FAQ

Ecoflac™ Plus IV Container

What material is used in the manufacture of Ecoflac™ Plus?

The container is produced from a medical grade polyethylene. This polymer is chemically inert and nontoxic; free from additives like plasticizers, stabilizers, and antioxidants.

The Ecoflac Plus Twincap sealant is manufactured from a new generation of thermoplastic elastomers. Thermoplastic elastomers are a polymer which exhibits the elasticity of rubber material, and is also recyclable.¹

How do B. Braun IV containers differ from those containing PVC?

B. Braun IV containers are biologically inert, and are not made with PVC or the plasticizer DEHP. This differs from PVC containers which have the potential for sorption of certain medications, including diazepam, nitroglycerin, cyclosporine or paclitaxel, potentially resulting in the release of DEHP into the fluid and/or absorption of the active ingredient with subsequent sub-therapeutic dosing.

Using IV containers that do not contain PVC and DEHP, minimizes patient exposure to the toxic DEHP plasticizer compared to using PVC containers containing DEHP.²

Does the Twincap contain latex?

The Twincap is not made with natural rubber latex.

² Bristol-Myers Squibb Company, Oncology Division. Taxol (Paclitaxel) Injection Administration, Equipment, 11/99 Equipment
Is the Twincap sterile under the sealant foil?

Yes. The cap is sealed to the container followed by terminal sterilization of the product to ensure that the surface under the foil is sterile.

Like with any product, please use strict aseptic technique when accessing the ports.

Can Ecoflac™ Plus IV containers be recycled?

Ecoflac Plus containers are made from polyethylene container that is recyclable with the number “4” indicating the resin identification number. However, the infusion set and the aluminum foil covering the ports should be removed before disposal. Please follow your facility’s protocol for recycling of fluid containers.

Can we use a marking pen to write on Ecoflac™ Plus IV containers?

We do not conduct biocompatibility testing on the inks used in the manufacture of marking pens. Therefore, we do not recommend using any marking pen on the fluid contact area of Ecoflac Plus containers.

How long can the Ecoflac™ Plus container be stored and at what temperature?

The shelf life of Ecoflac Plus at room temperature (77°F/ 25°C) is 3 years (36 months). The product should not be stored above or below the temperature stated on the label.

What are the residual volume specifications for the Ecoflac™ Plus IV container?

After administration, it is common for a small amount of solution to remain in an IV bag or container. The residual amount is negligible and should not significantly affect the therapeutic dose of IV additives.

What are the filling volume specifications of the Ecoflac™ Plus IV container?

For the fill volume of a large volume parenteral product, the United States Pharmacopeia (USP) states that each intravenous solution container is filled with “a volume in slight excess of the labeled 'size' or ‘that volume which is to be withdrawn’.” Under hospital use conditions, most of the excess solution is expended in the process of flushing and filling the administration set at the initiation of the infusion. For containers of 50 mL or greater volume, the USP <1151> recommends excess volume of 2% (3% for viscous solutions), which is considered sufficient to permit withdrawal and administration of the labeled volume.

The following table contains the fill volume range for 500 mL Ecoflac Plus, which is within USP <1151>:

<table>
<thead>
<tr>
<th>Fill volume range (mL)</th>
<th>510 – 535</th>
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Why is the graduation scale non-linear?
The Ecoflac™ Plus container collapses completely during infusion, without the need of venting the container. The non-linear graduation scale on the Ecoflac Plus label indicates the approximate delivered volume as the container collapses. To know the exact infusion volume, pumps are recommended.

We recommend using Ecoflac Plus unvented to ensure a closed system.

What is the proper spiking technique of Ecoflac™ Plus?
Always insert the infusion set at a right (90') angle. Avoid rotating the spike when piercing the port. Avoid a rotation movement to penetrate the ports, as this might result in coring and the rotating movement makes reseal of the ports less efficient.

Can the Ecoflac™ Plus IV container be pressure infused?
This container is not for use with pressure infusion. See product label.