

## Neutron<sup>®</sup> Needlefree Catheter Patency Device Use with Power Injectors

The Neutron device is FDA cleared  $\{510(k)100434\}$  as a standalone device and, in connection with pressure rated tubing sets, for use in power injector procedures. The devices will tolerate a maximum of 350 psig or a flow rate of 10 mL/sec of room temperature contrast media (Omnipaque<sup>M</sup> 300 Injection, GE Healthcare).

The internal volume of the Neutron device is low (0.1 mL), and the fluid path is comprised of a straight rigid cannula with an average flow rate of an 18G needle. This results in a non-turbulent flow pattern that presents minimal restriction and very low internal compliance. Actual infusion pressures required to deliver the desired volume of contrast media are typically far less than the maximum 350 psig.

The Neutron device should be flushed after each use in accordance with facility protocol. The Neutron device does not require change-out or replacement after the pressure infusion procedure and has been tested to tolerate multiple pressure infusion procedures.

If there are further questions or concerns, please visit our website at www.icumed.com or contact the corporate offices at 949-366-2183 or 800-824-7890.

Technical Services ICU Medical Inc.