Design and Realization of an Information System in context of medical single-use products

Sandra Cristina Nogueira Pacheco

Final Report / Internship submitted to

Escola Superior de Tecnologia e de Gestão

Instituto Politécnico de Bragança

July 2012

INSTITUTO POLITÉCNICO DE BRAGANÇA

Design and Realization of an Information System in context of medical single-use products

Sandra Cristina Nogueira Pacheco

Final Report / Internship submitted to

Escola Superior de Tecnologia e de Gestão

Instituto Politécnico de Bragança

for Master degree in

Biomedical Technology

Supervisor:

Elza Maria Morais Fonseca

Vice-supervisor:

Heidrun Ortleb

July 2012

Dedication

The God for having guided me, protected and shown where the steps that should follow, for being with me when I needed and always giving me the strength I needed.

To my parents for the example of determination and character, the strength and words always good and pride shown in the face of my achievements.

Thanks

This space is dedicated to all those with whom I could count not only the preparation of this Draft Final Master, but also to all those who have accompanied me throughout these years. Everyone is here my sincere thanks.

I thank Professor Elza Fonseca, Polytechnic Institute of Bragança, guided by the way my work in collaboration with the University of Jade, for their friendliness, willingness to aid every doubt or difficulty encountered throughout this work. My thanks for all that, and also for freedom of action that allowed me, and that was decisive for this work contributes to my personal development.

I am grateful to Professors Heidrun Ortleb and Nicole Jesse, University of Jade Hochschule / Whilhelmshaven of Germany, for I have received, supervised and guided this work during the Erasmus program. My great thanks not only for guidance and clarification of doubts, but the great effort they made to feel as if I were at home. I will remember them forever.

Thanks to my family for their support, understanding, motivation and strength that always accompanied me on this new stage of my life.

I would also like to leave a word of thanks to teachers who were accompanying me throughout these years, by the way teached and instilled in me the interest in different subjects

Last but not least, are also worth a note of appreciation that I was making friends in this city, so far from town, to Sonia companion on this journey and all those I met during the Erasmus program. Thank you for being with me when difficulties arose, and cheered me, making me sees that the best way is to always raise the head and fight for the best. Without your support and friendship it would have been much more difficult.

My heartfelt thanks to all those who took part, directly or indirectly, of this great stage of my life. All times keep in my heart forever.

Abstract

The reprocessing and the subsequent reuse of the single use medical products has been a subject of great debate and controversy in the world that has recently gained the attention of the medical industry. If, on the one hand, the people defend this practice because they need to decrease costs, on the other hand, is questionable the lack of security in the reprocessing of medical products. Among other factors, it is important to apply suitable the methods of cleaning and sterilization so there is no serious risk of contamination for the patient in touch with a reprocessed product.

It is therefore necessary to study and develop methods of reprocessing careful and effective for each product.

The main objective of this work was to develop a database about the reprocessing of single-use medical products, using the Microsoft Access 2010 tool.

In this manner, an effective and dynamic information system and dynamic was created, that would not only verify the suitable reprocessing for a medical products database, who have already into the system, but also allows the introduction of new products. This information system was developed in two languages and could be used by any enterprise or medical clinic that makes use of these products.

Keywords: Reprocessing, single-use medical device, information system, database.

Resumo

O reprocessamento e posterior reutilização dos produtos médicos de uso único tem sido um assunto de grande polémica e controvérsia a nível mundial que recentemente ganhou a atenção da indústria de medicina. Se, por um lado, se defende esta prática devido à necessidade de diminuir os custos, por outro, é questionada a falta de segurança no reprocessamento de produtos médicos. De facto, é fundamental que entre outros fatores, sejam aplicados os métodos de limpeza e esterilização adequados para que não haja riscos de contaminação graves para o paciente, que venha a fazer uso de um produto reprocessado.

Por este motivo é necessário estudar e desenvolver métodos de reprocessamento cuidadosos e eficazes para cada produto.

O objetivo deste trabalho é apresentar o desenvolvimento de uma base de dados que permita verificar qual o melhor reprocessamento de produtos médicos de uso único, utilizando a ferramenta Microsoft Access 2010.

Desta forma, foi criado um sistema de informação eficaz e dinâmico que permita não só verificar qual o reprocessamento adequado para uma base de dados de produtos médicos já introduzidos no sistema, mas também que possibilite a introdução de novos produtos. Este sistema de informação foi desenvolvido em duas línguas e poderá ser utilizado por qualquer empresa ou clínica que faça uso deste tipo de produtos.

Palavras-Chave: Reprocessamento, produto médico de uso único, sistema de informação, base de dados.

Index

Index of Images

Index of Tables

List of Abbreviations

HIV – Human Immunodeficiency Virus

CEE – European Economic Community

INFARMED – National Authority of Medicines and Health Products

FDA – Food and Drug Administration

ANVISA – National Agency of Sanitary Surveillance

CCIH – Control Committee and Hospital Infection

CME – Central Supply Sterile

DNA – Deoxyribonucleic Acid

RNA – Ribonucleic Acid

TASS – Toxic and Segment Syndrome

SQL – Structured Query Language

DBMS – Management System Database

DDL – Data Definition Language

DDQ – Data Query Language

DML – Data Manipulation Language

ID - Identity

VBA – Visual Basic for Applications

Chapter 1- Introduction

1. Introduction

The present work was developed under an Erasmus internship at Jade Hochschule University, in Wilhelmshaven, and it is included in the final project of the Masters in Biomedical Technology. The approach was mainly focused on the contextualization and development of an information system that reprocesses the single use of medical products through a database. The information system developed also allows the use through an interface in Portuguese or English.

In 1948, medical materials, designated as single-use materials were introduced in health services. Their purpose was to provide for public health care, materials easy to use and that at the same time enabled the reduction of the workload due to the fact they were disposable and in result avoid the reprocessing process [1]. With the evolution of technology these products became complex and increasingly used in hospitals and medical facilities, once its advantage were indisputable, mainly in the area of the video-assisted surgery [2].

In spite of its advantages, the cost of some of these products is quite high; therefore, institutions that never reprocessed began to do so due to the lack of economic power on public health. However, the reprocessing of single- use materials resulted in a great controversy worldwide. On one hand this practice is defended given the high cost of these materials, on the other hand, the lack of safety in single- use reprocessed materials, due to the effective cleaning, disinfection and sterilization methods not always are applied, possibly causing serious problems for the patients, has generated a lot of questions regarding the reprocessing and reuse of these materials [1, 2, 3]

Reprocessing or not the single- use medical products became a complex problem involving several ethical, medical, technical, economic, environmental and legal questions [1]. We should, however always pay special attention to the associated risk with this practice where there is the verified possibility of infection, endotoxins contamination of the material, the presence of toxic residues of the products used during the cleaning, sterilization or disinfection, biocompatible protein of patients who used these materials that can remain, functional reliability, absence of physical integrity and of material barriers, among others [1, 2]. However, the risk associated with the reprocessing of this kind of materials is unstable, varying accordingly to the type of material and its interaction with the human being.

The reprocessing and subsequent reuse of single use material should be very well thought of due to the possibility of causing physical a psychological harm. Besides al the mentioned issues two fundamental conditions should be verified, the possibility of complete and adequate cleaning, and the possibility of the product being tested for integrity and functionality, in accordance with their intrinsic characteristics. If these two conditions aren't verified shall not proceed with the reuse given the great risk of producing health threats to the patients.

In order to better clarify the reprocessing of single use medical products, and verify the steps they should be submitted to so that they can be reused, was developed through this work a database tool in Microsoft Access 2010.

1.1 Work Contextualization

This is work consists of different chapters, which will be briefly presented ahead.

Chapter 1 introduces to the topic, developing generally the current state of the single-use medical products reprocessing.

Chapter two aims to define some important concepts with a general approach to the medical devices focusing on the characterization of reusable products.

Chapter 3 explains the entire process of reprocessing and reuse, developing several other topics, such as the current situation of this process in the world, its advantages, disadvantages, risks and steps.

In Chapter 4 there is an approach to the single use products in orthopedic rehabilitation so that the influence of type, form, and other factors in the reprocessing is explained.

Chapter 5 reflects the practical side of this project, where it is presented the products structures and it is explained in depth the whole system of information developed in form of a database. The information system is developed in two languages. Allowing the user to select the process for reprocessing and/ or the introduction of new products in the database.

At last chapter 6 presents some conclusions and also some topics of interest for future development.

Chapter 2- Medical Products

2.1 Concepts and Terminology

In this chapter all the fundamental concepts needed for the full comprehension of this work are explained.

Reprocessing

The process applied to medical products in order to allow its reuse [4, 5].

Infection

Infection is verified when there is the presence and multiplication of microorganisms in tissues, fluids and body surfaces causing adverse effects. Infections can be caused by bacteria, viruses, fungi, protozoa and parasites. In a hospital environment, bacteria are the most common [4, 5].

Nosocomial infection

If an infection is acquired in a hospital environment, where there isn't any indication that the patient had any signs of infection, was not even in the case of incubation at the time of admission to hospital, the infection is considered a nosocomial infection [4, 5].

Contamination

When there is dirt in inanimate objects and material that can be easily infectious, such as organic fluids or inorganics substances such as powders or chemical waste, the existence of contamination is considered. Thus, all materials that have been used in the diagnostic or therapeutic procedure, or that have been exposed to clinical situations are considered contaminated. These materials should be regarded as biohazards and require specific conditions for handling, transport and reprocessing [4, 5]. The image 1 represents a contaminated hospital equipment.

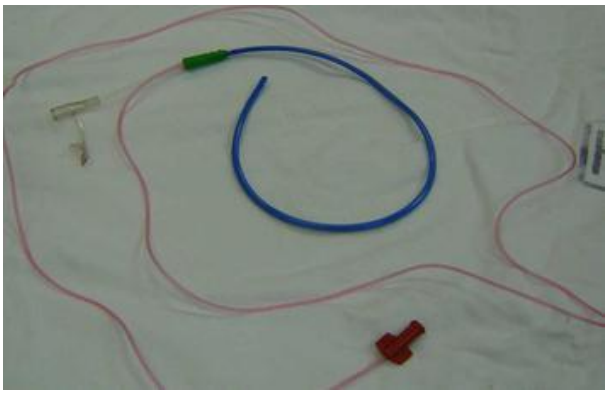


Image 1- Example of a hospital medical product contaminated with blood [6].

Decontamination

In order to reduce microorganism that may exist in the materials after their use and to make these materials safe for handling a procedure of decontamination should be performed. Decontamination is a process which includes three different levels: cleaning, disinfection, sterilization [4, 5].

Cleaning

Cleaning is the process of removing the dirt with a mechanical action, applying water with soap or detergent. This method has a removal efficiency of 80% of the organism, followed by the steps of disinfection and sterilization [4, 5].

Disinfection

Disinfection is the physical or chemical process that causes the destruction of most or even all of the pathogenic microorganisms, with the application of a disinfectant. This process is between 90% and 99% effective [4, 5].

Sterilization

Sterilization is the process applied to make a product free of viable microorganisms. This process can destroy or completely remove all type of microorganisms, including those resistant to most disinfectants and heat, such as spores [4, 5].

2.2 Devices

Devices or medical products are all the instruments, apparatus, equipment, materials or articles used both individually or combined, including software's used specifically for diagnosis or therapeutic purposes necessary for the proper functioning of medical devices. In image 2 shows some medical devices.

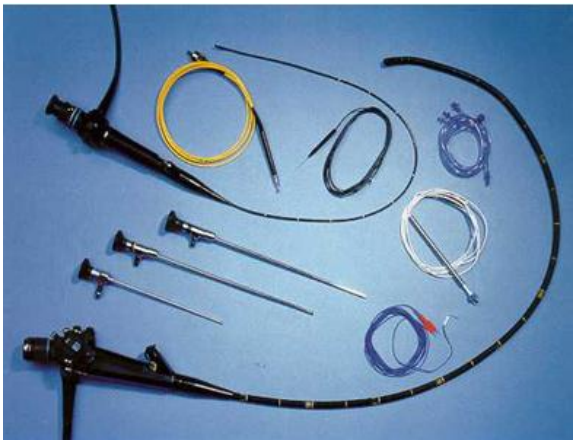


Image 2- Example of some medical devices [12].

Although these devices can be supported by pharmaceutical, immunological or metabolic means, their main effect can't be reached by these means. These devices are used by the manufacturer in human beings to obtain certain results, such as:

- Diagnosis, prevention, monitoring, treatment or mitigation of a disease;
- Diagnosis, monitoring, treatment, mitigation or compensation for an injury or disability;
- Study, replacement or modification of anatomy or a physiological process
- Conception control [6,7,8].

2.3 Classifications of Medical Products

According to the classification by Alvarado in Spaulding magazine [9, 10] medical products can be classified as critical, semi-critical and noncritical. The classification is the following:

- Critical products are those destined for penetration of the skin adjacent mucosa, sub-epithelial tissue and in the vascular system and as well as those directly connected with this system. These products have direct contact with blood and other contaminating fluids. In order to satisfy the goals intended for these products it is necessary previous sterilization. Some examples of critical products are chirurgical instruments, syringes, needles, gynecological speculums, among others [6, 7, 8, 9, 10].
- Semi critical products are all of those destined to enter in contact with broken skin of the patient or intact mucosa. These need high level disinfection or sterilization so that its quality and multiple uses are guaranteed. Some examples of these kinds of products are autoscope points, ambus, nabulizators among others [6, 7, 8, 9, and 10].
- Non critical products are all the products intended for external contact with the patient, interacting with integral skin. Only require cleaning and disinfection of low or medium level accordingly with the type of last use and the destined use. Thermometers, buttons of equipment used by the professionals, auxiliary tables for procedures, vats, among others, are some examples. [6, 7, 8, 9, 10].

Table 1 presents some medical products according to their classification [11].

Medical products can also be inserted in two large groups according with the possibility of being reutilized or not. Therefore we have those designated as single-use products which reuse is forbidden or those that are included in medical products that can be reused if submitted to several feasible techniques that ensure safety and don't alter their functional and original characteristics [6, 7, 8].

Then, there are the single-use products and reusable products. The reusable products are defined as any medical device, ontological or laboratorial whose destination is to be used for prevention, diagnosis, therapy, rehabilitation or contra conception, which can be reprocessed according to a validated protocol [8]. Single-use medical products are those used for prevention, diagnosis, therapy, rehabilitation or contra conception that can only be used once, according to manufacturer [6, 8].

Table 1- Example of some medical products and their classification.

Critical	Semi critical	Non critical
Cirurgichal instruments, metal instruments	Inhalers, nebulizer mask, plastic extenders, Guedel cannula	Thermometers
Tubes of latex, acrylic, silicone, Teflon	Válvulas de ambú with metal components	Sphygmomanometer coated with plastic
Glass and rubber for aspiration	Laryngoscope blade (without lamp) laryngoscope bulb	Laryngoscope cable
Fiber Optics: endoscopes, laparoscopes	Endoscopy of the digestive and respiratory field	Adapters and cables

Chapter 3- Reprocessing and Reuse of Medical Products

3.1 Brief Introduction

Initially the products now regarded as single-use medical products were designed to be reused. In fact, their characteristics, like design size and/ or the material they were made of, rubber, glass and metal, allowed their reuse once steam sterilized. Thus, these products were reprocesses from a simple swab, followed by saturation in disinfectants and finally, re-sterilized in heat [10, 13].

Since the 60's and with the development of plastic medical products, there was a preference for materials easily available and use, without any concern for the average lifetime, maintenance, malfunctioning, sterilization, among other factors [10, 13].

In the 80's transmissible diseases by blood appeared, such as hepatitis and HIV. In consequence, the risk of contamination between patients due to the increased use of sterilized products, so the use of single-use products developed [10, 14].

This way, science in conjunction with the advancement of technologies led to the development of single-use medical products increasingly sophisticated, complex and easier handling. The majority of these products were made of plastic, and therefore nonresistant to neither aggressive chemical treatments nor high temperatures. There were also new devices for performing not very invasive procedures with narrow lumens and more delicate mechanisms. Thus, the cleaning and sterilization process became more complicated also leading to the single-use medical products [10].

3.2 Reprocessing of Reusable Products

There are several medical devices at the time of the design process takes into account their future reuse by so the choice of raw materials and design is important [10]. When a reusable product is made it's necessary that the manufacturer provides information about the suitable process for reuse, including the different steps of cleaning, disinfection, storage, sterilization method and the number of times that it can be reused. Thus, the validation of the process of reprocessing to be used by the manufacturer in accordance with the design and material used in the device is ensured. Therefore, there is no alteration in the device by the process of reprocessing, so it will have a better performance and will be safer for a pre-determined number of reuses [10, 13].

3.3 Reprocessing of Single-Use Products

The single-use medical products aren´t designed as reusable, so the manufacturer does not have to provide any information in order to ensure and allow their safe reprocessing. The manufacturer only has to provide information about the characteristics and technical factors that can possibly bring any risks when reused. The user or reprocessing provider can define the most adequate procedure. According to the report of the Netherlands, the validation of the reprocessing process and, in particular, cleaning phase for single-use medical devices, cannot be performed in hospitals due to the lack of equipment, knowledge, experience and resources [10, 14, 15, 16, 17].

Note that the reuse of these kind of materials is not without risks to public health, beyond that one must take into account the relevant ethical, legal liability, economic and environmental reprocessing of single-use medical products [10,14,15,16,17].

These products must be reprocessed when: are opened and used, opened but not used, open and casually not used, expired or for [10, 14, 15, 16, 17].

3.3.1 Reprocessing in the European Union

Regarding safety and performance of medical products rules were changed in the 90's, with the directive 90/385/CEE of the council of 20th July of 1990 in accordance with the member-states legislations relating to active medical devices. Later this directive has been replaced by the directive 93/42/CEE of the council of 14th June 1993, concerning medical devices and by the directive 98/79/CEE of the European parliament and council of 27th October 1998, respecting the medical devices for diagnosis in vitro. These directives are the basis for the legal framework applicable to medical products, and aim to ensure a high level of protection of human health and safety and the functioning of the internal market. These state that [10]

> *"Not all single-use medical devices are subject to reprocessing, and this possibility depends on the material and geometry of the medical devices. (…) it is necessary to evaluate and validate the complete reprocessing cycle, including its functional performance from collection, after first use until the final sterilization and completion of the process."*

And also

> *"(...) the commission shall evaluate what measures should be proposed in the Review of medical devices regarding the reprocessing of single-use materials, to ensure a high level of protection for patients. The evaluation also will take into account potential economic, social and environment consequences of the measures."*

On September 5, 2007, the directive 93/42/CEE was changed for the last time, resulting in the directive 2007/47/EEC of the European parliament and the council in order to answer some concerns about patient safety providing additional clarification on the term "single-use". This new directive states that [10]:

> *"« single-use device» is a device destined to be used a single time in a single patient",*
>
> *The indication by the manufacturer that it is a device for single-use must be uniform through the community;*
>
> *If the device indicates it is for single-use, in the instructions of use must be provided information about known characteristic and technical factors that the manufacturer is aware that can be a risk in the case of reuse."*

Generally there is no policy of support for the reprocessing of single-use medical products in any regulatory authority, thus this practice is regulated by several national legislations. Germany is one of the few countries that allows this kind of practice and develops guidelines, however certain countries like France ban this practice and some member states don't have any specific regulation regarding this issue. Concretely and naming some European Union countries [17, 18, 19, 20]:

France, Italy and Spain- prohibit the reuse of medical products and have the some specific tools.

Sweden- allows the reuse in accordance with the requirements of the Medical Device Directive 93/42/EEC. Patients should be aware of the conditions for reuse.

United kingdom- does not allow the reuse of single-use medical products whatever the circumstance. However, England allows the reuse in monitored conditions, due to the concern about prions.

Finland- allows the reuse in accordance with the requirements of directive 93/42/EEC and requires that the reuse products function in similar ways and with

equivalents risks to those products without use. Safety and efficiency of the reused devices are the hospitals responsibility.

Germany- the reuse of single-use medical products is common, according to the validation of reprocessing and supervision from the country's sanitary authorities. It is not necessary that single-use devices have a label; there isn't any distinction in German law between single-use and multiple use products regarding their reprocessing. This country follows the directive 93/42/EEC from the national health council, the national health and security authority, national and international standards and the recommendations of scientific societies. It also has a Quality Management System governed by the complete system of quality management for medical devices, such as EN ISO 13485, with tracking and surveillance.

Portugal- INFARMED in 2010 announced an opinion of the Scientific Committee for Emerging Health Risks Recently Identified (CCRSERI), which states that:

> *"Not all single -use devices can be reprocessed, this possibility depends on the material and geometry of the device (...) it is necessary to evaluate and validate the complete reprocessing cycle including its functional performance from collection until completion of the process"*

Therefore it is possible to state that Portugal does not have any legislation prohibiting the reprocessing of single-use medical products.

3.3.2 Reprocessing Internationally

Internationally it should be noted:

USA- acquired the policy where the reused devices should be as safe and effective as the new devices. The Food and Drug administration (FDA) has been studying a safe way to reuse these devices in order to make the hospitals re-manufacturers and reinforce the idea of standards to control their quality [17, 18, 19, 20].

Canada- defends the reuse; however this practice is once again discussed and in consequence banned in some states. The reuse is not supervised by Health Canada since according to the laws it does not have the authority to do so [17, 18, 19, 20].

Australia- the reuse of single-use medical products is not approved by the Agency for Control of Therapeutic products, by the Health Department and by the National Council

of Experts. The companies that proceed with the reprocessing of a single-use product become the manufacturer of the reprocessed device, applying the appropriate assessment process [17, 18, 19, 20].

Japan- prohibited the reuse and the single-use devices should be labeled informing their condition and also prohibiting their reuse [17, 18, 19, 20].

Brazil- The reprocessing is allowed and it is one of the responsibilities of the health services. The companies and institutions that reprocess medical products must follow protocols in accordance with the guidelines of the ANVISA (National Health Surveillance Agency), and should be elaborated, validated and implemented according to the steps proposed by resolution 606/06. The Brazilian Association of Nurses from chirurgical, anesthesia recuperation, material center and sterilization advises that the institutions that proceed with the reprocessing should make a commission formed by the administrative director, nurse manager, CCIH member, chirurgical nurse, medic coordinators form usual units and chirurgical and a lawyer [17,18,19,20].

3.4 Advantages and Disadvantages of Reprocessing

Although it is a delicate and controversial matter, the reprocessing of single-use medical products has several advantages such as: cost reduction in what concerns the acquisition of new disposable products, since they are between 40% to 60% cheaper than the last (study held at hospital of São João in 2011, found that the reprocessing of these products would lead to savings of 1.091.900 euros per year), reduction of hospital and biological waste with a beneficial effect on the environment, identical safety to reusable medical products (" after reviewing the 8 year long dada of the FDA, the government accountability office concluded that: " there is no evidence that reprocessed single-use devices create an elevated health risk for patients" [21]), decrease in costs related to packaging, better management of environmental resources, improvement of health care due to the availability of budgetary resources for other activities and the avoidance of reprocess without quality or monitoring [19,20,21].

It should be noted that reprocessing companies grantee the individual analysis of each product, its tracking, but in the case of the reusable products are analyzed just by sampling [19, 20, 21].

Regarding the disadvantages you can point out the pyrogenic effects, the sterilization processes aren't able to completely eliminate the endotoxins, the repeated use of these products can lead to their functional deterioration, elevated costs related to the reprocessing activity, such as: facilities, equipment, validation/monitoring, training/qualifications, additional costs and indirect, for example, the processes or the patient's pain and his family, the negative impact on the environment due to detergents, disinfectants and solvents, and the fact that reprocessing isn't developed enough, and thus it is not 100% reliable for repeated use of these products [19,20,21].

Note that the subsequent reprocessing and reuse of single use medical products is ultimately rejected because of ethical, economic and technical, as seen in image 3. Thus, in accordance with image 3 you can see that 30% of the reasons for rejection of reprocessing are economic, 48% are due to technical exclusion and 22% of reasons are ethical. Regarding the economic issues, since the processes of reprocessing aren't developed enough, some products are not advantageous for reprocessing, which isn't feasible due to the fact that the validation process is too expensive, has a small number of products for reprocessing and risk of radioactive contamination. The technical reasons are fundamentally the impossibility of reprocessing implants and devices for prolonged use. What concerns the technical issues, these relate to the limitations of the process of reprocessing, specifically the lack of information about the product, it is impossible to disassembly and reassembly, the incompatibility with the process and insufficient steps for cleaning and disinfecting [19].

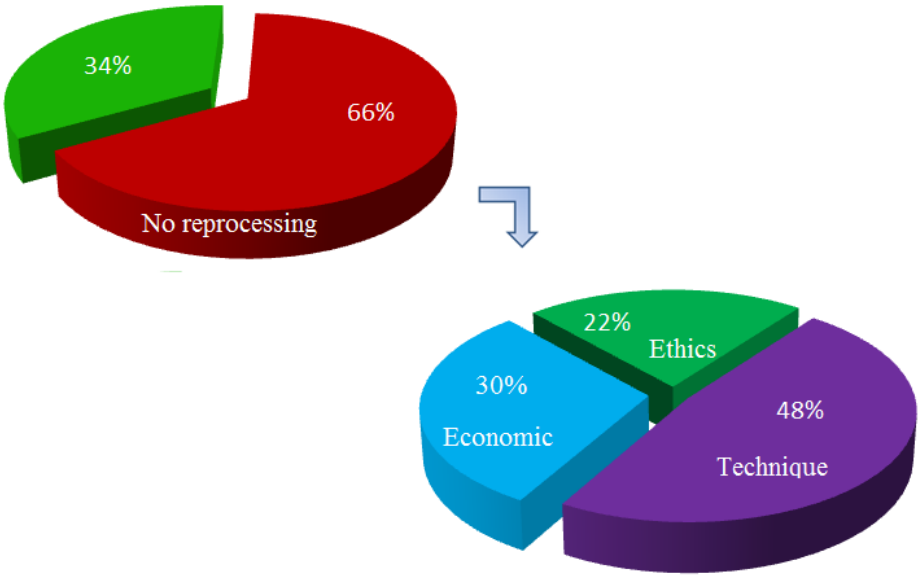


Image 3- Main reasons for not reprocessing single-use medical products.

3.5 The Reprocessing of Medical Products and Steps.

The reprocessing of single-use products should be carried according to a logic that includes several steps, depending on the type of products involved. These steps are: preparation, cleaning, drying, evaluation, packaging, labeling, disinfection, sterilization and quality control in order to obtain more efficiency with reprocessing so that there is no transmission and storage of microorganisms [11]. The flowchart in image 4 represents the general procedure for reprocessing medical products.

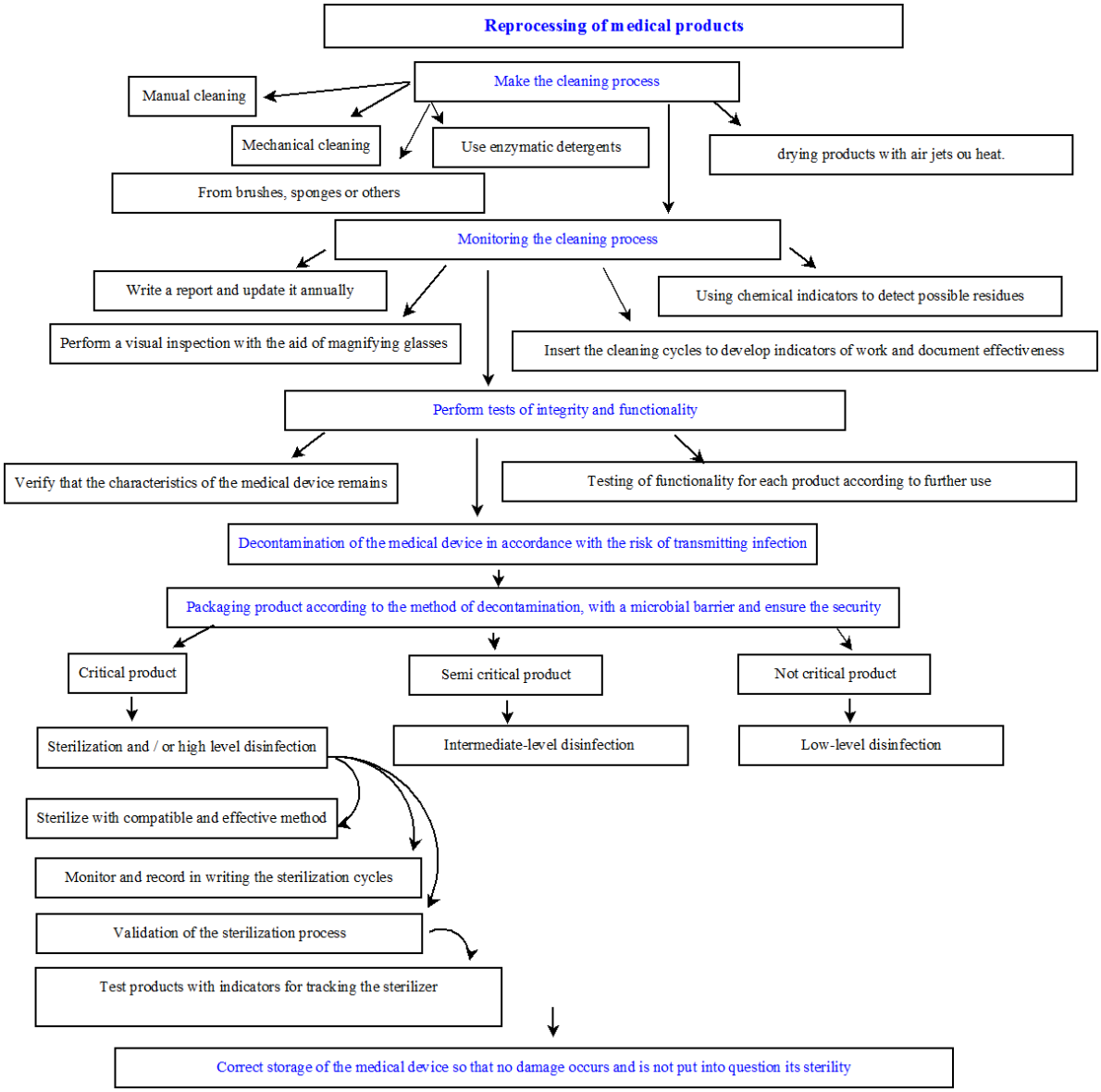


Image 4- General steps of the process for the reprocessing of medical products.

The quality of this procedure is essential mainly for safety of the users when performing invasive procedures and prevention of nosocomial infections since these products have a great risk of acquiring microorganisms either for the patients or for professionals if they aren't properly clean, disinfected or sterilized [4,5,11,23,24,25].

Thus it should be taken into account the sorting of articles are grouped to critical, non-critical or semi critical according to their potential for transmission of microorganisms that can cause infections and apply the most appropriate reprocessing method [4, 5, 11, 23, 24, 25]. The table 2 summarizes the type of products depending on to the level of infection and recommended treatment [4].

Table 2- Relationship between the type of product, risk of infection and level of treatment.

Product Type	Product Classification	Risk of Infection	Treatment Level
All products intended for penetration of the skin and adjacent mucous sub-epithelial tissue and the vascular system as well as those who are directly connected to this system.	Critical	High	Sterilization High-level disinfection
All products intended to contact with broken skin or the intact mucous.	Semi Critical	Medium	Intermediate-level disinfection
All products intended for the external contact with the patient interacting with intact skin and to not come into direct contact with the patient.	Non Critical	Low	Cleaning

According to the geometric shape and classification it should be assured appropriate reprocessing, meaning, ensure safe products with the same integrity as before use. This is important so that the reprocessed material don't present damages or risks to its structure that may interfere with functionality and contamination [23, 24].

3.5.1 Preparation

All medical products should be considered infected regardless the level of dirt.

The product must be reprocessed shortly after its use to prevent buildup of residue formed by blood or protein. These must be removed, if possible, and pre-soaked, and keep submersed in water for a few minutes in order to get rid of part of the dirt and facilitate the cleaning step. It must be used a soft brush must be used in order not to damage the products and their delicate tips, in order to get rid of all the blood, body fluids and fragments [23, 24].

3.5.2 Cleaning

This is the most important step of reprocessing because if it is improperly processed it can result in failure in any sterilization process performed. That is, if the cleaning process doesn't remove the grease and dirt of the products, these will act as a protection for the microorganisms acting as barrier of contact between these and the sterilization agents (chemical, physic or physical-chemical). It must be applied afterward the use and preparation of the product to prevent dryness of the secretions that has been exposed, such as blood, respiratory secretions or feces [11, 25, 26, 27].

At this stage it is not advised to emerge the products in germicidal solutions because we don't know the level of protection that this process can offer due to the fact that solutions 'activities decrease with the presence of organic matter. It should be noted also, other disadvantages such as the high cost, the impregnation of organic matter in the products, the toxicity of the same and the environment damages caused by the dumping of large volumes of disinfectants in the sewage system [11,25,26,27].

For a proper cleaning and decontamination in order to diminish the handling of contaminated material we should choose a cleaning equipment with a physical processes, such as the thermo-cleaning machines disinfectants [11,25,26,27], as you can see on image 5.

Image 5- Thermal disinfectant machine [12].

In order to reduce the occupational hazards, facilitating the mechanical action, enzymatic detergents should be used because they remove the organic matter, are nontoxic and biodegradable. Without these, the products should be emerged in running tepid water [11, 25, 26, 27].

One can also use ultra-sonic washing machines like the one represented in image 6, that increase the detergents action due to the presence of ultrasound, preferably indicated for non-disable materials, like the single-use materials. These manual machines make possible the cleaning of the inside part of materials that brushes can't reach. Thus and from cavitation, process that forms exploding bubbles in the materials surface produced by the vibration of ultrasound crystals. These function as suckers creating negative pressure in order to detach the dirt on the materials surface. However, if the materials allow the fitting, an ultra-sonic machine with pulse jet should be used, because it is more effective [11, 25, 26, 27].

Image 6- Ultrasonic cleaning machine [29].

If it is not possible to use any of the above methods, we should proceed with a manual cleaning by rubbing with the aid of a sponge or a brush, like the ones represented on image 7. However this method can only be used after immersion of the contaminated product in enzymatic detergents [11, 25, 26, 27].

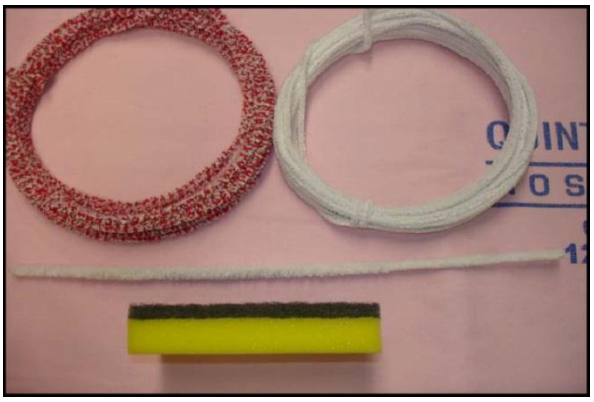


Image 7- Sponges and brushes used in manual cleaning [8].

Cleaning methods can be divided between physical if made with help of a special brush, sponge, water guns or compressed air and equipment like the thermal – disinfectants, ultrasonic disinfector or chemicals used with water, enzymatic detergents or hydrogen peroxide. It can be said that the manual cleaning is only the one made by brushing the dirt and it is mechanical when washing machines, ultra-sonic or thermal-disinfectants with turbulence, are used [11,25,26,27].

In case of the single-use products the suitable choice of method must be made considering the difficulty of cleaning. This way, low risk materials are those that can be dissembled totally or partially, transparent so that the level of dirt can be assessed, that allow the entrance and exit of water allowing the internal cleaning [11, 25, 26, 27].

The washing must be performed in running water. The water must be of good quality because of the several heavy metals e chlorine which causes the corrosion of the products [11, 25, 26, 27].

Once the cleaning process is over, validation is necessary which can be done in several ways, such as: simple visual analysis, expanded visual analysis using a lens, from tests to verify the effectiveness of the mechanical action and tests for detection of residues [11, 25, 26, 27].

3.5.2.1 Products Used in Cleaning

In the cleaning step may be used non-enzymatic or enzymatic detergents. Enzymatic detergents are detergents based on enzymes, especially proteases, lipases and amylases which besides causing the dispersion, emulsification and solidification also remove organic substances of the products. Are biodegradable, neutral concentrates, non-oxidizing with bacteriostatic action and therefore does not cause infection. Non-enzymatic detergents have low alkalinity of the associated anionic surfactant or anionic and nonionic whose formulation is based on polyphosphate, alkalizing agent and antioxidant agents [11, 26].

3.5.3 Drying

Prior to disinfection and sterilization it is required to dry the product since the presence of humidity can affect it. To perform this step it is recommended to use hot air dryers or greenhouses suitable for drying, medical compressed air (used mainly in products that have lumen) and clean rags, absorbent and dried pads [11, 25, 26, 27], as exemplified in image 8.

Image 8- Drying medical products using pads [8].

After this, it's necessary to check the material, preferably with the aid of a magnifier in order to detect any oxidation, secretions or wet. Can also be used 70% ethyl alcohol as a means of friction in order to make a more rapid drying process [11, 25, 26, 27].

If it is desired to increase the life of material one can be lubricate it with non-toxic and anti-corrosive products [11, 25, 26, 27].

3.5.4 Disinfection

The disinfection may be divided into three different types [11, 25, 26, 27]:

- **High-level disinfection**- causes the destruction of all vegetative bacteria, micro bacteria, fungi, viruses, and part of the spores. The washing should be done with sterile water and aseptic handling.
- **Intermediate-level disinfection** -results in the destruction of viruses, vegetative bacteria, but does not kill the spores.
- **Low-level disinfection** -allows the destruction of all bacteria in their vegetative state but does not destroy the spores, non-lipid viruses. It can destroy some fungi.

The disinfection of hospital products can be made from physical, chemical and physical-chemical methods [11, 25, 26, 27].

The physical methods are made from physical agents and the products are immersed in water at 100 ° C for about 30 minutes. These methods should be performed using automated systems and thermal-disinfectant machines with specific programs for different product groups [11, 25, 26, 27].

The chemical methods employ chemical agents who can only be applied to thoroughly cleaned and dried products which are then immersed in a disinfectant solution [11, 25, 26, 27].

The product must be completely immersed in the disinfectant because it works on contact. If the product has hollow areas, they shall be entirely the disinfectant solution. The container used for disinfecting must be made of plastic because in case it is metal can generate galvanic current and wear out the material, whereby this latter must be covered with tissue [11, 25, 26, 27].

After disinfection one should proceed with the washing of products with good quality water [11, 25, 26, 27].

3.5.4.1 Active Products Used in Chemical Disinfection

For that it can be safely used, the recycled products should be used with some active principles, such as: aldehyde (formaldehyde or glutaraldehyde), phenol (synthetic

phenol), quaternary ammonium, organic and inorganic compound-releasing active chlorine, alcohol, glycols, biguanides and peroxides [11, 25, 26, 27].

Aldehydes

Glutaraldehyde- displays bactericidal activity, viral, fungicidal and spore. The biocide activity occurs from a chemical alkylation reaction, resulting in the modification of DNA, RNA and protein synthesis of microorganisms. While the spores activity is given by hardening of the cell's walls of the spores. Their action will depend on factors such as the exposure time and conditions of the product. The product must be properly cleaned and dried to facilitate penetration of the agent [11, 25, 26, 27].

The detergent should be applied to high-level disinfection on thermo sensitive products for a period of 30 minutes of exposure in a 2% solution. It can also be applied as a sterilizer for an exposure period of 8-10 hours. It shouldn't be applied at temperatures above 25 ° C as it experiences changes in these cases. If there are changes in color and presence of deposits the solution must be replaced according to the recommendations of the manufacturer [11, 25, 26, 27]. Image 9 represents an example of Glutaraldehyde solution monitoring.

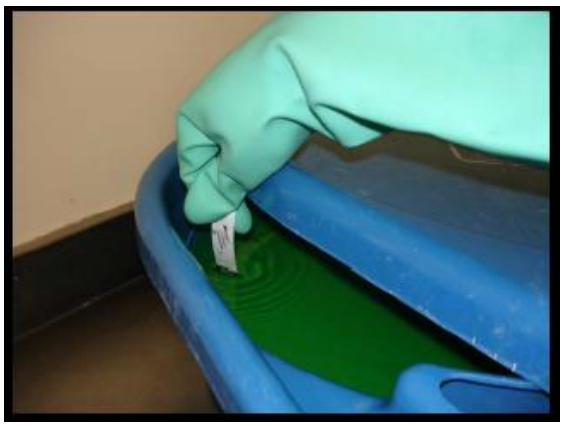


Image 9- Glutaraldehyde solution monitoring [9].

It shouldn't' be used in ventilated places since it is toxic and not biodegradable. The acid solutions made of this detergent base to have a lower micro biocide action and the lower corrosion than the basic solutions [11, 26].

Besides being used for disinfection it can also be used in sterilization by chemical methods [11, 25, 26, 27].

Formaldehyde- works similar to Glutaraldehyde and showed better at temperatures above 40 ° C. When it comes to disinfection and sterilization processes it can present some disadvantages such as low penetration power, non-uniform distribution and high toxicity [11, 25, 26, 27].

According to the manufacturer is applied at various exposure times. If it is used in the disinfection step should be applied a 4% solution for about 30 minutes, but if it is used in the sterilization step must be applied an 8% alcoholic solution or an aqueous solution at 10% for a minimum of 18 hours [11, 25, 26, 27].

This detergent also presents a solid form such as the formaldehyde polymers, commonly known as "formalin pellets". The sterilization step, in this case is performed with a 3% concentration in an oven preheated to 50 ° C for a period of time equal to four hours and a relative humidity of 100%, exemplified in image 10. It is not widely used because of its technical implementation in ideal conditions, it is extremely complicated [11, 25, 26, 27].

It may also be used in sterilization by chemical methods.

Image 10- Greenhouse for disinfection by formaldehyde in a medical product [8].

Alcohols

The alcohols acting from the denaturation of the proteins from the microorganisms and their bactericidal action increases if they are hydrated. Presents action tuberculicide fungicide, virucide but does not destroy the bacterial spores [11, 25, 26, 27].

Isopropyl alcohol- has a selective virus action, is more toxic and less germicide than alcohol [11, 25, 26, 27].

Ethanol alcohol at 70% (concentration equal to 77% which corresponds to 70% in weight) - and the toxicity is low and recommended for disinfection of intermediate or

medium level. In order to produce good results is to be used by rubbing, with three applications, spontaneous drying and during an exposure period of 10 minutes [11, 25, 26, 27], as image 11.

Image 11- A medical disinfection with 70% ethyl alcohol [30].

Inorganic Chlorine-Releasing Compounds

Examples of these compounds are: sodium hypochlorite, calcium or lithium. They are unstable products, thermo sensitive, photosensitive and inactivated when in contact with organic material such as blood, feces or tissue, with diminished activity when used in clear containers or high temperature. They cannot be used in metal since they are corrosive. It should be stored for a maximum of six months when it is in its diluted form. Usually, the sodium hypochlorite is marketed in liquid form, while the lithium and calcium hypo chlorites are easily available in powder form [11, 25, 26, 27].

These products can present hostile effects due to the fact that they are toxic and irritating to skin, mucosa and respiratory tract [11, 25, 26, 27].

Organic Chlorine-Releasing Compounds

These compounds exist only in a powder form. Comparing to hypochlorite they have a higher micro biocide activity, lower pH, increased stability, less corrosive and less toxic, are not as easily inactivated in the presence of organic matter and can be stored for a period of one year. It is recommended dilution when used because once active they become very unstable [11, 25, 26, 27].

Phenolic

They are used as disinfectants of intermediate level. Their toxicity has causes its lack of use and should never be used in disinfection of obstetric centers under the risk of causing hyperbilirubinemia in newborns [11, 25, 26, 27].

Iodine and Derivatives

It isn't common to find iodine for disinfection of hospital products or surfaces for these aren´t used often [11, 25, 26, 27].

Biguanides

They are commonly found only for antiseptics uses [11, 25, 26, 27].

Ammonium Quaternary

Low toxicity and are recommended only for the disinfection of surfaces, and in critical areas semi critical [11, 25, 26, 27].

Per Acetic Acid

It is a high level disinfectant which action may extend to bacteria, viruses, fungi and spores. Acts as an oxidizing agent which promotes protein denaturation with rupture of the cell membrane permeability. Does not become inactive on contact with organic material and does not promote the formation of toxic waste, however, is unstable and corrosive when diluted [11, 25, 26, 27, 29].

The inactivation of microorganisms depends on the exposure time, temperature and concentration. When used in concentrations varying from 0.001% to 0.002% has a rapid and effective action against microorganisms, including spores [11, 25, 26, 27, 29].

3.5.5 Packaging and Labeling

The process of packaging a product is made according to some factors such as the shape, size, and the means of sterilization and use of material, as exemplified in Image 12. This allows saving time and material, facilitate the work of the employee and maintain the standard of quality.

According to the procedure chosen one determines the contents of the packages. Thus, the packaging of products for sterilization should (11, 25, 26, 27):

- Be suitable for the places and methods of sterilization;
- Be safe and resistant;
- Provide a suitable barrier;
- Be compatible with the physical conditions of sterilization;
- Enable the removal of the air;
- Allow the penetration and subsequent removal of the sterilizing agent;
- Ensure the box contents to physical damage;
- Resist ruptures and contain no holes or toxic ingredients;
- Provide a positive relation for cost / benefit ;
- Do not create particles.

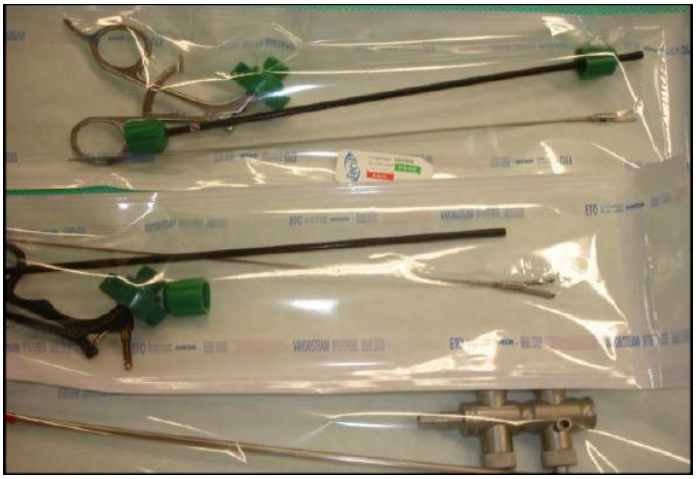


Image 12- Packing for storage of single-use medical product [8].

Thus, packages of medical products should be permeable to sterilizing agents, and allow the transport and storage of sterilized products with the guarantee that the conservation with its sterility, as well as enable the opening without the risk of contamination during its use.

3.5.6 Sterilization

The sterilization process depends on the efficiency of cleaning since the lower the microbial load is, greater becomes the efficiency of this process. Thus we cannot

guarantee the safety just with the exposure of a product to a sterilizing agent. This process is always applied in critical and semi critical products [11, 25, 26, 27].

The sterilization may be more or less effective according to the degree of penetration of the sterilizing agent through the package, product design and performance of the equipment. It is also essential to ensure not only the effectiveness of the process but also measures to prevent recontamination of the product after reprocessing, during the storage, transport or handling [11, 25, 26, 27].

The sterilization time will vary with the product in question and should be respected in order to enable contact of the sterilizing agent with the entire surface [11, 25, 26, 27].

There are several methods of sterilization and the choice depends on the product to be sterilized. These methods may be physical (saturated steam or autoclave, dry heat or greenhouse and gamma rays or cobalt), chemicals (glutaraldehyde, formaldehyde and per acetic acid) or physic-chemical (ethylene oxide, hydrogen peroxide plasma and steam formaldehyde.) The physic-chemical methods should be applied in thermo sensitive materials [11, 25, 26, 27].

3.5.6.1 Physical Methods

Physical methods use heat in different ways and some types of radiation to sterilize the product. The method used for hospital sterilization is the autoclave by saturated steam under pressure. The dry heat or greenhouse is a widely known method but, however, little used due to operational difficulties and the advancing technology of steam autoclaves [11, 25, 26, 27].

Saturated Steam Under Pressure (Autoclaving)

This process is suitable for heat resistant materials and also the most used in hospitals. This process allows the destruction of microorganisms from the coagulation of proteins [11, 25, 26, 27].

The apparatus used in this method are programmed according a ratio time / temperature so that with increasing temperature, the sterilization time decreases or increases [11, 25, 26, 27].

Saturated vapor is a gas subject to the laws of physics must be taken into account that with the change of temperature, pressure also changes [11, 25, 26, 27].

The action mechanism of this method involves the removal of air and saturated steam in the chamber, the articles are exposed to the steam and occurs and the exhaust steam by suction followed by drying the material and return to atmospheric pressure and input of the filtered air [11, 25, 26, 27]. Image 13 shows an example of an autoclave.

Image 13- Organization of medical products for sterilization in an autoclave [12].

This is the best method for sterilizing surgical instruments, including those permanents for the video-surgery [11, 25, 26, 27].

Steam Quality

The quality of sterilization depends on the physical state of the steam [11, 26].

Dry Saturated Steam

Is the effective way of sterilization and contains only water in the gaseous state by adding as much water as possible to the temperature and pressure [11, 26].

Wet Saturated Steam

When the boiler water or the condenser tubes are charged with the saturated steam to be injected into the autoclave chamber leads to an excess of water that may impair the drying of materials a wet saturated steam is formed [11, 25, 26, 27].

Superheated Saturated Steam

This results from the saturated steam subject to higher temperatures. Thus, this does not have any moist becoming less penetrating and impairing the process of sterilization.

There are several types of saturated superheated steam sterilization: sterilization by gravity, by high-vacuum, vacuum pulsed and ultra-rapid [11, 25, 26, 27].

Dry Heat

In this method is used electric equipment that has resistance, a thermostat to regulate temperature, lights, thermometer and switch. Heat is radiated from the side walls of the equipment and the base [11, 25, 26, 27].

This procedure requires longer exposure time and higher temperatures so that there is microbial death cell oxidation. It should not be applied to textiles, plastics, rubber and paper, being more suitable for glass, metals, powders, waxes and non-aqueous liquids such as Vaseline or paraffin [11, 25, 26, 27].

Radiation

This method uses as sterilizing ionizing radiation. This causes changes in cellular DNA, resulting in structural lesions which result in serious functional by diffusion of free radicals in the adjacent volume of microorganisms [11, 26].

The most used radiation in this process is over gamma radiation and the cobalt element 60 due to the high penetrating power in the materials and is often used in implants [11, 26].

The duration of this process depends on the distance of the material from the radiation source, the activity conditions of the source and nature of the product. The hazards of this process are evaluated using an electromagnetic panel and the amount of radiation is dosed by a dosimeter [11, 26].

3.5.6.2 Chemical Methods

Chemical methods are defined as dry sterilization and should only be applied when other methods are not available. These can be applied to the thermo sensitive products such as endoscopes, optics and optical fiber cables.

The use of these methods requires special care such as [11, 25, 26, 27]:

- The thorough washing and drying;
- The use of individual protection products;

- Complete immersion of the product in the disinfectant solution within a covered recipient;
- The control of the start time and end of the process;
- The products should be removed only when wearing sterile gloves;
- The washing should be done with distilled or deionized water and never with saline under the risk of deposit and corrosion of the material;
- The drying of the material should be done with a sterile pad or in the case of products with lumen ,with sterile compressed air;
- The product sterilized should be used immediately and never packed;
- The resulting disinfectant solution must be rejected or not according to the manufacturer's instructions.

The disinfectant used during chemical methods must have some essential features such as [11, 25, 26, 27]:

- Broad anti germs spectrum, meaning, be able to vanquish viruses, bacteria, fungi, spores;
- Not toxic to humans or the environment nor irritating;
- Odorless, soluble in water and do not stain the product;
- To facilitate the accurate monitoring of the concentration of the active principle and be stable in its concentrated state or in its diluted state.

In this kind of process, the sterilizing components most used are Glutaraldehyde, formaldehyde and per acetic acid [11, 25, 26, 27].

Glutaraldehyde and formaldehyde are applied in accordance as stated earlier in the topic relating to chemical disinfection. The per acetic acid it acts in order to oxidize enzymes essential to the survival and reproduction of biochemical reactions. This acid has the advantage of not leaving toxic residues which allows the sterilization step to last for approximately 20-30 minutes. However, it is necessary to be careful that no corrosion occurs [11, 25, 26, 27, 29]. Image 14 is an example of one reprocess for sterilization of a product with per acetic acid.

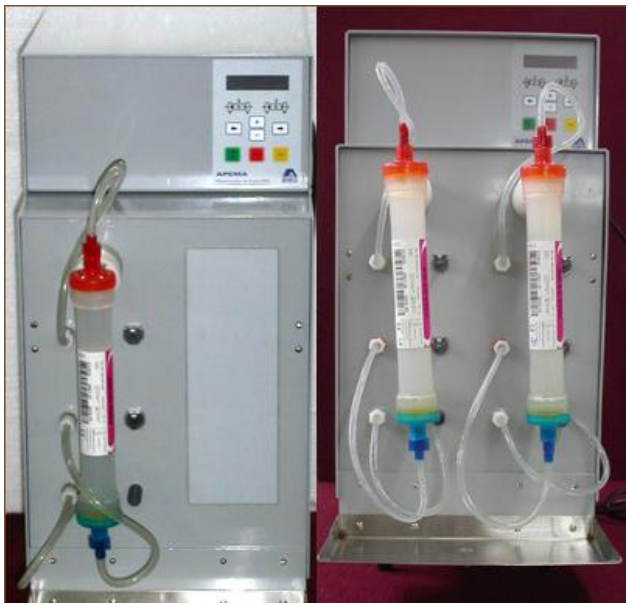


Image 14- Healthcare reprocess for sterilization from the per-acetic acid [31].

3.5.6.3 Physical-Chemical Methods

Ethylene Oxide

Ethylene oxide is a colorless gas with high effectiveness in killing bacteria, viruses, spores, fungi and micro bacteria. This acts to kill the microorganisms' proteins depending on the concentration, temperature, humidity and time of contact. It is commonly used in thermo sensitive products and should be used in autoclaves own since it is explosive and flammable [11, 25, 26, 27].

It has several advantages: high penetrating power and is relatively cheap but nevertheless the exposure to this gas can cause cancer, reproductive system abnormalities, genetic disorders and neurological diseases. Hence the importance of following strict and specific legislation, environmental monitoring and safety of employees [11, 25, 26, 27].

The sterilization process is divided into four phases: pre-humification, contact time with the material (about 3-4 hours), gas removal and removal of toxic waste and its sub products [11, 25, 26, 27].

Hydrogen Peroxide

This kind of sterilization generates plasma from the substrate hydrogen peroxide which is bombarded by high frequency waves. The destruction of microorganisms, including spores, resulting from the production of reactive free radicals, with positive or negative charges, and when excited tend to bind together, specifically, to enzymes, phospholipids, DNA and RNA. This reaction occurs very quickly, enabling fast sterilization [11, 25, 26, 27, 29].

This is a recommended method of thermo sensitive products and can be applied to metals, plastics, glasses, rubbers, acrylics. Cannot be used for sterilization of products containing cellulose and iron [11, 25, 26, 27, 29].

The equipment used in the hydrogen peroxide method is easy to install and operate where in the external front are placed ten ampoules. In each cycle of this step is used an ampoule [11, 25, 26, 27, 29].

Each cycle is divided into five phases: vacuum, injection, diffusion, plasma and ventilation. After each cycle, the machine issues a report so that there is control of pressure and duration of each stage [11, 25, 26, 27, 29].

This method has the following advantages: fast compared to other methods of low temperatures, the opportunity to work with temperatures between 50 ° C and doesn't produce waste. The disadvantages are mainly because it is expensive and differentiated, and the fact of having to carefully evaluate the cost / benefit ratio and selection of products to be sterilized according to the cost / cycle [11, 25, 26, 27, 29].

3.5.7 Quality Control and Validation of the Sterilization Process

Quality control of the sterilization process is a continuous process and its validation should be done by a professional. So should always accompany the technological changes in order to keep up to date [11].

The methods of monitoring the sterilizer can be made from physical tests, chemical and biological.

3.5.7.1 Methods for Monitoring the Sterilizer

Physical Testing

Performance Evaluator Sterilizer

These methods are used to evaluate the internal conditions of the autoclave. They consist on the use of thermometers for checking the temperature, and this should be 121 ° C and the use of nanometers to check the pressure [11, 26].

The instruments used should always be validated on a technical and periodic way and their reading should be done every 3 minutes [11, 26].

Qualifying Heat (thermal pair)

This process is applied in order to determine the penetration time of heat within the bottles. Two metallic wires are fused at one end and determine the temperature inside the equipment. At the other end is made the reading of the temperature outside the equipment from a recorder [11, 26].

This method is often used during the installation or after major repairs of autoclaves or ovens. It is not necessary to apply this method as a routine besides it is very expensive [11, 26].

Radiation Dosimeter

This method uses dosimeters to verify whether the dose received was compatible with the sterilization process in order to assess the amount of energy absorbed by the treated material [11, 26].

Chemical Tests

Chemical Indicators

The chemical tests that allow the immediate identification of potential equipment failures on the penetration of heat in greenhouses and autoclaves, and also assist in the identification of sterile products [11, 26].

Thus, paper strips are used with thermo chromic ink whose color changes according to the exposition to temperature of the product during the time recommended by the manufacturer. They should be used inside the packaging, in areas of difficult access of steam penetration or hard to remove air in autoclaves. It should be used in conjunction with biological tests [11, 26]. Image 15 shows some indicators.

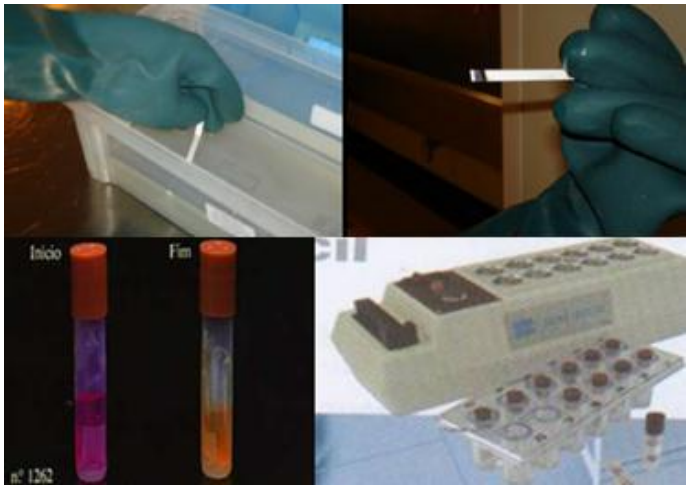


Image 15- Validation of the sterilization process from different indicators [12].

To differentiate the packaging of processed to unprocessed external indicators are used [11, 26].

According to the sterilization it may be used several internal markers [11, 26]:

- Class 1: indication of the process with, for example, the striped tapes. These indicate that the product went through the sterilization process and should be used in all products to be sterilized. Image 16 represents an example of an internal indicator of a class.

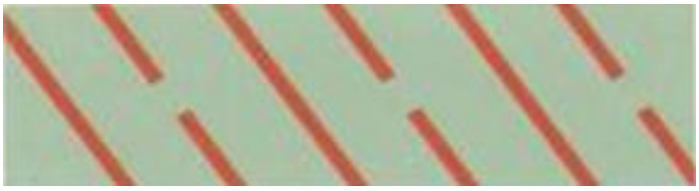


Image 16- Tape for sterilization control [12].

- Class 2: indicators that are used in specific cases such as the Bowie & Dick test. These indicators are used to evaluate the effectiveness of the vacuum system in pre-vacuum autoclave by detecting bubbles of air when steam is

admitted and forming the vacuum. The bubbles compromise the sterilization process and therefore should not exist. This method must be applied every day and before the loading. Image 17 is represented an example of a class two internal marker.

Image 17- Internal chemical indicator of class 2 [12].

- Class 3: unique parameters are indicators that can measure the most critical process as steam, temperature, saturated steam or time. Image18 is represented an example of an internal indicator of Class 3.

Image 18- Indicator parameter only [12].

- Class 4: multi-parameter indicators used to measure two or more parameters simultaneously and indicating the amount of exposure to the sterilization cycle. In Image 19 represent an example of an internal indicator of class 4.

Image 19- Indicator multiple parameter [12].

- Class 5: Integrated indicators which react with all critical parameters of the sterilization process by a certain break of sterilization. Image 20 is an example of an internal indicator of Class 5.

Image 20- Integrated indicator [12].

- Class 6: simulators which react with all critical parameters of the sterilization process. Allow the detection of failures in specific parameters. Image 21 represents an example of an internal indicator of class 6.

Image 21- Indicators of simulators [12].

Bowie & Dick Test

This test should be performed on the first day of the autoclave cycle. Initially, one should turn on the autoclave and subjecting it to a completely empty cycle, put the sheet placed in the middle of a range of tissues from 25 to 29 cm in height, is placed in the autoclave a test package in the direction of the drain and supported in the "rack" and starts the cycle that can be stopped before the drying stage and after the time determined by the temperature.

The result of this test can be positive if the test sheet doesn't show that there are some failures verified by the incomplete coloration that occurs mainly in the center, or negative if the change in coloration of the sheet is uniform throughout verifying the absence of residual air [11, 26].

Biological Test

Are used to control the sterilization and although it is recommended daily use, are usually only applied weekly.

Consists in placing indicators inside a selected packaging in a difficult place for steam to penetrate, place a pilot indicator for evaluating the incubator, after sterilization and cooling of the material one take out the indicator and the control indicator incubated

and observe the correct placement of the vials. The biological tests should be performed on all products containing prostheses and these should be retained until the end of incubation [11, 26].

Image 22 is shows the application of biological indicators.

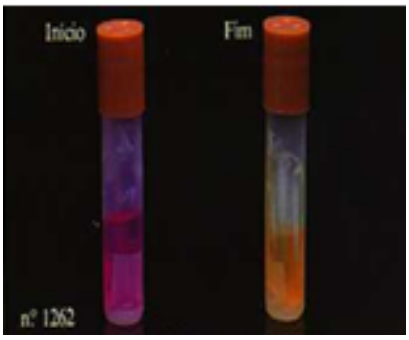


Image 22- Biological indicators [12].

In the preparation of biological test can be used many different bacilli, for example, steam autoclave at the *Bacillus stearothermophilus*, the process of dry heat, ethylene oxide and plasma hydrogen peroxide *Bacillus subtilis* variety *niger* and gamma radiation *Bacillus pumilus* [11, 26].

Sterility Testing of Biological Control

These tests are performed directly on the product sterilized in the laboratory in order to evaluate the effectiveness of sterilization. It is only reliable when done by someone highly skilled and is very useful when the occurrence of nosocomial infection from a specific agent [11, 26].

Assessment Chemical Sterilizers

These tests use different dilutions of a germicide for microbial growth. According to the chemical product used one selects the most effective test microorganism. In the case of sterilization should always evaluate the action of the spores. The used microorganisms are *Bacillus subtilis* and *Clostridium sporogenes*. For the results obtained are reliable they must obey specific details such as temperature, composition of culture mean, among others [11, 26].

Control of Sterilization by Ionizing Radiation: Gamma or Cobalt 60

This is a widely used in the industry, however, their high cost makes it impossible to use in hospitals. The maintenance of the functionality characteristics, biocompatibility and atoxicity after sterilization must be guaranteed by the functional quality of the products.

In order to ensure that a certain minimum dose is reached in all dimensions of the product should be handed dosimetric indicators [11, 26].

Monitoring of Sterilization Processes

This process requires a few steps as operational qualification at the time of installation, control of equipment and check the function of the equipment after repairs, renovations or changes in load or packaging [11, 26].

In the report should be appointed every step taken, the conditions of the cycles, loads of provisions, the types of products and packaging [11, 26].

In the end, it is recommended that the implementation of recommendations and reports are made by the Hospital Infection Control of the institution. The control of loads and sterilizers should be a routine since it is essential to the quality of reprocessing [11, 26].

This control can be accomplished by mechanical means (observe the pressure, time, temperature and preventive maintenance of the equipment) chemical means (such as test & Bowie-Dick, chemical integrators indicators on the inside and outside of the package), and biological means (biological tests that allow reading between 3 and 48 h of incubation) [11, 26].

Note that for these tests and means of control to be effective, products must be properly cleaned and dried [11, 26].

These steps should be reported and the responsibility of a manager appointed by the Central Sterilization and Clinical Engineering Service, Hospital [11, 26].

Expiration Date of the Sterilization

By the characteristics of the selected package, the method of sealing, the number and condition of the packaging and handling prior to use, the service must provide a suitable shelf life [11, 26].

The best storage conditions, meaning, closed sectors with sealed windows and, with a clean and temperature-controlled cabinets for easy viewing to control packaging, the greater the period of validity [11, 26].

Validation of the Sterilization Process

Evaluates whether the sterilization process actually served its purpose from practical and recorded experiments [11, 26].

This process cannot be applied in some cases such as the installation of new equipment or newly installed, not after preventive maintenance or modification of charges or packages [11, 26].

When purchasing equipment, validation must be performed by the manufacturer and a technical expert from the institution verifying the conditions of the equipment after installation, evaluation of temperature, mechanical condition of the equipment or pressure. Are then applied chemical and biological testing indicators to establish sterilization criteria [11, 26].

In this phase it is also made the programming cycles of scanned sterilizers [11, 26].

3.5.8 Storage

The storage of products after reprocessing should be carried out in accordance with some important information so that there is no damage of the product or is put into question its sterility and should only be done after validation of sterilization. These indications are [11, 26]:

- Thus, the products should be stored in clean places, organized, with no signs of infiltration or presence of insects.
- One should always check for damaged packaging, with signs of moist, passed the expiration date, or other characteristics that may jeopardize the sterilization of the material, remove these packages and reprocess these products.
- Always place the older reprocessed packages in front and the newly sterilized in the background.
- The sterile packaging should be handled with properly clean hands, with great care and the minimum possible.

- The cases should never be felt, opened and closed again, fall, loaded carelessly, exposed to moisture, etc.

Table 3 summarizes the main steps to be used in the reprocessing of products.

Table 3- Steps and products used in the reprocessing of medical products.

Steps	Type	Products Used	
Cleaning	Mechanical		
	Physic		
	Chemical		
	Manual		
Drying			
Disinfection	Chemical	Aldehydes	Glutaraldehyde
			Formaldehyde
		Alcohols	Ethyl Alcohol 70%
			Isopropyl Alcohol
		Inorganic compounds liberating active chlorine	Sodium hypochlorite
			Calcium
			Lithium
		Organic chlorine-releasing compounds	
		Phenolic	
		Iodine and derivatives	
		Biguanides	
		Quaternary Ammonia	
		Per Acetic Acid	
	Physical-Chemical	Ethylene Oxide	
	Physical		
Packaging and labeling			
Sterilization	Physical	Saturated steam under pressure (autoclaving)	
		Dry saturated steam	
		Moist saturated steam	
		superheated saturated steam	Sterilization by gravity
			Sterilization by pulsed high
			Sterilization by high vacuum
			Ultrafast sterilization
		Dry heat	
		Radiation	Gamma rays
			Cobalt 60
	Chemical	Glutaraldehyde	
		Formaldehyde	
		Per acetic acid	
		Ethylene oxide	
	Physico-chemical	Hydrogen peroxide	
Storage			

3.6 Risks of the Reprocessing of Single Use Products

When speaking of reprocessing single-use materials must take into account both ecological factors, such as issues relating to procedures that cause more damage to the environment, and real or potential risks that may arise from this procedure to the patient's health. Reuse of single-use medical products must be assessed by technical, legal, ethical and safety aspects [23].

3.6.1 Biofilms

Biofilms are the microbial masses containing cellular material extracellular that stick to the surface of the products immersed in liquids, for example, blood. To achieve the elimination of microorganisms in these masses is needed penetration of the sterilizing agent. Since the same when combined with biofilms become stronger [23].

The materials used in health care, especially those who come into contact with lumens or other internal spaces are subject to the formation of biofilms on the surface. The existence of biofilms is commonly associated with infections where the material is implanted, such as tracheal tubes, central venous catheters or bladder. However, there is not an association of infections after procedures with reused materials containing biofilms [23].

The biofilm formation is a defense mechanism of microorganisms and begins to form in the material more or less after one hour of his presence in them. When there is the presence of biofilm is necessary to apply methods for its destruction because the sterilizing and disinfecting agents do not have access to the microorganisms contained in biofilms. It is therefore extremely important the quality of water used in washing and the use of bacterial filters. Should have an appropriate mechanical cleaning by rubbing the surface with a sponge. In the case of not being able to apply this method, it is recommended that the application of the washing machine ultrasonic. With the use of enzymatic detergents there are cases of successful removal of biofilms, which is a major breakthrough [23].

The single-use materials because they are not removable hinder the removal of biofilm, which must be taken into account in the reprocessing [23].

3.6.2 Sterilization

Most materials are designed for single uses are thermo sensitive so can only be sterilized at low temperatures. Since the effectiveness of this process depends upon the contact of the sterilizing agent with the material surface and the diffusion of the same should be chosen a sterilizing agent presenting diffusivity and high guarantee the absence of residual dirt and biofilms. Note that diffusion of the agent decreases in materials non removable, such as single-use [23].

3.6.3 Endotoxins

Endotoxins are lipopolysaccharides comprising the membrane of gram-negative bacteria and are released when there is the death of the bacteria, growth or division. These are considered a threat to health since they are heat stable and only inactivated at temperatures above 180 º C and also because they can produce reactions that lead to the symptoms of chills and therefore irreversible shock and death. The endotoxins can also cause toxic ocular syndromes and induce the occurrence of aseptic loosening of orthopedic implants [23].

It should be avoided the contact of the products with tap water and its uncontrolled microbial contamination, wet skin and instruments. It is advisable, too, that the products are reprocessed, packaged and sterilized in the shortest possible time to be able to limit the time of contamination and bacterial growth.

3.6.4 Proteins and Prions

The protein residues in hospital supplies have led to diseases such as toxic syndrome of the anterior segment of the eye (TASS-segment syndrome and Toxic) and prion disease [23].

The TASS is caused by the presence of endotoxin, waste or other viscoelastic exogenous substances remaining in the material even after sterilization.

Thus, it is essential the quality of cleaning and washing mainly in the materials that cannot be removed [23].

The prion diseases result from the presence of small protein particle. During the cleaning phase in such cases it should be taken into that since it is dealing with proteins is necessary to remove prion particles and not only inactivate them [23].

Again, it should be noted that the characteristic of not removable single-use products does not allow the cleaning of all surfaces thereof its reuse in the case of gravity of prion disease is very dangerous [23].

3.6.5 Toxic Waste

Cleaning and sterilization of single-use materials means the use of products which may contain residues toxic to the patient. One should then apply some methods to reveal the level of toxicity of the products used in these phases, for example, placing samples of these products with cultured cells that show whether or not the product is toxic. It is also recommended the evaluation of materials for the level of toxicity; this is one of the basic parameters in the validation protocol for reprocessing single-use materials [23].

3.6.6 The Environment

It should be noted that the ecological risk generated from the reprocessing of single use products causes great controversy since it must always take into account that the procedure that causes less environmental impact. Thus arose the question whether it is better to drop large amounts of components that are not biodegradable or recyclable because they were contaminated with blood and excreta or whether it is better to consume high levels of electricity for their reprocessing and dispose germicides in the sewer system [20].

3.6.7 The Patient’s Health

The most commonly associated with risks for the reprocessing of single-use materials what regards the patient's health are those which arise from transmission of infectious agents. Also the toxicity from residues on products or substances which are used in previous uses or in steps of reprocessing, physical and chemical changes caused by past use or by reprocessing and the various changes, whether physical, chemical or functional, the material may suffer during the previous use or when subjected to reprocessing.

However, faults in steps relating to the reprocessing itself appear to cause major damage to the patient's health since they are the major cause of adverse events or infectious outbreaks [20].

Chapter 4- Single-Use Products for Orthopedic Rehabilitation

4.1 Introduction

The orthopedic rehabilitation is intended for patients recovering from surgery, injury or diseases associated with locomotors system. The severity of the orthopedic problems that need rehabilitation and the consequences are much dispersed. The pathology and surgical interventions most common in the locomotors system that require orthopedic rehabilitation are: hip prosthesis, knee prosthesis, prosthetic shoulder surgery to herniated discs, spinal surgery, fractures of the spine or limbs with or without surgical repair, amputations, among other [32].

On 22 October 2011, was published in Board Resolution / ANVISA No. 185, a fairly comprehensive definition of implant. Thus, an implant is:

> *"Any medical device designed to be fully introduced into the body or to replace a human epithelial surface or eye by means of surgical intervention and intended to remain in place after the intervention. It is also considered an implantable medical device, any product Medical intended to be partially introduced into the body with surgery and remain after this intervention for the long term. "*[33].

The role of orthopedic implants is essential, since that becomes available to the surgeon a precise bone anchoring; they play a supporting role in treating, consolidation of fractures, and reconstructive surgery [32, 34].

All orthopedic implants should be used in a single patient and only once, and therefore considered as single use products. Although these implants, after being used, does not appear to damage, their before utilization can lead to imperfections which consequently reduces the success of the implant if to be used again [34, 35].

4.2 Selection of the Implant

During treatment of degenerative and / or traumatic skeletal disorders must take into account certain points in the choice of the appropriate implant. The size and ergonomic shape of the implants are very important since when appropriate they increase the likelihood of success. Also, the patient-related factors such as weight, occupation or business activity, senility, mental illness or alcoholism, smoking and some degenerative

diseases as well as the sensitivity to foreign a body, may influence the success of the surgery. The correct handling of the implant is also important since improper use or handling operations of the implant can cause surface defects and / or focus voltage level on the axis of the implant resulting in disuse of the material. The post-operative care, the extraction of the material used for fixation after completing the consolidation process of implantation, compatibility of materials and information and training of surgeons are also important aspects in selecting the implant [35].

4.3 The Implant Material in Reprocessing

In order to maintenance and reprocessing of the implants are suitable is important to know which type of material are used well as their properties [34].

Stainless steels

Some implants are made of corrosion resistant steels, presenting with a metallic look, shiny or dull. The corrosion resistant steels have high levels of chromium and nickel that form a chromium oxide barrier on the surface of the material protecting it against corrosion and rust. This can be compromised by inappropriate use or negligent damage to the surface of the material, the chemical aggression, physical or electrochemical [34].

According to the composition and properties it can be distinguished two types of stainless steels. The martensitic steel that aren't corrosion resistant, have a high degree of hardness which can be adjusted through a heat treatment, have a high resistance to wear and high retention of the cutting edges. Austenitic steels cannot be hardened hot, have high corrosion resistance, elasticity and hardness [34].

Aluminum, titanium and its alloys

Aluminum is a very light material that from the electrochemical surface treatment produces a resistant layer of aluminum oxide which protects it from corrosion.

Titanium and its alloys are extensively used as a material for implants, and titanium is used only for applications such as color coding. The surface of these alloys can also undergo electrochemical treatment producing a protective oxide layer. Although the anodized aluminum, titanium and its alloys present good resistance to corrosion, the

contact with alkaline detergents and disinfectants or iodine solutions and certain metal salts may produce a chemical attack and dissolution of the surface, depending on the composition of the detergent. Thus, it is recommended the use of disinfectants, cleaners and detergents with a pH between 6 and 9.5. Products with a pH greater than 11 should only be used in accordance with the requirements of compatibility of material [34].

Plastics

In some implants are used for parts pure plastics or composite materials such as phenolic resin or plastic reinforced with carbon fiber.

All plastic support correct reprocessing, however, some plastics may soften during steam sterilization, but are not completely deformed to sterilization temperatures below 140 ° C. There is, however, the possibility of deformation of the material when subjected to repeated immersion in disinfectants with a pH outside the range of 4 to 9.5 due to an excessive effort. Note, also, discoloration or breaking of the plastic compound due to repeated use and effect of the rinse aids [34].

In table 4 [34] is shown the relationship between the temperature and pH at which the different materials can be subjected without suffering damage.

Table 4- Temperatures and recommended pH levels.

Material	Temperature	pH
Stainless steel	up to 150 °C	7 to 11
Aluminum	up to 150 °C	6 to 9.5
Titanium alloys	up to 150 °C	6 to 9.5
Plastics	up to 140 °C	4 to 9.5

4.4 Corrosion and Surface Changes or Damage

The surfaces of materials can be damaged or cause damage due to improper handling or contact with various substances. Knowledge of the causes of corrosion and damage to materials can prevent its occurrence [34].

Blood, secretions

The body fluids and residues, containing ions, can cause corrosion if they adhere or dry on the material over long periods of time. In order to avoid it, the materials must be immediately cleaned after each use [34].

Saline solutions, iodine tinctures and water

The ion of chlorine and iodine present in the solutions can cause corrosion of the materials. Thus, the contacts should be avoided with such ions from a rinse with distilled water to remove all traces. Tap water contains high concentrations of chlorides and minerals that may damage the materials. The materials should be thoroughly washed with distilled water and dried immediately. The prolongation of the drying step can remove moisture produced during the sterilization [34].

Detergents, disinfectants, and other additives

These products when used in high concentrations or acidic or alkaline detergents can damage the protective oxide layer of stainless steel, titanium or aluminum, leading to corrosion, discoloration or other changes in material properties and surface conditions. Should always be followed the manufacturer's recommendations with regard to quantity, concentration, contact times, temperatures and material compatibility. It is recommended to use products with a pH between 7 to 9.5. In the case of prolonged and repeated use, the auxiliary can affect certain plastics and lead to its discoloration or breakage. If materials are cleaned by automatic cleaning should follow the recommendations of the manufacturer of the cleaning and disinfecting, detergents, rinse aids and the other [34].

Wire brushes, files and other tools used for cleaning

The use of brushes, steel wool extra fine, wire brushes or files, or other types of cleaning with the abrasive effect on metals results in mechanical damage to the passive layer, leading to corrosion of the material [34].

Detergent residues on packaging

The tissues used in the packaging of material must not have detergents or other residues since these can be transferred to the surface of the material through the steam and cause damage on its surface [34].

Overexertion for materials

The materials are designed in accordance with a particular purpose and should be used for this purpose. Inappropriate use can lead to excessive mechanical stress and permanent damage, increasing susceptibility to corrosion [34].

Contact between products made of different materials

May form rust at the contact points where the stainless steel materials are left in prolonged contact with material that has damaged area and simultaneously wetted with an electrolyte. The steam, water, cleaning solutions or other liquid may function as an electrolyte. There is also the risk that the corrosion products formed may transfer to other instruments through the electrolyte. Different materials should, where possible, be cleaned and sterilized separately. The materials must be disassembled and cleaned open to avoid frictional corrosion and corrosion cracks. The protective layer in gaps can be damaged by mechanical or chemical action, leading to corrosion [34].

4.5 Reprocessing of Implants

The implants of single use should not be reprocessed with a result of compromising the structural integrity or cause device failure. This can lead to injury, disease or death of the patient. Reuse or reprocessing of these materials can cause contamination due to the transmission of infectious material from a patient to another. The implants contaminated with blood, tissues, body fluids and elements should not be reprocessed even if don’t appear damage since they can have small defects and may have patterns of internal tension which causes aging of the material [35].

The sterile products must be removed from the packaging with an aseptic technique. In cases where the label has been broken or improperly opened, the manufacturer assumes no liability [35].

All implants that are not under sterile conditions must be cleaned and sterilized steam before surgery. Before being cleaned, it must be removed from the package and proceed with cleaning before use and before maintenance or repair. Before steam sterilization, they must be placed in a suitable container or package [35].

4.5.1 Reprocessing Unsterilized Clinical Implants

The implants can be reprocessed several times if they are not contaminated with blood, tissues and / or body fluids, but should be treated as single use products. The cycles of rework which includes ultrasonic cleaning, washing mechanics and steam sterilization, display no significant effects in the implants. Note that the implants should not be reprocessed nor transported along with contaminated material [35].

4.5.2 Reprocessing Sterilized Clinical Implants

Although implants not contaminated with blood, tissues and / or body fluids can be reprocessed, throughout its use, these are subjected to shocks and high mechanical loads, and therefore cannot be used indefinitely. Handling and maintenance can extend the life of the material one should always verify that they are properly adjusted and in good working status [35].

4.5.3 Instructions of Cleaning and Sterilization for Implants

All implants must be cleaned and sterilized as soon as possible after use. They must be cleaned meticulously: the long, narrow tubes and blind holes. The cleaning agents should have a pH between 7 to 9.5. Cleaning agents with a pH up to 11 or higher should only be used when the provided information regarding the compatibility of the material allows it. One should always comply with the recommendations of the manufacturer for the detergent and enzymatic cleaning agent with regard to concentration, dilution, temperature, and exposure time and water quality. The implants should be cleaned in

new solutions, freshly prepared. Should not be used abrasive instruments like steel brushes. Whenever possible, implants should be cleaned from a machine for cleaning / disinfection. The implants can be reprocessed from manual cleaning and / or automatic cleaning and manual cleaning with pre ultrasonic cleaning [35].

4.5.3.1 Cleaning

Before Cleaning

Before cleaning one must open the materials that have serrated surfaces, threads or joints. It should separate the pointy and cutting material to prevent injury. They must be cleaned manually and placed in separate trays. All materials must be dissembled [35].

Manual Cleaning Method for Implants

Table 5 [35] is described all the steps for a manual for proper cleaning of implants.

Table 5- Cleaning Method Manual for implants.

Steps	Cleaning instructions
1	Prepare a fresh solution using deionized warm water or purified and an enzyme cleaning agent or detergent.
2	Carefully wash the implant.
3	Properly rinse the implants with warm water deionized or purified.
4	Dry the implant using a clean, smooth cloth or compressed air.

Method for Pre-Cleaning Implants

Table 6 [35] are described all the steps for proper pre-cleaning implants. This method should be carried out in an implant before proceeding to the automatic cleaning.

Table 6- Method of pre-cleaning to implants.

Steps	Minimum duration	Cleaning instructions
1	1 minute	Rinse the material with cold water tap. Remove any residue with a coarser brush or a clean soft cloth.
2	2 minutes	Manually wipe the material in a cleaning enzyme agent solution freshly prepared or detergent. Use a brush to remove dirt. Open joints, levers and other parts of materials for repeated exposure to the detergent solution. Wipe material immersed in water to prevent aeration of the contaminants.
3	1 minute	Rinse with cold water. Use a syringe, pipette or spray of water to rinse lumens and channels. Activate joints, levers and other moving parts of the material to properly rinse under running water.
4	15 minutes	Wipe material with an ultrasonic bath at 40 ° C. Prepare new detergent solution using a cleaning agent or enzyme detergent.
5	2 minutes	Rinse the material with warm deionized or purified water. Use a syringe, pipette or spray of water to rinse lumens and channels and other areas of difficult access. Activate joints, levers and other moving parts of the material to properly rinse under running water.
6	Visually inspect the material. Repeat steps 1-5 until there is no visible contamination of the material.	

Method for Automatic Cleaning Implants

Table 7 [35] are described all the steps for proper cleaning automatic implants. Whenever possible should be used an injection unit of micro-invasive surgery to process the lumens and cannulated structures.

Table 7- Method for automatic cleaning implants.

Steps	Minimum duration	Cleaning instructions
Pre-wash	2 minutes	Cold tap water.
Dry	10 minutes	Warm tap water (> 40 ° C), use detergent.
Neutralization	2 minutes	With hot tap water with neutralizer if necessary.
Rinse	2 minutes	Rinse with tepid water deionized or purified (> 40 ° C).
Thermal disinfection	7 minutes	≥94ºC
Drying	40 minutes	≥90ºC

4.5.3.2 Inspection

All implants reprocessed should undergo a visual inspection to identify possible areas of corrosion, damage, discoloration and residues. Implants that have these problems should be eliminated. Prior to packaging and sterilization, the materials that have been cleaned should be carefully inspected to check whether they are clean, intact and working properly. Should repeat the cleaning step until there is no visible contamination of the material. It is necessary to verify that the surfaces of materials are in good condition and if they have settings and proper functioning. No damaged materials should be used, with uncharacteristic marks and areas of corrosion. The materials with moving parts should be lubricated: joints, bearings with spring and threaded parts. If all of the above is verified, one should proceed to the assembly of disassembled material [35].

4.5.3.3 Packaging

The materials should be dry and cleaned, placed in a sterilization enclosure in a rigid container, reusable suitable for sterilization. Precautions must be taken to avoid contact of the implant and pointy material and with sharp cutting and other potential damage to the surface of the sterile barrier system [35].

4.5.3.4 Sterilization

Table 8 describes instructions for sterilization of implants. Drying times ranging from 20 to 60 min, according to the differences between the packaging materials [35].

Table 8- instructions for the sterilization of implants.

Type of cycle	Maximum time of sterilization	Temperature of sterilization	Time of drying
Removal by forced saturated steam (pre-vacuum)	Min. 4 minutes	Min. 132ºC Max. 138ºC	20 to 60 minutes
	Min. 3 minutes	Min. 134ºC Max. 138ºC	20 to 60 minutes

4.5.3.5 Storage

The packaged materials shall be placed in a clean environment, dry, protected from direct exposure to sunlight, moisture and pests and extreme temperatures. The materials must be used in order of date of receipt always verifying the expiry date [35].

Chapter 5- Development of an Information System for Single-Use Medical Products

5.1 Listing of Single Use Products

To better understand the reprocessing of single use medical products and see what are the steps that they must be submitted in order to be reused, was developed in this paper an information system database. I used the Microsoft Access 2010 which allowed the development of the application based on programming through a data structure, and the development of an interface to be used. It Was carried an extensive research involving several articles, about the reprocessing of single use products in order to figure out which process to be applied to each product. Since this is a controversial issue, and that has generated much controversy by not only who reprocesses the products, but the entities responsible for the safety of patients and hospitals, reprocessing seen so far as the ideal, can be changed in future.

After extensive research, we selected some classes of products, and among these, some products already are reprocessed in countries such as Brazil and Germany.

The database developed for verifying the best method for reprocessing for a total of 52 products of certain classes. The information system developed is available in two languages (Portuguese and English). I considered the following classes of products: lumen catheters, lumen catheters non-electric, cannulae, instruments with a lumen and technical functions, wires, instruments driven by light, balloon catheters, tubing systems, neurosurgery and ophthalmic instruments, neurosurgery instruments, ophthalmic and without lumen, cables and adapters, respiratory products, laparoscopic instruments, and others. Within these classes were also studied some products in depth. In Annex 1 you can see products belonging to the classes mentioned, in Portuguese and in English.

5.2 Databases

Initially the information was stored in file systems from files, but with the evolution of information systems, query and manipulate data was increasingly difficult, so these systems have become insufficient. Thus, in the 60s came the databases. These structures consisted of models of network and hierarchical models in which to query the data was needed to know the physical structure of the database and were static. Over time it was

found that these models brought inconsistency or loss of information due to the detection of anomalies in the insertion and modification of records. Thus, in the 70s, Edgar Frank Codd proposed the relational data model that due to its simplicity and the separation between the definition and manipulation of data, since it is based only on relationships, has become the most commonly used model up to today. This model is based on a mathematical theory of relationships, where each data has only one place in the database. The relational databases store its information in tables, where a column is the key by which the required information is sought. The other data or other items in the other columns are associated with a key. Currently, there are many different databases, the Entity-Relationship Model, Relational Model, Hierarchical Model, Object Oriented Model, and the most widely used is the Relational Model. Also noteworthy is the emergence of language SQL (Structured Query Language) which made the data handling simpler and more efficient [36, 37, 38].

The databases are then defined as a set of data that can be structured and manipulated from a Management System Database (DBMS) used to retrieve stored data. In addition to storing information, the databases can be used to prepare printed reports with information, run queries from information interfaces, and graphical tools to query data from an interface, among others. To make it easier for the user to use these properties of the database, they may be presented in different languages:

- DDL (Data Definition Language) - used to create and change the structure of the database;
- DQL (Data Query Language) - used to obtain and process data from its base;
- DML (Data Manipulation Language) - used to add and modify the data in the database [36, 37, 38].

The databases have other important features that make them indispensable to modern society: as simultaneous access, different views and building applications. The access allows simultaneous access by multiple users simultaneously and without contradiction, but these users cannot change the data at the same time. The different views allow restricted access to certain users. The applications allow: manage storage / handling of data, using programming languages integrated with the databases [36, 37, 38].

There are several database management systems that can be used to create databases; the most important are ORACLE, Informix, Adabas, SQL Server and DB2. To use the computer most often used are MySQL, Dbase, FoxPro and Access. The former are more reliable than the latter, however, are more suitable for domestic use in small businesses

or to access databases installed in large systems, from applications accessible to users who are not computer experts [36, 37, 38].

In this chapter, it will be explained the buildup of a database whose aim is to obtain information about the reprocessing of single use medical products. I used the Microsoft Access 2010 and based it on the relational model.

5.2.1 Microsoft Access

Microsoft Access provides three different methods to create a database using the Data Wizard, looking for models <Office Online> access or through an empty database. With the help of Data Wizard you can choose one of the built-in models and customize it to some extent. Then you create a set of tables, queries, forms, reports, and a navigation panel to the database. The tables do not have any data and this method may only be used when a model is very similar to what's intended. Another way to create a database is from the transfer of a model <Office Online>. A model is a database archive and displays the Access tables, queries, forms and reports. In this model, the table does not have the data and after opening the database is possible to customize the model. If we want to use a database with a structure already defined by the user, ideally we use a blank database [36, 37]. This work is created a database from an empty database (see Image 23).

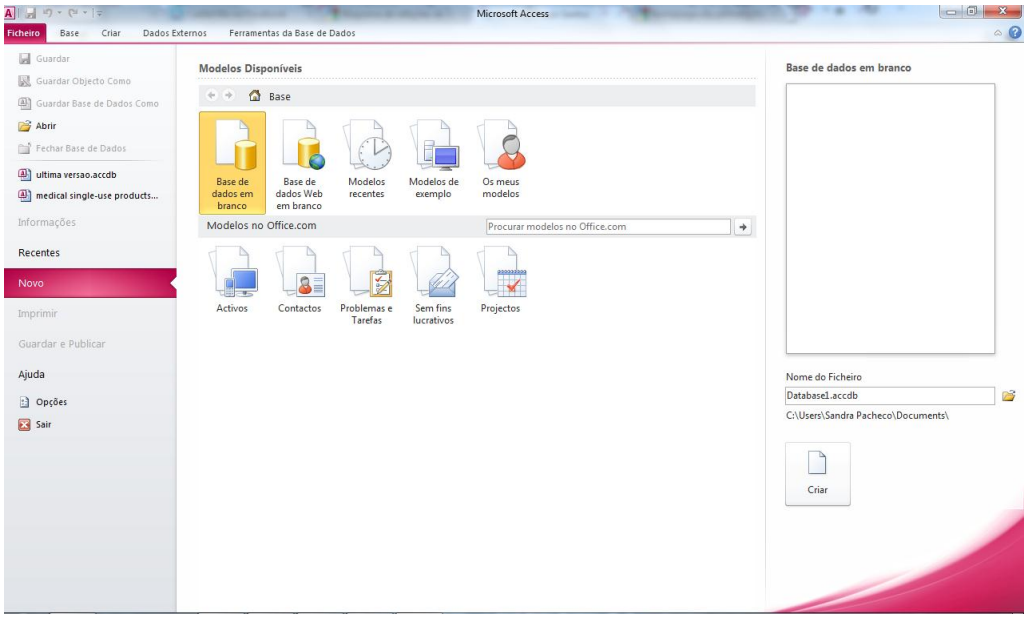


Image 23- Interface of Microsoft Access 2010 to create a database.

After opening the database, you create tables, forms, reports and other objects individually, using the various features of the Access buttons (see image 24). This is a more flexible method, but requires the user to set each element from the database separately.

Image 24- Object buttons of Access 2010.

A database in Access involves the creation and modification of tables, queries, forms, reports, macros, modules, and web pages. These entities may be referred, generally, as objects and each has a specific function, as can be seen in Image 25 [39].

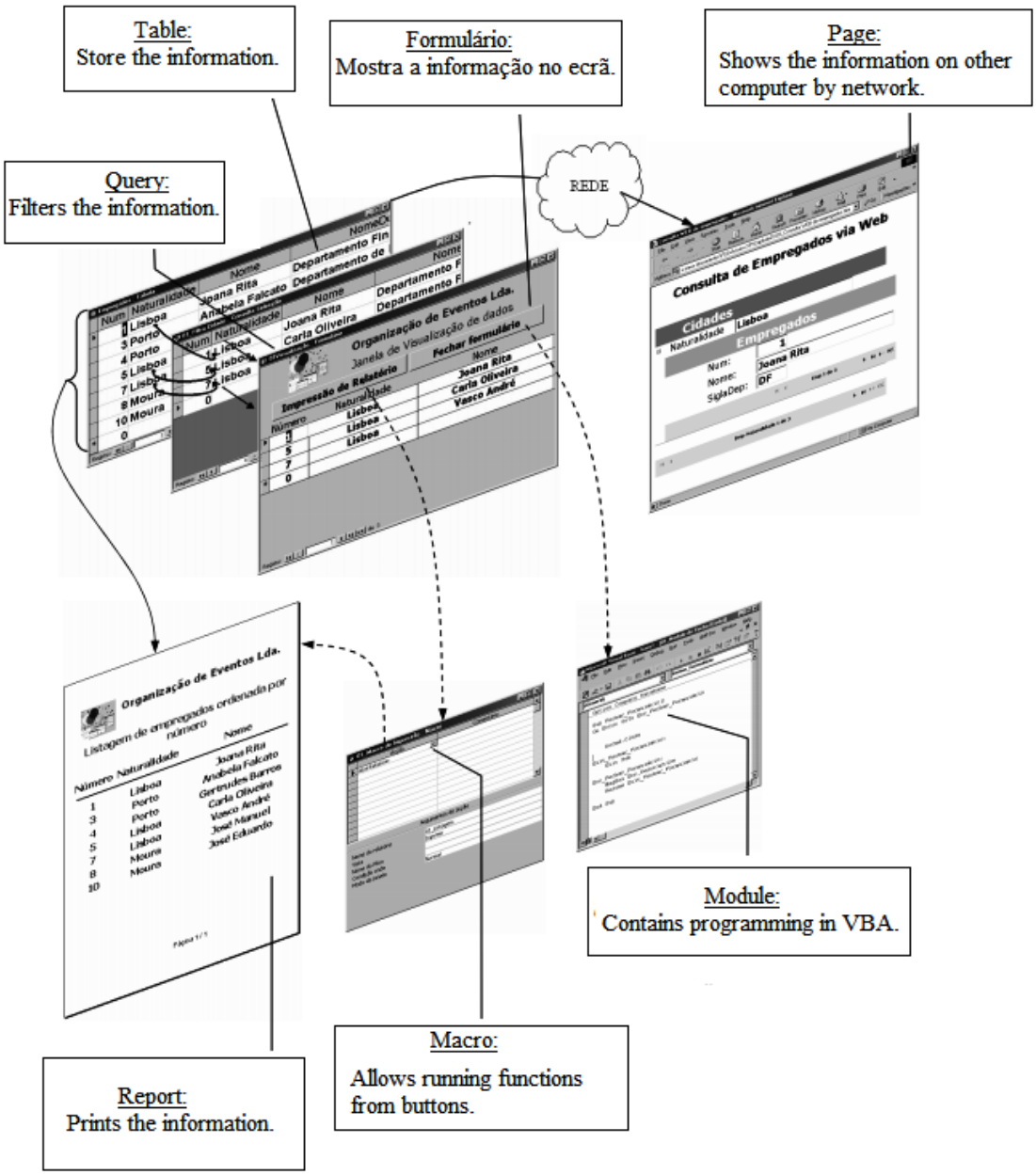


Image 25- Objects in access and their relation

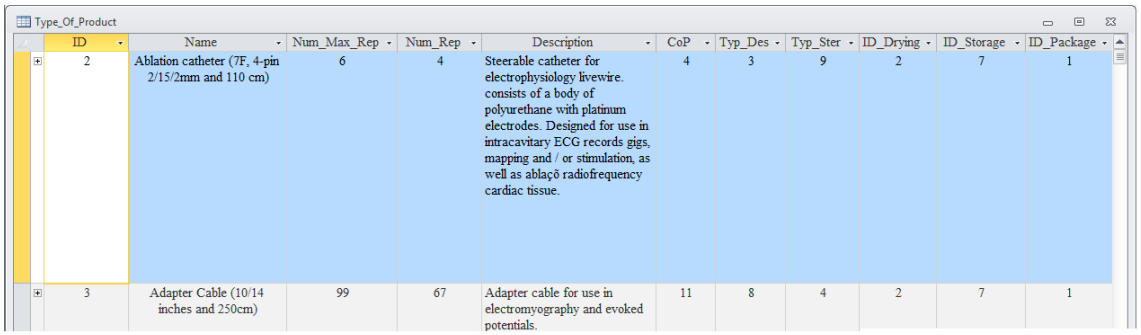
5.3 Development of a Database of Products for Single Use

5.3.1 Creation of Tables

Information in Access must first be organized so that after stored can easily be found by the user. The information is organized into columns (fields) that should contain only information of the same type to which must be assigned a meaningful name. One set of columns is called tables. These should be structured in order to know in advance how many columns the table should have and what their names are. Each line of these columns is called record and in each row, the information is related only to that same information in that line. When creating each table, Access automatically inserts a column called ID. This column is the primary key of the table and the information needed is searched from this column, as is identified in a unique entry in each table. Each key created in the tables, and in the development of this database for single-use medical products, corresponds to only one record in the table, which is known as the primary key [36, 37, 38].

When developing this database was created nine different tables: Type_Of_Product, Class_Of_Products, Type_Desinfection, Validation, Type_Cleaning, Drying, Storage, Type_Sterilization and Package. These tables are essential for insertion of the data considered necessary. Thus, all these tables contain fields with information about the reprocessing of medical products in order to be able verify what the best reprocessing for a certain product.

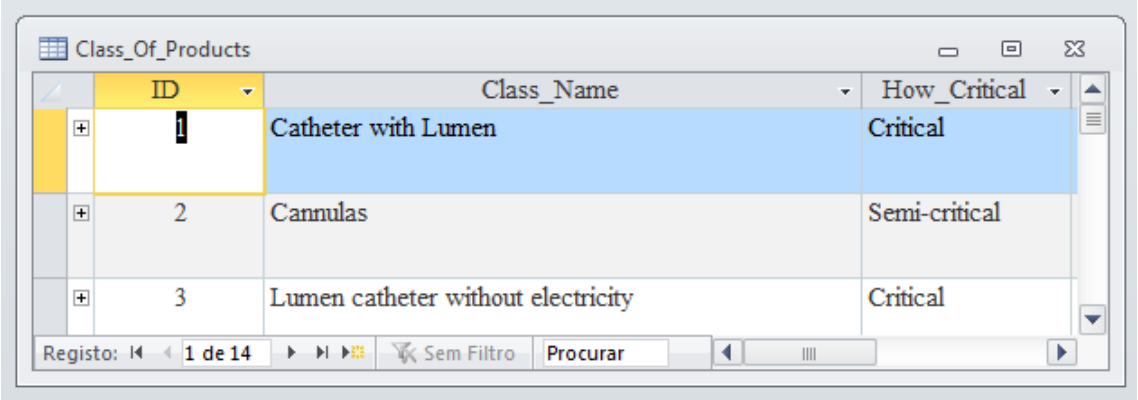
Table Type of Products is the main table and is related to the tables Class_Of_Products, Type_Desinfection, Type_Sterilization, Drying, Storage and Package, from the respective fields: CoP Typ_Des, Typ_Ster, ID_Drying, ID_storage Id_Package and, as can be seen in Image 26. Beyond these fields, this table contains the Name and Description fields of where are the records associated with the names and description of single-use medical products studied.


Type_Of_Product

ID	Name	Num_Max_Rep	Num_Rep	Description	CoP	Typ_Des	Typ_Ster	ID_Drying	ID_Storage	ID_Package
2	Ablation catheter (7F, 4-pin 2/15/2mm and 110 cm)	6	4	Steerable catheter for electrophysiology livewire. consists of a body of polyurethane with platinum electrodes. Designed for use in intracavitary ECG records gigs, mapping and / or stimulation, as well as ablaçõ radiofrequency cardiac tissue.	4	3	9	2	7	1
3	Adapter Cable (10/14 inches and 250cm)	99	67	Adapter cable for use in electromyography and evoked potentials.	11	8	4	2	7	1

Image 26- Representation of Table Type_Of_Product and its fields.

Table Class_Of_Products classifies all the materials in a given type from the field class_name (for example, in Table Type_Of_Product are discriminated various catheters, in this table all are classified as catheters). It further classifies them according to the use in critical products, semi-critical and non-critical, from the field How_Critical, as is shown in Image 27.


Class_Of_Products

ID	Class_Name	How_Critical
1	Catheter with Lumen	Critical
2	Cannulas	Semi-critical
3	Lumen catheter without electricity	Critical

Registo: 1 de 14 | Sem Filtro | Procurar

Image 27- Representation of the Class_Of_Products table and its fields.

The table Type_Desinfection has as fields Typ_Desinfection, Agent and Applying, as shown in Image 28. In the first field is made the registration of the various methods of disinfection, if disinfection is the physical, chemical or physico-chemical or if it is necessary or not to implement this step. In the field Agent is specified the kind of the agent for each type of disinfection, particularly if disinfection chemical it is possible to choose between various disinfecting agents such as glutaraldehyde, formaldehyde, per acetic acid or ethyl alcohol 70% but if the disinfection method is physico-chemical, the agent is ethylene oxide. On the field Applying is made a description of how to implement each agent.

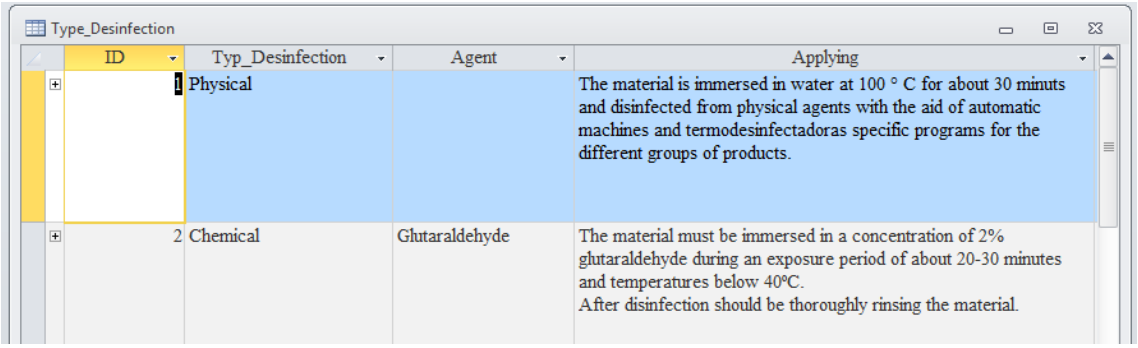


Image 28- Representation of the entire table fields Type_Desinfection.

The table Type_Cleaning has as fields Type_Clean and Descr. In the first field are inserted types of cleaning, making it possible to connect the products to a cleaning, physical, chemical, mechanical or manual, or more than one of these methods. In the second field is made a detailed description of the way these types are applied. In Image29, there is a table representing the Type_Cleaning and their fields.

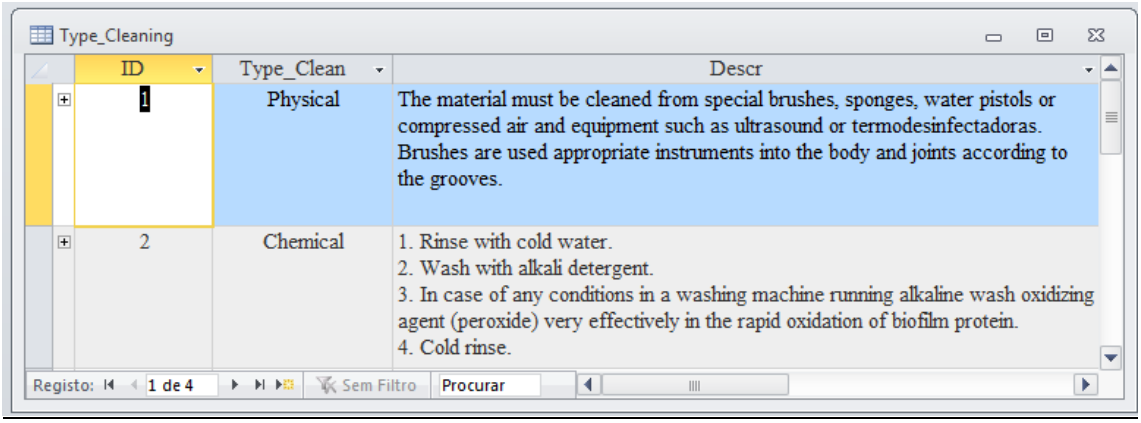


Image 29- Representation of the entire table fields Type_Cleaning.

The table Type_Sterilization has as fields Typ_Ster, Method and Application, as it can be seen in Image 30. The first field is for registration of the various methods of sterilization, meaning whether it is physical, chemical or physico-chemical or if is not necessary to implement this step. The field Method is specified the method for each type of sterilization. And in the field Aplication is made a description of how to implement each different method.

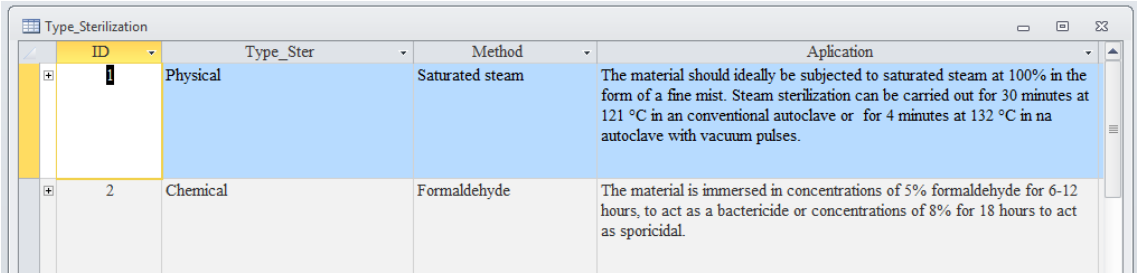


Image 30- Representation of the entire table fields Type_Sterilization.

The table Validation has as fields ID_Product and ID_Clening, as it can be seen in Image 31. This table exists only to relate the table Type_Of_Product with the table Type_Cleaning, since the relationship between them is different, as will be explained in the following point.

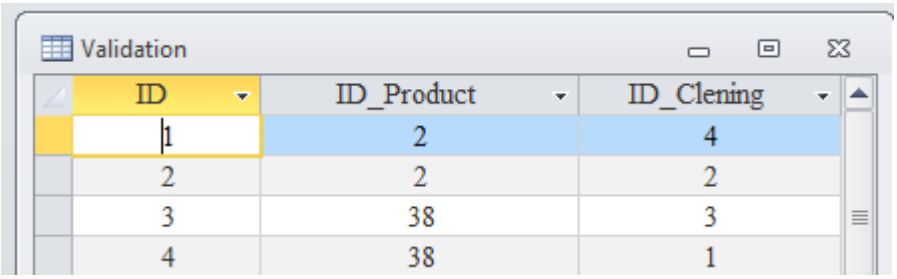


Image 31- Representation of all the fields on table Validation.

Image 32, 33 and 34 are represent the tables Drying, Storage Package, and with only one field each, Description, Features and Indications. These fields explain how these steps should be applied to medical products for reprocessing.

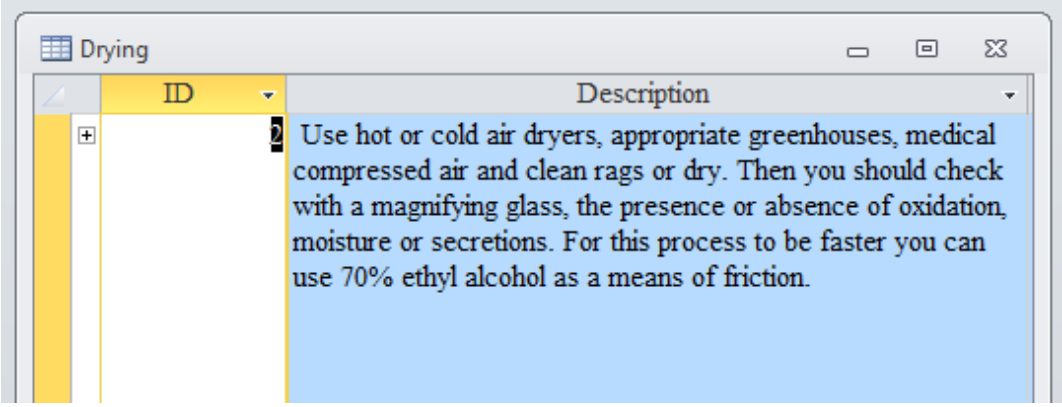


Image 32- Representation of the entire table fields Drying.

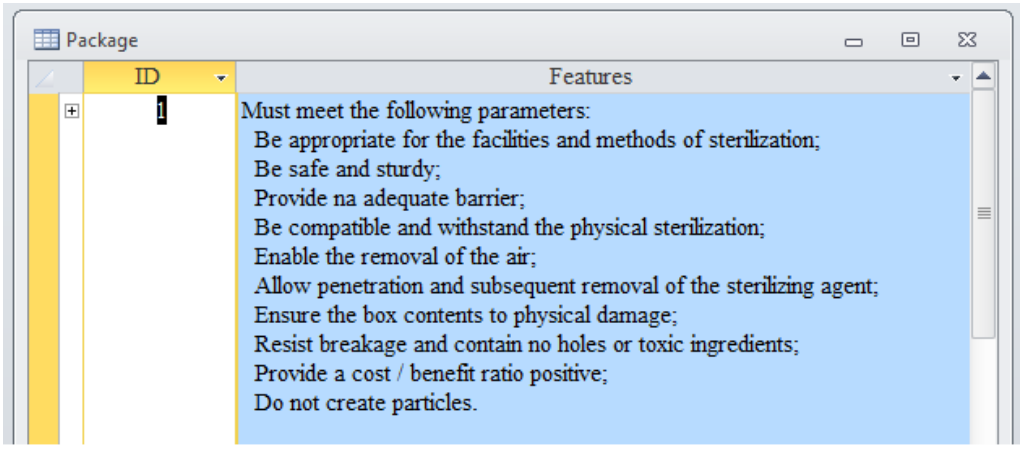


Image 33- Representation of the entire table fields Package**.**

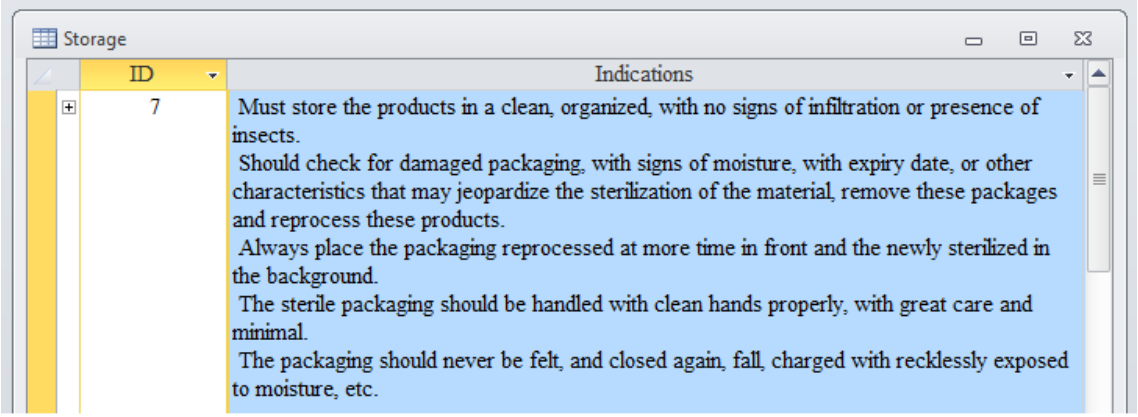


Image 34- Representation of the entire table fields Storage.

After creating all the tables, was performed the translation of all of these fields to Portuguese. For this, were created new fields with the same name as those described, only with the initials PT at the end of the name. These fields have exactly the same information described but translated into Portuguese so you can view all data in the table both in English and Portuguese. Image 35 shows an example of the table Drying with fields Description_PT and Description, which have exactly the same information and in two languages.

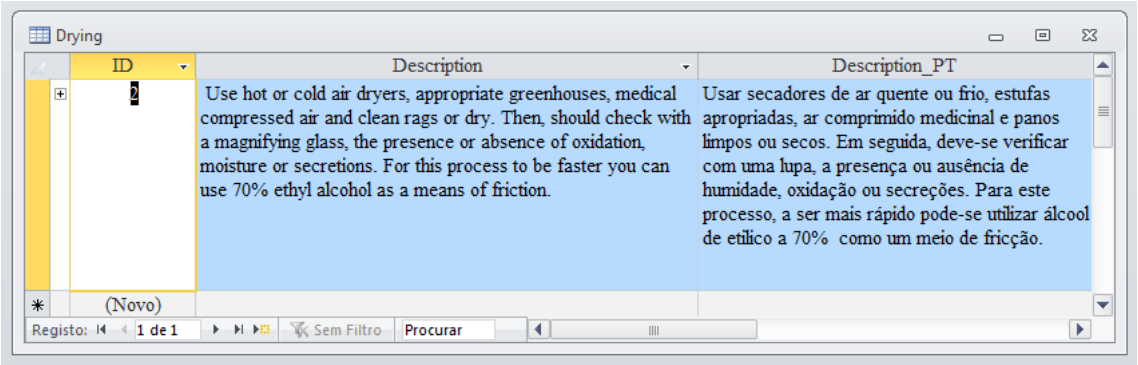


Image 35- Drying final table, with fields in Portuguese and English.

5.3.2 Creation of Entity-Relationship Diagram

The relationships between the tables can be of three types: one to one (1:1), one to many or vice versa (1: N, N, 1) and many to many (N:M). In a one to one relationship, an element is corresponds to another element in a table, always possible to know which element originated the other in a relationship. If the relationship is one-to-many or many to one, an element may correspond to one or more elements or the reverse, so that it is not always possible to know the element which originated another in a relation, since there are several alternatives. In a many to many relationship, several elements can origin of various elements in a relationship. Thus, it is impossible to say which is the origin element or destination in a given situation [36, 37, 38].

In the case where the relationship is many to many, should always decompose the relationship based on the creation of a separate table appearing two linkages of the type one to many. In this type of relationships (1: N), the key is always moved from side one (1) to the side many (N) [36, 37, 38].

After the tables are created with the desired information, one must establish a relationship between them, which is made from an entity-relationship diagram, as can be seen in image 36. These relationships are the hallmark of the relational model and are established based on common fields between the various tables. Thus, one of the tables should contain key elements of the other table it is related with.

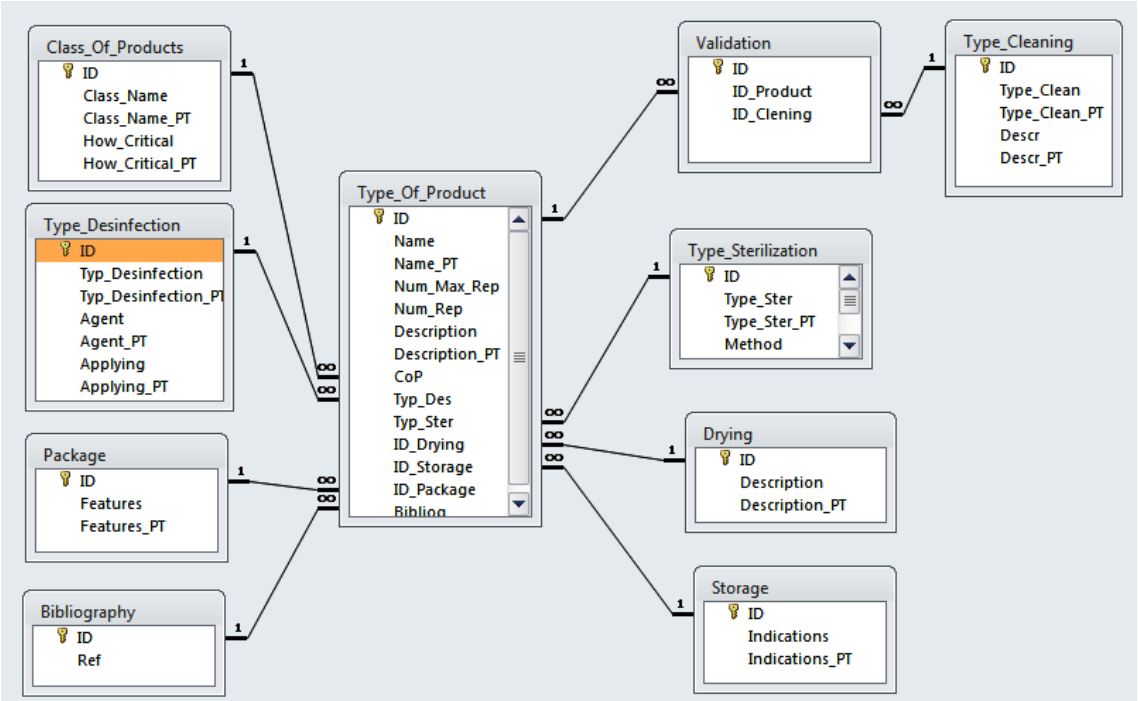


Image 36- Diagram of the entity-relation database for single-use products.

When the key of a record from a table is included as a field in another table, then the point of view of that table, it is said that this is an external key or foreign [36, 37]. For example, to relate the table Type_Of_Product with the table Class_Of_Products, the key of each class of products is introduced in the table Type_Of_Product from field CoP. Thus, for the table Type_Of_Product this is a foreign key.

5.3.2.1 Relationships in Entity-Relationship Diagram

In this subchapter shall be explained all the relationships made in the entity-relationship diagram of the developed database.

- Between the table Type_Of_Product and the table Class_Of_Products: this is a type of relationship many to one, since each product of table Type_Of_Product may only correspond to one type of product class in the table Class_Of_Products, and this table may contain more than one class of a product from the table Type_Of_Product.
- Between the table and the table Type_Of_Product and Type_Desinfection: this is a relationship of many to one type, since each product of table

Type_Of_Product can only be disinfected by a agent of table Type_Desinfection, however, the same agent of table Type_Desinfection can be used to disinfect more than one product from table Type_Of_Product.

- Between the table Type_Of_Product and the table Type_Sterilization: this is a relationship of many to one because each product of table Type_Of_Product can only be sterilized by a method one of table Type_Sterilization, however, the same method of table Type_Sterilization can be used to sterilize more than one product of the table Type_Of_Product.
- Between the table Type_Of_Product and the table Type_Cleaning: this is a relationship of many-to-many, whereby each product from the table Type_Of_Product can be cleaned by more than one method from the table Type_Cleaning, each method from the table Type_Cleaning can be used to clean more than one product of table Type_Of_Product. Thus, it was necessary to create the table Validation, giving rise to two types of relationships: one to many relationships between the table Type_Of_Product and the table Validation and between the table Type_Cleaning and the table Validation.
- Between the table Type_Of_Product and the table Drying: this is a relationship of many-to-one because each product from table Type_Of_Product only corresponds to a type of drying from the table Drying and the same way of drying a material is applied to all products from the table Type_Of_Product.
- Between the table Type_Of_Product and the table Storage: this is a type of relationship many to one, because each product from the table Type_Of_Product is packaged in only one way described in the Table Storage, however the same method can be applied to pack more than a product from table Type_Of_Product.
- Between the table Type_Of_Product and the table Package: this is a type of relationship many to one, because each product from the table Type_Of_Product is storage in only one way described in Table Package, however the same way of storing the products can be applied to one or more products from the table Type_Of_Product.

5.3.3 Creation of Queries

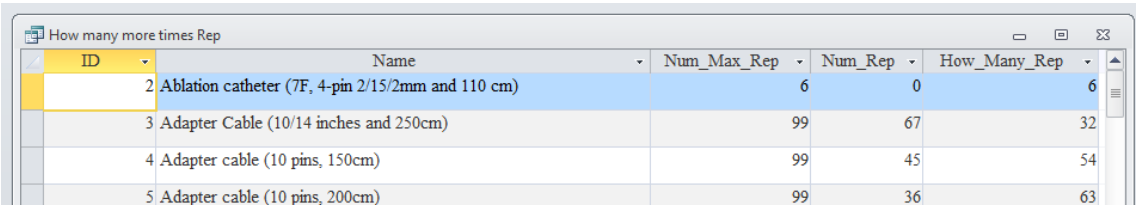
If a table has a lot of records ("too much" sounds negative), it is important to do specify helpful filtering conditions to find the information needed. Thus, it is necessary to specify the filtering conditions that allow only, is presented information set which meets these conditions [36, 37].

Thus, the user can reduce the amount of information that is displayed and be able to show exactly the information desired. This is done from the specification of the filtering conditions that can be produced more or less depending on the information which is necessary to have access. It is sometimes necessary to use this information later, so you can save the filtering specification from Query (Queries) [36, 37].

After the establishment of relations between the tables from the entity-relationship diagram is possible to consult the data tables in order to get just what you want. Using the Create button from the main interface and choose the option Access Query Wizard, Simple Query Wizard and through tables, you get the desired data.

During this work were carried out three consults, How many more times, Process and Steps.

The query How many more times Rep the indicates user the number of times that a product can be reprocessed (Num_Max_Rep), the number of times that a product has been reprocessed (Num_Rep) and how many times this product can be reprocessed (How_Many_Rep) as it can be seen in Image 37. For example, a cable adapter 10 pins and 250 cm may be reprocessed at most 99 times, and as has been subjected to reprocessing 89, so can only be reprocessed an additional 10 times.


How many more times Rep

ID	Name	Num_Max_Rep	Num_Rep	How_Many_Rep
2	Ablation catheter (7F, 4-pin 2/15/2mm and 110 cm)	6	0	6
3	Adapter Cable (10/14 inches and 250cm)	99	67	32
4	Adapter cable (10 pins, 150cm)	99	45	54
5	Adapter cable (10 pins, 200cm)	99	36	63

Image 37- Consultation How many more times Rep and the resulting data.

This query filters the data you want (and Num_Max_Rep Num_Rep) from the table Type_Of_Product. From a subtraction instruction is results the number of times a product may still be reprocessed .This is done using the structure view, and selecting the

data that is intended, as shown in Image 38. In this view, you can not only see the data tables and how to change them if necessary.

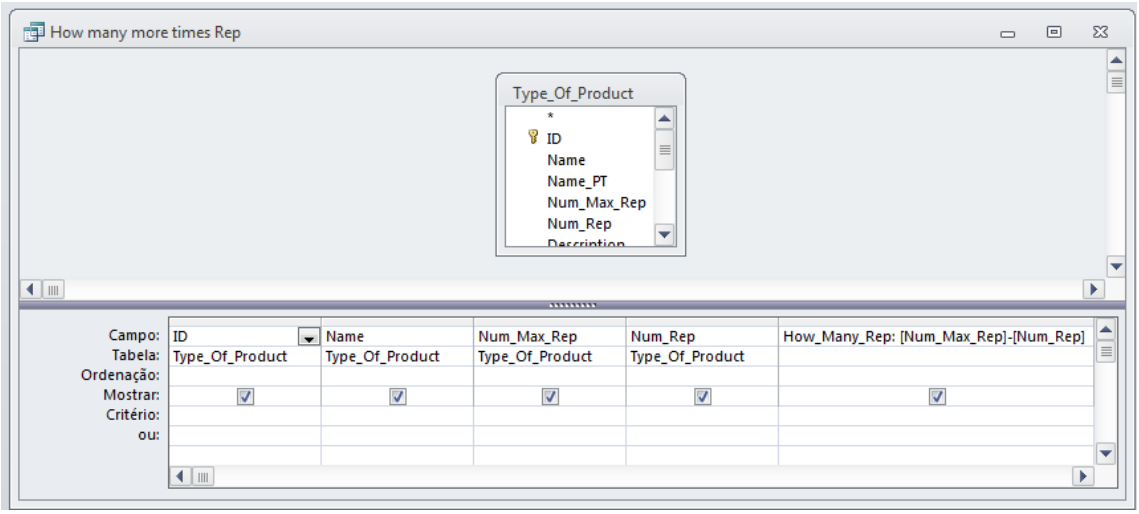


Image 38- Representation of the structure view of the query How many more times Rep.

The query Steps indicates the user, in general, which must be done during a product reprocessing. That is, from this query, we obtain important data on the reprocessing of a product, such as the characterization of a product (critical, non-critical and semi critical), product description, the type of cleaning, sterilization and disinfection, which is the agent disinfection and the proper sterilization process. Image 39 show the query Steps and the results obtained.

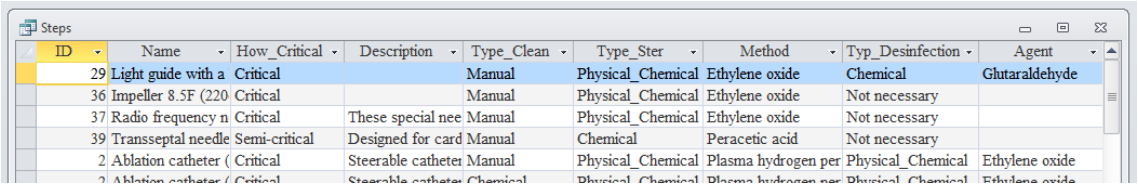


Image 39- Steps query and the data obtained after filtering.

The view of the query Steps shows that there is filtering in the data of the same product from the product ID and the relationship of all tables. Thus, as a result we obtain general information on reprocessing for each product. In Image 40 it appears which are the tables and fields used by this query to retrieve the information you want.

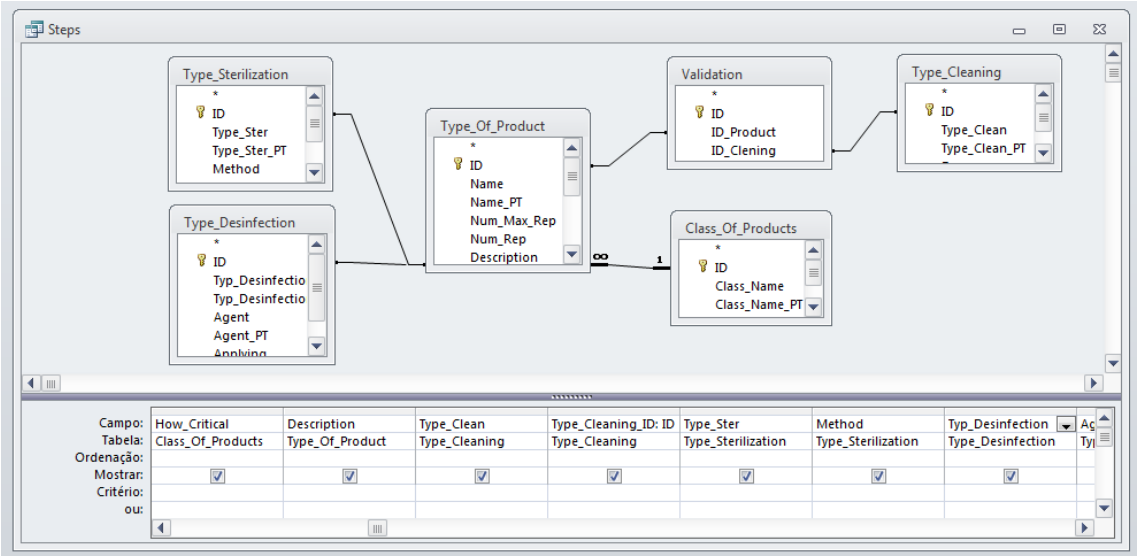


Image 40- Structure of the query Steps, fields and tables used to filter the data.

The query Process is a more detailed consultation of the reprocessing of a product, mening while the query Step only indicates to the user in a general way what should be done in processing, this shows you step by step how to proceed in each step. For example, for the sterilization phase, this query indicates the duration of this step, how to apply the method, among other steps. In Image 41 we can see that the result of the query consists of several fields, ID key (product ID), Name (name of product) Description (steps to follow in the drying stage), Features (steps to follow when packing the product) Indications (steps to follow in the step storage) Applying (steps to follow in the step disinfection), Descr (steps to follow in the cleaning step) and Application (steps to follow in the step sterilization).

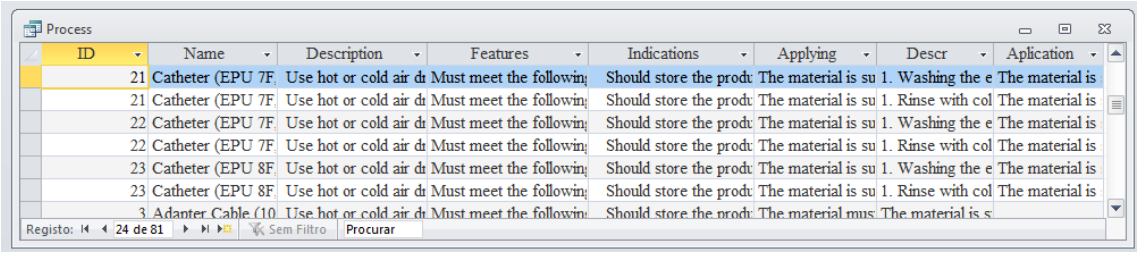


Image 41- Query Process and data obtained after filtering.

If the query Process is put in view structure (Image 42) it can be seen as in in the query Steps, that this query filters the data for the same from the product ID, from the product and relationship of all the tables. Thus, as a result it is obtained the reprocessing

steps detailed for each product, meaning, from this query it is possible to know the step by step to reprocess a product.

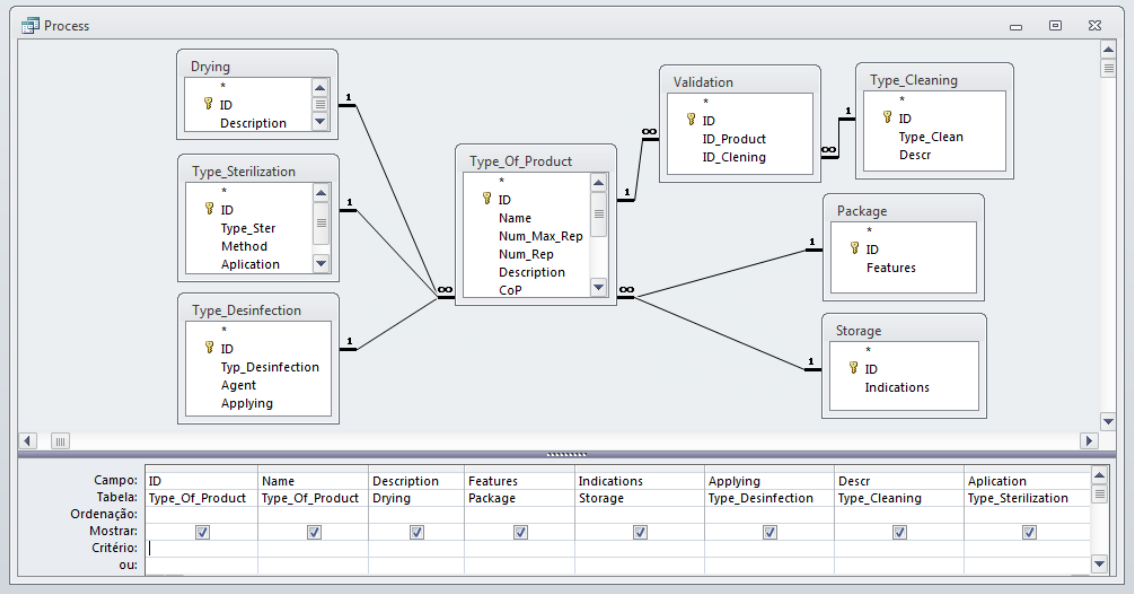


Image 42- Structure of the Query Process, fields and tables to filter the data.

Please note that all consultations described above were performed similarly to the fields whose information is in English and Portuguese, separately.

The creation of these consultations aimed to filtering the data necessary for automatic completion of the buttons created in the graphical interface. Thus, the interface will allow obtaining the reprocessing of medical products from the database in a simple way.

5.3.4 Creation of Forms and Graphic Interface

Another way to filter only the information that is intended is from a window, with a different visual appearance and bolder than in columns from the queries. In this window gives the name of the form. To these forms can be added objects to aid the user, such as buttons, headings, list boxes, aid messages, among others.

In this work were created five forms, 1, Start, RepProduct, AllProcess and New Product. The last four were created in English and Portuguese, whose difference is the name stands PT at the end of the forms in Portuguese.

The form 1 allows user to select the language to view the information. Thus, and as can be seen in image 43, the user must choose between the information in Portuguese or in English by clicking on the corresponding button it is opened the Start form according to the chosen language. This form also presents a button that allows the user to close the entire database.

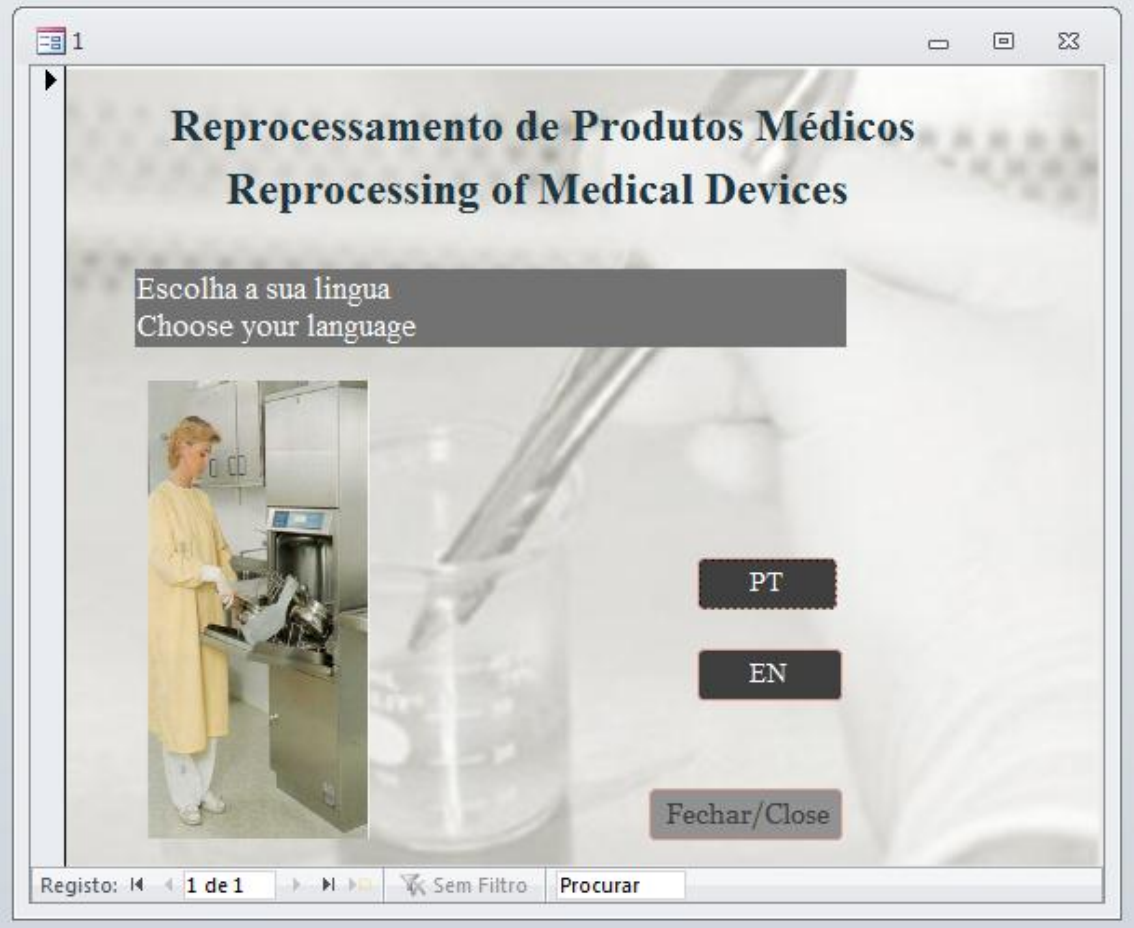


Image 43- Representation of Form 1.

The form Start possible to choose a product already inserted into the database by the combination of two boxes, the first serves to select the product class and the second to choose a product within the class chosen. Alternatively, the insertion of a new product from the selection of a button (New Product or Product Novo) which opens the form NewProduct. This form also has two different buttons, one to open the form RepProduct and another to close the form. In Images 44 and 45 we can see the Start Form in different languages.

Image 44- Representation of the Form Start, in English.

Image 45- Representation of the Form Start, in Portuguese.

The form new product allows the user to add a new product entering all the data reprocessing of the same in the different text boxes, as it can be seen in Images 46 and 47.

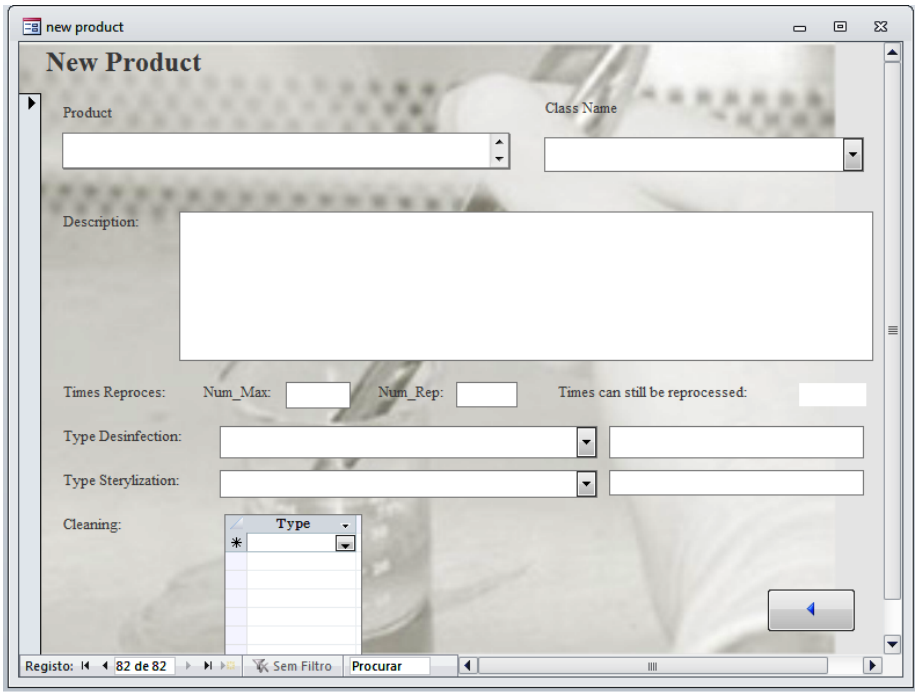


Image 46- Representation of new product forms, in English.

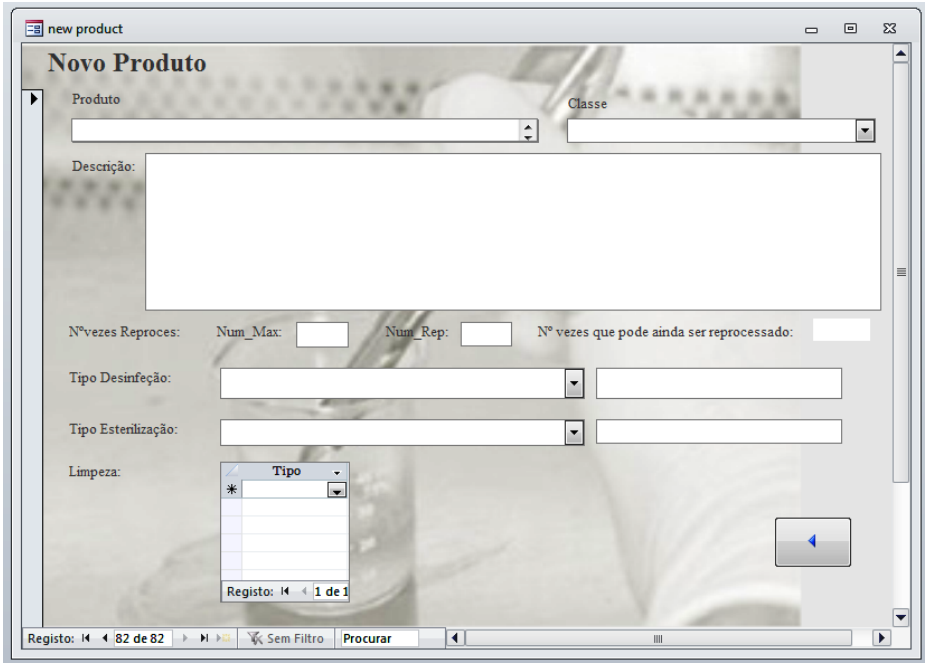


Image 47- Representation of new product forms, in Portuguese.

After choosing the product in the form and clicking on the Start button to open the second form (RepProduct), the name of the product selected is automatically entered in a combo box at the beginning of the second form, and are filled different data for the reprocessing of the product. From this form, such as in the query Steps is obtained a product description, the characterization in critical or noncritical and semi critical, product description, the type of cleaning, sterilization and disinfection, which disinfection agent and the method sterilization is most appropriate for the product. The difference between this and the query is that the data appears in a more attractive way and only refrying to the selected products, as displayed in Images 48 and 49.

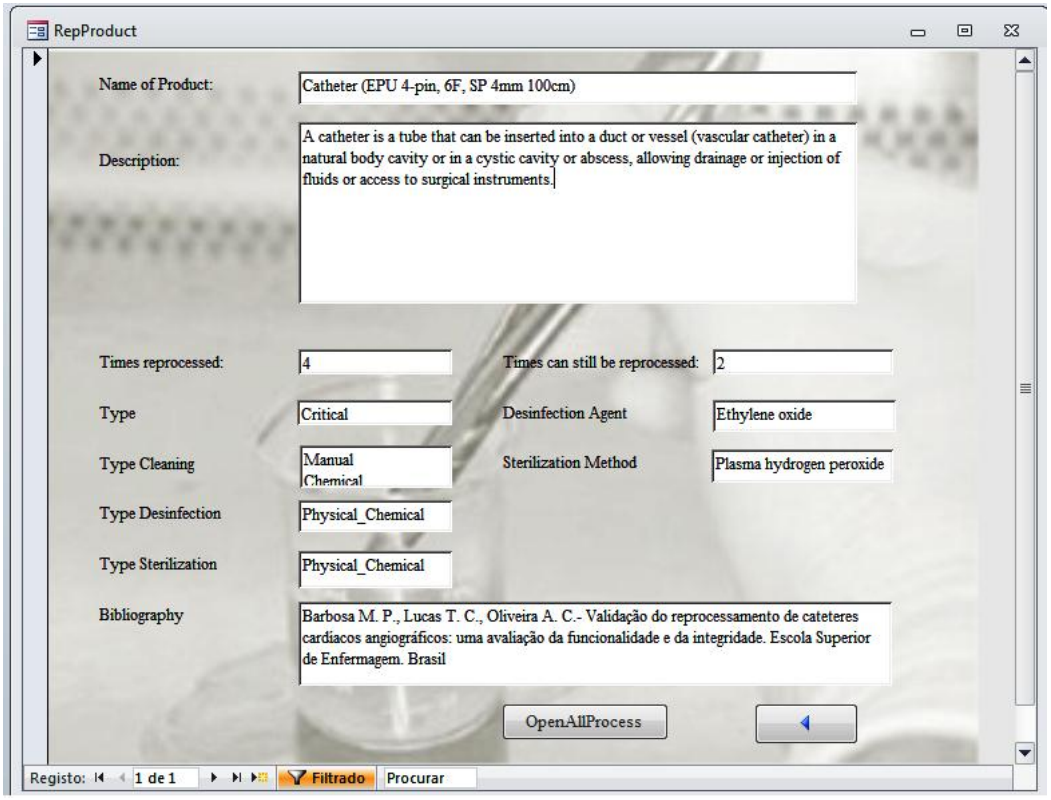


Image 48- Representation of the form RepProduct, in English.

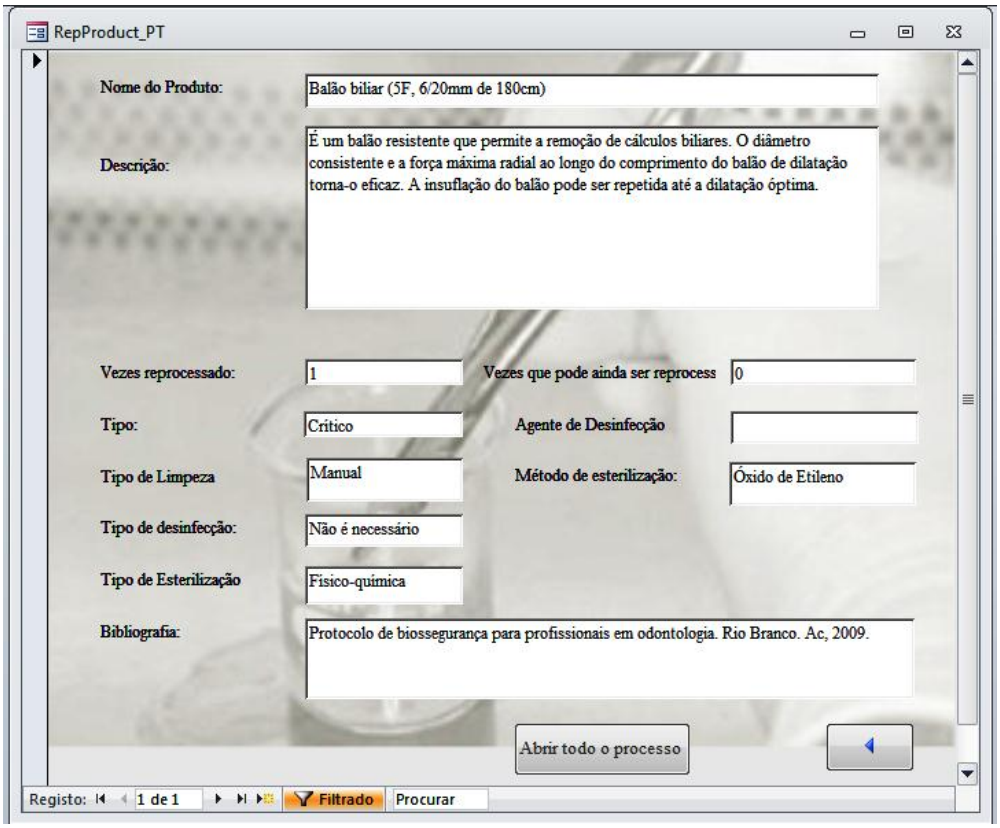


Image 49- Representation of the form RepProduct, in Portuguese.

After viewing this form you can press the button OpenAllProcess to open the third form AllProcess. This form describes step by step what is needed to reprocess the chosen product in the first form, as seen in Images 50 and 51.

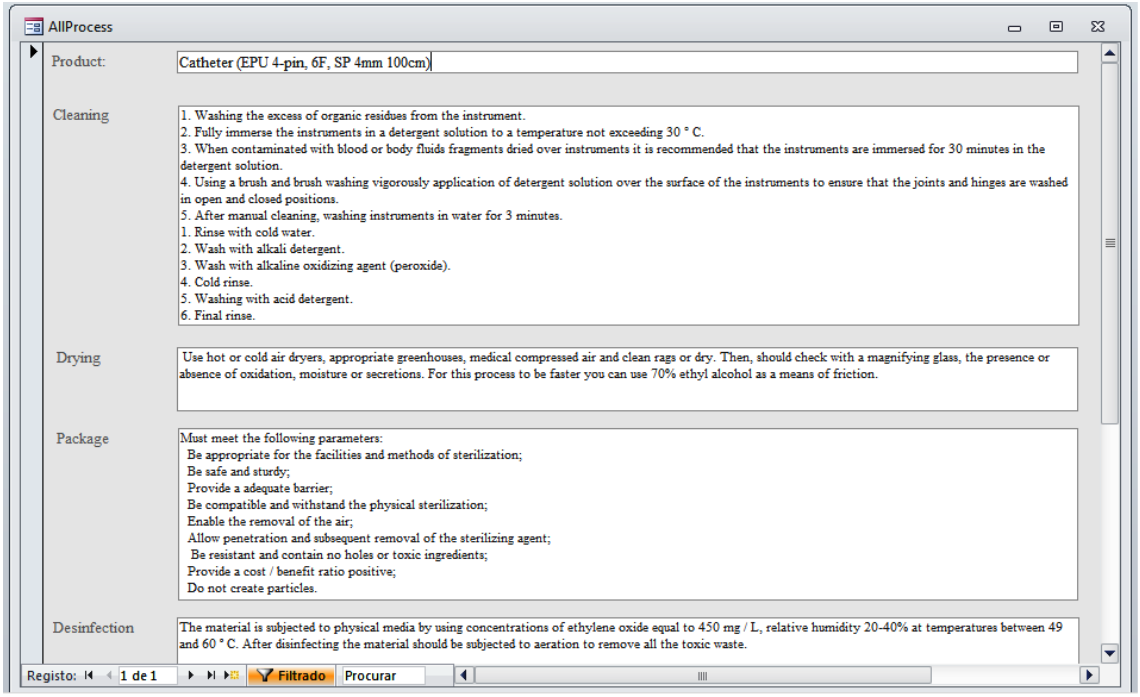


Image 50- Representation of the form AllProcess, in English.

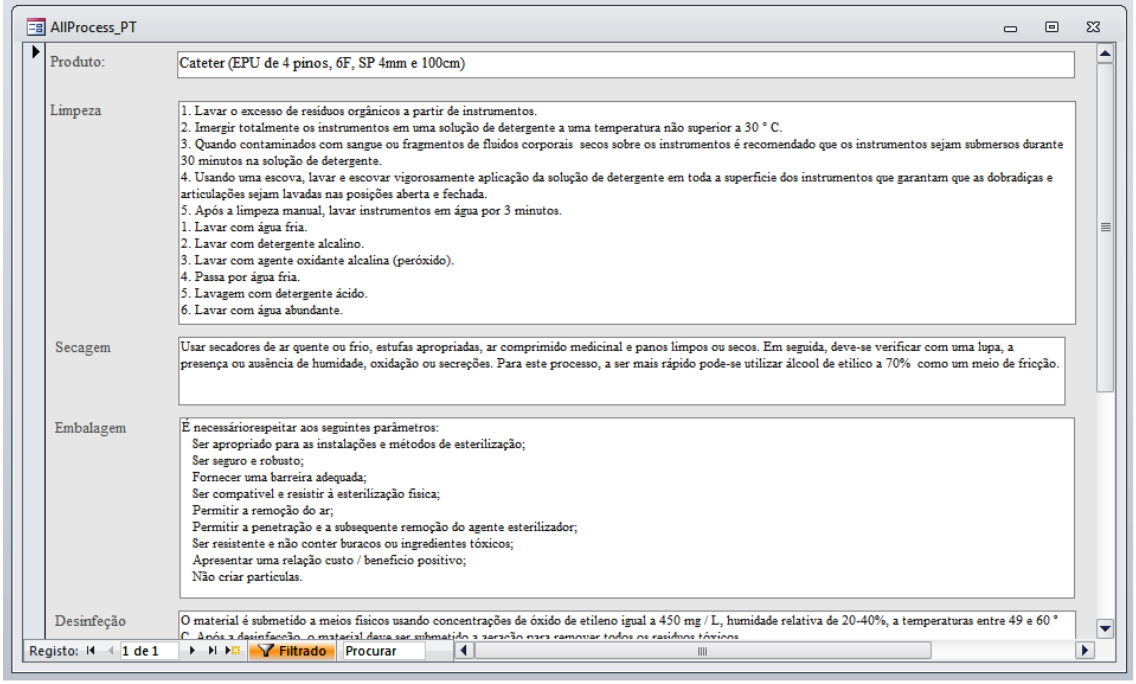


Image 51- Representation of the form AllProcess, in Portuguese.

These buttons can operate from the macros, meaning, a simple and accessible language to the user that automates some functions or from the development of a programming language, the Visual Basic for Applications (VBA). The latter allows the user to develop commands more flexible, strong and complex.

In creating these forms have been developed some code in VBA language that according with choose of the product and the relationships between tables allow autocomplete data boxes of different forms. Annex 2 shows the program developed in VBA language, in creating the interface.

These forms, taken together, form a graphical interface that enables any user, even if it has no knowledge of the Microsoft Access, access to all data in the database. Thus, it is possible for anyone to access the database via the interface and to know the process for reprocessing a medical device inserted in the database. It is also possible that the user enter a new product and the data for the reprocessing only from the interface created.

5.3.5 Creating the Report

Creating a report in this work was intended, after choosing a product in the form Start, to give a complete description of the process of reprocessing of the chosen product, as in the form AllProcess. This tool is very important since it allows the choice of any product from the interface and, from the button (Print) in this form, is obtained automatically, all the steps necessary for initiating the reprocessing of the selected product.

Thus, any user without any knowledge of the Microsoft Access may have access to any steps necessary to reprocess the product studied of the database developed, since one only has to select the product of interest in the first form. It should be noted that this report can be easily printed.

In annex 3 is represented a report obtained for the product Biliary balloon (5F, 6/20mm 180 cm), in English and in Portuguese, an example.

Chapter 6- Conclusions and Future Work

6. Conclusions and Future Work

Reprocessing or not the single-use medical products is a complex problem that involves several issues: medical, ethical, technical, economic, environmental and legal.

The effectiveness and safety of the reprocessing of single- use medical products depend, mostly, of the scientific basis of who does it, since procedures are required in accordance with certain rules and correctly established for that the security of reprocessing extends to the patient.

According to current knowledge, it is not possible to reprocess all single- use medical products indiscriminately. However, you can select them for testing and validate protocols for reprocessing and reuse, based on scientific knowledge, with well-established levels of evidence, using this knowledge to build national health policies with fewer restrictions on high technology resources for Public Health.

Reprocessing of single use medical products shall ensure that the process is of the highest level possible, reduces costs and increases efficiency, and that maintains the balance between medical, economy, quality and ecology, whether for health or for the environment.

The development of this work allows anyone, even if no knowledge of the Microsoft Access tools, to access the complete process, in Portuguese and in English, with all the necessary steps and discriminated in the reprocessing of any single- use product of the developed database. It is also possible to easily add a new product, just by entering data from forms created during reprocessing. Thus, it is always possible to modify and update the database with new data on the recycle products studied or add an infinite number of new products.

As further work would be interesting and very advantageous for the society to carry in several laboratory tests in single-use medical products, mainly in the more expensive ones in order to find an ideal method of reprocessing assuring and that their reuse is completely safe. These tests must evaluate several factors, both microbiological or mechanical, such as number of times that a product can be reprocessed without suffering modifications, evidence of infection, checking if the steps applied are suitable, verifying the presence of waste, presence of pyrogens, changes in the lumen and ductility of the product, among others. Thus, one could find a suitable reprocessing

process without undermining the health of the patient. From that reprocessing we would achieve some very beneficial aspects to society, such as large-scale reduction of costs in hospitals and institutions in buying disposable products, and reduction of hospital waste with great benefits for the environment.

Also, it would be interesting to spread the program of interface to different clinics, hospitals and services and translate the entire database in others different languages for easier use.

In conclusion, most of all the problems that arise related to the reprocessing of single-use medical products are that this may not be sufficiently developed. It is essential to end the inadequate reprocessing, due to quick and inadequate cleanup steps, in the hope that sterilization eliminates the substances that were not removed for cleaning. Of great importance is also investing in training specialists so that the reprocessing of medical products becomes more manual and less automatic, and thus more appropriate.

Chapter 7- Bibliography

[1] - Costa, E. A. M.- Risco e Proteção da Saúde: Reprocessamento de Produtos Médicos em hospitais de Salvador, BA. Instituto de saúde Coletiva-UFBA, 2011

[2] - Graziano K. U., Balsamo A. C., Lopes C. L. B. C., Zotelli M. F. M., Couto A. T., Pascoal M. H. L.- Critérios para a avaliação das dificuldades na limpeza de artigos de uso único. Revista Latino-Americana de Enfermagem, Janeiro-Fevereiro de 2006, (consultado no site http://www.scielo.br/pdf/rlae/v14n1/v14n1a10.pdf)

[3] - Pinto T. J. A., da Silva M. V.- Reutilização simulada de produtos médico-hospitalares de uso único, submetidos à esterilização com óxido de etileno. Revista Brasileira de Ciências Farmacêuticas, Junho de 2005.

[4] - Manual de Boas Práticas: Desinfeção de endoscopia Digestiva. Associação Nacional dos Enfermeiros Endoscopia Digestiva, Junho de 2004.

[5] - Comissão de Biossegurança - Manual de Biossegurança. Faculdade de Odontologia de Araraquara (UNESP), 2009.

[6] - Leichsenring, M. L.- Desafios para Validação no Reprocessamento no Hospital. Grupo de Reuso UNICAMP, Maio de 2006.

[7] - Neto, G. V.- Consulta pública nº98. Agencia Nacional de Vigilância Sanitária, Dezembro de 2006.

[8] - Oppermann, C. M. e Pires, L. C.- Manual de Biossegurança para Serviços de Saúde. Prefeitura Municipal de Porto Alegre, Porto Alegre, Janeiro de 2003

[9] - Oliveira, T. N.- Reprocessamento: Aspetos Éticos, Legais e Benefícios. Seminário Tendências da Autoria Médica: Desafios e Oportunidades, Fortaleza-Ceará

[10] - Relatório da Comissão ao Parlamento Europeu e ao Conselho- Relatório sobre a questão do reprocessamento de dispositivos médicos na união Europeia, de acordo com o artigo 12º.-A da diretiva 93/42/CEE", Bruxelas, Agosto de 2010.

[11] - Orientações Gerais para Central de Esterilização. Serie A Normas e Manuais Técnicos nº105, Ministério da Saúde, Secretaria de Assistência à Saúde, Coordenação-Geral das Unidades Hospitalares Próprias do Rio de Janeiro, Divisão de Controle de Infeção Hospitalar, Divisão de Enfermagem, Brasília, Abril de 2001.

[12] - Ferreira, S. A.- Esterilização e Desinfeção. Divisão de Infeção Hospitalar, Centro de Vigilância Epidemiológica "Prof. Alexandre Vranjac".

[13] - Segurança e eficácia dos cateteres de eletrofisiologia reusados versus cateteres novos. Centro cochrane do Brasil, São Paulo 2005.

[14] - Denser C. P. A. C.- Reprocessamento e reutilização de material odonto-médico-hospitalar de uso único: busca de evidências pela revisão sistemática de literatura científica. Universidade de São Paulo, Escola de Enfermagem, São Paulo, 2004.

[15] - Sampaio L.- Reprocessamento de material médico hospitalar garantindo o atendimento aos requisitos legais. Instituto Mário Pena, Hospital Luxemburgo.

[16] - Reuso: aspetos técnicos e de qualidade mostram riscos para usuário e paciente. Abimed: Associação Brasileira dos Importadores de Equipamentos, Produtos e Suprimentos Médico-Hospitalares, Seminário Comité de Saúde Câmara Britânica.

[17] - Falcão E.- Reprocessamento e Reutilização de Dispositivos de Uso Único, Enquadramento legal: a situação nacional e europeia. Administradora do Hospital de São João, Porto, Outubro de 2011.

[18] - Silva, L. C. F.- Legislação Nacional Sobre Reprocessamento de Artigos Hospitalares. Agencia Nacional de Vigilância Sanitária.

[19] - Vahle V.- System Solutions for Medical Devices: Allocation and High-Tech reprocessing of complex medical devices. Porto, Portugal, 12 de Outubro de 2011.

[20] - Neves M. J.- Reprocessamento de dispositivos médicos de "uso único": A controvérsia da questão. Direção de Produtos de Saúde, INFARMED I.P., Maio de 2008.

[21] - R2DU2: Problema ou Solução, Hospital São João, 12 de Outubro de 2011.

[22] - Frezatti, F., Graziano K. U., Psaltikidis, E. M.- Cálculo dos custos do reprocessamento de pinças de uso único utilizadas em cirurgia vídeo-assistida. Revista da Escola de Enfermagem (USP), 28 de Janeiro de 2005. p. 236 a 2466.

[23] - Souza R. Q., Schmitt C., Torres L. M., Graziano K. U., Lacerda R. A., Turrini R. N.- Complexidade da elaboração de um protocolo para reutilização de materiais de uso único. Revista Ciência Cuidado e Saúde, Outubro/Dezembro de 2010.

[24] - L. A. Medical- Instruções de Reprocessamento de Dispositivos Médicos Reutilizáveis, 5 de Novembro de 2008 (consultado no web site: http://www.lamedical.pt/files/File/Instrucoes%20de%20Reprocessamento.pdf.pdf).

[25] - Protocolo de Biossegurança Para Profissionais em Odontologia. Unidade de Saúde SESI/DR/AC, Rio Branco, 2009.

[26] - Manual de Processamento de Artigos em Serviços de Saúde. Grupo de Estudos em Centro de Material e Esterilização da Secretaria Municipal de Saúde de Contagem, Publicação Inicial, Outubro de 2010.

[27] - Protocolo de processamento de artigos e superfícies nas unidades de saúde Ribeirão Preto- SP.

[28] - Reprocessamento de artigos: importância da limpeza, processos físicos e químicos de esterilização (consultado no web site: http://www.sobracilrj.com.br/micobacterias/CBCF%C3%A1tima.pdf)

[29] - Demarzo D. - A evolução dos esterilizadores a baixa temperatura: plasma de peróxido de hidrogénio. Consultado no site: http://www.sbcc.com.br/revistas_pdfs/ed%2023/23ArtigoTecnicoEsterilizPlasma.pdf

[30] - Venturelli, A. C; Torres, F.C.- Avaliação microbiológica da contaminação residual em diferentes tipos de alicates ortodônticos após desinfeção com álcool 70%. Faculdade de Odontologia de Lins- Unimep, Curso de Odontologia da Universidade de São Paulo. 21 de Setembro de 2009

[31] - Web site: http://hhospitalar.com.br/especialidade.php?cod_espec=1, consultado em 3 de Fevereiro de 2012.

[32] - Reabilitação Ortopédica, consultada no web site http://www.hrmar.pt/index.aspx?showArtigoId=509&Descricao=1, em 4 de Abril de 20122.

[33] - ANVISA.- Resolução RDC nº185, de 22 de Outubro de 2001. Diário Oficial da União [da União da República Federativa do Brasil]. Brasília, 6 de Novembro de 2001.

[34] – Synthes- Compatibilidade dos instrumentos Synthes no processamento clínico. 8 de Março de 2011.

[35] – Synthes- Informações importantes. 8 de Março de 2011.

[36] - Pinheiro MG, Ganhette CC, Melo GCV, Amedeu CV e RM Morais- Sistema de Banco de Dados. São Paulo, 2006

[37] - Moraz, Eduardo- Crie Base de dados com o Acces. São Paulo: Digerati Books, 2006.

[38] - Alves, Paulo - Base de dados. Sistemas de Informática Médica, Instituto Politécnico de Bragança, Escola superior de Tecnologia e Gestão, 2011.

[39] - Noções elementares de base de dados, visualizada no website: http://www.fca.pt/docs-online/495-4cap01.pdf, em 3 de Fevereiro de 2012.

Annex

Annex 1

- Classes and products used in the database, in English.

Class Name of Product	Name of Product
Catheter with Lumen	Catheter (EPU 4-pin, 6F, SP 4mm 100cm)
	Guiding catheter (6F, 100cm)
Cannulas	Tracheostomy tube interior (9cm, 10mm)
	Transseptal needle (71cm)
	Guedel Cannula
Lumen catheter without electricity	Catheter (EPU 4-pin, 4F, SP 2mm and 110cm)
	Catheter (EPU 8-pin, 6F, SP 2/4mm and 105cm)
	Catheter (EPU 8-pin, 6F, SP-10: 2/2mm and 110cm)
	Catheter (7F EPU, and SP-1/3/1mm 110cm)
	Catheter (EPU 7F, 20 pole, and SP 2/6/2mm 115cm)
	Catheter (EPU 2-pin, SP: 2mm to 80cm)
	Catheter (EPU 7F, 4 pole, SP 2/5/2mm and 110cm)
	Catheter (EPU 7F, 4 pole, SP 2/5mm and 115cm)
	Catheter (EPU 8F, 32-pin, 80/110cm)
Instruments with lumen and technical functions	Ablation catheter (7F, 4-pin 2/15/2mm and 110 cm)
	Radio frequency needle electrode CT 1L (15 cm long, 10 mm)
Wire	Guide wire 0025 (480cm)
Tools driven by light	Fiber-optic wide-angle and half-width
Balloon catheter	Biliary balloon (5F, 6/20mm 180cm)
	PTA balloon catheter (5F, 160 cm and 5/40mm)
	PTA balloon catheter (5F, 75cm, 5/60mm)
	PTA balloon catheter (5F, 75cm, 6/40mm)
	Galaxy PTCA Balloon (140cm, 3.5/16mm)
Hose (piping) Systems	Pusher introducer tube bile (6F, a ring)
	Impeller 8.5F (220cm)
	Vitrectomy hose (female / male, 180cm)
Neurosurgical instruments and ophthalmic	Vitrectomy 23G (70cm, 0.6mm)
Neurosurgical instruments and ophthalmic without lumen	Probe laser eye (45)
	Light cable (0.5 mm)
	Light guide with a lancet (20G, 220cm)
Adapters and cables	Adapter Cable (10/14 inches and 250cm)
	Adapter cable (10 pins, 150cm)
	Adapter cable (10 pins, 200cm)
	Adapter cable (10 pins, 250cm)
	Adapter cable (10 pins, 50cm)
	Adapter cable (10 pins, 90cm)
	Adapter cable (pin 1, 250cm)
	Adapter Cable (4 pin, 150cm)
	Adapter cable (EPU, 200cm)
Others	Hand pump for inflation
	Micro scalpel angled spring range (4.1 mm width)
Respiratory products	Exhalation valve
	Mask with inflatable bulge
	Capnograph
	Respirator
	Guide wire for respiratory therapy
	Venturi mask
	Connectors
Products for laparoscopy	Needle Veress
	Trocar (5 or 10 mm)
	Reducer
	Clipador

- Classes and products used in the database, in Portuguese.

Nome da Classe do Produto	Nome do Produto
Cateter com Lúmen	Cateter (EPU de 4 pinos, 6F, SP 4mm e 100cm)
	Cateter guia (6F, 100cm)
Cânulas	Tubo de traqueostomia interior (9cm, 10mm)
	Agulha transeptal (71cm)
	Cânula de Guedel
Cateteres com lúmen sem eletricidade	Cateter (EPU de 4 pinos, 4F, SP 2mm e 110cm)
	Cateter (EPU de 8 pinos, 6F, SP 2/4mm e 105cm)
	Cateter (EPU de 8 pinos, 6F, SP-10: 2/2mm e 110cm)
	Cateter (EPU 7F, SP-1/3/1mm e 110cm)
	Cateter (EPU 7F, 20 pole, SP 2/6/2mm e 115cm)
	Cateter (EPU de 2 pinos, SP: 2mm e 80cm)
	Cateter (EPU 7F, 4 polos, SP 2/5/2mm e 110cm)
	Cateter (EPU 7F, 4 pole, SP 2/5mm e 115cm)
	Cateter (EPU 8F, 32 pinos, 80/110cm)
Instrumentos com lúmen e funções técnicas	Cateter de ablação (7F, de 4 pinos, 110cm e 2/15/2mm)
	Agulha de elétrodo de radiofrequência CT 1L (15cm, 10 mm)
Fios	Fio guia 0.025 (480cm)
Ferramentas acionadas pela luz	Cabo de fibra ótica de grande angulo e meia largura
Cateter balão	Balão biliar (5F, 6/20mm de 180cm)
	Cateter balão PTA (5F, 160cm e 5/40mm)
	Cateter balão PTA (5F, 75cm, 5/60mm)
	Cateter balão PTA (5F, 75cm, 6/40mm)
	Balão galáxia PTCA (140cm, 3.5/16mm)
Sistemas de Mangueira	Empurrador introdutor de sonda biliar (6F, um anel)
	Impulsor 8.5F (220cm)
	Mangueira de virectomia (fêmea/macho, 180cm)
Instrumentos neurocirúrgicos e oftalmológicos	Virectomia 23G (70cm, 0.6mm)
Instrumentos neurocirúrgicos e oftalmológicos sem luz	Sonda laser ocular (45º)
	Cabo de luz (0,5mm)
	Cabo de luz (20G, 220 cm)
Adaptadores e cabos	Cabo adaptador (10/14 polegadas e 250cm)
	Cabo adaptador (10 pinos, 150cm)
	Cabo adaptador (10 pinos, 200cm)
	Cabo adaptador (10 pinos, 250cm)
	Cabo adaptador (10 pinos, 50cm)
	Cabo adaptador (10 pinos, 90cm)
	Cabo adaptador (1 pinos, 250cm)
	Cabo adaptador (4 pinos, 150cm)
	Cabo adaptador (EPU, 200cm)
Outros	Bomba de mão para inflação
	Micro bisturi angulado de gama primavera (4,1 mm de largura)
Produtos respiratórios	Válvula de exalação
	Máscara com bojo inflável
	Capnógrafo
	Respirador
	Fio guia para terapia respiratória
	Máscara de Venturi
	Conectores
Produtos para laparoscopia	Agulha de Veress
	Trocartes (5 ou 10 mm)
	Redutor
	Clipador

Annex 2

- **Code used in the Start**

```
Option Compare Database
Option Explicit


Private Sub CmdOpenRepProduct_Click()
    If IsNull(fmName) Or fmName = "" Then
        MsgBox "You have to choose a product."
    Else
        DoCmd.OpenForm "RepProduct", , , "Name='" & fmName.Column(1) & "'"

        End If
End Sub


Private Sub fmClassProduct_Change()
    fmName = ""
End Sub


Private Sub fmClassProduct_Enter()
    fmClassProduct.RowSource = "SELECT ID, Class_Name FROM
Class_Of_Products ORDER BY Class_Name;"
End Sub


Private Sub fmName_Enter()
    If IsNull(fmClassProduct) Then
        fmName.RowSource = ""
    Else
        fmName.RowSource = "SELECT ID, Name FROM Type_Of_Product
WHERE CoP=" & fmClassProduct & " ORDER BY Name;"
    End If
End Sub
```

- **Code used in the form new_product**

```
Option Compare Database


Private Sub Num_Rep_afterupdate()
Dim dif As Integer
dif = Val(Num_Max_Rep) - Val(Num_Rep)
Texto27 = dif
End Sub


Private Sub Num_Rep_Click()
Dim dif As Integer
Num_Rep = 0
dif = Val(Num_Max_Rep) - Val(Num_Rep)
Texto27 = dif
End Sub
```

- **Code used in the form RepProduct**

```
Option Compare Database
Option Explicit


Private Sub cmdAll_Click()

    DoCmd.OpenForm "AllProcess", , , "Name='" & Me!TxtProduct & "'"
End Sub


Private Sub Form_Load()
```

```
Me.TimesCanRep = DLookup("How_Many_Rep", "How many more times Rep",
"ID =" & DLookup("ID", "Type_Of_Product", "name='" & TxtProduct & "'"))

Me.TimesRep = DLookup("Num_Rep", "How many more times Rep", "ID =" &
DLookup("ID", "Type_Of_Product", "name='" & TxtProduct & "'"))



 Dim rs As Recordset
 Set rs = CurrentDb.OpenRecordset("Steps")
 rs.Filter = "Name like '" & TxtProduct & "'"
 Set rs = rs.OpenRecordset

 Do While Not rs.EOF
   If IsNull(Me.TxtCleaning) Or Me.TxtCleaning.Value = "" Then
     Me.TxtCleaning = rs!Type_Clean
   Else
    Me.TxtCleaning = Me.TxtCleaning & vbCrLf & rs!Type_Clean
   End If
    rs.MoveNext
 Loop

 rs.close



Me.TxtType = DLookup("How_Critical", "Steps", "name='" & TxtProduct & "'")

Me.TxtDesinfection = DLookup("Typ_Desinfection", "Steps", "name='" &
TxtProduct & "'")

Me.TxtSterilization = DLookup("Type_Ster", "Steps", "name='" & TxtProduct &
"'")

Me.TxtMethodSter = DLookup("Method", "Steps", "name='" & TxtProduct & "'")

Me.TxtDesinfectionAgent = DLookup("Agent", "Steps", "name='" & TxtProduct
& "'")

Me.TxtBibliog = DLookup("Ref", "Bibliogra", "name='" & TxtProduct & "'")
```

```
    Set rs = CurrentDb.OpenRecordset("Type_Of_Product", dbOpenDynaset)
    rs.Filter = "Name like '" & TxtProduct & "'"
    Set rs = rs.OpenRecordset
    Me.TxtDescription = rs("Description")

End Sub
```

- **Code used in the form AllProcess**

```
Option Compare Database


Private Sub cmdRpt_Click()

DoCmd.OpenReport "AllProcess", acViewPreview, , "[Código]=" & Me.Código

End Sub

Private Sub Comando23_Click()

On Error GoTo Err_Comando23_Click

    Dim stDocName As String

    stDocName = "RELAT"
    DoCmd.OpenReport stDocName, acPreview
    Application.Reports(stDocName).FilterOn = Me.FilterOn
    Application.Reports(stDocName).Filter = Me.Filter

Exit_Comando23_Click:
    Exit Sub

Err_Comando23_Click:
    MsgBox Err.Description
    Resume Exit_Comando23_Click

End Sub


Private Sub Form_Load()
```

```
 Dim rs As Recordset
 Set rs = CurrentDb.OpenRecordset("Process")
 rs.Filter = "Name like '" & TxtNameProd & "'"
 Set rs = rs.OpenRecordset

 Do While Not rs.EOF
    If IsNull(Me.TxtCle) Or Me.TxtCle.Value = "" Then
       Me.TxtCle = rs!Descr
    Else
      Me.TxtCle = Me.TxtCle & vbCrLf & rs!Descr
      textclean = Me.TxtCle
    End If
      rs.MoveNext
 Loop

 rs.close

'textclean = Me.TxtCle

Me.TxtDrying = DLookup("Description", "Process", "name='" & TxtNameProd
& "'")

Me.TxtPackage = DLookup("Features", "Process", "name='" & TxtNameProd &
"'")

Me.TxtDesinfection = DLookup("Applying", "Process", "name='" &
TxtNameProd & "'")

Me.TxtSterilization = DLookup("Aplication", "Process", "name='" &
TxtNameProd & "'")

Me.TxtStorage = DLookup("Indications", "Process", "name='" & TxtNameProd
& "'")



End Sub
```

Annex 3

- Example of a report obtained from the information system developed for the product biliary balloon (5F, 6/20 mm and 180 cm) in English.

Product:	Biliary balloon (5F, 6/20mm 180cm)«
Cleaning	1. Washing the excess of organic residues from the instrument. 2. Fully immerse the instruments in a detergent solution to a temperature not exceeding 30 ° C. 3. When contaminated with blood or body fluids fragments dried over instruments it is recommended that the instruments are immersed for 30 minutes in the detergent solution. 4. Using a brush and brush washing vigorously application of detergent solution over the surface of the instruments to ensure that the joints and hinges are washed in open and closed positions. 5. After manual cleaning, washing instruments in water for 3 minutes. 1. Rinse with cold water. 2. Wash with alkali detergent. 3. Wash with alkaline oxidizing agent (peroxide). 4. Cold rinse. 5. Washing with acid detergent. 6. Final rinse.
Drying	Use hot or cold air dryers, appropriate greenhouses, medical compressed air and clean rags or dry. Then, should check with a magnifying glass, the presence or absence of oxidation, moisture or secretions. For this process to be faster you can use 70% ethyl alcohol as a means of friction.
Package	Must meet the following parameters: Be appropriate for the facilities and methods of sterilization; Be safe and sturdy; Provide a adequate barrier; Be compatible and withstand the physical sterilization; Enable the removal of the air; Allow penetration and subsequent removal of the sterilizing agent; Be resistant and contain no holes or toxic ingredients; Provide a cost / benefit ratio positive; Do not create particles.
Disinfection	
Sterilization	The material is subjected to physical media by using concentrations of ethylene oxide from 450mg / L to 1200 mg / L, with relative humidity of 45% to 80 at temperatures between 29 and 65 ° C for 2-5 hours. After sterilization the material should be subjected to mechanical aeration (8 to 12 hours, with temperatures between 50-60 ° C) or aeration at room temperature (7 days at 20 ° C) to remove all the toxic waste.
Storage	Should store the products in one place organized, clean, with no signs of infiltration or the presence of insects. Should check for damaged packaging, with signs of moisture or other characteristics that may compromise the sterility of the material and remove these packages. Place the packaging reprocessed more time in front and the newly sterilized in the background. Sterile packaging should be handled with clean hands and with great care. The packaging must not be closed again if it falls or is recklessly exposed to moisture.

- Example of a report obtained from the information system developed for the product biliary balloon (5F, 6/20 mm and 180 cm) in Portuguese.

Produto	Balão biliar (5F, 6/20mm de 180cm)
Limpeza	1. Lavar o excesso de resíduos orgânicos a partir de instrumentos. 2. Imergir totalmente os instrumentos em uma solução de detergente a uma temperatura não superior a 30 ° C. 3. Quando contaminados com sangue ou fragmentos de fluidos corporais secos sobre os instrumentos é recomendado que os instrumentos sejam submersos durante 30 minutos na solução de detergente. 4. Usando uma escova, lavar e escovar vigorosamente aplicação da solução de detergente em toda a superfície dos instrumentos que garantam que as dobradiças e articulações sejam lavadas nas posições aberta e fechada. 5. Após a limpeza manual, lavar instrumentos em água por 3 minutos.
Secagem	Usar secadores de ar quente ou frio, estufas apropriadas, ar comprimido medicinal e panos limpos ou secos. Em seguida, deve-se verificar com uma lupa, a presença ou ausência de humidade, oxidação ou secreções. Para este processo, a ser mais rápido pode-se utilizar álcool de etilico a 70% como um meio de fricção.
Embalagem	É necessário respeitar aos seguintes parâmetros: Ser apropriado para as instalações e métodos de esterilização; Ser seguro e robusto; Fornecer uma barreira adequada; Ser compatível e resistir à esterilização física; Permitir a remoção do ar; Permitir a penetração e a subsequente remoção do agente esterilizador; Ser resistente e não conter buracos ou ingredientes tóxicos; Apresentar uma relação custo / benefício positivo; Não criar partículas.
Desinfeçao	
Esterilização	O material é submetido a meios físicos usando concentrações de óxido de etileno a partir de 450 mg / L a 1200 mg / L, com humidade relativa de 45% a 80, a temperaturas entre 29 e 65 ° C para 2-5 horas. Após a esterilização, o material deve ser submetido a aeração mecânica (8 a 12 horas, com temperaturas entre 50-60 ° C) ou de arejamento à temperatura ambiente (7 dias a 20 ° C) para remover todos os resíduos tóxicos.
Armazenamento	Deve armazenar os produtos num lugar organizado, limpo, sem sinais de infiltração ou presença de insetos. Deve-se verificar se há embalagens danificadas, com sinais de humidade ou outras características que possam comprometer a esterilização do material e remover essas embalagens. Colocar as embalagens reprocessada há mais tempo em frente e as recém-esterilizadas em segundo plano. A embalagem estéril deve ser manuseado com as mãos limpas e com grande cuidado. A embalagem não deve ser fechada novamente se cair ou se for exposta de forma imprudente à humidade.