:11-14.

Hesse A, Peters KP, Koch HU. Type I Allergies to Latex and the Aeroallergenic Problem. Euro J Surg Supp. 1997;579:19-22

Hospital Authority of Hong Kong. http://www.ha.org.hk/haho/ho/cico/cicobiweeklyvol6no19.pdf Accessed March 2, 2017.

http://www.cdc.gov/niosh/nas/rdrp/ch4.1a.htm



HAZARDS ASSOCIATED WITH GLOVE POWDER

http://www.citizen.org/publications/print_release.cfm?ID=6629

http://www.fda.gov/MedicalDevices DeviceRegulationandGuidance/GuidanceDocuments/ucm113316.htm

http://www.glovegeeks.net/index.php/Newsflash/the-gloving-of-america.html

http://www.gpo.gov/fdsys/pkg/FR-1999-07-30/html/'99-19191.htm

http://www.infectioncontroltoday.com/news/2008/04/survey-reveals-or-nurses-concerned-about-complica.aspx

http://www.latexallergyresources.org/articles/article-occupational-latex-allergy-causing-your-patients-asthma

http://www.repertoiremag.com/Article.asp?Id=855

http://www.sciencedaily.com/releases/2011/08/110817120231.htm

http://www.who.int/injection_safety/toolbox/docs/AM_HCW_Safety.pdf

Hunt TK, Slavin JP, Goodson WH. Starch Powder Contamination of Surgical Wounds. Arch Surg. 1994 Aug;129:825-7

Jackson EM, Arnette JA, Martin ML, Tahir WM, Frost- Arner L, Edlich RF. A Global Inventory of Hospitals Using Powder-Free Gloves: A Search for Principled Medical Leadership. J Emerg Med.2000 Feb;18(2): 241-6

Japan Ministry of Health and Welfare. https://www.pmda.go.jp/files/000216103.pdf Accessed March 2, 2017.

Liss GM, Tarlo SM. Natural Rubber Latex-related Occupational Asthma: Association with Interventions and Glove Changes over Time. Am J Ind Med. 2001 Oct;40(4):347-53

Keller KM, Altman GB. Practice Powder-free and Latex Safe. Nurse Pract. 2003 Aug;28(8):55-7.

McCall, Brian P. PhD, Horwitz, Irwin B. MSIR, MBA, and Kammeyer-Mueller, John D. Have Health Conditions Associated With Latex Increased Since the Issuance of Universal Precautions? Am J Public Health. 2003 April; 93(4): 599–604.

Moriber-Katz, S. et al. Contamination of perfused donor kidneys by starch from surgical gloves. Am J Clin Pathol. 1998; Jul90(1): 81-84.

Newsom SW, Shaw M. Airborne Particles for Latex Gloves in the Hospital Environment. Eur J Surg.Suppl. 1982;579:31-33

Newsom SW, Shaw M. A Survey of Starch Particle Counts in the Hospital Environment in Relation to the Use of Powdered Latex Gloves. Occup Med (London). 1997 Apr;47(3):155-8

Odum, B.C. et al. Influence of absorbable dusting powders on wound infection. J. Emerg. Med. 1998; vol. 16(6): 875-9.

Pittet D, Boyce JM. Hand Hygiene and Patient Care: Pursuing the Semmelweiss Legacy.Lancet Inf Dis. 2001; Apr 9-20

Phillips ML, Meagher CC, Johnson DL. What is "Powder-free"? Characterisation of Powder Aerosol; Produced during Simulated Use of Powdered and Powder-free Latex Gloves. Occup Environ Med. 2001 Jul;58(7):479-81

Phillips VL, Goodrich MA, Sullivan TJ. Healthcare Worker Disability Due to Latex Allergy and Asthma: A Cost Analysis. AM J Public Health. 1999 July;89(7): 1024-8

Poole CJ, Nagendran V. 2001 Low prevalence of clinical latex allergy in UK healthcare workers: a cross-sectional study. Occup Med (Lond) 51: 510-512

Saudi Food and Drug Authority Prohibits Manufacturing, Importing, Selling, Distributing of Powdered Gloves. http://www.spa.gov.sa/viewstory.php?lang=en&newsid=1578447 Accessed January 31, 2017.

Schmid TK, Christoph Broding H, Niklas D, Drexler H. Latex Sensitisation in Dental Students Using Powder-free Gloves Low in Latex Protein: A Cross-sectional Study. Contact Dermatitis. 2002 Aug;47(2):103-8

Sheikh KM, Duggal K, Relfson M, Gignac S, Rowden G. An Experimental Histopathologic Study of Surgical Glove Powders. Arch Surg. 1984 Feb;119: 215-9

Sjosten, A.C.E. et al. Post-operative consequences of glove powder used pre-operatively in the vagina in the rabbit model. Human Reproduction. 2000; vol. 15: 1573-1577. Sussman GL, Beezhold DH. Allergy to Latex Rubber. Ann Inter Med. 1995 Jan;122(1):43-6

The Health Research Group. www.citizen.org/publications/release. HRG Publication #1432. Petition to FDA to Ban Cornstarch Powder on Latex Gloves

Truscott W. Post Surgical Complications Associated with the Use of USP Absorbable Dusting Powder. Truscott, 2000 – Surg Tech Internat. VIII:65-78

Truscott W. Glove Powder Reduction and Alternative Approaches. Methods. 2002 May;27(1):69-76

Turjanmaa K, Mäkinen-Kiljunen S. 2002 Latex allergy: prevalence, risk factors, and cross-reactivity. Methods 27: 10-14

US Food and Drug Administration. https://www.federalregister.gov/documents/2016/12/19/2016-30382/banned-devices-powdered-surgeons-gloves-powdered-patient-examination-gloves-and-absorbable-powder Accessed January 31, 2017

Van den Tol MP, Haverlag R, van Rossen MEE, Bonthuis F, Marquet RL, Jeekel J. Glove Powder Promotes Adhesion Formation and Facilitates Tumour Cell Adhesion and Growth. Br J Surg. 2001,188:1258-63

www.fda.gov/cdrh/glvpwd/html

Woods JA, Morgan RF, Watkins FH, Edlich RF. Surgical Glove Lubricants: From Toxicity to Opportunity. J Emerg Med. 1997 Mar-Apr;15(2):209-20

Yip E, Cacioli P. The Manufacture of Gloves from Natural Rubber Latex. J Allergy Clin Immunol. 2002 Aug;110(2):S3-14

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