

*Summary of Safety and Effectiveness
for Bloodpack Needle Protector (BNP)*

Submitter

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Date summary was prepared

March 20, 1998

Name(s) of the device

Bloodpack Needle Protector (BNP)

Identification of predicate device(s)

Medsep Phlebotomist Protection Device
Manufactured by Medsep Corporation
BK900034

Fenwal Needle/Tube Sampling Protector Needle Safety Cover
Manufactured by Baxter Healthcare Corporation
BK920003

Medisystems Apheresis Needle with Guard
Manufactured by Medisystems Corporation
K932074

Description of the device

The Bloodpack Needle Protector (BNP) is a disposable, single-use, non-sterile needle protector, which is used as an aid in preventing accidental needle stick injuries upon completion of blood collection procedures. The BNP is designed such that it is compatible with current bloodpack needle sets produced by most major manufacturers.

The hinged assembly allows the BNP to be included on the bloodpack needle assembly at time of manufacture or during the collection process (i.e. before needle insertion or just prior to withdrawal). After the venopuncture is made, blood flow must be established before the BNP is engaged. The BNP employs a two-stage engagement and locking mechanism. The first stage of engagement is for stabilizing and adjusting the needle hub, while preparing for shielding the needle. The second stage shields and locks the needle,

which prevents sharps exposure. An audible click can be heard when the needle assembly has been pulled into the locked position. The needle shielding is always engaged away from the needle and behind the needle assembly.

Intended Use

The Bloodpack Needle Protector is an aid in the prevention of accidental needle stick injuries upon completion of blood collection procedures.

Comparison of device characteristics to predicate

Technological Characteristics			
Characteristic	Predicate Devices: Medsep, Fenwal and Medisystems	Device: BNP	Explanation (if necessary)
Intended use	Use in avoiding needle sticks in healthcare workers after collection of blood samples (Medsep and Fenwal)	Same	
Materials	Polypropylene (Medsep, Fenwal, and Medisystem)	Same	
Sterilization	Not Sterile (Fenwal)	Same	
Technological aspects of the sharps injury prevention components and how they integrate into the device	The protector fits over the needle and tubing. The tubing is then pulled with one hand until the assembly is locked into place (Medsep and Medisystem)	Same	
Design	The needle is secured inside the protector by folding and locking the device over the needle. (Medsep)	Same	

Clinical Testing

Following successful clinical trials in 1996, the Australian Red Cross Blood Service in the Australian Capital Territory (ACT), located in Canberra, Australia, began using the BNP in all of its blood collections from July 1996 to the present. Since the introduction of the BNP, there have been no needlestick injuries reported. The average annual collection at the ACT is 18,000.

Another prospective clinical trial was conducted to evaluate the impact of the BNP on factors such as donor comfort, procedural utility and safety, during and after standard blood collection. The trial involved 14 Phlebotomists and 1,000 donors. The results from the trial are summarized in the table below.

Clinical Trial Results	
Inquiry	Result
Donor Comfort	96.6% of donors reported comfort level on needle withdrawal as either no different, comfortable, or very comfortable.
Prevention of needle hub rotation	99.9% of users agreed or strongly agreed that the BNP prevented rotation of the needle hub.
Ease of engagement	99.8% of users found the BNP easy or very easy to engage
Ease of withdrawal	98.9% of users found this easy or very easy.
Ease of disposal	All of users found disposal of the BNP easy or very easy.
Bumping of needle hub	No users, with one exception, found that the BNP bumped the needle hub.
Sharp points after shielding	No users noted any sharp points once the needle was engaged in the BNP.

Conclusion

The intended use, design, materials of fabrication, and performance of the BNP are the same as the predicate devices. Therefore, the BNP is substantially equivalent to the predicate devices and devices marketed in interstate commerce prior to May 28, 1976.