

A newly modified prefilled syringe to prevent plunger/piston misassembly

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To the Editor:

Prefilled syringes are intended to be used as a strategy to minimize errors in the administration of potent cardiovascular drugs and to provide rapid access for critically ill patients [1]. We previously reported a case of dopamine leakage from a Prefilled Inovon[®] injection 0.3 % syringe (marketed by Kyowa Hakko Kirin, Tokyo, Japan; manufactured by Terumo, Tokyo, Japan) caused by plunger/piston misassembly [2]. In the conventional assembly, the rigid plunger head is molded with a small number of male threads, and the cylindrical wall of the elastic rubber piston is thin (Fig. 1a). When the male screw thread molded at the top end of the plunger could not engage entirely with the female screw thread molded on the inside wall of the rubber piston, the cylindrical rubber wall of the piston gradually became partially contorted as pressure was applied to the plunger after continuous infusion was started, possibly leading to erratic drug delivery (personal communication from Terumo Corporation [2]).

Recently, the manufacturer has modified the design of the syringe to prevent plunger/piston misassembly. The primary components of the modified assembly (Fig. 1b) are a rubber piston preassembled with the plunger head that has a short plastic collar (yellow part in Fig. 1b), and a plastic plunger with a protruding connector. The plastic plunger head is preassembled with the rubber piston in the

plastic barrel and therefore establishes a tight plunger/piston connection. The designs of the rubber piston and the plunger head are unchanged. However, the new plunger has a connector consisting of a protrusion with two hooks. The operator places the plunger into the barrel and inserts the connector into the plunger head/piston assembly until a click is heard. The click signifies correct assembly of the system and ensures correct drug delivery. The newly modified Prefilled Inovon syringe was marketed in March 2012. The manufacturer has used this improved prefilled syringe for another drug, nitroglycerin (Nitroglycerin[®] injection 25 mg/50 ml syringe; marketed and manufactured by Terumo, Tokyo, Japan), and this product was launched in December 2011. These modified prefilled syringes are expected to be widely accepted for clinical use by anesthesiologists and other practitioners, but the problem of leakage has not been solved. The manufacturer should conduct a follow-up survey of manifestations of the plunger/piston misassembly. We recommend that manufacturers provide safe and reliable prefilled syringes that are carefully designed to prevent erratic drug delivery.

References

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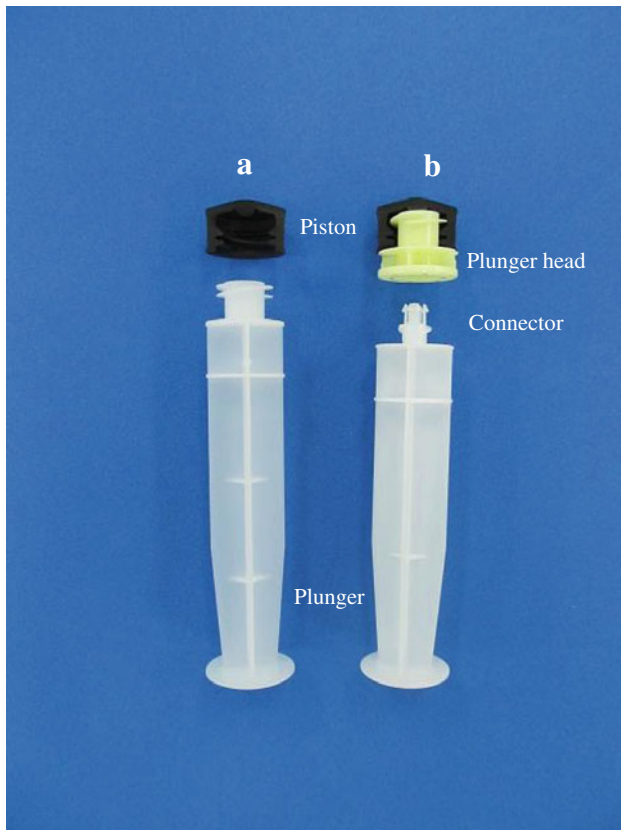


Fig. 1 The design of the conventional (**a**) and the modified (**b**) plunger/piston assembly in the Prefilled Inovan 0.3 % injection syringe (Kyowa Hakko Kirin and Terumo, Tokyo, Japan). The plunger is separated from the sagittally sectioned piston. The conventional assembly consists of a plunger and a piston. The modified assembly consists of a preassembled plunger head/piston and a modified plunger body with a connector with two hooks. The plunger body is firmly connected to the plunger head/piston and makes an audible “click” during assembly before use