



FIGURE 3 Dual chamber cartridge with external bypass (Genotropin).

required if the drug is to be administered via intravenous injection. Two corticosteroids are marketed in the Act-O-Vial (Table 1), which is a DCV available in the following vial sizes: 1, 2, 4, 6, and 10 mL. A recent publication reviews the rational selection of glass and elastomeric components for a DCV package (7).

Dual Chamber Cartridge

A DCC consists of a syringe barrel with two chambers that are separated by a middle plunger. The front chamber contains a lyophilized drug and is capped by an elastomeric closure part that is thin enough to be punctured by a double-sided needle (i.e., a pen needle). The rear chamber contains the diluent and is closed at the bottom with an elastomeric end plunger. A bypass exists between the two chambers to allow for liquid to flow from the rear chamber to the front chamber. The bypass may consist of either an external channel or internal grooves, where the grooves are cut into the inside of the glass. Figure 3 shows an example of DCC with an external bypass feature. DCCs on the market are available in 1-mL and 3-mL standard formats.

A DCC is typically used in conjunction with a pen injector for reconstitution and delivery to the patient. Pen injectors are available in disposable and reusable formats. The DCC is preloaded in the pen injector for the disposable ready-to-use format. The user/patient must load the DCC into the pen injector for the reusable format. The first time the pen is utilized the user has to disinfect the rubber septum, attach a pen needle, reconstitute the cartridge, prime the pen to remove air, and set the dose. Additional uses for this system only require the user to disinfect the rubber septum, attach a pen needle, set the dose, and inject. The needle is removed after each injection. Thus, at time of use there are five steps prior to dosing. Several examples of DCCs are illustrated in Table 1.

Dual Chamber Syringe

A DCS is similar to a DCC except that the DCS is designed to be used without a device at time of use. Therefore, a DCS becomes equivalent to a prefilled syringe after reconstitution. A typical DCS, which is illustrated in Figure 4, includes a plunger rod and flange. Prior to reconstitution, the user affixes a needle to the DCS. This may be a pen needle or luer needle depending on the type of front closure. The plunger rod pushes liquid from the rear chamber through the bypass into the front chamber in a controlled fashion. This is typically