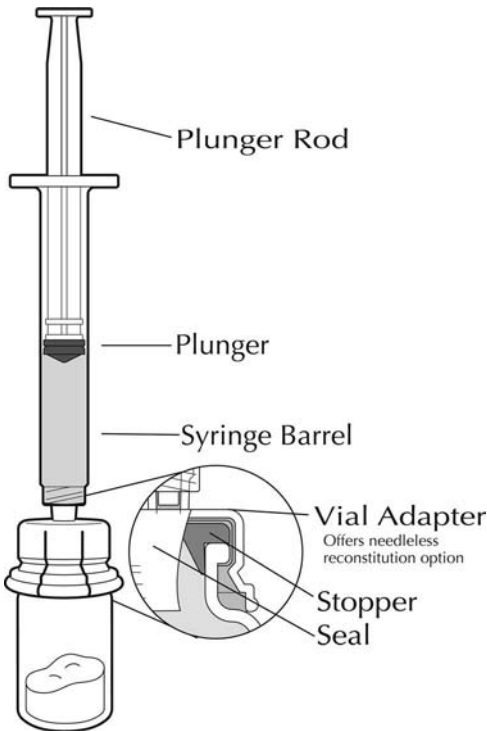


**TABLE 1** Typical CCS Components Used in Lyophilization and Materials of Construction

Component	Materials of construction
Chambers, storage containers, tank liners, single-use bags (1)	Stainless steel, polycarbonate, polyvinyl chloride, thermoplastic elastomers, cyclic polyolefin
Tubing (2)	Polyvinyl chloride, silicone, polyurethane, latex
Gaslets, seals (2)	Styrenebutadiene rubber, ethylene propylene diene monomer, thermoplastic elastomers
Filters, connectors (3)	Polyesters, polypropylene, nylon, polytetrafluoroethylene, polyethersulfone
Elastomeric closures for lyophilization and reconstitution (4)	Butyl, chlorobutyl, bromobutyl
Vials for lyophilization and reconstitution (4)	Glass, cyclic olefins
Reconstitution, transfer, and administration devices (syringe, plunger, tip caps, needle) (5)	Cyclic olefins, polyethylene, butyl rubbers, polycarbonate, tungsten pins, stainless steel

Abbreviation: CCS, container closure systems.



**FIGURE 3** Diluent in prefilled syringe and transfer device on lyophilized product.

pharmaceutical product. An adaptation of a preliminary hazard analysis (PHA) model to indicate the critical components for leachable and extractable evaluation is shown in Table 2 (4). The model assesses each potential hazard for the likelihood of leachables and consequence is based on the highest risk score of 120 (severity, 0–5; frequency, 1–3). The model highlights the key considerations for CCS properties relative to pharmaceutical lyophilization and a system for