FAQ EXCEL® Plus IV Container



How are B. Braun IV containers different from those that contain PVC?

B. Braun IV containers are biologically inert and are not made with natural rubber latex, PVC or the plasticizer DEHP. The U.S. Environmental Protection Agency (EPA) has determined that DEHP is a probable human carcinogen and it is included on the Proposition 65 list of chemicals known to the State of California to cause cancer, birth defects or other reproductive harm. DEHP is a toxic chemical that can leach into medications and other fluids administered to patients intravenously. Products not made with DEHP help protect susceptible populations such as male neonates, pediatric patients, pregnant and lactating women and chemotherapy patients.

Can we use a marking pen to write on EXCEL Plus IV Containers?

We do not conduct any biocompatibility testing on the inks used in the manufacturing of marking pens. Therefore, we do not recommend using any marking pen on the fluid contact area of EXCEL Plus IV Containers.

How long and at what temperature can EXCEL Plus IV Containers be placed in a warming cabinet?

B. Braun conducted container integrity, as well as separate chemical and biological stability testing, on the following products to support warming up to 40°C for a period of up to 28 days or until expiration, whichever is sooner.^{1-3,5} Products should not be returned to stock after warming.

Product Description	Item Number(s)
0.9% Sodium Chloride Injection USP	Q8000, Q8001
0.45% Sodium Chloride Injection USP	Q8020
Lactated Ringer's Injection USP	Q7500, Q7501

COMING

Please note that exposure of pharmaceutical products to heat should be minimized whenever possible and that excessive heat should also be avoided. B. Braun product manufactured in the EXCEL Plus IV Container should be stored at room temperature (20° – 25°C) whenever possible. Refer to full prescribing information for recommended storage conditions.

How long and at what temperature can EXCEL Plus IV Containers be placed in a refrigerator?

B. Braun conducted container integrity, as well as separate chemical and biological stability testing, on the following products to support refrigeration at 2°-8°C for a period of up to 30 days or until expiration, whichever is sooner.¹⁻⁴ Products should not be returned to stock after refrigeration.

Product Description	Item Number(s)
0.9% Sodium Chloride Injection USP	Q8000, Q8001
0.45% Sodium Chloride Injection USP	Q8020
Lactated Ringer's Injection USP	Q7500, Q7501

COMING SOON

The labeling for EXCEL® Plus IV Containers states to protect from freezing. B. Braun product manufactured in the EXCEL Plus IV Container should be stored at room temperature (20° - 25°C) whenever possible. Refer to full prescribing information for recommended storage conditions.

Can EXCEL Plus IV Containers be transported in a pneumatic tube system?

While the EXCEL Plus IV Container design offers clinical, safety and environmental benefits, it is not as indestructible as PVC. Consequently, they must be handled differently with each type of pneumatic tube system.

The EXCEL Plus IV Container can withstand transport in a well-maintained, 6-inch pneumatic tube system.⁶ When possible, foam padding should be used when transporting IV bags. Padding can cushion the impact and protect the container from sharp edges inside the carrier. In 6-inch carriers, special foam inserts can be used for this purpose. Reduce the potential for the container film getting pinched by placing the container in the carrier on its side and performing a visual check.

What are the volume specifications for solutions in the EXCEL Plus IV Container?

The fill volumes for EXCEL Plus IV Containers account for water vapor transmission loss over the shelf life of the products and volume remaining in the container after drainage.

The United States Pharmacopeia (USP) requires containers of injections to have "a volume in slight excess of the labeled 'size' or the volume that is to be withdrawn," referred to as excess volume. For labeled volumes of 50 mL or more, USP <1151> recommends excess volume of 2% (3% for viscous solutions), which is considered sufficient to permit withdrawal and administration of the labeled volume.⁷

The volume specifications for EXCEL Plus IV Containers are as follows.8-10

Container Size	Target Fill Volume	Fill Range
500 mL	540 mL	531 - 548 mL
1000 mL	1052 mL	1043 - 1060 mL

How long can the EXCEL Plus IV Container be stored without its plastic overwrap?

All EXCEL Plus IV Containers, without any additions, can be stored at 25°C for 30 days without plastic overwrap (or until its expiration date, whichever is sooner). This storage time is based on B. Braun testing. We recommend that you follow your facility protocol regarding proper storage of drug product containers.

What are the additive volume specifications for the EXCEL Plus IV Container?

The maximum capacity of additional volume to the containers are listed below.¹²

Container Size	Maximum Additive Volume
500 mL	50 mL
1000 mL	200 mL

Can EXCEL® Plus IV Containers be pressure infused?

B. Braun has conducted compatibility testing and recommends the following pressure cuffs for use with the EXCEL Plus IV container.13,14,15

500 mL EXCEL PLUS
Unifusor® Pressure Infusors 903SGA
Mason Tayler Infu-Stat™ MTM305
Smiths Medical MEDEX™ C-Fusor® MX4705
BD Carefusion Vital Signs® IN800048
BD Carefusion Vital Signs® IN800012
Ethox Medical™ Infu-Surg® 4005
Medical Unifusor® 1103X-5
PremierPro® Pressure Infusor 8800
1000 mL EXCEL Plus
BD Carefusion Vital Signs® IN900012
Mason Tayler Infu-Stat MTM310
Smiths Medical MEDEX C-Fusor MX4810
Medical Unifusor® 1104X-5
Ethox Medical™ Infu-Surg® 4010
PremierPro® Pressure Infusor 8801
Unifusor Pressure Infusors 904SGA

The EXCEL Plus IV Container is designed to withstand pressure infusion up to 300 mmHg for 24 hours.

What are the dimples on the back side of the EXCEL Plus IV Container?

The trays used for the sterilization process cause the dimpled texture on the back of the container. This does not affect the integrity of the container.

Can EXCEL Plus IV Containers be recycled?

EXCEL Plus IV Containers are made of a rubberized blend of propylene and ethylene and are recyclable with the number "7" as the resin identification number. Please follow your facility's protocol for the recycling of fluid containers.

References:

- 1. ESIG-CORP-8002988
- 2. RPT-PH-1009451
- 3. RPT-DFL-1000009 4. RPT-PH-1013887
- 5. RPT-DFL-1000022
- 6. ESIG-CORP-8003445
- 7. USP (2022). General Chapter 1151 Pharmaceutical Dosage Forms.
- 8. ESIG-CORP-8003025 9. ESIG-CORP-8003464
- 10. REF-DFL-1007519
- 11. ESIG-CORP-8001317
- 12. ESIG-CORP-8003469
- 13. ESIG-CORP-8003277
- 14. ESIG-CORP-8003443
- 15. SPEC-CORP-8000039

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