

# BiCart<sup>®</sup>

Essential component of a system designed for ultrapure dialysis fluid to avoid treatment related inflammation



The BiCart cartridge is central to the dialysis fluid delivery system:

- A hygienic method of bicarbonate supply from a dry-concentrate cartridge
- Eliminating the risk of contamination and bacterial growth
- Lighter and smaller container, removing strain associated with lifting heavy canisters
- Cap closure for cleaner post-treatment environment
- Less storage space required

Tougher hygienic and ergonomic demands required an upgraded bicarbonate supply. With its introduction, the BiCart cartridge set a new global standard in bicarbonate dialysis.

## General description

The BiCart polypropylene cartridge containing sodium bicarbonate enables on-line production of liquid bicarbonate concentrate.

Water passes through the BiCart cartridge when attached to its designated holder, thus producing a saturated bicarbonate solution, ready to use.

This concentrated solution is then proportioned in the dialysis machine.

Product code: 109 183 (EU-pallet)  
109 733 (container-pallet)

Units per box: 10

## Specification

Contents: Each BiCart cartridge contains 720 g of sodium bicarbonate powder (USP and Ph.Eur. grade)

Capacity: Together with a suitable acid concentrate each BiCart cartridge will yield enough sodium bicarbonate solution to produce 200 l of dialysis fluid with a bicarbonate concentration of 34 mmol/l

Duration: 6 h 45 min at 500 ml/min dialysis fluid flow rate  
4 h 50 min at 700 ml/min dialysis fluid flow rate

Storage: below +40°C

Shelf Life: Please refer to product label and box

## Quality control

Quality control as well as manufacturing procedures for the BiCart cartridge follow the current Good Manufacturing Practice (GMP) for pharmaceuticals as well as European and US legislation for medical devices.

The inspection of components, the process control and finished product testing are rigorous. All documentation and test- and inspection results are examined and reviewed.

The information herein may be subject to change without further notice. For further information and operating instructions, please refer to the operator manual.

**CE 0086** The products meet the applicable provisions of Annex I (Essential Requirements) and Annex II (Full quality assurance system) of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

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## Requirements on acid concentrate

The acid concentrate must be designed for use with pure bicarbonate concentrate and have a dilution ratio of 1:35 (1+34) or 1:45 (1+44). As an example, Gambro concentrate 204 can be used. When mixed 1:35 (1+34) the result is (mmol/l):

Sodium	103
Potassium	2
Calcium	1.75
Magnesium	0.5
Chloride	109.5
Acetate	3

Together with the sodium bicarbonate concentrate from the BiCart cartridge, the final dialysis fluid will have a sodium concentration of 140 mmol/l and a bicarbonate concentration of 34 mmol/l at a normal machine setting.

## Water purity

Water for diluting concentrated hemodialysis solutions shall be of a suitable quality (AAMI, Ph.Eur., BP).

