UDC 21474

CLOSED-SYSTEM TRANSFER DEVICE

Derevenchuk D.O., Shi Guangtian
Lanzhou Jiaotong University, School of Mechanical Engineering

Contamination by antineoplastic drugs is a common problem, with residues found on the skin of more than a quarter of nurses who came into contact with patients on chemotherapy regimens. Surfaces in hospital pharmacies, operating rooms, and treatment areas can also retain residues from antineoplastic drugs and other pharmaceuticals. Once released into the environment, anyone in the area is at risk of ingesting them, which could cause skin irritation and even long term complications, such as infertility, miscarriage, congenital malformation, and leukemia or other types of cancer. Many drugs pose a significant danger to medical personnel, who are constantly working with them. Dangerous medicines include: cytostatics, antibiotics, antiviral agents, hormone-like substances, etc. A new transfer system device (PYQ) protects medical personnel from unsafe drugs.
Keywords: drugs contamination, disposable sterile dispenser, transfer device.

Introduction. Working directly with or near to unsafe drugs can lead to many unpleasant consequences: skin rash, nausea, changes in blood counts, impaired functioning of the reproductive system (decreased fertility, problems with bearing, premature births, spontaneous abortions, congenital malformations), development of neoplastic processes. And cytostatics can be found in biochemical analyzes of all personnel who work with the appropriate drug or in the same room. It should be noted that the international agency for the study of cancer has established long ago that many chemotherapeutic drugs are oncogenes or possible oncogenes. Once released into the environment, anyone in the area is at risk of ingesting them, which could cause serious complications. The device is a preassembled syringe that prevents medical professionals from hazardous drugs, drugs contamination or air-bubble migration. Other products on the market – transfer devices and syringes do not protect medical workers from hazardous drugs as disposable sterile dispenser device.

Research Objectives and Methodology. The researchers found several possible ways of getting dangerous drugs into the body: through the skin, inhalation route, ingestion (involuntary penetration of the hand into the mouth), injection pathway (needle prick, tools). Accordingly, dangerous manipulations are distinguished: opening the vial with a needle to dissolve or set the drug, removing the needle after the preparation, transferring the syringe, inserting the needle into the vein or catheter, removing the needle after the injection. An extremely high level of contamination with preparations of all surfaces of premises for their preparation and/or administration was also detected. Proper waste disposal is an important safety factor. Wastes contaminated with dangerous preparations should be stored separately from other wastes in special closed containers.

The main purpose of this study is to provide valuable information on the effective design of transmission systems in order to protect health workers from the harmful effects of drugs. A disposable sterile dispenser of the device is a system used to transfer drugs from one reservoir to another, while limiting the potential for aerosolization and drug contamination. After being connected to the reservoir, the device equalizes the pressure gradient between the vessel containing the drug and the syringe. The study includes the SolidWorks 3D program to create a disposable dispenser device.

The existing dispensing method has the following deficiencies:

– Complex technological process.
– A large number of medicaments are wasted.
– It's easy to cause infection.
– Produces a large number of medical debris.

Disposable sterile dispenser device advantages:

– Simplified process control.
– Reduces the waste of medications.
– Prevents penetration of air and foreign objects.

– Relevant for all categories of drugs (difficult to soluble, antineoplastic).

– Reduces a large number of medical debris.

In choosing an appropriate system, it is important to take into account all available efficacy data and to make an informed choice, as not all CSTDs are equally effective in containing hazardous medications. Examining and comparing the design characteristics of different systems – including differentiation of closed from air-cleansing systems – is a key consideration in this choice.

Limiting exposure to hazardous drugs is important due to the potential for harm to pregnant women and due to the increased risk of chromosomal abnormalities associated with hazardous drug exposure in all health care workers.

Proposed disposable sterile dispenser device designed for healthcare personnel.

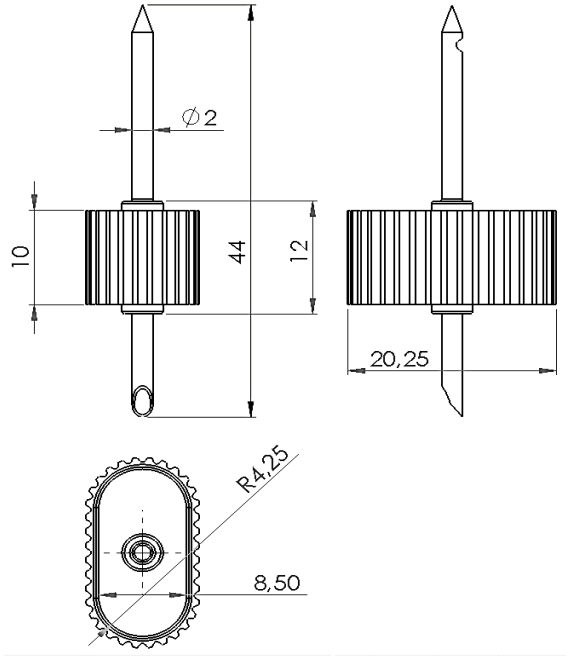

Fig. 1. Disposable sterile dispenser device

Materials:

Needle – Austenitic stainless steel.

Austenitic stainless steel is a specific type of stainless steel alloy. Stainless steels may be classified by their crystalline structure into three main types: austenitic, ferritic and martensitic.

Body – Polypropylene.

Polypropylene (PP), also known as polypropene, is a thermoplastic polymer used in a wide variety of applications. An addition polymer made from the monomer propylene, it is rugged and unusually resistant to many chemical solvents, bases and acids.

Cover – Transparent polypropylene.

Fig. 1-1(a) shows proposed design as to create a transfer device design to compare to other devices.

Principle of operation. The disposable sterile dispenser device has two needles. One needle is connected to the container with the medicine when the second needle is connected to the empty ampule. After that, the liquid is transferred from the container to the ampoule by squeezing the container, thus preventing microbial ingress into media-filled vials even after repeated inoculation. Since the disposable sterile dispenser no further setup, quicker deployment times are available and thereby contributing to ease of use and overall hospital productivity. After transfusion of drugs from the container into the ampoule, the drug transfer device can not be reused. The device is disposable. On the ampoule there are no traces of the drug, which allows you to safely store the ampoules in boxes.

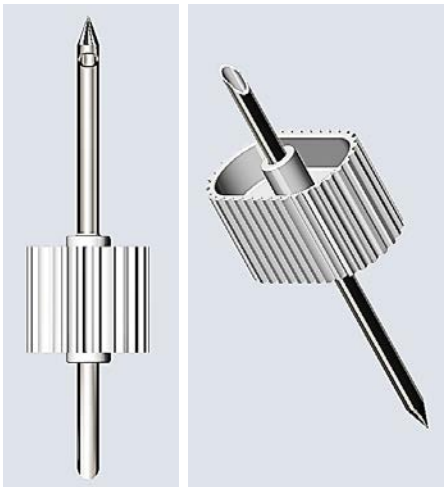

Fig. 1(a). Disposable sterile dispenser device (3D model)

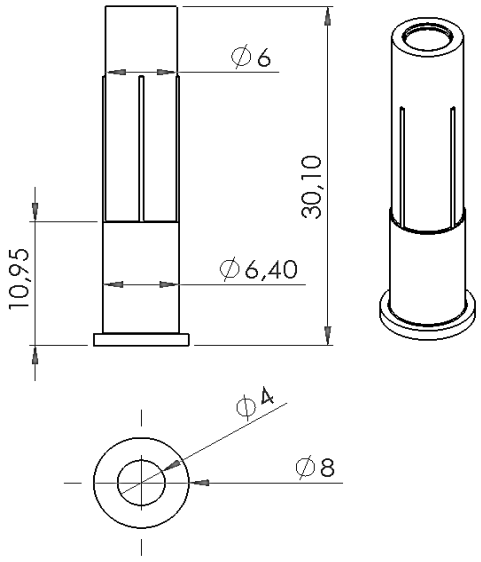

Fig. 2. Cover for disposable sterile dispenser device

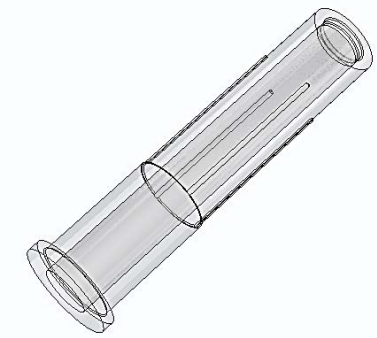

Fig. 2(a). Cover for disposable sterile dispenser device (3D Model)

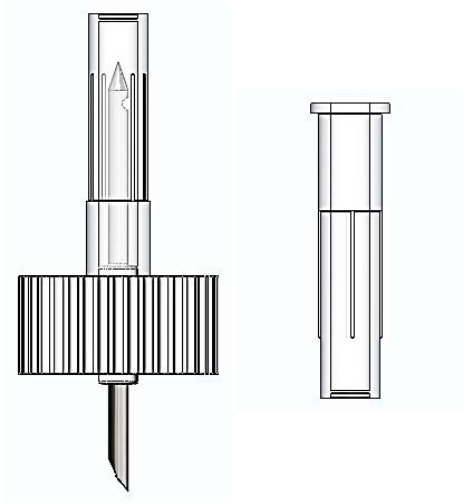

Fig. 3. Cover and disposable sterile dispenser device connected together (3D Model)

Conclusions. One of the modern and promising approaches to protecting medical personnel is the use of closed systems for the dilution, mixing and administration of drugs. Closed systems are devices that mechanically prevent the drug and its vapors from entering the system. The use of such systems makes the administration of chemotherapeutic drugs safer. In some countries, hospitals that use closed systems have been able to weaken the safety measures for nurses who administer chemotherapy drugs. This reduced the costs of the hospital and made it possible to make the process of administering drugs less frightening for patients. The weakening of safety measures is possible only with the use of closed systems – sealed systems that prevent aerosols, vapors and liquids from getting into the environment during the preparation and administration of preparations. Such systems allow the mixing and administration of preparations using various standard vials, syringes, intravenous systems and infusion bags. The use of closed systems allows almost completely prevent the effects of medicines on medical personnel.

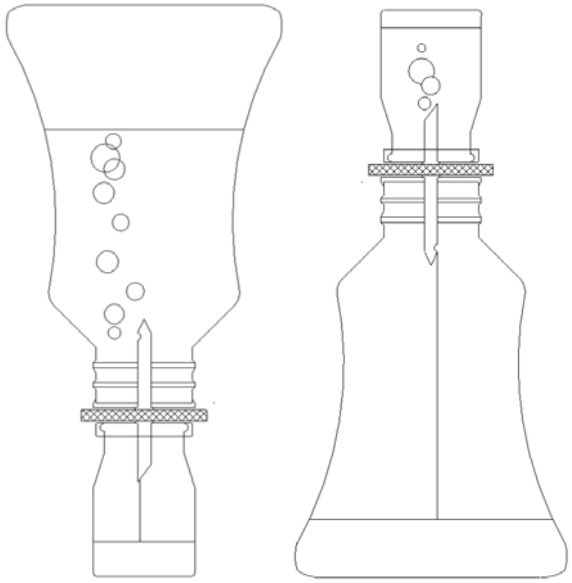

Fig. 4. Principle of operation of the Disposable sterile dispenser device

Referenses:

1. http://www.cdc. gov/niosh/docket/review/docket288/pdfs/a-vapor-containment-performance-protocol-for-closed-system-transfer-devices.pdf – Accessed November 2015.
2. Valanis B., Vollmer W.M., Steele P. Occupational exposure to antineoplastic agents: self-reported miscarriages and stillbirths among nurses and pharmacists. J Occup Environ Med. 1999; 41(8): 632-638.
3. Sessink P.J., Connor T.H., Jorgenson J.A., Tyler T.G. Reduction in surface contamination with antineoplastic drugs in 22 hospital pharmacies in the US following implementation of a closed-system drug transfer device. J Oncol Pharm Pract. 2011; 17(1): 39-48.
4. Wick C., Slawson M.H., Jorgenson J.A., Tyler L.S. Using a closed-system protective device to reduce personnel exposure to antineoplastic agents. Am J Health Syst Pharm. 2003; 60(22): 2314-2120.
5. Clark B.A., Sessink P.J. Use of a closed system drug-transfer device eliminates surface contamination with antineoplastic agents. J Oncol Pharm Pract. 2013; 19(2): 99-104.
6. Massoomi F. Assessing Vial Transfer Devices for Handling Hazardous Drugs. http://www.pppmag.com/article_print.php?articleid=515 – Accessed November 2015.
7. Page M.R. USP <800>: New Regulations to Protect Health Care Workers from Hazardous Drugs. http://www.specialtypharmacytimes.com/publications/specialty-pharmacy-times/2015/april-2015/usp-800-new-regulations-to-protect-health-care-workers-from-hazardous-drugs – Accessed November 2015.
8. Page M.R. Selection of Closed-System Transfer Devices: Tips for Engaging Nursing and Pharmacy Stakeholders in Purchasing Decisions. http://www.specialtypharmacytimes.com/publications/specialty-pharmacy-times/2015/october-2015/selection-of-closed-system-transfer-devices-tips-for-engaging-nursing-and-pharmacy-stakeholders-in-purchasing-decisions – Accessed November 2015.

Деревенчук Д.О., Shi Guangtian
Ланьчжоуський Транспортний університет, Факультет машинобудування

ЗАКРИТА СИСТЕМА ПРИСТРОЮ ПЕРЕДАЧІ ЛІКІВ

Анотація
Забруднення протипухлинними препаратами є відомою проблемою. Залишки препаратів виявляються на шкірі більш ніж чверті медсестер, які контактують з пацієнтами під час хіміотерапії. Поверхні в лікарняних аптеках, операційних, зонах лікування також можуть зберігати залишки протипухлинних препаратів та інших лікарських засобів. Існує ймовірність, що, перебуваючи в навколишньому середовищі, такі залишки можуть випадково потрапити всередину організму людини, що може викликати роздратування шкіри і навіть довгострокові ускладнення, такі як безпліддя, викидень, вроджені вади розвитку і лейкоз або інші типи раку. Багато ліків становлять значну небезпеку для медичного персоналу, який постійно працює з ними. Небезпечні ліки включають: цитостатики, антибіотики, противірусні засоби, гормоноподобниє речовини і т. д. Новий пристрій системи перенесення захищає медичний персонал від небезпечних ліків.
Ключові слова: забруднення медикаментами, одноразовий стерильний диспенсер, пристрій переносу.

Деревенчук Д.А., Shi Guangtian
Ланьчжоуский Транспортный университет, Факультет машиностроения

ЗАКРЫТАЯ СИСТЕМА УСТРОЙСТВА ПЕРЕДАЧИ ЛЕКАРСТВ

Аннотация
Загрязнение противоопухолевыми препаратами является известной проблемой. Остатки препаратов обнаруживаются на коже более чем четверти медсестер, которые контактируют с пациентами во время химиотерапии. Поверхности в больничных аптеках, операционных, зонах лечения также могут сохранять остатки противоопухолевых препаратов и других лекарственных средств. Существует вероятность, что, находясь в окружающей среде, такие остатки могут случайно попасть внутрь организма человека, что может вызвать раздражение кожи и даже долгосрочные осложнения, такие как бесплодие, выкидыш, врожденные пороки развития и лейкоз или другие типы рака. Многие наркотики представляют значительную опасность для медицинского персонала, который постоянно работает с ними. Опасные лекарства включают: цитостатики, антибиотики, противовирусные средства, гормоноподобные вещества и т. д. Новое устройство системы переноса защищает медицинский персонал от небезопасных лекарств.
Ключевые слова: загрязнение медикаментами, одноразовый стерильный диспенсер, устройство переноса.