Hummingbird Med - Nexus Medical

Micro T Split Septum T-Connector



NEXUS Split Septum T-Site TECHNICAL SPECIFICATION
For use with the Hummi Micro-Draw Blood Transfer Device
Order # NMT8046
Nexus Medical 510(k): K092930

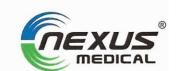


Technical Specifications

- Swabbable, Septum Surface
- Split Septum T-Site accessible only with Hummi Micro-Draw Blood Transfer Device
- Priming Volume 0.25mL (+/- .01)
- 150 septum insertions with the Hummi Micro-Draw Blood Transfer Device
- Pressure tested to 20 psi positive pressure for 1-hour with the Hummi Micro-Draw Blood Transfer Device
- Pressure tested to -10 psi vacuum for 15-seconds with the Hummi Micro-Draw Blood Transfer Device
- Split Septum Insertion force < 1 foot pound with the Hummi Micro-Draw Blood Transfer Device</p>
- Female connectors compatible with all ANSI and ISO 594 compliant female and male connector

Materials

- Materials used in the Nexus Split Septum T-Site, including extension sets, are medical grade and have been utilized in other legally marketed devices throughout the industry. These include polycarbonates, ABS, silicones, isoprene and non-phthalate PVC.
- Materials are Latex-Free and DEHP-Free
- Materials meet the requirements of US Pharmacopeia Class VI which includes testing for acute systemic toxicity, intracutaneous toxicity and implantation test. These tests measure and determine the biological response of animals to the plastic by either direct or indirect contact, or by injection of the specific extracts prepared from the material under test.
- Additionally, the materials meet ISO 10993-1 standards for external communicating devices, specifically blood path/indirect devices, with prolonged exposure (24 hrs to 30 days). This includes additional testing for cytotoxicity, sensitization, subacute and subchronic toxicity and hemocompatibility. These tests determine additional biological responses to the plastic using standard laboratory tests.



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