

Baxter

Ultra SteriSet
BLOODLINE TUBING SYSTEM

ULTRA STERISSET

ON-LINE FLUID PREPARATION FOR CONVECTIVE THERAPIES

Ultrapure dialysis fluid line with a unique sterile
and non-pyrogenic device



ULTRA STERISET

The **Ultra SteriSet** infusion line is an essential component of the Baxter **Ultra system**. Its sterile ultrafilter membrane constitutes an effective barrier for micro-organisms and pyrogens, and is designed to help effectively reject them by size eliminate. When fed with ultrapure dialysis fluid,

it prepares a non-pyrogenic substitution fluid¹ that can be infused directly into the patient's bloodstream. To assure the performance of the **Ultra SteriSet** device, all products are pressure-tested in production and test for the integrity of the ultrafilter, lines and components.

COMPONENTS AND MATERIALS

Ultrafilter

Membrane	Polyamix	PAES + PVP + PA
Potting material	Polyurethane	PUR
Housing & fluid ports	PolyEthylene	
	TerePhtalate glycol	PETG

Lines

Tubing	Polyvinyl chloride	PVC
Protective caps	High density polyethylene	PE-HD

Ultrafilter specifications

Effective membrane area (m ²)	0.2
Fiber inner diameter (µm)	200
Effective fiber length (mm)	125
Total volume – in use (ml) ²	78
Maximum TMP (mmHg)	600
Sterilization agent	Gamma rays

PERFORMANCE

Field of application

Bacteria, endotoxins and particules retention in infusion fluid¹

Max pressure drop values for given filtrate flow

Filtration flow QF (ml/min)	200	400
At pressure drop <i>f_p</i> (mmHg)	300	600

Determined with 0.9% sodium chloride solution at 37°C.

Pressure drop *f_p* is measured between fluid inlet and filtrate outlet.

Typical retention values for bacteria and endotoxins²

Bacterial challenge: *Brevundimonas diminuta* ATCC 19146 in saline lactose broth, cell diameter approx. 0.3 µm ≥ 7

Endotoxin challenge: *E. coli* O55:B5 endotoxin ≥ 3.5

LRV = Logarithmic reduction value

LRV = log₁₀ [number of organisms in challenge suspension/number of organisms in filtrate]

For safe and proper use of the device, please refer to the Instructions for Use

CE 2797

The product is CE marked in accordance with the requirements in the EC Council Directive 93/42/EEC. For further information and operating instructions, please refer to the operator manual.

1. Please refer to instructions for use
2. Internal data