Executive Summary

1. Introduction

Even though many Korean medical centers have been reusing single use devices after sterilization processing, there were no regulations or recommendations established by a legal legislative unlike countries like USA, Germany and Australia that allows the reuse of single use devices.

The issue of reusing single use devices has been brought up to the society's attention when the reuse of disposable pain adjustment devices has aired on the news in 2003. From then on, the issues of hospitals billing the insurance for the use of single use devices when they have been reusing them have brought up to the society's attention.

However, the insurances were also taking such conditions into their consideration and took the liberty of assuming the reuse of single use devices and applied such assumptions when calculating the costs paid out to the hospitals for using single use devices. Therefore, in order to prevent continuous loss of capital by using single use devices only once, the reuse of single use devices has become prevalent in the Korean medical practices.

In February 2009, Anti-Corruption and Civil Rights Commission has brought up the issue of "hospitals wrongfully billing the insurance for the use of new single use device when they are actually reusing them after sterilization". Not only that, but they went further and addressed the lack of Food and Drug Administration(FDA) regulations to control the reuse of single use devices and the risk of relying solely on sterilization company's standards. Also, they have addressed the existence of two opposing views from Korea Food and Drug

Administration(KFDA) and the Ministry of Health, Welfare and Family Affairs regarding this matter. They also addressed the risk of "lethal secondary infections" from the reuse of single use devices and suggested "Regulations to control wrongful insurance billings for single use devices" to the congress to "define single use devices and prevent the reuse of single use devices".

The issue of reusing single use devices has been debated for 30-40 years in other countries as well. The first issue that has been debated regarding the establishment of regulations for reuse of single use devices has to do with increased infection rates and deterioration of device functions that leads to increased patient mortality and morbidity. Second issue had to do with increased medical costs due to frequent use of single use devices without reusing them. Finally, environmental issues regarding the disposal of single use devices have been debated in order to establish related regulations.

Therefore, this research is focused on reviewing the current policies regarding the reuse of single use devices, performing safety and effectiveness analysis on the reuse of single use devices and introducing legal, social and ethical issues to aid the establishment of national regulations regarding the reuse of single use devices.

2. Research Method

The major questions of this research are as the followings:

1. What are the policies in major countries for the reuse of single use devices?
2. Is the reuse of single use devices clinically effective and safe?
3. What are the social and ethical principles that must be considered regarding the reuse of single use devices?

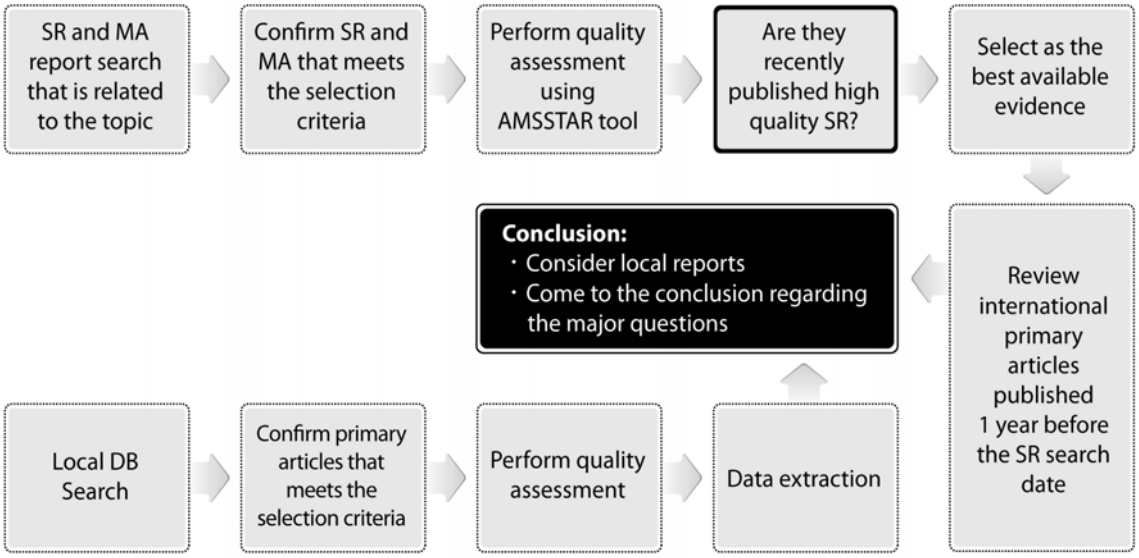
In order to answer above questions, the following methods have been used to carry out the research.

First, extensive research on foreign reports and data regarding the

reuse of single use devices has been performed to understand foreign policies and regulations.

Second, we performed the systematic review using previous systematic reviews to investigate the safety and efficacy regarding the reuse of single-use medical devices. To conduct research device we assessed the relevance and quality of four systematic reviews. We chose recently published and well-conducted systematic review as best available evidence and additionally investigated the primary articles published in Korean. Finally, we adopted the conclusion of AETMIS(Agence d'evaluation des technolgoies et des modes d'intervention en sante) Health echnology Assessment report as the best available evidence haemodialysis membrane, the findings of studies published in Korean were consistent with the results of AETMIS H. Our review as a comprehensive review using existing systematic reviews in methodology. Out of eighty six systematic reviews searched from Ovidmedline, Embase, Cochrane library, CRD database, primary articles published since 2007, and 114 Korean primary researches searched from Koreamed and Kmbase, we selected one report that addressed the safety of reprocessed single-use medical devices, three reports that deals with safety and efficacy, and five Korean researches for the evaluation.

Two reviewers independently applied the selection criteria and the quality of the selected studies was evaluated independently by two reviewers using AMSTRAR tool and modified NHMRC assessment tool.



Third, review on FDA's point of view on current safety and efficacy as well as related GAO report has been performed to confirm the safety and efficacy of reusing single use devices.

Fourth, interviews have been performed to confirm whether or not current Korean medical centers are able to perform sterilization processes that abide to strict FDA regulations.

Finally, reviews on medical technology evaluation reports as well as other reports that deal with social and ethical issues regarding the reuse of single use devices have been performed.

3. International Status

There are various views from different countries regarding the reuse of single use devices. Each country's policies are different based on each nation's medical system as well as their views on the safety of reusing single use devices. However, even though the policies may differ, they all agree on the basic principle that the patient's safety comes first before any other values. The national policies regarding the reuse of single use devices may be grouped to four large

categories. The first category is the countries that allow the reuse of single use devices under strict sterilization regulations. The second category is the countries that bans or not recommends the reuse of single use devices for safety purposes. Finally, there are some countries that do not have a legislation on the reuse of single use devices even though reuse of single use devices is prevalent in their countries. (Table 1)

Table 1. Country Classification for Policies Regarding Reuse of Single use Devices

Banned	Not recommended	Accepted under high quality standards	No legislation but performed
France (Recommendation), Spain, Austria, Portugal, Canada (Manitoba and Northwest State)	UK, Hungary, Canada (New Brunswick, Ontario, British Columbia), Italia, Switzerland	Germany, USA, Australia, Denmark, Sweden, Belgium, Norway, Netherlands, Canada (Quebec)	Singapore, Japan, Taiwan, Greece, New Zealand, Poland, Finland

Countries that ban the reuse of single use devices are France, Spain and Austria. In the case of France, there is no ban against the reuse of single use devices. However, government's strong recommendations against the use of single use devices prevent French medical centers from reusing single use devices. Similar to France, UK also strongly recommends medical centers not to reuse single use devices after the preliminary use. It is the UK government's view that there is lack of systemic review on the safety and efficacy of reusing single use devices after the preliminary use. Therefore, the government feels that patients are exposed to unnecessary risks when the medical centers reuse single use devices. In the case of Canada, different province have different views on this matter. Countries like Singapore, Japan and Taiwan do not have a formal opinion that has been imposed on the national medical society to regulate the reuse of single use devices.

Countries that have decided that the reuse of single use devices is safe as long as a strict quality control system is imposed upon the medical society allows by law to reuse single use devices. USA, Germany and Australia are the examples. Germany allows the reuse of single use devices as long as the medical centers go through the authorized standard procedure. Germany has imposed the Robert Koch Institute Recommendations regarding the sterilization process of used single use devices to control their medical society. Also, Australia allows the reuse of single use devices as long as the medical centers abide to their TGA guidelines.

In United States, since the introduction of Medical Device User Fee and Modernization Act(MDUFMA) in 2002, it has been tweaked until 2006. This regulation forces sterilization companies to register as medical device sterilization companies in USFDA and submit the list of medical devices that they wish to handle. Also, the sterilization company must be able to report adverse effects from reusing single use devices, follow up on sanitized medical devices, control quality based on cGMP and perform labeling as well as validation in order to be approved as a medical device sterilization company. Only the single use devices that have been notified for its reuse before being launched in the market (510k) are allowed to be reused for medical purposes as well.

4. Basis for the Safety and Efficacy of Reusing Single use Devices

4.1 Evaluating Medical Technology

Conclusion regarding the clinical efficacy of reusing single use devices has been drawn up from NZHTA(New Zealand Health Technology Assessment) report published in 2004 and CADTH(Canadian Agency for Drugs and Technologies in Health) published in 2008 in combination with health technology assessment report from AETMIS(Agence d'evaluation des technolgoies et des

modes d'intervention en sante) published in 2009.

Additionally, we selected five Korean researches on the reuse of hemodialysis membrane(dialyzer) and the disposable blade in automated microkeratome. The results of the safety and efficacy of reprocessed hemodialysis membrane consisted with previous AETMIS report. In primary studies published since 2007, ultrasound catheter, Arthroscope shaver blade/abrader, and nasopharyngoscope sheaths were examined to identify the safety after reprocessing.

Based on 2009 AETMIS conclusions, we evaluated 19 single-use medical devices (15 critical medical devices and 4 semi-critical medical devices) and categorized them into the following groups to provide the evidence for their safety and efficacy after reprocessing of its single use.

Table 2. Evidence for Reuse of Single use medical Devices

Medical Devices		Evidence
critical	PTCA catheter	B
	Balloon catheter	C
	Electrophysiology catheter for diagnostic purposes	B
	Central vein catheter	C
	Disposable angioscopy	C
	Argon beam coagulation detector	C
	Perfusion cannula	C
	Disposable plastic trocar / disposable laparoscope devices	B
	Dialyzer	A
	Sphincterotome	B
	Phacoemulsification needle tip	C
	Forceps for biopsy	D
	Disposable blade for micro-cornea incision	C
	Ultrasound catheter (AcuNav- catheter)	C
	Arthroscope shaver blade/abrader	C
semi-critical	Components of orthopedic external fixator	B
	Breathing circuit filter	C
	Artificial airway/ Bronchoscope stopcocks	C
	nasopharyngoscope sheaths	C

A : there is sufficient evidence to conclude that it is safe and effective to reuse single-use medical devices

B : There is sufficient laboratory evidence that support the safety of reusing these single use devices. However, it needs well designed clinical trial in human.

C : In small number of scientific studies, they had low level of evidence conducted in vitro nature of these studies.

D : All of studies conducted in vitro may not be safe after being reprocessed.

Single-use medical devices must be recycled only if there is sufficient amount of evidence that supports that reuse after reprocessing does not increase the risk in any ways for the patients as well as the hospital staffs compared to the use of multiple-use medical devices.

There is a lack of data to evaluate the safety and efficacy of reprocessing and reuse of devices labeled single-use enlisted in FDA. Therefore, we need to perform the researches to demonstrate that device integrity remains substantially equivalent to its predicate device after a maximum number of times of reuse.

4.2 Summary on FDA and GAO Report

There are some perspectives that argue the reuse of single use devices is safe because there are no reported serious complications despite its prevalence around the globe. US Regulations and laws regarding this matter have been strengthened in 2002 as well as FDA regulations on monitoring and reporting the complications that may have occurred from reusing single use devices. Even though the data that has been collected through these regulations has its limitations, FDA has concluded that there are no significant evidences that support the increase of risk due to reuse of single use devices; thus not cost-effective to perform detailed tests on this matter. In 2008, Government Accountability Office (GAO) has noted that despite of FDA's efforts to collect data related to the safety of reusing single use devices, there are insufficient amount of data and research that allow FDA to conclude the reuse of single use devices are not as safe and efficient as the initial use of single use devices. Also, they have added that there are no questions aroused from FDA's monitoring and complication analysis methods.

5. Case Study : Electrophysiology Catheter for Diagnostic purposes

Electrophysiology catheter is a single use device that costs 580,000 ~ 1,800,000 Wons per piece and was billed for 7,759,290,000 ~ 23,859,290,000 Wons to the insurance in 2008. In this research, the study on US sterilization processes for the reuse of Electrophysiology catheter has been performed to evaluate whether or not it could be applied to the Korean medical system. The sterilization processes has been researched from USFDA and sterilization company's websites and are as shown in picture 3. In order to determine whether or not this method could be applied to the Korean medical system, six major Korean medical centers have been interviewed and four medical centers have been visited to observe their sterilization processes. From this research, it has been determined that it would be difficult to implement US sterilization processes to the Korean medical centers. Currently, the Korean medical centers are relying on eye-inspections to determine the efficacy of sterilization process and replied that it would be impossible to implement electrochemical tests to determine the efficacy of their sterilization processes. The comparison of US and Korean sterilization processes are as shown in Figure 2 and 3.

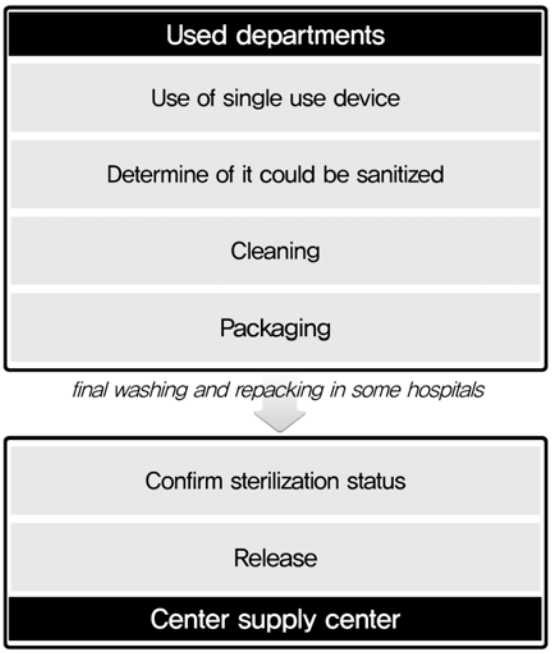


Figure 2. Korean Sterilization Process

Figure 3. US Sterilization Process

When all of the single use devices are reused, it would be impossible to estimate the economical benefits from it due to variable factors that play its role such as: scope of market for reused single use devices, lack of data on inefficacy of sterilization processes, maximum number of use before the device looses its integrity, labor cost and facility costs. Therefore, the reuse of Electrophysiology catheter has been selected as a case study to estimate its economical benefits. When the calculation assumes that the maximum reuse frequency of Electrophysiology catheter is two to six times based on international researches, Korean insurance should be able to save 2.4 ~4.1 billion Wons from reusing Electrophysiology catheter.

6. Social, Ethical and Legal Considerations

The basic principles that deal with ethical issues are the principle of beneficence, principle of non-maleficence, principle of respect for

autonomy and the principle of justice. Additionally, contractarianism, utilitarianism and land ethic perspective must be considered as well.

The principle of beneficence and non-maleficence deals with the potential risk of patients due to the reuse of medical devices designed for a single use only. Evidences for such perspectives may be obtained from medical technology evaluation data and international researches provided in articles 4.

From contractarianism's point of view, the agreement to reuse single use devices must be made by both parties thus requires consent from the patient before its reuse. Normally, when there is a risk of danger, it is normally accepted for the physicians to provide the patients with necessary information. However, when there is no evident risk for reusing the medical device, there is no need to increase the patient's anxiety by providing unnecessary information because the patient has granted the doctors with right to make decisions based on the patient's best interests. However, some may argue that the patients have the right to know whether or not the medical devices are being reused or not. Countries like Sweden, Belgium and Australia require patient consent before reusing sterilized single use devices. However, there are no such regulations in place in USA and Canada. In the case of United States, US FDA has implemented strict regulations regarding the process of single use devices before being reused. After the devices have been sterilized to FDA standards, those devices may be sold in the market with FDA approval. Since both new and sterilized single use devices have FDA's approval to be sold in the market, USFDA argues that there is no need for patient's consent in reusing sterilized single use devices. In other words, as long as the doctors act on the patient's best interest, they are obligated to explain and receive consent for the medical procedures but not obligated to inform and receive consents for the medical devices used during the procedures.

The principle of justice deals with social regulations and

management systems regarding the reuse of single use devices. In other words, it deals with the existence of regulation for controlling the sterilization processes, follow-up system for potential risks and possible compensations in the case of accidents.

The utilitarianism perspective deals with the overall benefit made from the decision of allowing the reuse of single use devices. According to this perspective, there is a need to minimize individual risks for reusing medical devices while considering the social benefits that could be created from it. In other words, economical benefits as well as the benefits from reducing medical garbage must be considered along with social and environmental benefits to include the land ethic perspectives.

7. Conclusion

This research has reviewed medical evidences of reusing single use devices and different country's policies regarding this matter as well as social and ethical perspectives.

Medically, there are two contrasting perspectives. The first perspective argues that there are not enough clinical evidences to support that the reuse of single use devices are as safe as the initial use of single use devices. The second perspective argues that there are no concrete evidences to say that the reuse of single use devices increase the risk for both patient and physicians despite the enforced system that makes medical centers to report complications aroused from reusing single use devices. From the former's perspective, Dialyzer is the only single use device that may be reused based on concrete evidences to support its safety and efficacy even after the initial use. Also, it recommends the reuse of Electrophysiology catheter, trocar, sphincterotome and orthopedic external fixator only when there are extensive regulations on their sterilization processes in place. The latter perspective, taken by USFDA and GAO, argues

that after implementing an extensive system that both monitors the reuse of single use devices and controls their complications, it can be concluded that there are no evidences that support the increased risk for patients due to reusing single use devices.

Therefore, this research concludes that there is an essential need to consider the potential danger to patients, existence of follow up system for reused single use devices and the scope of social benefits before determining the national policy on reusing single use devices.