

Volume of Intralipid® 30%		Required Minimum Volume of Dextrose/ Amino Acid Solutions		Final Volume of Admixture	Final fat Concentration
1 mL	+	0.5 mL	=	1.5 mL	20%
100 mL	+	50 mL	=	150 mL	20%
250 mL	+	125 mL	=	375 mL	20%
500 mL	+	250 mL	=	750 mL	20%

Because of the potential for life threatening events, caution should be taken to ensure that precipitates have not formed in any parenteral nutrition mixture. Perform all manipulations in a suitable work area, such as a laminar flow hood.

**Failure to follow the Mixing Guidelines and Limitations below, including recommended storage temperature, storage time, order of mixing, etc., may result in an unstable admixture.**

Intralipid® 30% (A 30% I.V. Fat Emulsion) may be mixed with Amino Acid and Dextrose Injections where compatibility have been demonstrated. Additives known to be incompatible should not be used. Please consult with pharmacist. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives (e.g., Vitamins and Minerals).

When being mixed the following proper mixing sequence must be followed to minimize pH related problems by ensuring that typically acidic Dextrose Injections are not mixed with lipid emulsions alone:

1. Transfer Dextrose Injection to the TPN admixture Container
2. Transfer Amino Acid Injection
3. Transfer Intralipid® 30% (A 30% I.V. Fat Emulsion)

Note: Amino Acid Injection, Dextrose Injection and Intralipid® may be simultaneously transferred to the admixture container. Admixing should be accompanied by gentle agitation to avoid localized concentration effects.

Additives must not be added directly to Intralipid® and in no case should Intralipid® be added to the TPN container first. Bags should be shaken gently after each addition to minimize localized concentration.

If the admixture is not used immediately, the in-use storage time and conditions prior to use are the responsibility of the user and should normally not be longer than 24 hours at 2-8°C. After removal from storage at 2-8°C, the admixture should be infused within 24 hours.

It is essential that the admixture be prepared using strict aseptic techniques as this nutrient mixture is a good growth medium for microorganisms.

Supplemental electrolytes, trace metals or multivitamins may be required in accordance with the prescription of the attending physician.

The prime destabilizers of emulsions are excessive acidity (low pH) and inappropriate electrolyte content. Careful consideration should be given to additions of divalent cations (Ca<sup>++</sup> and Mg<sup>++</sup>) which have been shown to cause emulsion instability. Amino acid solutions exert a buffering effect protecting the emulsion. The admixture should be inspected carefully for “breaking or oiling out” of the emulsion. “Breaking or oiling out” is described as the separation of the emulsion and can be visibly identified by a yellowish streaking or the accumulation of yellowish droplets in the admixed emulsion. The admixture should also be examined for particulates. The admixture must be discarded if any of the above is observed.

#### HOW SUPPLIED

Intralipid® 30% (A 30% I.V. Fat Emulsion) is supplied as a sterile emulsion in a Pharmacy Bulk Package in the following fill sizes:

500 mL: 0338-0520-13

#### STORAGE

Intralipid® 30% should not be stored above 25°C (77°F). Do not freeze Intralipid® 30%. If accidentally frozen, discard the bag.

#### REFERENCES

1. Padley FB: “Major Vegetable Fats,” The Lipid Handbook (Gunstone FD, Harwood JL, Padley FB, eds.), Chapman and Hall Ltd., Cambridge, UK (1986), pp. 88-9.
2. Levene MI, Wigglesworth JS, Desai R: Pulmonary fat accumulation after Intralipid® infusion in the preterm infant. Lancet 1980; 2(8199):815-8.
3. American Academy of Pediatrics: Use of intravenous fat emulsion in pediatric patients. Pediatrics 1981; 68:5(Nov) 738-43.

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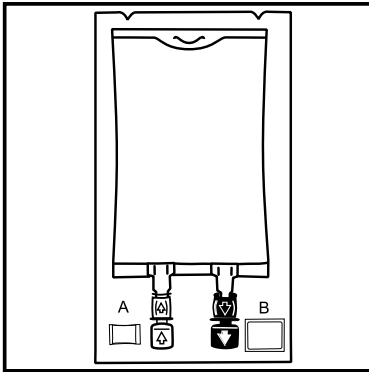
Manufactured for  
**Baxter Healthcare Corporation**  
Deerfield, IL 60015 USA

Manufactured by  
**Fresenius Kabi**,  
Uppsala, Sweden

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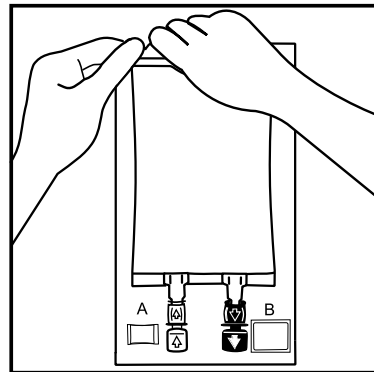
## Instruction for Use - Intralipid® 30% Pharmacy Bulk Package Container

1.



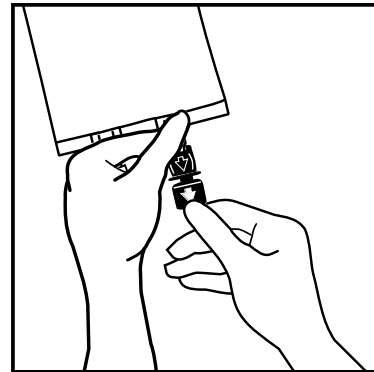
1. The integrity indicator (Oxalert™) **A** should be inspected before removing the overwrap. If the indicator is black the overwrap is damaged and the product should be discarded.

2.



2. Remove the overwrap by tearing at the notch and pulling down along the container. The Oxalert sachet (**A**) and the oxygen absorber (**B**) should be discarded.  
Place the bag on a clean, flat surface or hang on a support hook.

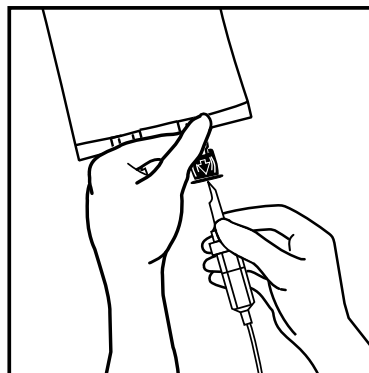
3.



3. Break off the tamper-evident arrow flag from the blue infusion port.

Use a compounding set with a diameter of 5.6 +/- 0.1 mm.  
Follow the instructions for use for the compounding set.

4.

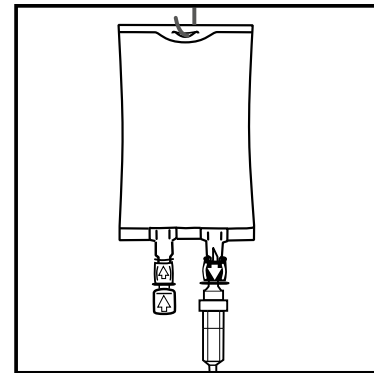


4. Hold the base of the infusion port firmly and insert the spike straight through the center of the septum by rotating the wrist slightly if needed.

**NOTE: Assure that the spike is inserted straight into the port and not at an angle.**

Inspect the bag and contents for particulate matter in a well-lit environment prior to use. Discard the bag if there are any signs of discoloration or particulates.

5.



5. Hang the bag in the hanger cut and start transfer to the compounding bag.

