ISOLATOR FOR USE IN SURGERY OR AS A CLEAN ROOM AND METHOD OF USING THE SAME

This application is a continuation of application Ser. No. 07/075,249, filed July 16, 1987, entitled "Isolator for Use in Surgery or as a Clean Room and Method of Using the Same", now abandoned, which was a continuation of application Ser. No. 726,088, filed Apr. 23, 1985, now abandoned, which was a continuation-in-part of application Ser. No. 676,204, filed Nov. 28, 1984, entitled "Surgical Isolator", now abandoned, which was a continuation of Ser. No. 485,210, filed Apr. 15, 1983, entitled "Surgical Isolator", now abandoned.

This invention relates to an isolator for providing a contaminant-free atmosphere in which a surgical procedure can be performed or equipment sensitive to environmental contamination can be assembled and to a method of using the same.

A large amount of effort is spent in the avoidance of contamination of surgical wounds by disease organisms in the operating room. All instruments and dry goods coming into contact with the surgical field are sterilized, either in an autoclave or with chemicals. Chemicals are used to sterilize the patient's skin in the area of the surgery. The surgical team scrub their hands and arms for at least five minutes after which hands and arms are bathed in alcohol. Sterilized gowns, caps, and masks that filter the team's exhaled air are worn by the surgical team along with sterile gloves that cover their hands. Thereafter, the surgical team avoids contact with non-sterilized objects. Further, the air in the operating room is constantly changed and filtered.

Even with all this preparation and attention to sterilization, a significant percentage of supposedly clean operations result in wound infections, which means that operating aseptically on man remains only a concept and not an accomplished procedure.

One of the problems is that disease organisms are ubiquitous in operating room air, on the patient's skin, in his gastrointestinal tract, and in the exhalations of all persons in the room. Also, the individuals of the surgical team shed disease organisms as they move around the operating room during the surgery For example, it has been determined that 30,000 to 60,000 particles are shed each minute from each person in the operating room. Foreign particles that have been shown to cause granuloma, a type of infection, include lint, wood fibers, talc dust and related agents. These particles come from drapes, gloves, wrapping materials and other items found inside the operating room (OR). Bacterial contaminants are released into the atmosphere from the skin and hair, by breathing and passing gas, and from the urinary tracts of the surgical team and the patient.

There are certain types of surgery that experience a higher than normal rate of infection. It is these surgeries where the use of the isolator of this invention is most important. Surgeries involving the implantation of a prosthetic device or artificial organ is a common example. The dose of bacteria necessary to invade the wound and cause an infection is reduced when foreign matter, such as an implanted device, is introduced into the body. Repeated experimental and clinical studies have proven that the mere presence of a foreign body can seriously impede the human body's immune system. Over 50,000 bacteria may be required to cause a surgical wound infection in normal operations whereas only 100 bacteria can cause infection when an implant device, even though inert, is introduced. In some implant surgeries, it has been theorized that a single bacterium may be all that is necessary to cause a deep wound infection.

Certainly many wound infections can be attributed to endogenous (patient) causes It is generally agreed, though, that airborne contamination during surgery contributes in some degree to the number of infections. Indeed, there is much empirical evidence and many major comprehensive studies that suggest it as the prime contributor. The complications that develop from wound infection can be very serious and it is a continuing problem that plagues the operating community as well as the patient The isolator of this invention will provide surgeons and patients with an extra preventative measure against surgical wound infections.

Therefore, it is an object of this invention to provide an isolator and a method of using the isolator that includes a tent or bag of flexible, impervious material for placing on the area of the patient where the surgery is to be done and pumping a continuous stream of filtered air that flows from one side of the bag across the surgical wound to exhaust ports on the opposite side of the bag to maintain the bag inflated at a pressure above atmospheric and to constantly change the air in the isolator.

It is a further object of this invention to provide such an isolator and a method of using the isolator where the instruments and other material used during the surgery is moved into and out of the bag through a door in the side where the exhaust ports are located so the air is always moving in a direction to keep any contaminants outside the bag from entering the bag while the door is open.

It is a further object to provide such an isolator and method in which the instruments and other material are moved into and out of the bag through an air lock, the doors of which have exhaust ports through which most of the air flows to the outside.

It is a further object and feature of this invention to provide an isolator having an air lock that can be severed from the isolator when the surgery is completed to protect the instruments that have been used during the surgery from the air in the operating room so the instruments will be readily available, if needed, during the period between the completion of the surgery and the moving of the patient from the operating room.

The first surgical isolators were developed for use in gnotobiotics where germ-free laboratory animals were obtained by delivering such animals from their parents by Caesarean section directly into an aseptic environment. Later a plastic isolator for use on humans was designed by Levenson, et al and described in an article entitled "A Plastic Isolator for Operating in a Sterile Environment" American Journal of Surgery, 104, 891–899, 1962. A subsequent isolator was developed by McLauchlan, et al and described in an article entitled "The Surgical Isolator", British Medical Journal, 1(903): 322–4, 23 Feb., 1974. Both of these isolators are discussed in "Air Contamination Control in Hospitals" by Joseph R. Luciano, Copyright 1977, Plenum Press, New York, pages 355–359.

Both the Levenson and McLauchlan isolators included bags of thin, flexible, plastic material inflated with sterile air. Both have jackets or sleeves that extend into the bag and that cover the surgeon and his assistant's arms during the surgery. The jackets and sleeves are closed at their ends by the gloves that the surgeons