

FEB 11 1997

**510K SUMMARY**

K964858

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**Date Submitted:** November 26, 1996  
*Revised January 17, 1997*

**Name of Device** Common Name: Sharps Disposal Container  
Tradename: Bemis Two Gallon Chemotherapy Container  
Classification Name: Sharps Disposal Container  
**510(k) Number:** K964858

**Predicate Device:** Baxter Two Gallon Chemotherapy Container

**Description of the Device**

The Bemis Two Gallon Chemotherapy Containers are designed for use in areas with controlled access such as nurse's stations, pharmacies, and chemo treatment rooms. They feature a gasketed lid and screw-on plastic cap.

The Bemis Two Gallon Chemotherapy Containers have a volume of 6 qt. and weigh 1 lb. 2 oz. with dimensions of 8.5"H x 11.5"W x 7.6"D. Two Gallon Chemotherapy Containers are injection molded of polypropylene plastic and are available in translucent white. These containers are NOT reusable.

Bemis Two Gallon Chemotherapy Containers are puncture resistant with integral sidewalls and bottom and have a typical wall thickness of .070". ASTM *proposed* standard for puncture resistance states "...the average puncture force for the sharps contact areas of each region of nominal uniform thickness of the container shall not be less than 3/4 lb./ft. with no one value less than 2.8 lb./ft." according to *ECRI Puncture Resistance* criteria. Testing was done on the Bemis Two Gallon Chemo Containers using this standard. All wall thicknesses of .050" will pass the puncture tests, however, Bemis will reject any parts with wall thicknesses less than .055".

The containers are leakproof on the sides and bottom. The lids are gasketed to guard against spills. According to *ECRI Health Devices Leak Resistance* criteria "...there shall be no leakage of the contents over a 24 hour period when filled with water and positioned in an upright position." The Bemis Two Gallon Sharps Containers passed this requirement when tested using this method.

The Two Gallon Chemotherapy Containers are labeled with the Biohazard warning symbol that is 1½" in height. The label color is orange-red and yellow, with lettering and symbol in contrasting color in accordance with OSHA regulations. The labels are attached directly to the surface of the container by a permanent adhesive. The labels boldly indicate fill level of three-quarter capacity. While no standards exist for overflow detection, *FCRI Overflow Warning* criteria specifies that contents be viewed to determine fill level. Bemis Two Gallon Chemotherapy Containers are translucent white, therefore, allowing visibility of fill level.

The Bemis Two Gallon Chemotherapy Container is designed for use in areas with **controlled access**. According to *FCRI Inlet and Closure Characteristics* criteria, the inlet should accept sharps safely and easily with one-handed operation. There is no limitation to hand access for this container as the opening is designed to accept other objects related to chemotherapy waste. Following final closure, the container remains closed during normal handling.

*FCRI Freestanding Capability* criteria specifies that the container should be stable in its upright position when tipped to 20 degrees, and when in the closed position, contents should not spill out when toppled. Testing done on the Bemis Two Gallon Chemo Container at a topple angle of greater than 20 degrees, showed the container retaining its solid contents.

No standards exist for impact resistance of sharps containers. The *proposed Canadian Standard CAN/CSA - Z316.6 on Impact Resistance* states that containers, when in the final closure position and dropped from a distance of 24 inches, remain intact (lid remains on container) and sharps do not escape. Bemis Two Gallon Chemo Containers passed this test.

There are no features to bend, break, or shear the needle.

Two Gallon Chemotherapy Containers can be used freestanding or locked on wall mounted brackets. A key that is unique to this bracket is used to unlock containers from the bracket. The containers are shipped in two pieces and require assembly by the user. Instructions are included in every case.