

5th March 2024

To Whom it may concern,

The SimplFusor IFU contains guidance to start the infusion between 1 and 8 hours after filling the device. This is stated as a preference to ensure the optimal performance of the device. Like all elastomeric pumps, Simplfusor works by the internal pressure generated by the silicone elastomer when filled with solution. The longer a solution is stored within the elastomer the lower will be the pressure. Lower pressure reduces the nominal flow rate of the device, resulting in a slightly longer duration of treatment. The longer the device is stored before starting the infusion the greater will be this effect. This affects all elastomeric pumps in a similar manner. Clinicians should consider this gradual reduction in flow rate that will occur with longer storage times when determining the proper care for patients."

Signed by,



Freddie Lee, CEO