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510K SUMMARY

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Name of Device Common Name: Sharps Disposal Container
Tradename: **Bemis Two Gallon Sharps Container**
Classification Name: Sharps Disposal Container

Predicate Device: *Baxter* Two Gallon Sharps Container

Description of the Device

The Bemis Two Gallon Sharps Containers are designed for use in areas with controlled access such as labs and pharmacies. They contain features for both temporary and final closure.

The Bemis Two Gallon Sharps 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 Sharps Containers are injection molded of polypropylene plastic and are available in translucent red and beige. These containers are NOT reusable.

Bemis Two Gallon Sharps 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 Sharps 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. 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 Sharps Containers are labeled with the Biohazard warning symbol that is 1½" in height. The label color is orange-red, 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 overfill detection, *ECRI Overfill Warning* criteria specifies that contents be viewed to determine fill level. Bemis Two Gallon Sharps Containers are translucent with clear lids, therefore, allowing visibility at all levels.

The Bemis Two Gallon Sharps Container is designed for use in areas with **controlled access**. According to *ECRI 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 such as butterfly needles, test tubes and vials. Following final closure, the container remains closed during normal handling.

ECRI Freestanding Capability criteria specifies that the container should be stable in it's upright position when tipped to 20 degrees, and when in the temporary closed position, contents should not spill out when toppled. Testing done on the Bemis Two Gallon Sharps 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 Sharps Containers passed this test.

There are no features to bend, break, or shear the needle. The lid also incorporates a "needle key" which can be used to unscrew needles from blood collection tube holders. After blood collection, the needle is inserted into the slotted opening and slid to the left or right until firmly seated. It is then turned counter-clockwise to unscrew the needle from the tube holder.

Two Gallon Sharps Containers lock 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.