

# TECHNICAL DATA SHEET

## Lympha™ — Acetate-free liquid hemodialysis concentrate with glucose in bag



Figure 1.

### PRODUCT DESCRIPTION

The Lympha™ solution is single use medical device and is used on machines for blood purification by extracorporeal circulation. The solution is used for the preparation of hemodialysis (HD) dialysate. In currently available HD systems, dialysate is prepared using fixed ratio proportioning systems, utilizing a volume of “acid” concentrate, “base” concentrate and dialysis-quality water to prepare the final dialysate solution. The operating principle is a combination of all electrolytes present in the concentrated solution for hemodialysis. The compound is used after dilution and the addition of sodium bicarbonate solution. This dialysate is then used within the dialyzer for blood purification.

The device enables elimination of urea and other nitrogenous waste for extra-renal purification and the correction of hydroelectrolytic and plasma acid-base imbalances.

The Lympha™ solution is packaged in 3.8 or 5.5 liter bags (Figure 1) and available in two series: the BS6xxx series to be used with Flexya hemodialysis system and the BS9xxx series for use with brands other than Bellco.

### CODES AVAILABLE

| CFN         | Model                 | Description                              | CND     | GMDN  |
|-------------|-----------------------|--|---------|-------|
| BS642L038/T | LYMPHA™ bag 642 3.8 L | Concentrated acid solution in 3.8 L bags | F040399 | 35849 |
| BS643L038/T | LYMPHA™ bag 643 3.8 L | Concentrated acid solution in 3.8 L bags | F040399 | 35849 |
| BS644L038/T | LYMPHA™ bag 644 3.8 L | Concentrated acid solution in 3.8 L bags | F040399 | 35849 |
| BS645L038/T | LYMPHA™ bag 645 3.8 L | Concentrated acid solution in 3.8 L bags | F040399 | 35849 |
| BS646L038/T | LYMPHA™ bag 646 3.8 L | Concentrated acid solution in 3.8 L bags | F040399 | 35849 |
| BS648L038/T | LYMPHA™ bag 648 3.8 L | Concentrated acid solution in 3.8 L bags | F040399 | 35849 |
| BS652L038/T | LYMPHA™ bag 652 3.8 L | Concentrated acid solution in 3.8 L bags | F040399 | 35849 |
| BS653L038/T | LYMPHA™ bag 653 3.8 L | Concentrated acid solution in 3.8 L bags | F040399 | 35849 |
| BS654L038/T | LYMPHA™ bag 654 3.8 L | Concentrated acid solution in 3.8 L bags | F040399 | 35849 |
| BS655L038/T | LYMPHA™ bag 655 3.8 L | Concentrated acid solution in 3.8 L bags | F040399 | 35849 |
| BS656L038/T | LYMPHA™ bag 656 3.8 L | Concentrated acid solution in 3.8 L bags | F040399 | 35849 |
| BS657L038/T | LYMPHA™ bag 657 3.8 L | Concentrated acid solution in 3.8 L bags | F040399 | 35849 |
| BS642L055/T | LYMPHA™ bag 642 5.5 L | Concentrated acid solution in 5.5 L bags | F040399 | 35849 |
| BS643L055/T | LYMPHA™ bag 643 5.5 L | Concentrated acid solution in 5.5 L bags | F040399 | 35849 |
| BS645L055/T | LYMPHA™ bag 645 5.5 L | Concentrated acid solution in 5.5 L bags | F040399 | 35849 |
| BS648L055/T | LYMPHA™ bag 648 5.5 L | Concentrated acid solution in 5.5 L bags | F040399 | 35849 |
| BS652L055/T | LYMPHA™ bag 652 5.5 L | Concentrated acid solution in 5.5 L bags | F040399 | 35849 |
| BS653L055/T | LYMPHA™ bag 653 5.5 L | Concentrated acid solution in 5.5 L bags | F040399 | 35849 |
| BS654L055/T | LYMPHA™ bag 654 5.5 L | Concentrated acid solution in 5.5 L bags | F040399 | 35849 |

|             |                       |  |         |       |
|-------------|-----------------------|--|---------|-------|
| BS655L055/T | LYMPHA™ bag 655 5.5 L | Concentrated acid solution in 5.5 L bags | F040399 | 35849 |
| BS656L055/T | LYMPHA™ bag 656 5.5 L | Concentrated acid solution in 5.5 L bags | F040399 | 35849 |
| BS657L055/T | LYMPHA™ bag 657 5.5 L | Concentrated acid solution in 5.5 L bags | F040399 | 35849 |
| BS658L055/T | LYMPHA™ bag 658 5.5 L | Concentrated acid solution in 5.5 L bags | F040399 | 35849 |
| BS682L055/T | LYMPHA™ bag 682 5.5 L | Concentrated acid solution in 5.5 L bags | F040399 | 35849 |
| BS942L038/T | LYMPHA™ bag 942 3.8 L | Concentrated acid solution in 3.8 L bags | F040399 | 35849 |
| BS943L038/T | LYMPHA™ bag 943 3.8 L | Concentrated acid solution in 3.8 L bags | F040399 | 35849 |
| BS945L038/T | LYMPHA™ bag 945 3.8 L | Concentrated acid solution in 3.8 L bags | F040399 | 35849 |
| BS948L038/T | LYMPHA™ bag 948 3.8 L | Concentrated acid solution in 3.8 L bags | F040399 | 35849 |
| BS957L038/T | LYMPHA™ bag 957 3.8 L | Concentrated acid solution in 3.8 L bags | F040399 | 35849 |
| BS973L038/T | LYMPHA™ bag 973 3.8 L | Concentrated acid solution in 3.8 L bags | F040399 | 35849 |
| BS942L055/T | LYMPHA™ bag 942 5.5 L | Concentrated acid solution in 5.5 L bags | F040399 | 35849 |
| BS943L055/T | LYMPHA™ bag 943 5.5 L | Concentrated acid solution in 5.5 L bags | F040399 | 35849 |
| BS945L055/T | LYMPHA™ bag 945 5.5 L | Concentrated acid solution in 5.5 L bags | F040399 | 35849 |
| BS948L055/T | LYMPHA™ bag 948 5.5 L | Concentrated acid solution in 5.5 L bags | F040399 | 35849 |
| BS954L055/T | LYMPHA™ bag 954 5.5 L | Concentrated acid solution in 5.5 L bags | F040399 | 35849 |
| BS956L055/T | LYMPHA™ bag 956 5.5 L | Concentrated acid solution in 5.5 L bags | F040399 | 35849 |
| BS957L055/T | LYMPHA™ bag 957 5.5 L | Concentrated acid solution in 5.5 L bags | F040399 | 35849 |

## STERILIZATION METHOD AND VALIDITY

Non-sterile and non-pyrogenic solution

Shelf life: 18 months

## TECHNICAL CHARACTERISTICS

The technical characteristics of Lympha™ bag are reported below.

| Components                | Materials                                      |
|---------------------------|--|
| Bag                       | Polyvinyl chloride (PVC) with TOTM plasticizer |
| Tube                      | Polyvinyl chloride (PVC) with TOTM plasticizer |
| Clamp                     | Polypropylene (PP)                             |
| Male Luer Block Connector | Low Density Polyethylene (LDPE)                |
| Overwrapping bag          | Low Density Polyethylene (LDPE)                |
| Solution                  | See table "Solution composition"               |

## Solution composition

| Model                 | Volume (L) | Dilution | Na <sup>+</sup> (mmol/L) | K <sup>+</sup> (mmol/L) | Ca <sup>++</sup> (mmol/L) | Mg <sup>++</sup> (mmol/L) | Cl <sup>-</sup> (mmol/L) | H <sup>+</sup> (mmol/L) | C <sub>6</sub> H <sub>12</sub> O <sub>6</sub> (g/L) |
|-----------------------|------------|----------|--------------------------|-------------------------|---------------------------|---------------------------|--------------------------|-------------------------|---|
| LYMPHA™ bag 642 3.8 L | 3.8        | 1:45     | 103.00                   | 2.00                    | 1.50                      | 0.50                      | 111.00                   | 2.00                    | 1.00  |
| LYMPHA™ bag 643 3.8 L | 3.8        | 1:45     | 103.00                   | 2.00                    | 1.25                      | 0.50                      | 110.50                   | 2.00                    | 1.00  |
| LYMPHA™ bag 644 3.8 L | 3.8        | 1:45     | 103.00                   | 2.00                    | 1.65                      | 0.50                      | 111.30                   | 2.00                    | 1.00  |
| LYMPHA™ bag 645 3.8 L | 3.8        | 1:45     | 103.00                   | 3.00                    | 1.50                      | 0.50                      | 112.00                   | 2.00                    | 1.00  |
| LYMPHA™ bag 646 3.8 L | 3.8        | 1:45     | 103.00                   | 3.00                    | 1.65                      | 0.50                      | 112.30                   | 2.00                    | 1.00  |
| LYMPHA™ bag 648 3.8 L | 3.8        | 1:45     | 103.00                   | 2.00                    | 1.75                      | 0.50                      | 111.50                   | 2.00                    | 1.00  |
| LYMPHA™ bag 652 3.8 L | 3.8        | 1:45     | 103.00                   | 2.50                    | 1.50                      | 0.50                      | 111.50                   | 2.00                    | 1.00  |
| LYMPHA™ bag 653 3.8 L | 3.8        | 1:45     | 103.00                   | 1.00                    | 1.25                      | 0.50                      | 109.50                   | 2.00                    | 1.00  |
| LYMPHA™ bag 654 3.8 L | 3.8        | 1:45     | 103.00                   | 1.00                    | 1.50                      | 0.50                      | 110.00                   | 2.00                    | 1.00  |
| LYMPHA™ bag 655 3.8 L | 3.8        | 1:45     | 103.00                   | 1.00                    | 1.75                      | 0.50                      | 110.50                   | 2.00                    | 1.00  |
| LYMPHA™ bag 656 3.8 L | 3.8        | 1:45     | 103.00                   | 3.00                    | 1.25                      | 0.50                      | 111.50                   | 2.00                    | 1.00  |
| LYMPHA™ bag 657 3.8 L | 3.8        | 1:45     | 103.00                   | 3.00                    | 1.75                      | 0.50                      | 112.50                   | 2.00                    | 1.00  |
| LYMPHA™ bag 642 5.5 L | 5.5        | 1:45     | 103.00                   | 2.00                    | 1.50                      | 0.50                      | 111.00                   | 2.00                    | 1.00  |
| LYMPHA™ bag 643 5.5 L | 5.5        | 1:45     | 103.00                   | 2.00                    | 1.25                      | 0.50                      | 110.50                   | 2.00                    | 1.00  |
| LYMPHA™ bag 645 5.5 L | 5.5        | 1:45     | 103.00                   | 3.00                    | 1.50                      | 0.50                      | 112.00                   | 2.00                    | 1.00  |
| LYMPHA™ bag 648 5.5 L | 5.5        | 1:45     | 103.00                   | 2.00                    | 1.75                      | 0.50                      | 111.50                   | 2.00                    | 1.00  |
| LYMPHA™ bag 652 5.5 L | 5.5        | 1:45     | 103.00                   | 2.50                    | 1.50                      | 0.50                      | 111.50                   | 2.00                    | 1.00  |
| LYMPHA™ bag 653 5.5 L | 5.5        | 1:45     | 103.00                   | 1.00                    | 1.25                      | 0.50                      | 109.50                   | 2.00                    | 1.00  |
| LYMPHA™ bag 654 5.5 L | 5.5        | 1:45     | 103.00                   | 1.00                    | 1.50                      | 0.50                      | 110.00                   | 2.00                    | 1.00  |
| LYMPHA™ bag 655 5.5 L | 5.5        | 1:45     | 103.00                   | 1.00                    | 1.75                      | 0.50                      | 110.50                   | 2.00                    | 1.00  |
| LYMPHA™ bag 656 5.5 L | 5.5        | 1:45     | 103.00                   | 3.00                    | 1.25                      | 0.50                      | 111.50                   | 2.00                    | 1.00  |
| LYMPHA™ bag 657 5.5 L | 5.5        | 1:45     | 103.00                   | 3.00                    | 1.75                      | 0.50                      | 112.50                   | 2.00                    | 1.00  |
| LYMPHA™ bag 658 5.5 L | 5.5        | 1:45     | 103.00                   | 3.00                    | 1.75                      | 0.50                      | 112.50                   | 2.00                    | 1.00  |
| LYMPHA™ bag 682 5.5 L | 5.5        | 1:45     | 103.00                   | 4.00                    | 1.50                      | 0.50                      | 113.00                   | 2.00                    | 1.00  |
| LYMPHA™ bag 942 3.8 L | 3.8        | 1:45     | 103.00                   | 2.00                    | 1.50                      | 0.50                      | 112.00                   | 3.00                    | 1.00  |
| LYMPHA™ bag 943 3.8 L | 3.8        | 1:45     | 103.00                   | 2.00                    | 1.25                      | 0.50                      | 111.50                   | 3.00                    | 1.00  |
| LYMPHA™ bag 945 3.8 L | 3.8        | 1:45     | 103.00                   | 3.00                    | 1.50                      | 0.50                      | 113.00                   | 3.00                    | 1.00  |
| LYMPHA™ bag 948 3.8 L | 3.8        | 1:45     | 103.00                   | 2.00                    | 1.75                      | 0.50                      | 112.50                   | 3.00                    | 1.00  |
| LYMPHA™ bag 957 3.8 L | 3.8        | 1:45     | 103.00                   | 3.00                    | 1.75                      | 0.50                      | 113.50                   | 3.00                    | 1.00  |
| LYMPHA™ bag 973 3.8 L | 3.8        | 1:45     | 103.00                   | 3.50                    | 1.50                      | 0.50                      | 113.50                   | 3.00                    | 1.00  |
| LYMPHA™ bag 942 5.5 L | 5.5        | 1:45     | 103.00                   | 2.00                    | 1.50                      | 0.50                      | 112.00                   | 3.00                    | 1.00  |
| LYMPHA™ bag 943 5.5 L | 5.5        | 1:45     | 103.00                   | 2.00                    | 1.25                      | 0.50                      | 111.50                   | 3.00                    | 1.00  |
| LYMPHA™ bag 945 5.5 L | 5.5        | 1:45     | 103.00                   | 3.00                    | 1.50                      | 0.50                      | 113.00                   | 3.00                    | 1.00  |
| LYMPHA™ bag 948 5.5 L | 5.5        | 1:45     | 103.00                   | 2.00                    | 1.75                      | 0.50                      | 112.50                   | 3.00                    | 1.00  |
| LYMPHA™ bag 954 5.5 L | 5.5        | 1:45     | 103.00                   | 1.00                    | 1.50                      | 0.50                      | 111.00                   | 3.00                    | 1.00  |
| LYMPHA™ bag 956 5.5 L | 5.5        | 1:45     | 103.00                   | 3.00                    | 1.25                      | 0.50                      | 112.50                   | 3.00                    | 1.00  |
| LYMPHA™ bag 957 5.5 L | 5.5        | 1:45     | 103.00                   | 3.00                    | 1.75                      | 0.50                      | 113.50                   | 3.00                    | 1.00  |

## PACKAGING

| Model       | Primary packaging – Pouch |                  |
|-------------|---------------------------|------------------|
|             | Material                  | Pouch weight (g) |
| LYMPHA™ bag | Overwrapping bag          | 27.44            |

| Model            | Secondary packaging – Box                                   |                          |         |
|------------------|---|--------------------------|---------|
|                  | Box   | Weight <sup>1</sup> (kg) | Pcs/Box |
| LYMPHA™ 3.8L bag | American Cardboard Box<br>Dimensions: 36.2 × 23.6 × 21.4 cm | 12.3                     | 3       |
| LYMPHA™ 5.5L bag | American Cardboard Box<br>Dimensions: 36.2 × 23.6 × 21.4 cm | 11.8                     | 2       |

<sup>1</sup> Max box weight filled with products

## STORAGE AND DISPOSAL CONDITIONS

Storage conditions: store at temperatures between +4 and +30 degrees Celsius.

Disposal: remove from the place of dialysis immediately after use, any unused portion of solution should be discarded. Disposal must be carried out in accordance with the regulations in force.

## BIOCOMPATIBILITY

Biocompatibility tests of the LympHa™ solution have been performed according to applicable ISO 10993-1 standard series.

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