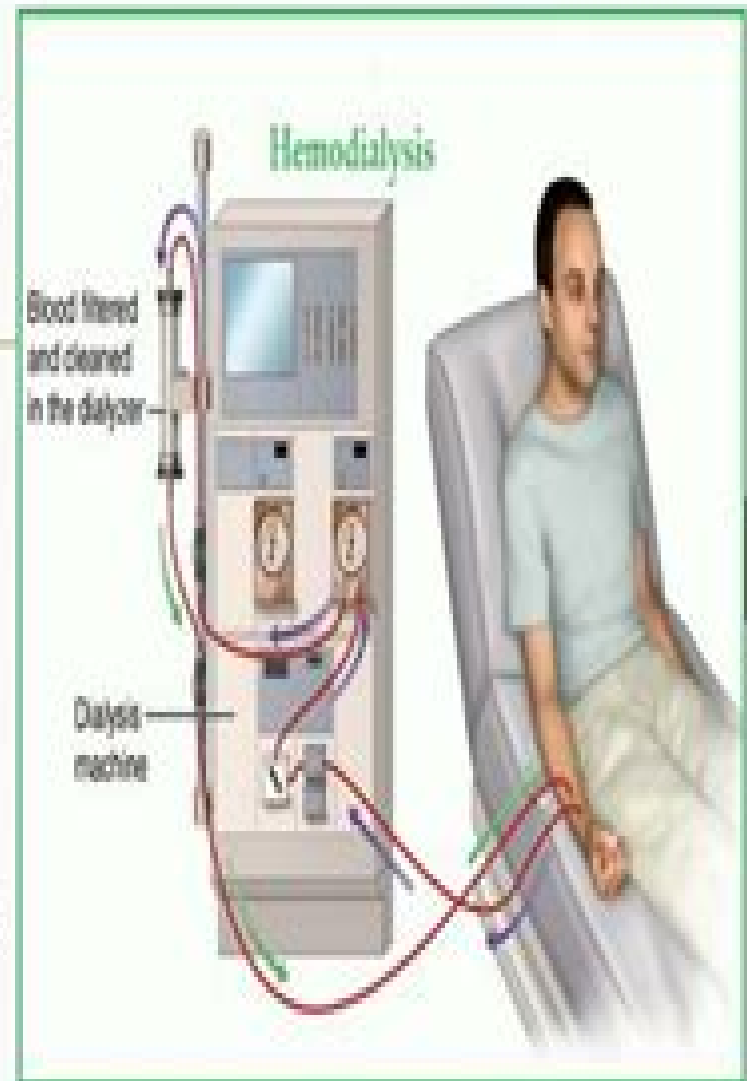


- The design phase is critical in determining the safety and performance of hemodialysis catheters. Manufacturers must follow stringent design control processes to ensure the final product meets the intended use and complies with regulatory requirements. This involves thorough risk assessments, design verification and validation, and documentation of design changes. Marshmedi Innovation strongly emphasizes these design control processes to create catheters that meet regulatory standards and address the evolving needs of healthcare professionals and patients.
-
- The materials used in hemodialysis catheters must be biocompatible to minimize the risk of adverse patient reactions. Manufacturers must carefully select and test materials to meet the biocompatibility standards of ISO 10993. Marshmedi Innovation places a premium on sourcing materials that meet these standards and contribute to the longevity and performance of their hemodialysis catheters.
-
- Robust risk management practices are essential in the production of hemodialysis catheters. Manufacturers must identify, evaluate, and mitigate potential risks throughout the device's lifecycle. This involves constantly monitoring the manufacturing process, post-market surveillance, and responsiveness to emerging issues. Marshmedi Innovation employs a comprehensive risk management strategy to ensure that their catheters not only comply with current standards but also anticipate and address potential challenges in the future.



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Disposable Dialysis Devices United States. Congress. Senate. Special Committee on Aging, 1986

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