Dear Healthcare Professional:

This is the information you have requested regarding the intentional warming of both irrigation and intravenous solutions in plastic bag containers and irrigation solutions in plastic pour bottle containers manufactured by Baxter Healthcare Corporation (Baxter).

Baxter recommends that these solutions be stored according to the conditions specified on the individual product labeling. The expiration dating is based on stability data generated from product samples stored at the equivalent of a constant 25°C (77°F). While stored under labeled conditions, our product remains pharmaceutically acceptable. Prolonged storage at higher temperatures may accelerate concentration and pH changes in the final product.

Baxter has established the following guidelines for customers who wish to intentionally warm our solutions. We do not recommend the use of microwave radiation to warm or thaw solutions. Instead, we recommend the use of controlled temperature warming cabinets.

**Warming Recommendations for Large Volume Intravenous (IV) Solutions in plastic bags:**

IV solutions of volumes 150mL or greater can be warmed in their plastic overpouches to temperatures not exceeding 40°C (104°F), and for a period no longer than 14 days. Once the VIAFLEX plastic containers have been in the warming cabinet for their maximum time period, the containers should be removed from the warming cabinet and identified as having been warmed. They should not be subsequently returned to the warmer. The VIAFLEX plastic containers may continue to be used until the labeled expiration date provided they have not been warmed more than once.

**Warming Recommendations for ARTHROMATIC and UROMATIC Irrigation Solutions in plastic bags:**

Solutions can be warmed in their overpouches to temperatures not exceeding:

1. 45°C (113°F) and for a period no longer than 14 days, -- or --
2. 66°C (150°F) and for a period no longer than 72 hours.

Once the containers have been in the warming cabinet for their maximum time period, the containers should be removed from the warming cabinet and identified as having been warmed. They should not be subsequently returned to the warmer. The ARTHROMATIC/UROMATIC plastic containers may continue to be used until the labeled expiration date provided they have not been warmed more than once.

**Warming of Irrigation Solutions in Plastic Pour Bottles:**

The following two sets of guidelines have been established to aid clinicians when intentionally warmed irrigation solutions in plastic pour bottles are needed:

1. Solutions can be warmed to temperatures not exceeding 50°C (122°F) and for a period no longer than 60 days.
Once the plastic pour bottle containers have been warmed for their maximum time period, (at temperatures not exceeding 50 °C), the containers should be removed from the warming device and discarded.

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(2) Solutions can be warmed to temperatures not exceeding 66°C (150°F) and for a period no longer than 72 hours.

Once the plastic pour bottle containers have been warmed for their maximum time period, the containers should be removed from the warming device and identified as having been warmed. They should not be subsequently returned to the warmer. If unopened once the containers have reached their maximum time period of 72 hours (at temperatures not exceeding 66 °C, the plastic pour bottle containers may continue to be used until the labeled expiration date, provided they have not been warmed more than once.

Baxter has generated data on file that confirms that when the above warming guidelines have been followed, all products should remain acceptable for use until their labeled expiration dating.

Notes:

Please note that test results were generated for products only at the times and temperatures specified above. No extrapolation on temperatures and times can be supported by Baxter.

The temperatures listed are the highest temperatures the products were tested at. If you wish to warm to a lower temperature, that is acceptable; however, the time in the warmer cannot be extended (i.e. when warming IV solution bags at 98°F, the maximum time in the warmer remains at 14 days). For those products, which have two temperature guidelines, warming to temperatures between the two guidelines would result in having to follow the upper temperature time guidelines. (i.e. For pour bottles, if the desired warming temperature is above 122°F, the guidelines for warming at 150°F must be followed e.g. warm at 135°F only for 72 hours maximum.

The times listed in the above recommendations are the amount of time the products can remain in the warmer during a single warming session. Baxter has not tested these products in warm-cool-warm cycles; i.e. Baxter has no information on products placed in a warmer for a time period shorter than the maximum recommended time, then removed and allowed to cool, and then re-warmed for another time period. Once a product is removed from the warmer and allowed to cool, it should not be placed back into the warmer, even if the total warming time would then equal the recommended warming time.

Intentional warming of our containers does not affect the sterility of those containers and the solutions they contain. Our containers are terminally sterilized at higher temperatures and container seals are able to withstand those temperatures. Unless the container has been breached during shipping, handling, or storage, the solution remains sterile throughout its life. We do recommend that clinicians check the integrity of all of our containers prior to use, whether intentionally warmed or not. In addition, please note that the warming temperatures listed in this letter are provided only as a guideline to insure the chemical stability of the warmed products. Baxter has no recommendations or information on what are appropriate temperatures for these solutions during actual administration/use.

I hope this information has been helpful to you. If I can be of further assistance, please contact Medical Information at 1-800-933-0303.
Sincerely,

Deborah M Schmitz RN BS
Manager Medical Affairs
Medication Information
Global Medical and Clinical Affairs
Baxter Healthcare Corporation