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**510(k) SUMMARY
CARBOMEDICS HANDLE**

The reusable CarboMedics Handle is a one-piece, injection molded handle and is provided in one size only. The CarboMedics Handle is intended for use with the CarboMedics Valve Holder (referred to herein as the "Valve Holder") for the purpose of assuring a firm grasp of the valve and to facilitate sewing ring exposure. The threaded end of the CarboMedics Handle is inserted into the Valve Holder. The CarboMedics Handle consists of a threaded polysulfone tip injection molded to a bendable handle. The CarboMedics Handle is a reusable instrument. It is supplied non-sterile and must be cleaned and sterilized prior to initial use and each reuse.

The reusable CarboMedics Handle is manufactured using a polysulfone injection molding process. The CarboMedics Handle consists of a white polysulfone threaded tip injection molded onto a bendable stainless steel shaft, injection molded to a white polysulfone handle. Polysulfone has a history of use in medical device applications, including various instrumentation approved with the CarboMedics® Prosthetic Heart Valve. Biocompatibility tests were conducted on the white polysulfone in accordance with Tripartite Guidance and meets requirements of ISO 10993 for biomaterial testing. Acceptable results were obtained from all biocompatibility tests.

The one-piece injection molded handle is similar to handles used successfully with other CarboMedics instrumentation. The handle of a similar device has been tested to ensure that the handle exhibits torque and pull-out strengths that will exceed the requirements for the intended function. The purpose of the performance testing was to qualify the design and performance of this device. CarboMedics performed a pull-out test to determine the amount of force required to separate the molded tip from the steel shaft. Using a minimum failure load of 25 lb_f, the results were an average of 75.2 lb_f with a standard deviation of 19.9 lb_f. CarboMedics also performed a push-out test to determine the amount of force required to separate the steel shaft from the handle. Using a minimum push-out load of 75 lb_f, the results were an average of 113.5 lb_f with a standard deviation of 0.4 lb_f. This testing showed the design to be suitable for its intended use and capable of performing its function in a safe and effective manner.

CarboMedics considers the reusable CarboMedics Handle safe, effective, and substantially equivalent in intended use, design, and function to the CarboMedics Valve Holder Handle (VH-100), approved for market on July 6, 1994, 510(k) #K942736.

Common name of the device: Valve Holder Handle

Trade name or Proprietary name: CarboMedics Handle

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