



# Irrigation FAQ (TITAN XL™ and PIC™)

## What are the overfill volume specifications for PIC (Plastic Irrigation Containers) and TITAN XL irrigation containers?

The United States Pharmacopeia (USP) requirements for the fill volume of a large volume product state that each intravenous solution container must be filled with "a volume in slight excess of the labeled 'size' or 'that volume which is to be withdrawn'."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> recommended excess volume is 2%, which is considered sufficient to permit withdrawal and administration of labeled volume.

The overfill volume for the PIC and TITAN XL irrigation container includes the 2% overfill recommended by the USP <1151> to compensate for the residual volume left in the container after drainage, and addition of a sufficient amount of solution (approximately 2%) to allow for water vapor transmission losses out of the container over the shelf life of the product. The remaining overfill volume, which is accounted for by the variation in the amount of solution dispensed by the filling equipment, assures that the product contains at least the labeled volume plus the overfill volumes.<sup>2</sup>

Solutions in the PIC and TITAN XL irrigation container are formulated to ensure that the vapor transmission losses do not affect the claimed solution volumes and concentrations over the shelf life of the product.

## How long and at what temperature can TITAN XL irrigation containers be placed in a warmer?

The labeling for TITAN XL products contains a statement that exposure of pharmaceutical products to heat should be minimized and that excessive heat should also be avoided. The labeling also recommends that the product be stored at room temperature (25°C); however, brief exposure at 40°C does not adversely affect the product.

B. Braun conducted chemical and biological stability testing at 25°C of the solutions in the TITAN XL container with the overwrap intact, throughout the labeled shelf life of the product. In addition, chemical and biological stability testing was conducted at 40°C for six (6) months. B. Braun also conducted functional integrity testing of the TITAN XL container after exposure to 40°C for 14 days. The 40°C stability and functional testing demonstrate that 40°C exposure for 14 days has no impact on the solution or TITAN XL container. Product that has been exposed to 40°C and not used within 14 days must be discarded and not returned to storage.<sup>1</sup>

## Can TITAN XL irrigation containers be used with power irrigators or pressure cuffs?

Practitioners are advised that the TITAN XL irrigation container system is not for use with pressurized irrigation systems. B. Braun has qualified the current TITAN XL irrigation container-closure system only for indications and applications that are consistent with the FDA-approved product labeling. When using the TITAN XL irrigation container in combination with other devices or sets, it is always the responsibility of the practitioner to make an independent determination that the combined irrigation system is suitable and safe for use in the intended application. For best performance we recommend the use of compatible B. Braun sets.

## How long can the TITAN XL irrigation container be stored without its overwrap?

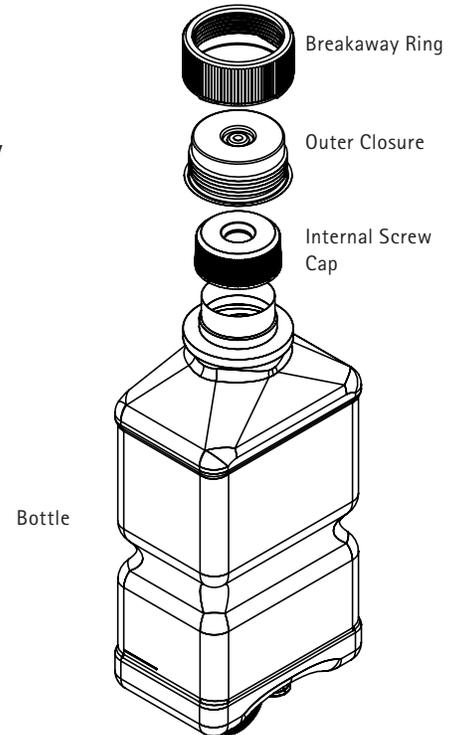
The TITAN XL 2000 mL and 3000 mL size containers, without any additions, can be stored at 25°C for seven (7) days without its plastic overwrap (or until its expiration date, whichever is sooner). This storage time is based on B. Braun testing. We recommend that you follow your facility protocol regarding proper storage of drug product containers.<sup>3</sup>

## Can I stack TITAN XL™ irrigation containers?

Due to the size and weight of TITAN XL bags, they must be handled with care. In storage, minimize stacking and do not stack higher than five (5) units for up to seven (7) days.<sup>4</sup>

## What components make up the PIC™ irrigation container closure system?

The closure system of the PIC irrigation container is composed of three parts: the breakaway ring, the outer closure with tamper-evident seal, and the internal screw cap. The internal screw cap is not welded on the bottle and can be manually removed after the removal of the outer closure. The outer closure is welded onto the container and can only be removed by using the breakaway ring. The breakaway rings are interchangeable and can be used on all sizes of PIC units.



## How do I open the PIC irrigation container?

To remove the tamper-evident outer closure of the PIC irrigation container, grasp the container with your non-dominant hand and turn the breakaway ring counterclockwise with the other hand until resistance is felt. Then, continue twisting the breakaway ring sharply in a counterclockwise direction until the entire outer closure breaks free. A cracking noise should be heard indicating the tamper-evident seal has been broken. Continue turning the breakaway ring until the outer closure separates from the container.

To use as pourable irrigation, simply remove the internal screw cap and pour. PIC containers provide a no-drip lip to minimize the potential of fluid and environmental contamination during pouring procedures.

## Only the breakaway ring came off the PIC irrigation container. Now what do I do?

If after twisting you are left holding an open ring, you have turned it in the wrong direction. Rethread the breakaway ring by twisting it on the outer closure in a counterclockwise direction. Initially, the ring will tighten. While twisting the container in the opposite direction, turn the breakaway ring sharply to remove.

If the breakaway ring is in the bottom of the case or otherwise not present on the bottle, you will just see the threads of the outer closure. Rethread the breakaway ring onto the bottle following the steps listed above.

## What should I do if the PIC™ irrigation container breakaway ring is broken or I cannot remove the breakaway ring and outer closure?

If the breakaway ring on the PIC irrigation container is broken, please return it with the container. If the breakaway ring is difficult to turn to break the seal, place the unit aside and use an alternate unit. Please notify B. Braun.

## How long and at what temperature can PIC irrigation containers be placed in a warmer?

Our PIC irrigation container package insert states: "Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. It is recommended that the product be stored at room temperature (25°C); however, brief exposure up to 40°C does not adversely affect the product."

Our PIC irrigation container package insert also states: "Do not warm above 150°F (66°C)." The integrity of our PIC irrigation container can be maintained when warmed at carefully controlled temperatures up to 150°F for a maximum of 72 hours. It is recommended that warming cabinets be set at a controlled temperature not to exceed 150°F in order to assure minimum bottle distortion. Unused product must be discarded and not returned to storage.<sup>5</sup>

## What are the dimensions of the PIC irrigation container?

The dimensions of the PIC containers are as follows:<sup>6</sup>

| Volume  | Length   | Width    | Height   |
|---------|----------|----------|----------|
| 500 mL  | 4.09 in. | 2.81 in. | 5.59 in. |
| 1000 mL | 4.09 in. | 2.81 in. | 8.61 in. |
| 2000 mL | 5.67 in. | 4.09 in. | 8.61 in. |
| 4000 mL | 6.14 in. | 5.63 in. | 11.8 in. |

## The PIC bottle is discolored. Should I be concerned?

The PIC container yellow discoloration has no impact on the stability or quality of the drug products throughout the product expiry.

The discoloration is isolated to the container only and may vary from lot to lot due to the age of the product. B. Braun conducted testing that demonstrates the discoloration does not migrate from the container to the solution and does not compromise the solution integrity.<sup>7</sup>

1 Warming Recommendations for B. Braun Irrigation Solutions in 2L/3L Plastic Container, Report # PH-SD-1004987

2 United States Pharmacopeia <1151>, 38th revision, May 1, 2015.

3 TITAN XL Water Vapor Transmission Rate Regression Analysis Report, Report # RPT-PH-1007268

4 Summary Report Lab Notebook Study on Stacking of 3L TITAN Containers, Report # RPT-PH-1007457

5 Stability Study of Various Irrigation Solutions in the PIC Container at 150°F (66°C) for 72 Hours, Report # RPT-1004378

6 PIC drawings from Clinical & Technical Support Product Information Database

7. Extractables/Leachables Study Report for the Plastic Irrigation Container (PIC) Closure System, Report # RPT-PH-1006019