particularly those formulated at low concentrations may be less likely to adsorb to plastic vial or syringe surfaces than a glass container. Third, most glass syringes use a silicone lubricant to facilitate movement of the plunger. The West Daikyo CZ syringe is silicone free, and the cap and plunger are coated with Daikyo's FluroTec® brand coating to reduce extractables and provide lubrication (54). Silicone may be incompatible with certain drug formulations and can cause protein aggregation and possibly increase immunogenicity risk (56). Baxter compared the stability of three model protein therapeutics packaged in BD Hypak® and a silicone-free copolymer syringe by measuring absorption, aggregation, silicone levels, and tungsten levels. Absorption was low for both formats and aggregation was equivalent or lower for some proteins when stored in the copolymer syringe format. Silicone levels were equivalent or lower in the formulations stored in the copolymer syringe, while tungsten levels were significantly lower in the products stored in the copolymer versus plastic syringe (57).

Sterilization of Small-Volume Plastic Containers

As with flexible containers, care must be taken during thermal sterilization of plastic syringes and vials to prevent melting. The West Daikyo CZ resin can withstand autoclave temperatures of 121°C (56). BD also claims that their Sterifill SCF™ can be autoclaved after filling (58). While many glass syringes require EtOH sterilization, the Schott ready-to-fill TopPac COC® syringes are gamma sterilized and can be guaranteed stable for up to two years (52). In a review of polyolefin composite materials, it was concluded that a polyolefin's leachables profile is not dramatically impacted by irradiation (53).

Marketed Products Filled in Small-Volume Plastic Containers

Plastic syringes have gained wide use in nondrug applications such as contrast media and viscoelastics (52). BD offers the PosiFlush™ line of polypropylene syringes prefilled for saline flush and heparin lock flush applications. APP Pharmaceuticals produces Acyclovir in 10 and 20 mL plastic vials for IV administration (59). Hospira offers 0.9% sodium chloride injection, USP, Sterile Water for Injection, USP, as well as sodium lactate injection, USP in plastic flip-top vials (60). However, plastic syringes and vials have been slow to enter the marketplace. Companies are hesitant to move existing drugs currently packaged in glass into plastic containers because of regulatory filing barriers. Table 7-7 is a listing of injectable products packaged in plastic syringes, vials, and other containers according to Daikyo/West (61).

Environmental Impact of Plastic Containers

Beyond benefits of less weight and breakage, the use of plastic containers for parenterals also has environmental benefits and a potential cost savings to hospitals in the area of waste reduction. The increase in availability and use of disposable products has increased the quantity

Table 7-7 Products Packaged in Daikyo CZ® Vials and Syringes

Location	Container	Product
Japan	Syringes	Contrast media MRI Hyaluronic acid Calcitonin
Japan	Vials	Fluconazole Oncology products Anticoagulant products
United States	Vials	Acyclovir Hyaluronic acid
Europe	Syringes	Contrast media MRI
Europe	Vials	Oncology products Blood plasma

Source: Courtesy of Daikyo/West Pharmaceutical Services, Inc.