ANALYSIS OF THE SINGLE-USE LABEL OF STERNOTOMY BLADES

Análise do rótulo de uso único de lâminas para esternotomia

El análisis de la etiqueta del unico uso de las hojas de esternotomía

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ABSTRACT: Objective: To analyze the legitimacy of label single-use blades to sternotomy by assessing the risk of sterilization failure and functionality. **Method:** Analytical research, based in an algorithm for decision making regarding the reuse of materials. **Results:** Based on the reference adopted, it was possible to classify the sternotomy blade reprocessing as low risk in terms of infection and loss of functionality after repeated use. **Conclusion:** The reuse of sternotomy blades is safe. The possibility of reuse must be defined at each use, taking into account the functionality informed by the surgeon. The integrity of the saw must be further confirmed by visual inspection using magnifying lens. Therefore, the material shall not be marketed as single use.
KEYWORDS: Equipment reuse. Patient safety. Sterilization. Cross infection. Health surveillance of products. Equipment and supplies.

RESUMO: Objetivo: Analisar a legitimidade do rótulo de uso único de lâminas para esternotomia por meio da avaliação do risco de falha na esterilização e na funcionalidade. **Método:** Pesquisa analítica, baseada em um fluxo para tomada de decisão de reúso de materiais de uso único. **Resultados:** Com base no referencial adotado, foi possível classificar o reprocessamento da lâmina para esternotomia como de baixo risco, tanto para infecção como para falha funcional. **Conclusão:** O reúso das lâminas para esternotomia é seguro, sendo o número máximo desta prática determinado pela avaliação da funcionalidade, a cada reúso, sob responsabilidade do cirurgião que a utilizou, complementada pela inspeção visual quanto à integridade dos "dentes" da serra por meio de lentes intensificadoras de imagem. Assim, não procede o material ser comercializado como de uso único.
PALAVRAS-CHAVE: Reutilização de equipamento. Segurança do paciente. Esterilização. Infecção hospitalar. Vigilância sanitária de produtos. Equipamentos e provisões.

RESUMEN: Objetivo: Analizar la legitimidad de la etiqueta cuchillas de un solo uso a esternotomía mediante la evaluación del riesgo de falla en la esterilización y la funcionalidad. **Método:** Investigación analítica basado en un flujo para la toma de decisiones reutilización de un solo. **Resultados:** En base a la referencia adoptada, fue posible clasificar el reprocesamiento de la hoja de esternotomía como de bajo riesgo de infección y para la insuficiencia funcional. **Conclusión:** La reutilización de hojas de esternotomía es seguro, con el número máximo de esta práctica se determinará en la evaluación de la funcionalidad, cada reutilización bajo la responsabilidad del cirujano que utiliza complementado mediante inspección visual que la integridad de los "dientes" de la sierra a través de lente intensificador de imagen. Por lo tanto, el material no se comercializa como un solo uso.
PALABRAS CLAVE: Equipo reutilizado. Seguridad del paciente. Esterilización. Infección hospitalaria. Vigilancia sanitária de produtos. Equipos y suministros.

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INTRODUCTION

A single-use health-related product is any product intended to be used in the prevention, diagnosis, therapy, rehabilitation, or contraception, usable only once, according to the specification of the manufacturer, and endorsed in Brazil by the National Health Surveillance Agency – ANVISA[1].

The single-use health-related products are being manufactured for over half a century. These emerged with the goal of providing assistance materials with guaranteed quality, ready to use, and also decreasing the overburden of health professionals, attributed to the reprocessing of materials. However, mainly due to the incorporation of high-cost technologies in products with single-use features, they have become less affordable to be used only once[2]. As a strategy, the health-care facilities began to reuse these products[3].

In Brazil, the current legislation[4] provides support for the health-care facilities to reuse products that are not included in the negative list[5], even if contradicting the indications of manufacturers to not reprocess them. The permission to reuse is subject to the demonstration of safety through validation tests[6].

In heart surgery, the total longitudinal sternotomy is the most common incision performed by surgeons to access the heart and great vessels because it allows an ample access to these structures[7]. To perform sternotomy, a saw with a stainless steel blade, labeled by the manufacturer as a single-use medical device, is used (Figures 1 and 2).

As shown in Figure 2, the blade for the sternotomy is a surgical instrument with a simple conformation and no internal spaces, of steel, and therefore autoclavable by saturated steam under pressure, non-implantable, without risk of being contaminated with prion particles and of high cost. This characterization leads to the question of why the product is for single use.

An author[8] stated that the permission for a category of products that manufacturers "recommended for single use" can mean legal basis for endless battles because it preserves the exemption from the manufacturer of the damage associated with the products if it occurs in reprocessing conditions. The conditions in which the manufacturer has this permission are not clearly determined in the legislation.

That said, this research intends to assess the legitimacy of the single-use label of sternotomy blades, focusing on the risk of infection and inadequate performance of the reprocessed product.

METHOD

This research was characterized as an analytical research. In the bibliographic search of the theoretical and methodological framework, the decision-making flow chart for reusing medical products designed for single use — "Reprocessing and reuse of single-use devices: review prioritization scheme" — proposed by the Food and Drug Administration of the United States of America (FDA-USA)[9] proved to be the most robust

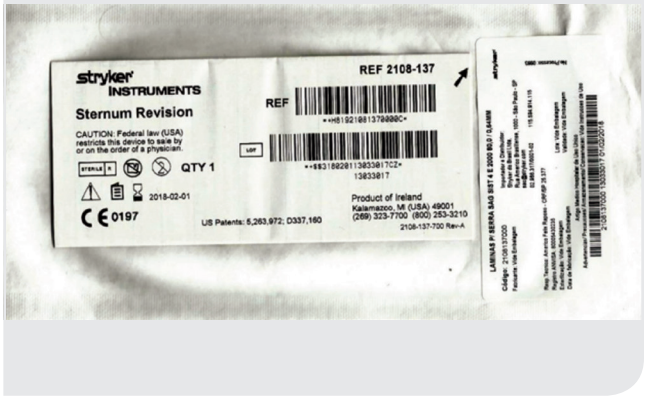


Figure 1. Package of the blade used for sternotomy.

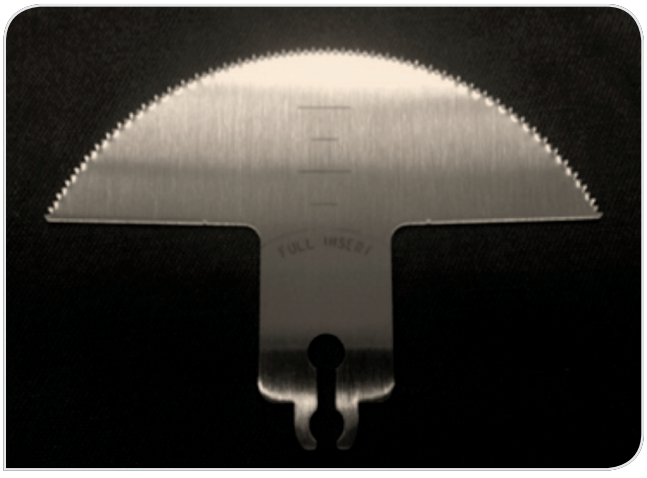


Figure 2. Stryker® brand blade used for sternotomy.

framework to answer the research question. Other bibliographical references on the subject were found in the systematic search through a research, without restrictions of time and language, in the Virtual Health Library (VHL) with the specific descriptor "equipment reuse," and incorporated into the development of the work. A search in a tree of scientific articles was also adopted, using the articles that were found, when it seemed appropriate, which contributed to the development of the work.

For purposes of categorization of injuries in the analysis of the blade for sternotomy due to functional failure in its reuse, the following definitions were used:

- **Light injury** – Product that is not used in cavities or internal spaces of the human body, which can be promptly replaced by a new one when the functional failure is discovered. For example, blades for sternotomy and electrocautery pens.
- **Serious injury** – Product that is used in cavities or internal spaces of the human body, which cannot be promptly replaced by a new one when there is a functional failure. For example, laparotomy stapler and angioplasty catheter.

RESULTS

The scheme proposed by the FDA-USA is presented as follows (Figures 3 and 4), with emphasis on the characteristics that apply to the saw blade used to perform sternotomy:

On the basis of the FDA-USA flow chart presented in Figure 3, the sternotomy blade is a critical device of simple conformation. The cleaning can be assured as shown in Figure 2.

As for functionality, the risk of a possible functional failure can be categorized as light injury because it is a "product not used in cavities or internal spaces of the human body, and, when the functional failure is discovered, it can be promptly replaced with a new one[9]".

DISCUSSION

The reprocessing and reuse of single-use products are controversial issues, although this practice is widespread in many countries. The high cost of some of them did cause an increase in hospital care costs, and this has stimulated, from the 1970s on, the growth in the reprocessing of this category of products to reduce costs. The reprocessing of single-use products can lead to recognized health risks if it is not carried out safely[10].

Entities and public agencies in other countries interfere, prohibiting the practice of reprocessing single-use devices. Agencies such as the Health Industry Manufacturers Association of the United States of America (HIMA), the Society of Gastroenterology Nurses (USA), and the Australian National Department of Health and Human Services disapprove the reuse of any product labeled by the manufacturer as single use because of the lack of rigorous tests to show the safety of this process[10].

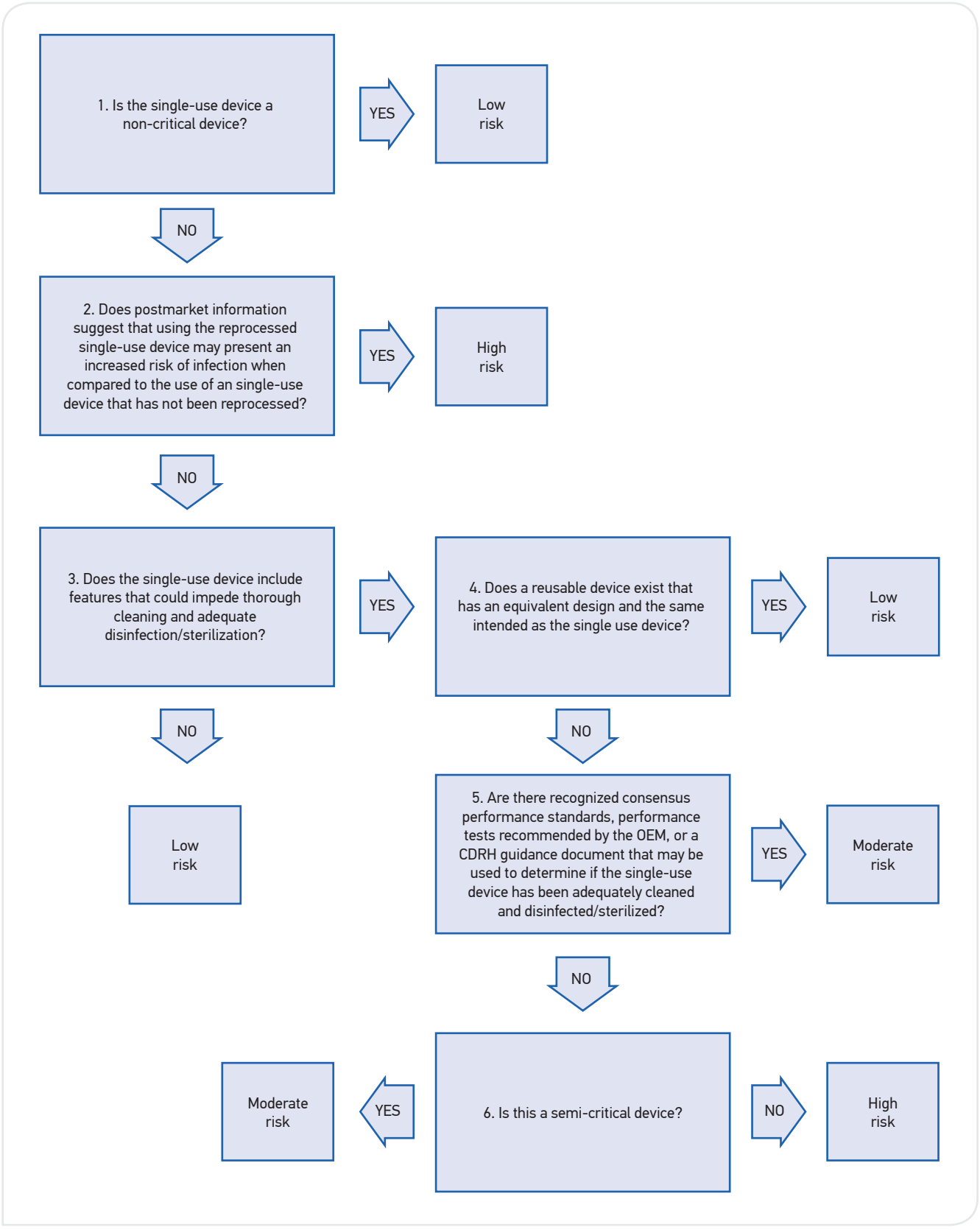
In France, the United Kingdom, Italy, Spain, and Switzerland, the reuse of single-use materials is prohibited, although the investigations in different countries adopt different rigors of the law — France and Britain have strict postures. In Africa, Asia, Eastern Europe, Central America, and South America — countries with few health and financial resources — the practice of reuse is prevalent[10].

The practice of reuse, however, is not limited to countries with few economic resources, but it is a universal problem, generating controversies[11]. Regarding the extension of the practice of reprocessing single-use devices, the American organization called General Accounting Office estimated in 2000 that 20 to 30% of the country's hospitals reused single-use devices[12]. Data from a Canadian organization, obtained through an extensive survey made in that country in 2001, suggested that 40% health institutions reprocessed single-use devices[13].

In Germany, Sweden, and the United States, remanufacturing outsourced companies process the materials under a regulation similar to the one used by the original manufacturers of the devices, following the guidelines of the Good Manufacturing Standards[13].

Though the practice of reuse is a reality, we must admit that it involves complex legal, security, ethical, and economic questions to be widely discussed[14].

The professional experience on the processes of a hospital specialized in Cardiology enabled the authors of this work to state that the single-use sternotomy blade is a widely reprocessed product in the daily routine due to the possibility of adequate cleaning and sterilization and the fact that it maintains satisfactory functionality after several processings.



OEM: Original equipment manufacturers; CDRH: Center for Devices and Radiological Health. Source: Food and Drug Administration, 2000.

Figure 3. Decision-making flow chart for the reuse of single-use products regarding the risk of infection, FDA-USA, 2000.

The lack of clearly defined criteria for the labeling of products for health as single use, which is one of the critical difficulties in the existing national legislation[8], and the professional experience of the researchers satisfactorily evaluating the performance of reused blades for sternotomy, as well as the safety in their reprocessing, led the authors to write this article based on the FDA guide "Reprocessing and reuse of single-use devices: Review Prioritization Scheme"[9].

On the basis of this decision-making flow chart, the single-use health-related products that are "noncritical" or "semi-critical," and even some "critical" with analytical judgment of low risk, may have the reuse authorized, provided there is a certainty of preserved functionality. Examples of this category would be the materials destined for the patient's health and comfort, such as bedpans, urinals, and kidney dishes (noncritical materials), Guedel cannula sets, some endoscopic and amnioscopic accessories (semicritical materials), sternotomy blades, and electrophysiology electrodes (critical materials). For this category of materials, clear routines for decontamination should be established: cleaning, disinfection, or sterilization, monitoring of the reused material's performance and criteria for disposal.

Ideally, all materials to be reused in health care should be cleaned and sterilized, but the Sterilized Material Centers have finite work capacity. Thus, the health-care facilities follow the classification based on the potential risk of these materials to transmit infection, thus classified[15]:

- **Critical** – these are the ones that come in direct contact with noncolonized human tissues and therefore considered sterile. These type of materials present high risk of infection transmission when contaminated with any type of microorganisms. Precleaning and sterilization of these devices are mandatory. For example, surgical instruments, intravenous catheters, and implant materials.
- **Semicritical** – these are the ones that come in contact with colonized mucous or broken skin (but limited to this) and can be exemplified by flexible endoscopes. The higher the density of the microbiota resident in a mucosal surface, the lower the chances of an exogenous microorganism adduced by the material to break into this place, "gaining" space. This category of materials should at least be subjected to high level disinfection after careful cleaning[16].
- **Noncritical** – these are the materials that come in contact only with intact skin, which is an effective barrier against most microorganisms, or materials that do not come into direct contact with the patient. They require cleaning with water, detergent, and friction from each use as a minimum procedure. For example, thermometers, stethoscopes, material for hygiene in bed (kidney trays and dishes), bedpans, and urinals.

This classification has been used as a guide for the adequate election of anti-infective protection methods related to materials.

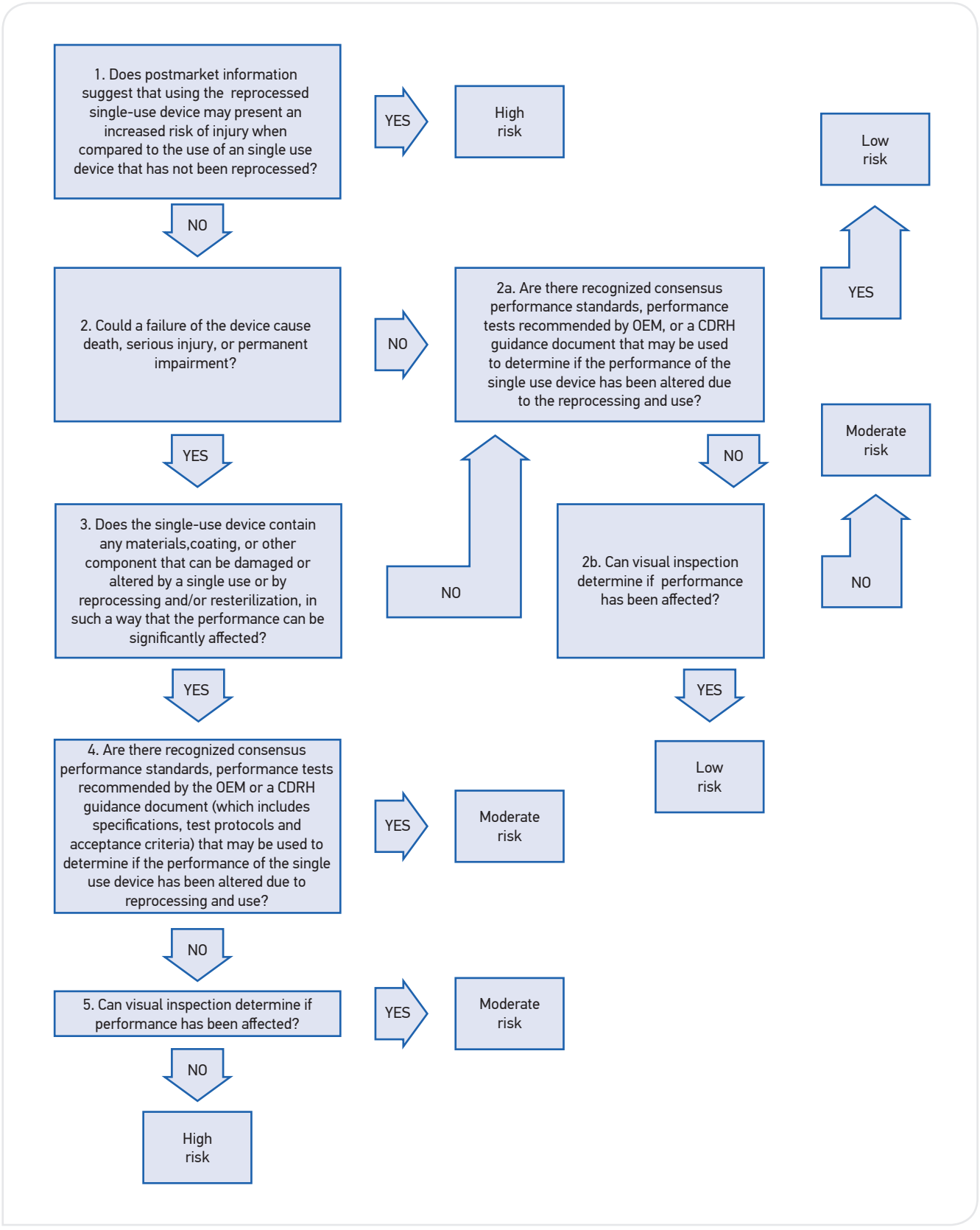
In the classification of materials, according to potential risk of infection[15], the blade used for sternotomy is classified as a critical article as it comes into direct contact with sterile human tissue.

Cleaning is considered the core of the safe reprocessing. In the literature, there are established criteria for the evaluation of the difficulties in cleaning single-use products[17]. Applying these criteria, the material in question presents zero risk. The sternotomy blade is a solid article without internal spaces and thus subject to safe cleaning, allowing the friction of its entire surface, and to sterilization by saturated steam under pressure. The unit cost of the material under analysis also justifies its reuse: a new sternotomy blade currently costs around R$ 253.00.

ANVISA, through the RE no 2606/2006[6] allows the reuse of single-use products in the conditions of absence of risk and justified reuse, but demands a reprocessing protocol with training for staff and monitoring the results.

In the institution where the authors develop their professional activities, there is a clear routine for the reuse of the sternotomy blades to guarantee the cleanliness and sterility of the blade, described as follows:

- Immersion in an enzymatic detergent solution with concentration, time, and temperature according to the recommendations of the manufacturer.
- Manual cleaning with the help of brushes with soft and firm bristles.
- Additional automated cleaning in ultrasonic washer for 10 minutes.
- Rinse in clean running water.
- Drying with the help of a clean and soft compress.



OEM: Original equipment manufacturers; CDRH: Center for Devices and Radiological Health. Source: Food and Drug Administration, 2000.

Figure 4. Decision-making flow chart for reuse of single-use products regarding the risk of inadequate performance, FDA-USA, 2000.

- Visual inspection as to the effectiveness of the cleaning and integrity of the "teeth" of the blade using 8X image intensifier lenses[18].
- Packaging in surgical grade paper/film and placing inside a metal box with the saw and the battery.
- Sterilization in a high-pressure saturated steam autoclave with prevacuum at 134°C for 5 minutes.

That said, this material, which is classified as "low risk for infection," like the majority of surgical instruments, can be safely reused concerning the issue of decontamination of critical material, refuting the single-use recommendation of the label.

As for the functional risk, the manufacturer states in its instruction manual that the stress and the tension of the cleaning and sterilization change the physical and chemical characteristics of the blade. However, it does not present supporting data that this process may lead to an injury risk. It also states that complex systems are needed to control the blade's cutting quality every time it is reprocessed, and that the cost required to test all the blades at each reprocessing, to compare them to a new blade, is high*.

Despite these indications by the manufacturer, the practice of reuse does not suggest that the reuse increases the risk of injuries to the blade when compared to a new one. The authors have no knowledge of reports of failure in the performance of the blade that has caused injuries.

So far, there are no performance evaluation tests for the blade other than the evaluation through visual inspection to ensure the integrity of the "teeth" of the blade. Although subject to questioning, the functionality of the blade used for sternotomy is verified by the cardiac surgeon during the surgical procedure, and this classifies it as of "moderate functionality risk" in the decision-making flow chart proposed by the FDA[9]. That is moderate, and not serious, because the blade with impaired function can be promptly replaced by a new one without causing harm to the patient. The Sterilized Material Center does not have know-how nor infrastructure to pretest the functionality of the sternotomy blade regarding its incision function.

Brazil is a country of scarce resources, and the single use of the sternotomy blade characterizes waste. Some manufacturers of non-reprocessable devices of complex conformation and high cost have advanced on the issue of their reuse. The surgery material industry for robotics is one of them. The clamps of the surgical kit for this type of surgery currently have a considerable unit cost of around US$ 2,500.00. The manufacturer, recognizing the need for reuse of these, authorizes a maximum number of 10 reuses, accompanied by instructions for reprocessing. One can only hope that all companies producing expensive single-use materials mirror the spirit of the robotic surgery industry!

CONCLUSION

The sternotomy blade marketed as of single use does not justify the single-use recommendation because it is a product subject to safe consecutive cleaning and sterilization through saturated steam under pressure. In addition, the functionality is preserved for several reuses. If there is a failure in the performance of the blade, the injury to the patient is considered mild because the blade may be readily replaced by a new one. The risk analysis of the reuse of the sternotomy blade marketed as single-use provided an opportunity for the reflection about the pressing need for more rigorous criteria in the registration of products as single use by ANVISA as the health regulating agency of Brazil. Although the existing legislation provides legal support for the health institutions when it comes to reusing single-use devices through validation, the reuse of single-use products causes discomfort in the relationship between the institution and the manufacturer, the health authority and the patient, and his or her family members.

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