Pharmaceutical Aseptic Services Group

www.pasg.nhs.uk

For the Attention of NRFit Device Manufacturers

PASG Statement for NRFit Syringes and Caps

In 2016 the NHS Pharmaceutical Aseptic Services Group (PASG) issued a guidance document intended for both the NHS and device manufacturers in relation to NRFit devices intended for drug storage – ***NHS Guidance to Device Manufacturers introducing Neuraxial Syringes and Syringe Caps into the UK NHS on the Pharmaceutical Testing Requirements to allow Drug Storage in their Syringes***

available at https://pasg.nhs.uk/pasg-guidance

This document detailed the testing requirements required by the NHS from device manufacturers before introducing new NRFit syringes and caps into the NHS. The PASG position hasn't changed since the original publication of this guidance in that PASG requires the tests detailed in the document to be carried out by device manufacturers in order to ensure drug storage has been validated in these devices.
N.B. Due to an update of the website, the required testing protocols can be accessed via the link above rather than the links provided in the original document.

The reason for this requirement is that NRFit syringes and caps are only intended for neuraxial applications, and have been developed to avoid wrong route chemotherapy which requires Pharmacy aseptic preparation and storage prior to use. Safe handling requirements for cytotoxic drugs prevent them being drawn up in clinical areas, therefore by default NRFit syringes and caps have to be used as storage devices, and there is a requirement that the supplier will have undertaken the necessary validations to demonstrate that the syringes can safely store medicines for a period of time.
PASG advice to the NHS remains not to use NRFit syringes & caps for drug storage without this level of testing and assurance for patient safety.

David Lovett
Principal Pharmacist for Aseptic Services, University Hospitals of Leicester Hospitals NHS Trust on behalf of NHS Pharmaceutical Aseptic Services Group
david.lovett@uhl-tr.nhs.uk

Pete Phillips
Director, Surgical Materials Testing Laboratory, Princess of Wales Hospital, Bridgend
pete@smtl.co.uk

Mark Santillo
SW Regional Quality Assurance Officer, Torbay & South Devon NHS Foundation Trust
mark.santillo@nhs.net

Tim Sizer
Regional Pharmaceutical Quality Assurance Officer South West, Southmead Hospital, Bristol