ERASMUS+ KA2 Strategic Partnership
2018-1-TR01-KA203-058252 Immersive Business and Engineering English in Virtual Reality: A tool for the Sustainable Mobility of the Skilled Workforce in the EU (I-BEE-VR)

Step 1: Review the patent document of an energy harvesting device and the review notes of the production manager of the firm which would like to mass produce the device. The notes include the possible quality issues and suggested solutions during the manufacturing process of the product. Give a 5 minute presentation on the quality issues and solutions of the product and video-record your presentations and upload them on the specified platform.

NOTES

The device with the patent number EP 3 497 382 B1 is an energy harvesting device based on cavitation and heat generation through collapsing cavitating bubbles. The device comprises a liquid's flow path having an upstream and downstream side and proposes an energy harvesting method from liquid streams.

According to the Patent Document, the energy harvesting device

- might be a solution to the increasing energy demand on earth.
- is recommended for manufacturing since market size is high and the production cost is low.
- has low operational costs
- is not complicated, easy to manufacture

According to the Quality Inspection tests on the prototype, a table is provided for the possible issues and suggested solutions:

QUALITY ISSUES	SOLUTIONS
sealing issues- leaks	quality sealing materials (impermeable materials)
clogging issues	quality filters
pressure regulation issues	renewing the pressure control units
fabrication issues related to small dimension	improving the clean rooms in the factory

Adapted from Koşar A. (2019). EP 3 497 382 B1. Retrieved from https://worldwide.espacenet.com/patent/search/family/057184776/publication/EP3497382B1?q=Kosar%20ali

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Answer Key:

The students will analyze a prototype. The analysis will be done from the patent document, and the review on the same product the students will be provided with a template of possible issues (this time quality issues) and possible solutions (quality issues) and video-record them for the teacher to evaluate.

ISSUES	SOLUTIONS
Metal Debris Problem-soft tissue reaction, disturbed sleep, mood swings and anxiety, hearing loss, visual problems, and tinnitus.	• the issue should be monitored through a heightened level of trace amounts of the metals cobalt and chromium in the blood of a patient. • a revision of the implant should be completed as early as possible. • all patients implanted with a metal on metal implant that has a large diameter head (36 mm or greater) will require annual follow-up for the life of the implant. • the metal hip could be removed • recalling the life-threatening implants
• The device is not tested • Regulations are not universal	• a unique serial number is required. • The implant should be tested for safety. • Universal regulations should be created

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Step 2: Read the following extract, then fill in the table provided with the possible safety and solutions and write a report the introduction of which is already given.

Metal on Metal Hip Implants

ISSUES

The majority of patients who receive a metal on metal hip replacement do well with the implant and are thought to be at low risk of developing serious problems. A small number of patients implanted with metal on metal hip replacements may develop a metal debris problem that can lead to a progressive soft tissue reaction in proximity to the joint. The metal debris problem does not occur in every patient but in some patients it occurs through the build-up of microscopic metal debris through wear at the articular surface of the joint.

There are also physical differences between a device marketed in different countries under the same name. Devices used in a country may not be available in another country. There are also substantial differences in the practice of "mixing and matching" implant components among the countries.

ACTION

The issue should be monitored through a heightened level of trace amounts of the metals cobalt and chromium in the blood of a patient. Early revision surgery of poorly performing hip replacements is likely to lead to a better outcome of revision surgery. Where appropriate a revision of the implant should be completed as early as possible. Importantly all patients with implanted with a metal on metal implant that has a large diameter head (36 mm or greater) will require annual follow-up for the life of the implant.

Strict and universal regulations on the implant and its components should be created for all the countries in the world.

Adapted from https://www.medsafe.govt.nz/hot/alerts/mom-hip-implants.asp
and https://www.fda.gov/medical-devices/metal-metal-hip-implants/concerns-about-metal-metal-hip-implants

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TABLE:

ISSUES	**SOLUTIONS**
HEALTH ISSUES •	• • • • •
THE REGULATIONS AND TESTING • •	• •

REPORT

The aim of this report is to mention the issues encountered during the safety inspection process of the metal hip implant without a code number. Before the release of the product, a number of safety tests were not performed. Although the product proved conformance to a majority of criteria, two specific issues were detected after its release and use.

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ANSWER KEY:

SAMPLE REPORT

The aim of this report is to mention the issues encountered during the safety inspection process of the metal hip implant without a code number. Before the release of the product, a number of safety tests were not performed. Although the product proved conformance to a majority of criteria, two specific issues were detected after its release and use.

Regarding the health issues, the inspections on the device revealed a specific issue: metal debris problem. Based on the findings of the results, this problem leads to soft tissue reaction, disturbed sleep, mood swings and anxiety, hearing loss, visual problems, and tinnitus. As a solution to this problem, it is suggested that the issue should be monitored through a heightened level of trace amounts of the metals cobalt and chromium in the blood of a patient, if required, a revision of the implant should be completed as early as possible. Also, all patients implanted with a metal on metal implant that has a large diameter head (36 mm or greater) will require annual follow-up for the life of the implant. If these cannot solve the problems, the metal hip could be removed. If the problem is repeatedly observed, the device should be recalled from the market.

It is also revealed that the device is not tested before the release. This evidently leads to life-threatening consequences. It is urgently suggested that the device should be tested and each device should have a unique serial number so that when a problem occurs the company can contact the person with the implant to warn her/him. Besides, regulations for the implant are not universalized and this result in substantial differences in the practice of "mixing and matching" implant components among the countries. Therefore, universal regulations should be created and the implants should be manufactured according to these regulations.

In conclusion, the issues detected pertaining to safety processes have been presented. In addition to the solutions suggested in detail above, preventive action procedures should be conducted before the manufacturing process of the generator is initiated. This will definitely increase prospective customer safety of the product.