

Contamination of the environment according to the preparation (administration) technique

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Contamination during preparation

Two different systems for the reconstitution and preparation of cytotoxic drug containing infusion bags are compared in a contamination study using both wipe samples of the Biological Safety Cabinets + surroundings and urine analysis of technicians and pharmacists involved in the preparatory activities. The Classical system (open) uses luer lock seringue and needles, the PhaSeal® system (closed) uses special devices.

This PhaSeal® system system claims to be a complete closed and safe sytem for preparation and administration of cytotoxic drug. It consists of 3 different devices (cfr fig 1-3)

- A protector to be placed on vials with the intention to capture in a sort of balloon all overpression that occurs during the preparation.
- An injector to be placed on a luer syringe to enclose the needle
- A connector to be able to inject in infusion bags or perfusion lines

Fig 1.

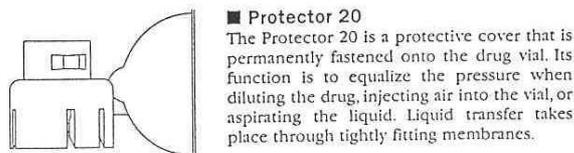


Fig 2.

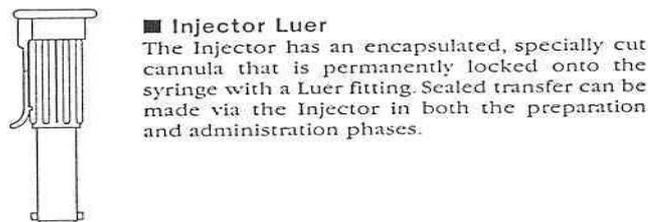
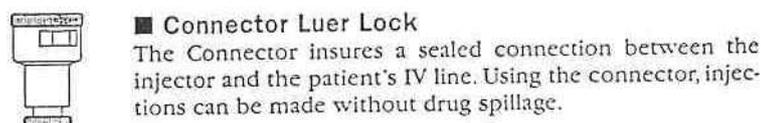


Fig 3.



Analysis were performed by Exposur Control (the Netherlands) using gas chromatography in tandem with mass spectroscopy.

The results of the wipe sampling and the urine tests indicate that :

- Contamination occurs rapidly
- Contamination once installed is hard to remove

- When working with the PhaSeal system there is no increase (even a slight decrease) of contamination of the surrounding area.
- When working with the Classical system a minimal 10 fold increase in contamination of the surrounding area occurs.
- Working with the PhaSeal system leads to only 1 positive urine test of a assistant preparing cytotoxic drugs.
- Working with the Classical system leads to 4 positive urine tests of a assistants preparing cytotoxic drugs, 1 positive urine test of a pharmacist, just present in the same room and 1 negative sample.
- Vertical class II Biological Safety Cabinets have not the protection capacity people assumed they have, especially if the external exhaust fails .
- The cleaning procedures should be further examend to new more potent products.

Contamination during administration:

Observations revealed that a simple connection or disconnection of a normal infusion bag to an infusion line results in a rate of leakage of 25 % during the connection handling and of 100 % in the disconnection handling.

We defined as a “leakage” from the moment on that more than 1 droplet appears in the environment.

In order to increase the safety for the nurses during the administration we developed a Cyto Administration Set (CAS) for intravenous administration of cytotoxics.

The technique of CAS is based on a dry connection

The set consists of 3 different elements:

- A infusion bag with Break-A-Way (BAW) seal.(fig 4)
- A CAS infusion line with luer lock connection for the cytotoxic containing infusion bags and spike connection for the non cytotoxic containing infusion bags.
Several types of sets are available (1 spike + 1 luer lock // 2 spikes + 4 luer lock) (fig 5)
- A special connector in case a glas bottle is needed as container for the cytotoxic drug (fig 6)

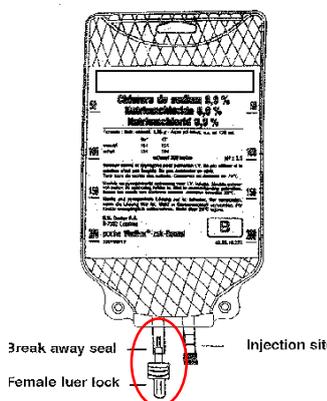


FIGURE 1

Fig 4.

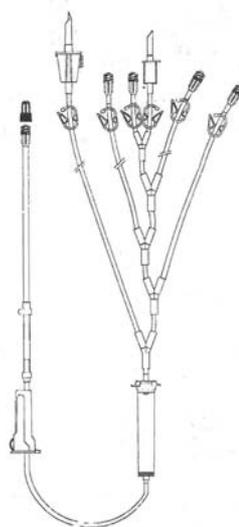


Fig 5.

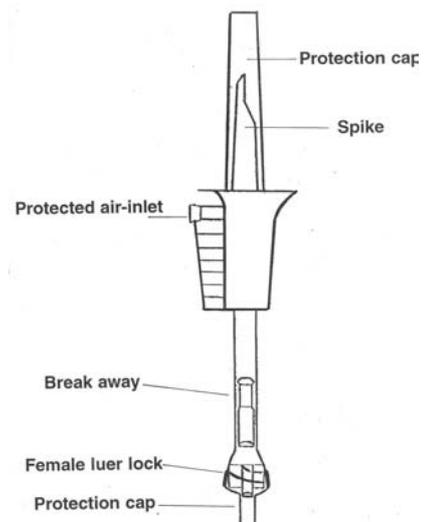


FIGURE 3

Fig 6.

The CAS infusion bag is prepared in the pharmacy by injecting the cytotoxic drug into the bag using the PhaSeal system .

Meanwhile the nurses can start the treatment of the patient with the standard-infusion, the premedication and hydration solutions by connecting them with the spikes.

When the prepared infusion bags are delivered on the ward, a dry connection is made by means of the luer-luer connection.

Once the connection is done, the BAW seal is broken and the cytotoxic drug can flow into the infusion line.

Once the cytotoxic containing bags are connected, they remain connected and the whole set is discarded as risk waste after the treatment.

Handling this way eliminates all risks of leakage while connecting the special infusion bags to the set and makes the personal protection measurements superfluous.