Self-retaining weighted thermoplastic ampoule holder for aflibercept and ranibizumab vials

Anti-VEGF agents aflibercept and ranibizumab are packaged into single-use ampoules by the supplier. To aspirate the agent from the vial, the rubber elastomeric stopper is pierced under sterile conditions with a blunt drawing up needle. Under typical conditions, practice support staff are required to stabilize the vial base with their hands and tilt the vial to ensure that the entire contents are aspirated. This step prolongs procedure time and poses a risk of needle stick injury to staff. We have designed an ampoule holder of reusable construction that provides a safe, portable and inexpensive option for single-handed drug withdrawal.

The ampoule holder comprises a weighted base with thermoplastic polymer surface (such as polyca-prolactone polymorph) containing a central cylindrical hole to accommodate a glass anti-VEGF vial of aflibercept and ranibizumab (Figs). The size of the cavity is such that vials are held securely while inserted but can be easily extracted post-procedure.

Thermoplastic polymer permits custom fitting, is hard but durable and provides some flexibility for the fragile glass vials. The polymer is moulded around a vial to provide a precise fit. The base of the

Figure 1. Thermoplastic vial holder with mild steel casing – side view.
Figure 3. Entire contents of the vial remain visible and may be withdrawn with a single-handed technique.

Figure 2. Thermoplastic vial holder with mild steel casing – superior view.

cavity is angled at 20–30 degrees. When hardened, the polymorph will provide a tilted, self-gripping holder compatible with both vials that may be cleaned after use and sterilized as required.

The base of the cylindrical cavity is angled such that the entire contents of the vials are visible and can be aspirated with a single-handed technique (Fig. 3). A non-slip silicone base and weight is added to the assembly to improve stability and allow for withdrawal of needle without the need for external counter traction. The superior surface of the vial holder is planar and inclined congruently with the cavity base to orient the injection administrator to the incline direction. The vial holder is stored safely and securely at the periphery of the sterile field during the injection procedure.

The frequency of intravitreal injections of anti-VEGF agents for a variety of retinal diseases has significantly increased in recent years. Ranibizumab and aflibercept both made the top 50 list of pharmaceutical product by global sales in 2014, ranking 7th and 20th, respectively.\(^1\) Although millions of intravitreal injections are administered annually, the current technique whereby support staff stabilize the vial base with their hand is both cumbersome and potentially unsafe.

The use of this thermoplastic vial holder allows a single-handed aspiration technique. This both reduces the theoretical risk of needlestick injuries and allows to injection administrator to practice independently where staff resources are limited.
Current vial holders are also often inappropriate for use with small quantities of medication and may compromise the sterility of the injection administrator. The inverted positioning of some vial holders restricts aspiration of smaller quantities of liquid and has been designed for use with larger vials. Others require fastening to a wall and are not portable. Horizontal construction of some vial holders necessitates contact with the syringe cradle by the injection administrator and loss of sterility. This vial holder is portable, does not compromise the sterility of the administrator and is designed for use with small vials.

Polymorph is a hand-mouldable thermoplastic polymer consisting of small transparent plastic granules that melt in hot water above 62 degrees. Polymorph has been used successfully in the ophthalmic setting including scleral indentation and iPhone slit lamp photography adapters. This product is inexpensive, configurable and manufactured from bio-degradable, readily available supplies. Construction of the holder may be reproduced for under $5 USD.

This simple inexpensive thermoplastic polymer vial holder, consisting of a central cylindrical hole that accommodates a single vial of aflibercept or ranibizumab, reduces the theoretical risk of needle stick injuries and allows independent administration of intravitreal injections.
REFERENCES


