



PhaSeal from Carmel Pharma, Inc.

CHEMOTHERAPY AGENTS CAN BE OF great benefit to the health of cancer patients. However, they pose serious risks to the health care workers that handle them. In addition to the attention given to these risks by the NIOSH Hazardous Drug Alert, several clinical studies have shown that leakage during the preparation and administration of these drugs leads to the contamination of laminar airflow workbenches, biological safety cabinets, and drug vials, to name a few. Studies have also found traces of cytostatic agents in health care workers' urine. Exposure to these hazardous agents can potentially lead to liver damage, leukemia, non-Hodgkin's lymphoma, and skin cancer, as well as miscarriages and birth defects in the children of those exposed. Fortunately, there are mechanisms health care workers can use to reduce or prevent such harmful exposure.

The University of Utah Health Sciences Center has used Carmel Pharma's PhaSeal System as part of our chemotherapy procedures for the past five years. The only clinically proven closed-system drug transfer device on the market, PhaSeal is in use at the University of Utah Hospital, as well as the Huntsman Cancer Hospital and ambulatory clinic. We employ the device when compounding chemotherapy drugs in the pharmacy and administering them to patients on the nursing units. In fact, we use PhaSeal in the pharmacy when compounding 95% of our overall doses. We use the system whenever we can, as it offers vital worker protection from exposure to hazardous drugs.

Product Features

PhaSeal ensures a dry connection using double membranes that act as seals to ensure the leak-free transfer of drugs, during both the compounding and administration

We use the system whenever we can, as it offers **vital worker protection** from exposure to hazardous drugs.

processes. PhaSeal's sealed expansion chamber captures aerosols and vapors, while maintaining equal pressure in the vial during drug preparation, thereby preventing employee and surface contamination. PhaSeal's needle-safe design provides a sealed transfer and enables the user to retrieve all of the drug from the vial during the transfer process.

PhaSeal in Use

In the pharmacy, technicians first apply an appropriately sized PhaSeal protector to the vials that will be compounded. Using PhaSeal, the technicians then reconstitute the drugs and add other components to the IV bag via the PhaSeal connector, which is attached to the permanent spike. We then prime the tubing with non-chemother-



apy agents, so that it is ready to administer on the nursing units. Per USP <797> mandates, our pharmacy staff only uses PhaSeal while compounding in a biological safety cabinet or compounding aseptic isolator.

Our nurses then hook PhaSeal up to the patient access device – usually just a port – to safely administer the drug. Again, PhaSeal acts as a closed system to prevent worker exposure to hazardous drugs.

Workflow Changes

We have found PhaSeal to be easy to use and incorporate into our workflow. It

took almost no time at all to bring the staff up to speed. We did take some time to help our nurses adjust their tubing set ups, which had to be altered, until they became comfortable with the new “plumbing” of PhaSeal.

Reduced Exposure

We conducted two studies at the University of Utah Hospital to measure the impact of PhaSeal on worker exposure to hazardous drugs. First, we conducted a pre-PhaSeal study and found that all 17 locations tested in our infusion center were positive for contamination. We also conducted 24-hour urine tests on our full-time nurses, pharmacists, and pharmacy technicians. The tests revealed that all of the nurses and pharmacists were positive for exposure, as were 30% of our technicians.

We decontaminated the entire infusion center and implemented PhaSeal as part of our chemotherapy preparation and administration practices, and after six months, conducted the same study again. While we still found some evidence of surface contamination, it had significantly decreased since the implementation of PhaSeal. Furthermore, we found no evidence of personnel contamination.

When we opened the Huntsman Cancer Hospital, we started using PhaSeal on day one. After six months, we collected surface and personnel urine samples, and, compared to the infusion clinic study, the level of contamination was significantly lower. Our findings are consistent with those published by other PhaSeal users. All in all, we have found PhaSeal to be a valuable tool in our efforts to prevent worker exposure to hazardous drugs. ■

James A. Jorgenson, RPh, MS, FASHP is the director of pharmacy services at the University of Utah Health Sciences Center. He completed his BS in pharmacy and MS in hospital pharmacy at the University of Minnesota, as well as a residency in hospital pharmacy administration at United and Children's Hospital in St. Paul, Minnesota. Jorgenson also serves as associate dean for clinical affairs at the University of Utah College of Pharmacy, where he is responsible for experiential teaching site development.

WHERE TO FIND IT:
Carmel Pharma **Circle reader service number 85**
or visit www.carmelpharma.com