REPROCESSING OF PRODUCTS: STATE OF THE ART IN THE LIGHT OF THE STUDIES OF KAZUKO UCHIKAWA GRAZIANO

Reprocessamento de produtos: estado da arte à luz dos estudos de Kazuko Uchikawa Graziano

Reprocesamiento de productos: estado del arte a la luz de los estudios de Kazuko Uchikawa Graziano

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ABSTRACT: Objective: To review the state of the art reprocessing of products in the light of Professor Kazuko Graziano's studies. **Method:** Integrative literature review, with the name of the author as a descriptor and the selection of 34 articles. **Results:** The studies are comprehensive, mainly experimental and outline processes of cleaning and rinsing, disinfection, sterilization and packaging of processed articles and in emblematic areas for the reuse of materials such as orthopedics, ophthalmology, endoscopy and video-assisted surgeries. **Conclusion:** The scientific evidence of these studies is valuable for the field of product reuse and the quality and safety of health care practice insofar as they clarify doubts and support changes in attitudes related to work processes. These studies also contribute to the control of health services by supporting Sanitary Vigilance with theoretical contributions on the risks of product reprocessing, and the Brazilian Health Surveillance Agency (ANVISA) by updating the national policy for the reuse of health products (HP).
Keywords: Equipment and supplies. Sterilization. Retrospective studies.

RESUMO: Objetivo: Revisar o estado da arte sobre reprocessamento de produtos à luz dos estudos da Professora Kazuko Graziano. **Método:** Revisão integrativa de literatura, tendo como descritor o nome da autora e com a seleção de 34 artigos. **Resultados:** Os estudos são abrangentes, majoritariamente experimentais e perpassaram pelos processos de limpeza e enxágue, desinfecção, esterilização e acondicionamento de artigos processados e em áreas emblemáticas para o reúso de materiais como ortopedia, oftalmologia, endoscopia e cirurgias videoassistidas. **Conclusão:** As evidências científicas desses estudos são valorosas para o campo do reúso de produtos e para a qualidade e a segurança da prática assistencial na medida em que clarificam dúvidas e subsidiam mudanças de atitudesprocessos de trabalho. Esses estudos contribuem, também, para o controle sanitário de serviços de saúde ao subsidiar as Vigilâncias Sanitárias com aportes teóricos sobre risco em reprocessamento de produtos e a Agência Nacional de Vigilância Sanitária (ANVISA) na atualização da política nacional de reúso de produtos para saúde (PPS) do país.
Palavras-chave: Equipamentos e provisões. Esterilização. Estudos retrospectivos.

RESUMEN: Objetivo: Revisar el estado del arte sobre reprocesamiento de productos a la luz de los estudios de la Profesora Kazuko Graziano. **Método:** Revisión integrativa de literatura, teniendo como descriptor el nombre de la autora y con la selección de 34 artículos. **Resultados:** Los estudios son abarcadores, mayoritariamente experimentales y pasaron por los procesos de limpieza y enjuague, desinfección, esterilización y acondicionamiento de artículos procesados y en áreas emblemáticas para el reúso de materiales como ortopedia, oftalmología, endoscopía y cirugías video-asistidas. **Conclusión:** Las evidencias científicas de esos estudios son valerosas para el campo del reúso de productos y para la calidad y la seguridad de la práctica asistencial en la medida en que clarifican dudas y subsidian cambios de actitudes-procesos de trabajo. Esos estudios contribuyen, también, para el control sanitario de servicios de salud al subsidiar las Vigilancias Sanitarias con aportes teóricos sobre riesgo en reprocesamiento de productos y la Agencia Nacional de Vigilancia Sanitaria (ANVISA) en la actualización de la política nacional de reúso de productos para salud (PPS) del país.
Palabras clave: Equipos y suministros. Esterilización. Estudios retrospectivos.

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INTRODUCTION

Reprocessing medical devices is the core activity of a Center for Material and Sterilization (CMS) and consists of making a contaminated device ready to use again. It includes cleaning, disinfection and sterilization, but also technical-functional safety practices by means of integrity and functionality tests[1-3]. In order to develop activities related to the reprocessing of products, the CMS depends on a management system that requires structure (physical, material and human), planning, quality and process safety. A group of trained professionals along with the development of technologies related for medical devices decontamination. Thus, the knowledge and training of professionals working at CMS is an indicator of service quality, offering cleaning, disinfection and sterilization practices based on scientific evidence in addition to contributing to the reduction of the residual risk inherent to such practices.

Several authors worldwide have dedicated to study theory and practices of medical devices reprocessing, namely William Rutala, David Weber, Michele Alfa, Lawrence Muscarella, Francesco Tessarolo, Marc Kraft, Axel Krammer, Zvi Fireman, and others.

In Brazil, the Nursing School of Universidade de São Paulo is responsible for the majority of scientific production in this area. The studies are mainly led by Professor Kazuko Uchikawa Graziano, one of the most important researchers in this area. Professor Graziano's scientific production dates from the end of the 1980s and includes individual and partner research, theoretical, methodological and experimental studies, doctoral theses, masters' dissertations and post-graduate studies. In addition to being comprehensive, her work has contributed to advances in knowledge about the subject, clarified myths regarding reprocessing practices of certain devices at CMSs across the country, and provided scientific evidence for decision-making on the reuse of medical products.

In this context, this study was guided by the following questions: What is state of the art reprocessing practice based on Kazuko Uchikawa Graziano's studies? To which extent have her studies enabled advances in knowledge in the area of medical device reprocessing and demystified practices incorporated in day-to-day routine of CMS.

OBJECTIVES

- Review the state of art medical device reprocessing in the light of the studies conducted by Professor Kazuko Uchikawa Graziano;
- Summarize the scientific production of Professor Kazuko Graziano regarding medical device reprocessing;
- Highlight the technological innovations in medical device reprocessing resulting from these studies.

METHOD

An integrative literature review which aims to summarize research results on a particular area of knowledge contributing to evidence-based practice, among other factors[4].

The following steps were used in this study: identification of study object, preparation of guiding questions, definition of inclusion and exclusion criteria, organization and analysis of data, summarization of results and presentation of review.

The articles were selected from the following databases: Virtual Health Library (VHL), PubMed and Scopus portal. The name of the author under study, "Kazuko Graziano" was used as the descriptor.

The inclusion criteria of the publications were: to be primary studies and systematic reviews that deal with the reprocessing and / or reuse of medical devices, published between the years 2006 and 2016 in the English or Portuguese language. Articles written in other languages and which were published outside these periods were excluded, in addition to works published by the author unrelated to the theme of reprocessing and/or reuse of medical devices.

The search for the data was performed online from January to March 2017 and 283 articles were initially obtained. After reading the title and abstract, 208 articles were excluded, as well as 41 repeated studies in the databases. Thus, the final sample of this review consisted of 34 articles.

After the selection, the available full articles were read, and the abstracts were read for those articles which were not available in full. At this stage, the studies were analyzed with a data collection instrument that included: article title, objectives, method, results and conclusion.

In this study, the term medical device is used as a synonym for medical product, device, equipment, material and medical article, according to the Brazilian Health Surveillance Agency (ANVISA). The term decontamination is used to describe the process of inactivation and/or elimination of microorganisms, applied to medical devices in order to provide safety to the users and includes the cleaning, disinfection and sterilization processes. Despite the considered differences, the

terms reprocessing and medical device processing are also used synonymously.

RESULTS

Twelve (35.2%) of the 34 articles analyzed are experimental studies, 10 (29.4%) are literature reviews, 6 (17.6%) are methodological studies, and 6 (17.6%) had varied methodologies (2 exploratory field, 1 multiple case, 1 descriptive, 1 analytical research and 1 pilot study).

Due to diversity and the high number of the selected articles, the present study is presented according to a grouping of the studies by using five related themes in order to improve the organization of the findings, facilitate the production of a review of the author's scientific production and to highlight the scientific innovations as a result of her work. The following is a summary of the articles from this integrative review.

Table 1 presents six studies undertaken by Professor Kazuko Graziano and her collaborators on the reprocessing of medical instruments used in laparoscopy, endoscopy, dialyzers and laryngoscopes.

Table 2 shows studies on the reprocessing of ophthalmic and orthopedic medical instruments, which are known as problematic when it comes to reusing and reprocessing medical devices.

Table 3 lists some studies developed by the author on the reprocessing of medical devices labeled as single use (SU).

Table 4 presents studies related to methods of cleaning, disinfecting, sterilizing and storing reprocessed medical devices (articles 20-31).

Table 5 displays three studies with diverse themes related to the reprocessing of medical devices (articles 32-34).

DISCUSSION

The 34 studies presented in Tables 1 through 5 review the entire field of activities related to the reuse of medical devices with researches that included not only cleaning, rinsing, disinfection, sterilization and packaging methods of reprocessed articles, but also in the principal areas which reprocess and reuse medical devices such as orthopedics, ophthalmology, endoscopy, hemodialysis, video-assisted surgeries as well as single use products. This demonstrates the challenges and the pioneering nature of the research conducted by Professor Kazuko Graziano and her collaborators.

In the cleaning process, the author and her collaborators developed criteria for the evaluation of single use products regarding the possibility of cleaning and subsequent reuse (Article 17)[17]. They verified the absence of toxicity and Toxic Anterior Segment Syndrome (TASS) associated with enzyme detergent residues and supported the routine cleaning of ophthalmic instruments with enzymatic detergent (Article 7)[7]. They also confirmed the failure of the cleaning and sterilization processes of single-use vitrectomy probes, contraindicating the reuse of these products (Article 8)[8], and identified that when the cleaning process of critical products is performed with validated procedures, the type of water used in the final rinse has little influence on the cytotoxicity of these products (Article 22)[22].

Regarding video-assisted surgery, a study is evidenced that microbiologically proved that the sterilization of previously assembled laparoscopic instruments is safe. This evidence breaks the classic paradigm of sterilizing only disassembled materials, as recommended in the literature (Article 1)[1].

Regarding the area of endoscopy, Article 3 proved to be innovating by proposing an evaluation method for the decontamination efficacy of automated flexible endoscope processors, operational method, and management and decision-making instrument at the time of purchase of an automated endoscope disinfection equipment, due to the diversity of brands and models in the market[3]. Article 4 identified that the automated method, including the initial cleaning step and consecutive disinfection using 2% glutaraldehyde solution was the most efficient at removing biofilms from endoscopes and emphasized the importance of the process, as the agents have a greater ability in biofilm detachment[4].

Article 5 analyzed the decontamination of dialyzers and identified the risk of pathogen transmission in manual and automated methods. Thus, it contributed to renal therapy services by reflecting on the practice of reusing hemodialysis capillaries[5].

Article 6 showed that the handle and the blade of the laryngoscope are a single set and should be classified as semi-critical products. Therefore, they require high level cleaning and disinfection to ensure proper reuse[6].

Regarding orthopedic surgery, the author and collaborators demonstrated that domestic drills, although not

Chart 1. Synthesis of studies selected in databases. Kazuko Graziano, Brazil, from 2006 to 2016.

Theme 1. Processing of laparoscopic, endoscopic, dialyzing and laryngoscopy instruments				
Article	**Authors/journal**	**Objective**	**Methods**	**Conclusion**
1. Microbiological evaluation of the steam sterilization of assembled laparoscopic instruments[5]	Camargo et al. Rev Latino-Am Enferm. 2016	To evaluate the safety of steam sterilization of assembled laparoscopic instruments with contamination challenge.	Experimental study.	Saturated steam sterilization under pressure from assembled laparoscopic instruments is microbiologically safe, breaking the classic paradigm of autoclaving only unassembled materials.
2. Steam sterilization of previously assembled laparoscopic instruments[6]	Camargo et al. Acta Paul Enferm. 2008	To describe the state of the art of the basic studies in search of safety in the autoclaving of previously assembled laparoscopic instruments, considering the difficulties to assemble at the time of surgery.	Literature review.	Although the studies allowed favorable conclusions for the practice of processing the assembled laparoscopic instruments, this study concludes by recommending a new experimental study using contamination challenge.
3. Methodological proposal for the evaluation of the disinfection efficiency of the automatic flexible endoscopes processor[7]	Graziano et al. Rev Latino-Am Enferm. 2016	To propose a method to evaluate the effectiveness of automated flexible endoscope processors by analyzing the feasibility and results applied to a specific make and model.	Methodological research applied in a domestic manufacturing equipment. The disinfectant used was 0.2% peracetic acid.	The proposed method proved to be feasible and reliable as to the rigor of the imposed challenge, being able to serve as an evaluation model for similar equipment and to assist in the acquisition of this type of product.
4. Removal of biofilms in endoscope canals: evaluation of currently used disinfection methods [8]	Bálsamo et al. Rev Esc Enferm USP. 2012	To evaluate the action of high level disinfection after previous cleaning with brushing to remove biofilms in sample bodies simulating the channels of flexible endoscopes, as well as comparing the available methods in health services.	Experimental, laboratory and comparative study, where the efficiency of five high-level disinfection methods for the removal of biofilms were tested.	Although the aldehydes had fixed properties, the most efficient method was 2% glutaraldehyde in automated equipment that included a preliminary cleaning step to disinfection, and the least efficient was acid electrolytic water in automated equipment. This study suggests that cleaning is more important in biofilm removal than consecutive disinfection. It shows and warns the ability of microorganisms to form biofilms in just 1 hour after contamination, reinforcing the need to clean the endoscope as soon as possible after use in order to avoid an environment conducive to its development.
5. Evaluation of the effectiveness of manual and automated dialyzers reprocessing after multiple reuses[9]	Toniolo et al. Am J Infect Control. 2016	To evaluate methods of manual and automated reprocessing of dialyzers in relation to microbiological contamination.	Experimental study. Fluid thioglycollate culture medium was injected into the hemodialysis capillaries after reprocessing 12 times by manual method and 20 times by automated method, as permitted by Brazilian Legislation.	In both methods, microorganisms were identified in the dialysate and in the blood chambers. It was concluded that reprocessing of dialyzers may pose a safety risk because of exposure of microorganisms to the patient.
6. Laryngoscope handles reprocessing: integrative review[10]	Bruna et al. Rev SOBECC. 2016	To identify the classification of laryngoscope cables according to the risk of causing infection and highlight the type of reprocessing required.	Integrative review.	This study showed that laryngoscope cables and blades should be understood as a single set, however cables normally neglected in processing should also be classified as semi-critical articles that require cleaning followed by high level disinfection.

Chart 2. Synthesis of selected studies in databases. Kazuko Graziano, Brazil, 2006 to 2016.

Theme 2. Processing of ophthalmic and orthopedic instruments				
Article	**Authors/Journal**	**Objective**	**Methods**	**Conclusion**
7. Cytotoxicity of cannulas for ophthalmic surgery after cleaning and sterilization: evaluation of the use of enzymatic detergent to remove residual ophthalmic viscosurgical device material[11]	Tamashiro et al. J Cataract Refract Surg. 2013	To evaluate the cytotoxicity of reusable cannulas for ophthalmologic surgery after being filled with ophthalmological viscoelastic product and cleaned with enzymatic detergent.	Experimental Study.	The cleaning protocol adopted in this study reached the potential to minimize the occurrence of Toxic Syndrome of the Anterior Segment of the Eyes (TASS), associated with residues of viscoelastic solution and enzymatic detergent.
8. Evaluation of microbial growth in reprocessed single use probes for vitrectomy in care practice [12]	Pinto et al. Rev Esc Enferm USP. 2012	To evaluate microbial growth in reprocessed single use vitrectomy probes in care practice.	Exploratory field study.	The reprocessed vitrectomy probes in this study showed microbial growth, pointing to the related risk as this practice is performed. It was concluded that the reprocessing of single-use vitrectomy catheters is not safe under the conditions of this study and, therefore, this practice is not recommended.
9. Evaluation of the sterilization efficacy of domestic electric drills used in orthopedic surgeries[13]	Goveia et al. Braz J Microbiol. 2009	To evaluate the efficacy of ethylene oxide (ETO) sterilization in new domestic drills subjected to contamination challenge.	Experimental, laboratory and randomized study.	Demonstrated effective sterilization of drills with ETO. However, it does not intend to support the improvised use of domestic drills in surgeries, although the results confirm the effectiveness of ETO sterilization.
10. Analysis of the microbial load in instruments used in orthopedic surgeries[14]	Pinto et al. Am J Infect Control. 2010	To determine the microbial load in instruments used in orthopedic surgeries.	Exploratory field study.	Most of the microorganisms evidenced in the analyzed instruments (78%) were vegetative bacteria, characterizing in a low challenge of the cleaning and sterilization process correctly employed in CMEs. However, the microbial recovery in surgical instruments used in clean surgeries, evidenced the importance of antibiotic prophylaxis.
11. Is ventilation of electric drills a source of contamination for surgery? [15]	Goveia et al. Acta Ortop Bras. 2009	To evaluate micribiologically the air generated by the motor drive of electric drills in orthopedic surgery.	Experimental, laboratory and randomized study.	It was concluded that although the air from the drill motor ventilation mobilizes contaminants to the operative field, the microbial amount does not present a risk of surgical site infection.
12. Use of electric drills in orthopedic surgery [16]	Goveia et al. Acta Ortop Bras. 2007	To describe the state of the art of research on the use of domestic electric drills in orthopedic surgeries, in view the difficulties of cleaning and sterilizing the equipment.	Literature Review.	There were no studies evaluating the risks of using drills in orthopedic surgery. It concludes by suggesting investigations to confirm the effectiveness of sterilization of this equipment and if the activated motor produces contaminated aerosols during surgery.

Chart 3. Synthesis of selected studies in databases. Kazuko Graziano, Brazil, from 2006 to 2016.

Theme 3. Processing of single use health products				
Article	**Authors/Journal**	**Objective**	**Methods**	**Conclusion**
13. Calculation of the reprocessing costs of single-use tongs used in video assisted surgeries[17]	Psaltikidis et al. Rev Esc Enferm USP. 2006	To develop a methodological proposal to calculate the reprocessing of disposable forceps used in video-assisted surgery.	Methodological study.	A flow chart was developed for each phase of reprocessing, which allowed the subsequent identification of cost components in terms of labor, materials and overhead expenses.
14. Analysis of the cost of reprocessing single-use tweezers used in video-assisted surgery [18]	Psaltikidis et al. Rev Latino-Am Enferm. 2006	To analyze the cost of reprocessing single use medical products used in video-assisted surgery, adopting methodology proposed by Psaltikidis.	Multiple case study.	It concluded that the methodological proposal allowed the calculation and cost analysis of the reprocessing of the studied tweezer.
15. Efficacy of sterilization of reprocessed single-use diathermy pencils [19]	Batista Neto et al. Rev Latino-Am Enferm. 2010	To evaluate the efficacy of reprocessing single-use diathermy pencils (ESUs) using two different methods of cleaning (manual or automated), followed by sterilization by low temperature methods: hydrogen peroxide plasma, ethylene oxide and steam at low temperature and formaldehyde.	Experimental, laboratory and randomized study.	It has been shown that the probability of sterilization of the reprocessed SSUs is highly dependent on the cleaning and sterilization methods applied. From the microbiological point of view, the findings indicate that SUTC present the same problems as reusable pencils. The main contribution was to provide support for the revision of the concept of single use products and to contribute to demystify the idea that reusable products are always safe in terms of sterility.
16. Single-use label analysis for sternotomy blade [20]	Bulgarelli et al. Rev SOBECC. 2015	To evaluate and legitimize the single-use sternotomy blade label, focusing on the risk of infection and the risk of inadequate performance of the reprocessed product.	Analytical study.	Sternotomy blade marketed as single -use (UU) does not justify the single -use recommendation because it is a product capable of consecutive cleaning and sterilization by saturated steam. The analysis of the risk in reusing the blade for sternotomy marketed as UU provided an opportunity to reflect on the urgent need for stricter criteria for the registration of products as one-time use by ANVISA.
17. Criteria for assessing difficulties in cleaning single-use items [21]	Graziano et al. Rev Latino-Am Enferm. 2006	To identify in the University Hospital the products of single use products in the University Hospital indicated for reprocessing, according to criteria to evaluate the difficulties in cleaning; to classify the SOPs according to the criteria established in the instrument elaborated and to evaluate their applicability.	Methodological research.	Nine criteria were elaborated in order to evaluate the difficulties in cleaning up PUU. The application of these criteria allowed a diagnosis of the degree of risk involved in the cleaning of each evaluated PUU.
18. Reprocessing of cardiac catheters: a review [22]	Ribeiro et al. Braz J Cardiovasc Surg. 2006	To describe the state of the art in the reuse of cardiac catheters in relation to the reprocessing effect on the physical, mechanical and functional integrity of the catheters. Evaluate the effectiveness of the cleaning and sterilization techniques of these catheters, as well as risks for patient users.	Literature review.	This study evidenced that there is clear evidence of the occurrence of physical and mechanical alterations after reprocessing of cardiac catheters. Doubts persist about the safety of reuse in the area of cleaning and sterilization of hemodynamic catheters.

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Chart 3. Continuation.

Theme 3. Processing of single use health products				
Article	**Authors/Journal**	**Objective**	**Methods**	**Conclusion**
19. Evaluation of sterility of reprocessed single use laparoscopic instruments [23]	Lopes et al. Rev Latino-Am Enferm. 2011	To evaluate the efficacy of sterility of single use laparoscopic instruments used in video laparoscopic surgery after contamination challenge.	Experimental study	Absence of microbial growth in the studied samples. This study allowed us to confirm the initial hypothesis that it is possible to sterilize single-use products used in video laparoscopic surgery. It clarifies that the reuse of single-use medical products may be possible if the processing is of a good quality. It reinforces the need to establish maximum acceptable parameters for organic residues.

Chart 4. Synthesis of selected studies in databases. Kazuko Graziano, Brazil, from 2006 to 2016.

Theme 4. Studies related to methods of cleaning, disinfecting, sterilizing and packaging health products				
Article	**Authors/Journal**	**Objective**	**Methods**	**Conclusion**
20. The practice of disinfection of high-speed hand pieces with 70% w/v alcohol: an evaluation[24]	Pinto et al. Am J Infect Control. 2016	To analyze the effectiveness of the processing of high-speed dental hand pieces with 70% alcohol without prior cleansing.	Experimental study.	This study concluded that 70% alcohol disinfection of high-speed dental hand pieces without prior cleansing is not a safe decontamination method.
21. The impact of the use of different types of gloves and bore hands for preparation of clean surgical instruments[25]	Bruna et al. Rev Latino-Am Enferm. 2016	To determine whether there is a difference in safety in the use of different types of gloves and bare hands during inspection and disposal of the instruments after cleaning and to identify / quantify the microbial load after handling these instruments without gloves.	Experimental study divided into two stages: cytotoxicity analysis of samples handled using gloves and bare hands and microbiological analysis of samples handled with bare hands.	The different types of instrument handling with various glove types were equivalent in relation to cytotoxicity. The study concluded that the preparation of instruments with bare hands (without gloves) seems to be the ideal recommendation.
22. The impact of the last rinse on the cytotoxicity of critical products capable of processing	de Souza et al. Rev Esc Enferm USP. 2015	To evaluate the cytotoxicity of products submitted to contamination challenge, cleaning based on standard operating procedure validated and final rinse in different types of water: tap, deionized, distilled, reverse osmosis and ultra-purified, in order to demonstrate their ability to cause injury and cell death.	Experimental study.	The results did not demonstrate cytotoxicity, independent of the water quality used in the last rinse. This result was only achieved through a validated cleaning operating procedure, based on scientific literature, legislation and official recommendations.
23. Efficacy and effectiveness of alcohol in the disinfection of semi-critical materials: systematic review [27]	Ribeiro et al. Rev Latino-Am Enferm. 2015	To discuss effectiveness of semi-critical (SC) disinfection with and without previous cleaning.	Systematic literature review.	It was found that disinfection with 70% alcohol was satisfactory in products such as nasopharyngoscopes, laryngoscopes, tonometer tip, products with low structural complexity. The results of this study demonstrate that the disinfection of SC products can be achieved in products with or without previous cleaning. The lack of product complexity may be a factor contributing to satisfactory disinfection.

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Chart 4. Continuation.

Theme 4. Studies related to methods of cleaning, disinfecting, sterilizing and packaging health products				
Article	**Authors/Journal**	**Objective**	**Methods**	**Conclusion**
24. Cytotoxicity of PVC tubes sterilized in ethylene oxide after exposure to gamma radiation [28]	de Souza et al. Rev Esc Enferm USP. 2013	To investigate the potential cytotoxic effect of gamma radiation sterilized PVC materials and re-sterilization in ethylene oxide (ETO), with a mechanical aeration process.	Experimental study.	The results show safety in the use of PVC materials previously sterilized in gamma radiation and re-sterilized in ETO. However, three factors may limit these findings: 1) Type of aeration conducted by companies providing sterilization; 2) Product characteristics; 3) Test for the detection of residues of ETO and its by-products ethylene glycol and ethylene-chiridrine.
25. Temperature and humidity in the storage of autoclaved materials: integrative review [29]	Bruna e Graziano. Rev Esc Enferm USP. 2012	To identify and analyze the theoretical foundations that led to the establishment of temperature parameters(T) and relative humidity (RH) of the air of the storage sector of sterilized materials as possible sources of contamination of the stored materials.	Integrative review of the literature.	The studies of this review reinforce the thesis that T and UR of the environment have little or no impact on maintaining the sterility of adequately packaged materials, confirmed by an experimental laboratory study published in Bruna CQM, Pinto FMG, Graziano KU. The influence of environmental temperature and air humidity on the maintenance of sterility of surgical instruments in different wraps. Infection Control and Hospital Epidemiology 2012; 33: 1277-80.
26. Periodic sterility assessment of materials stored for up to 6 months at continuous microbial contamination risk: laboratory study[30]	Moriya et al. Am J Infect Control. 2012.	To test the hypothesis that the storage time of sterile packets has no effect on the susceptibility of the contamination, even under conditions of deliberate bacterial exposure.	Experimental study.	No microbial growth was identified in the experimental group, which consisted of test pieces packed in cotton, SMS, crepe paper and surgical grade intentionally contaminated in its external part, in any time interval analyzed. (7, 14, 28, 90 e 180 days). Guideline recommendations suggest that contamination of a sterilized product occurs only because of an event and this study supports these recommendations.
27. Low Temperature Sterilization Methods and New Technologies [31]	Goveia et al. Rev Latino-Am Enferm. 2007	To identify in the literature evidence of antimicrobial activity, toxicity, adverse events and the applicability of sterilization technologies at low temperatures.	Literature review.	This review has identified a limited number of publications and that these consist of basic laboratory research with over-dimensioned challenges that do not reflect clinical practice. Presence of salt and serum in the tested material presented a protective action against the microorganisms in the sterilization process. Materials with narrow lumens are more challenging than longer lumens in relation to the success of sterilization The current literature available is not sufficient enough to elect the low temperature method in place of ethylene oxide.
28. Evaluation of maintenance of sterility of moist / wet materials after steam sterilization and storage for 30 days [32]	Moriya e Graziano. Rev Latino-Am Enferm. 2010	To evaluate the maintenance of the sterility of moist/wet products after being submitted to the steam sterilization process and stored for 30 days.	Experimental, laboratory and randomized study.	The presence of moisture inside surgical boxes packed with an SMS sheet and intentionally contaminated after undergoing steam sterilization did not interfere in the maintenance of content sterility even after 30 days of storage.

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Chart 4. Continuation.

Theme 4. Studies related to methods of cleaning, disinfecting, sterilizing and packaging health products				
Article	**Authors/Journal**	**Objective**	**Methods**	**Conclusion**
29. Compatibility and incompatibility between gamma radiation and ethylene oxide as successive methods of sterilization [33]	de Souza e Graziano. Rev Esc Enferm USP. 2010	To analyze the literature and show compatibilities and incompatibilities between gamma and ethylene oxide (ETO), with successful methods of sterilization.	Integrative literature review.	This study concludes by recommending new studies with more sensitive analytical methods such as gas chromatography, biological reactivity test in cell cultures to resolve the chronic doubt of the compatibility/incompatibility of ETO sterilizing previously pre-irradiated materials.
30. Ozone in the sterilization of health care products: an integrative literature review [34]	Souza et al. Rev Esc Enferm USP. 2011	To evaluate whether there is sufficient data in the scientific literature that supports the incorporation of ozone as a sterilizing physical-chemical agent of health products.	Integrative Litererature review.	Ozone is shown as a promising method of sterilization. However, further experimental studies are still needed to substantiate evidence of its possibilities and limitations.
31.Flash Sterilization from the Perspective of Empirical Evidence[35]	Rocha et al. Rev SOBECC. 2008	To evaluate the main differences between the conventional and flash steam sterilization regarding the achieved physical parameters.	Pilot study.	From the technical point of view, the two cycles resemble each other and the major difference lies in the number of pulse vacuum in relation to the physical parameters reached. Flash sterilization can only be performed if all the fundamental steps of reprocessing are met.

Chart 5. Synthesis of selected studies in databases. Kazuko Graziano, Brazil, from 2006 to 2016.

Theme 5. Various studies related to the processing of health products				
Article	**Authors/Journal**	**Objective**	**Methods**	**Conclusion**
32. Reprocessing of medical products: a proposal for a regulatory model for Brazilian hospitals [37]	Costa et al. Rev Esc Enferm USP. 2011	To propose an alternative model of reprocessing of medical products in order to contribute to the formulation of policies aimed at controlling improvements in the quality of health services in the country.	Descriptive study developed with Consensus Conference technique.	The proposition of a regulatory model for reprocessing medical products, self-explanatory and presented in 2 flowcharts. The first classifies medical products into reprocessable and non -reprocessable. The second describes the steps necessary for reprocessing, normalizing the processes involved.
33. Micro-organisms of the subclass Coccidia: resistance and implications for the processing of health care materials [38]	de Souza et al. Rev Esc Enferm USP. 2012	To provide reflection on the need for disinfection or sterilization of endoscopes that come in contact with the digestive tract, based on the risks related to the subclass Coccidia.	Literature review.	He recommended that health services adopt measures to control the quality of the water used for the final rinsing of endoscopes. High-level chemical germicides are urgently needed against Cryptosporidium, ensuring the use of standard precautions in the processing of endoscopes.
34. Evaluation indicators of dental-medical-hospital articles processing: elaboration and validation [39]	Graziano et al. Rev Esc Enferm USP. 2009	To elaborate and validate evaluation indicators for the processing of dental and medical articles.	Methodological research.	Product processing indicators were developed. Each indicator presents components to be evaluated, how information is obtained and the formula for calculating compliance measures.

recommended for use in health services, are subject to sterilization in ethylene oxide (Article 9)[9]. In addition, they showed that the air produced by the motor of this equipment does not mobilize sufficient amounts of contaminants that could cause surgical site infections (Article 11)[11].

Single use medical devices were also studied by the author and her collaborators. They developed a proposal for calculating the cost of reprocessing disposable tweezers used in laparoscopic surgeries, whereby the manager was responsible for the decision to reuse these medical devices in view of the cost-effectiveness (Articles 13 and 14)[13,14]. Three studies confirmed the possibility of sterilizing diathermy pencils, sternotomy blades and laparoscopic instruments, all of which are single-use (Articles 15, 16 and 19)[15,16,19], raising questions regarding the criteria that manufacturers follow regarding labelling products, registered with ANVISA, as single use products. Article 18 described the state of the art regarding the reuse of cardiac catheters and concluded that it implies physical and mechanical alterations, however there are still doubts surrounding the subject[18].

The authors analyzed the effectiveness of the disinfection of dental handpieces with 70% alcohol without previous cleaning. They concluded that the method is not suitable for these materials (Article 20)[20].

The handling of clean instruments during the preparation of the instrument boxes was analyzed according to the use of different types of gloves and handling without gloves (bare hands). In these cases, the authors recommended that clean instruments should ideally be prepared without gloved hands, with the idea of reducing the amount of health care waste. This is considered a financial advantage for the institutions as well as reducing potential allergies for the workers who work in CMS due to frequent contact with latex. The conclusion is contrary to the prevailing norm that recommends the use of non-sterile gloves for the preparation of products after cleaning[36] (Article 21)[21].

The influence of temperature and relative humidity on the storage rooms for sterilized products was studied and the data showed that these conditions have no impact on maintaining the sterility of adequately packaged products (Article 25)[25]. In addition, the research showed that storage time and effect on product contamination were determined under deliberate bacterial exposure conditions and no microbial growth related to exposure time was identified, confirming the literature data that confirms that the validity of products depends on an event that may break the integrity of the packaging and consequently contaminate the product (Article 26)[26].

Article 27 concluded that ethylene oxide sterilization is the gold standard among low temperature sterilization methods[27]. Article 30 recommends further studies in order to clarify evidence on possibilities and limitations of ozone as a sterilizing agent[30].

The cytotoxicity of PVC materials sterilized in gamma radiation and resterilized in ethylene oxide with a mechanical aeration process was also evaluated and the results provided safety in the use of these (Article 24)[24].

It was concluded that flash sterilization can only be performed if all the fundamental steps of reprocessing are fulfilled (Article 31) [31].

Article 32 proposed an alternative regulatory model for the reprocessing of medical devices[32], which aims to fill existing gaps in the current Brazilian normative framework[40,41], in particular RE 2,605 / 2006, by eliminating the need of a list of products which are prohibited from being reprocessed in the country. Article 34 elaborated evaluation indicators for the processing of studies, providing support for the measurement of the adequacy of the reprocessing stages of medical devices [34].

In view of its particular resistance to chemical disinfectants, the microbial resistance of the subclass Coccidia was analyzed in article 33. The data showed that these microorganisms are more resistant than the microbacteria and are only eliminated with 6-7% hydrogen peroxide, which raises questions about the indicated method for the decontamination of medical devices contaminated with this pathogen, especially the colonoscopes.[33]

Technological innovations in the reprocessing of medical devices as a result of Professor Kazuko Graziano's studies

Analyzing the previously classified and detailed production of Kazuko Graziano, and considering technological innovation as a "process of designing or aggregating new functionalities or characteristics of a product, process or method"[42], we identify the following technological innovations in the medical device reprocessing field:

1. Evidence of microbiological safety in the sterilization of assembled laparoscopic instruments;
2. Evidence of the sterilization capacity of some products labeled by the manufacturers as single use, such

as laparoscopic instruments, diathermy pencils and sternotomy blades;
3. Proposition of a methodology to evaluate the effectiveness of automated flexible endoscope processors;
4. Considerations regarding methods for the removal of biofilms from endoscope channels;
5. Technical considerations regarding the reprocessing methods of dialysers;
6. Proposition regarding the risk classification of the laryngoscope as a semi-critical device for both the handle and the blades;
7. Proposition of a cleaning protocol for ophthalmic instruments with potential to minimize Toxic Anterior Segment Syndrome (TASS);
8. Evidence regarding the contraindication of the reuse and reprocessing of single-use vitrectomy probes;
9. Evidence of the sterilization capacity of domestic drills used in orthopedic surgeries, although contraindicated due to bone damage;
10. Evidence of the absence of microbiological risk arising from the air of the motor of electric drills used in orthopedic surgeries;
11. Construction of a methodology to calculate the cost of reusing and reprocessing single-use instruments used in video-assisted surgery;
12. Production of criteria to evaluate the difficulties regarding cleaning single-use medical devices;
13. Evidence of the contraindication of disinfecting high speed dental pens with 70% alcohol, without previous cleaning;
14. Recommendation for the preparation of clean instruments with bare hands (without the use of gloves);
15. Evidence that validated cleaning procedures contribute to the absence of cytotoxicity of critical products;
16. Evidence that the disinfection of semi-critical products with alcohol 70% is achieved with greater safety when these products have simple conformation;
17. Evidence regarding the safety of the use of PVC materials previously sterilized in gamma radiation and resterilized in ETO;
18. Evidence that temperature and relative humidity do not have an impact on the sterility of adequately packaged medical products or devices;
19. Evidence that the validity of product sterilization is a related event, not time related;
20. Considerations related to ETO as gold standard among low temperature sterilization methods and the need for further studies to incorporate ozone as a sterilizing agent;
21. Evidence that flash sterilization can be effective as long as the fundamental steps of product reprocessing are met;
22. Proposition of an alternative regulatory model for medical device reprocessing;
23. Considerations regarding the need for the provision of high-level disinfectant for the elimination of Coccidia subclass micro-organisms;
24. Creation of evaluation indicators for medical device reprocessing.

CONCLUSION

This study showed the significant increase in the national scope of publications on reprocessing of medical devices by Professor Kazuko Graziano and her collaborators, during the analyzed period (between 2006 and 2016).

The scientific evidence from studies is not only valuable to the field of reprocessing reusable medical devices by filling gaps in the knowledge but it is also valuable to the quality and safety of health care practice as it clarifies not only doubts and myths about these processes, but, above all, uncovers old routines implanted by common sense, supporting changes in practices that are sometimes obsolete within Brazilian CMSs.

In addition, their research has contributed to the sanitary control of health services by providing the Sanitary Surveillance of the country with theoretical contributions on risks regarding product reprocessing. Their research is also relevant regarding their work with ANVISA through their methodological and critical proposals regarding the agency's conduct in updating the country's policy on reprocessing reusable medical devices.

Finally, the technological innovations in product reprocessing highlighted in this research reveal the advance in knowledge made possible by the research of the author that evidence her transforming role in the scenario of product reprocessing in the country.

DECLARATION

We declare that Professor Kazuko Uchikawa Graziano was informed about the production of this article and agreed to it.

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