

SECTION II - SUMMARY OF SAFETY & EFFECTIVENESS INFORMATION

Proprietary Name: Terumo® Phlebotomy Needle Cap Holder

Common Name: Phlebotomy Needle Cap Holder

Description: The Phlebotomy Needle Cap Holder is a single-piece molded device made of a single thermoplastic.

Intended Use: The Terumo Phlebotomy Needle Cap Holder is designed for multiple use. The device is intended to aid the phlebotomist in covering the donor phlebotomy needle subsequent to the removal of the needle from the donor's arm.

Substantially Equivalent Devices:

- Cutter Phlebotomist Protection Device
- Fenwal® Needle/Tube Sampling Protector Device

The Terumo device and the above devices are all intended to assist in recovering the used phlebotomy needle. The Cutter and Fenwal devices also permit collection of blood samples into evacuated blood collection tubes. In all three devices the needles are manually placed into a cap or covering assembly.

Although the physical characteristics differ among the devices, the devices are substantially equivalent in their intended indication for recovering the used needle.

All three devices are made of a thermoplastic material.

Performance testing in the blood bank setting demonstrated the Terumo device performed as well as or better than the Baxter device.

Prepared 5/14/95 by:

Sandi Hartka
Manager Regulatory Affairs
Terumo Medical Corporation

for: Terumo Medical Corporation
2100 Cottontail Lane
Somerset, NJ 08873