

## Route of Access

Probe's MicroEye® device has been designed and developed from the beginning with safety in mind. It carries the CE mark for sale in Europe and Probe Scientific hold Certification Standards: Directive 93/42/EEC, ISO 13485:2003 – Medical Device Certification, from a Notified Body appointed by a Competent Authority.

The MicroEye® is a blood sampling device which is inserted into the peripheral vascular system or subcutaneous, intramuscular, and adipose tissue for periods of up to 48 hours. Like any device that must access the blood or tissue, it is termed invasive, as by definition, in whole or in part, it penetrates inside the body, either through a body orifice or through the surface of the body.

The current MicroEye® has been developed to be used with all common existing 18G peripheral venous access devices (e.g. blood catheters). This means that it can be used with existing blood 'lines' which are typically given to most people entering hospital as in-patients. When it is used in this manner the MicroEye® does not require the patient to have any additional cannulae inserted. Thus it is minimally invasive and non-injurious. Furthermore because its deployment is very similar to existing practice (i.e. the use of a mandrel within the blood catheter) it requires no special skills or training for setup. It has been termed a 'plug-and-play' system.

Probe Scientific is developing variants of its existing product so these can be used with alternative vascular access devices such as 'long-lines' and multi-lumen catheters. It is Probe's intention to work with world-leading companies that specialise in vascular access to ensure that the benefits of continuous and automated real-time online monitoring (CAR-TOM) technology can be used in all appropriate and common clinical procedures and practices.

