

RECONNECTION

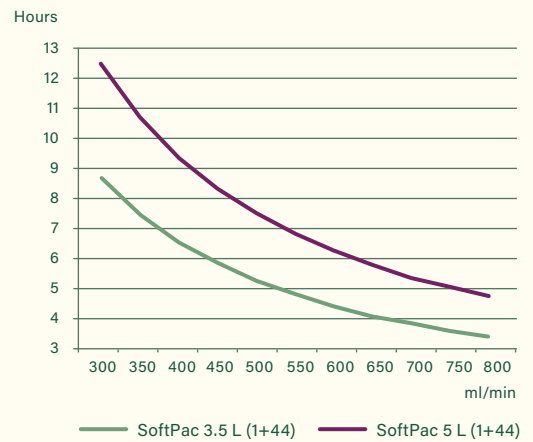
Possibility to use the Vantive **SoftPac** concentrate for next treatment may provide value for clinics and may reduce the environmental impact¹

MAXIMISING RESOURCES

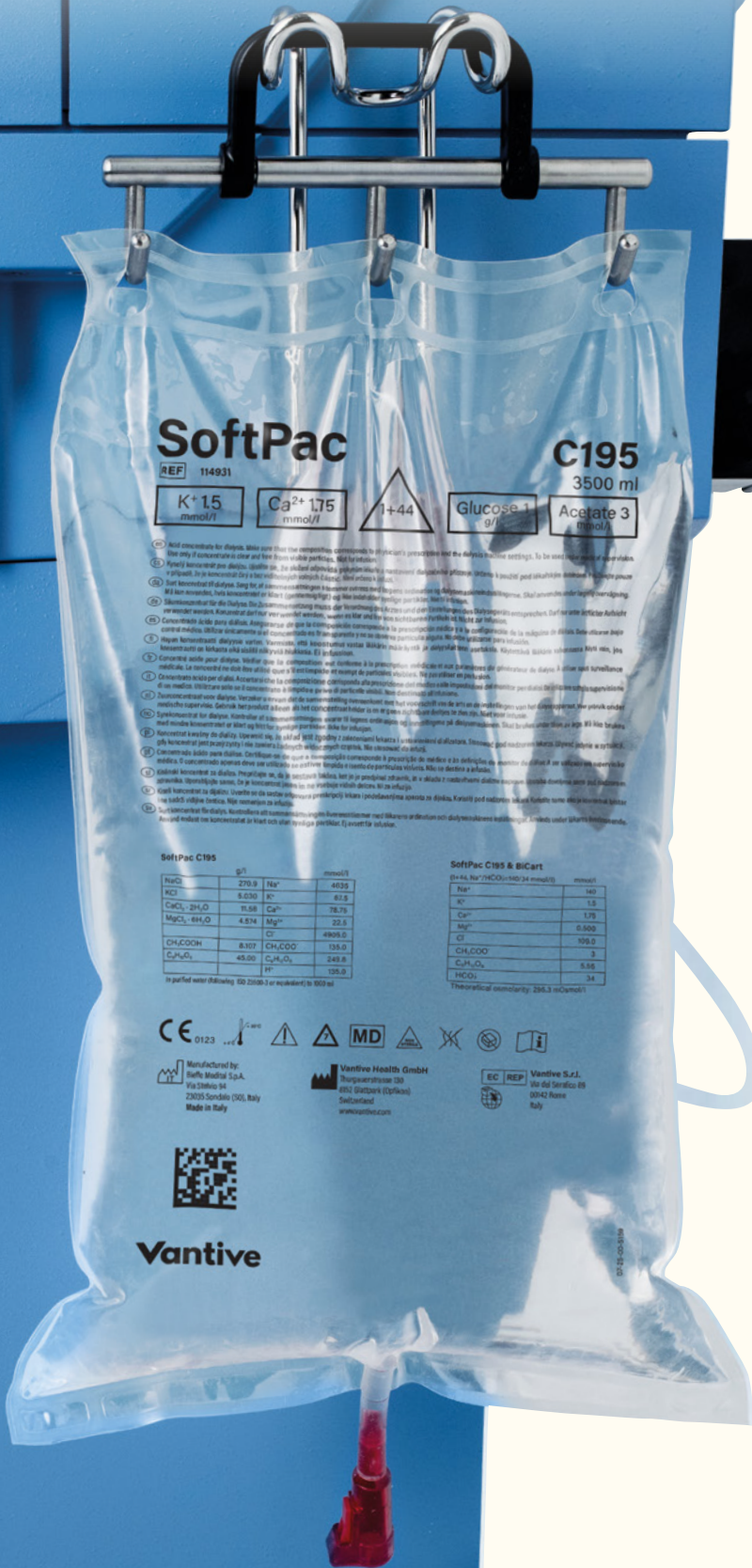
The **SoftPac** concentrate has been proven throughout customer usability studies to be very convenient on re-connection. This may help clinics maximise their resources by keeping concentrate changeover simple and easy and may reduce time for preparation. After the frangible pin has been broken clinics are able to use the concentrate while still retaining fluid purity.

CHOOSE YOUR BAG SIZE FOR RECONNECTION BASED ON YOUR DIALYSIS FLOW RATE

Calculated duration of the SoftPac concentrate products versus dialysis fluid flow rate at concentrate settings of $\text{Na}^+/\text{HCO}_3^- = 140/34 \text{ mmol/l}^2$.



Please observe: The effective treatment time will depend on the volume of concentrate consumed during setups.



SoftPac

C195

REF 114931 3500 ml
 K⁺ 15 mmol/l Ca²⁺ 1.75 mmol/l 1+44 Glucose 1 g/l Acetate 3 mmol/l

- (1) SoftPac concentrate for dialysis. Make sure that the concentrate corresponds to the patient's prescription and the dialysis machine settings. To be used in conjunction with a dialyzer.
- (2) K⁺ concentration per dialysis. Ca²⁺ concentration per dialysis. Acetate concentration per dialysis. Glucose concentration per dialysis. Theoretical osmolality per dialysis.
- (3) In the concentrate tray a red frangible pin is located. Break the pin to activate the concentrate. The frangible pin is located in the concentrate tray. Break the pin to activate the concentrate.
- (4) SoftPac concentrate for dialysis. Make sure that the concentrate corresponds to the patient's prescription and the dialysis machine settings. To be used in conjunction with a dialyzer.
- (5) Break the frangible pin. The frangible pin is located in the concentrate tray. Break the pin to activate the concentrate.
- (6) Concentrate for dialysis. Make sure that the concentrate corresponds to the patient's prescription and the dialysis machine settings. To be used in conjunction with a dialyzer.
- (7) Break the frangible pin. The frangible pin is located in the concentrate tray. Break the pin to activate the concentrate.
- (8) Concentrate for dialysis. Make sure that the concentrate corresponds to the patient's prescription and the dialysis machine settings. To be used in conjunction with a dialyzer.
- (9) Break the frangible pin. The frangible pin is located in the concentrate tray. Break the pin to activate the concentrate.
- (10) Concentrate for dialysis. Make sure that the concentrate corresponds to the patient's prescription and the dialysis machine settings. To be used in conjunction with a dialyzer.
- (11) Break the frangible pin. The frangible pin is located in the concentrate tray. Break the pin to activate the concentrate.
- (12) Concentrate for dialysis. Make sure that the concentrate corresponds to the patient's prescription and the dialysis machine settings. To be used in conjunction with a dialyzer.
- (13) Break the frangible pin. The frangible pin is located in the concentrate tray. Break the pin to activate the concentrate.
- (14) Concentrate for dialysis. Make sure that the concentrate corresponds to the patient's prescription and the dialysis machine settings. To be used in conjunction with a dialyzer.
- (15) Break the frangible pin. The frangible pin is located in the concentrate tray. Break the pin to activate the concentrate.
- (16) Concentrate for dialysis. Make sure that the concentrate corresponds to the patient's prescription and the dialysis machine settings. To be used in conjunction with a dialyzer.
- (17) Break the frangible pin. The frangible pin is located in the concentrate tray. Break the pin to activate the concentrate.
- (18) Concentrate for dialysis. Make sure that the concentrate corresponds to the patient's prescription and the dialysis machine settings. To be used in conjunction with a dialyzer.
- (19) Break the frangible pin. The frangible pin is located in the concentrate tray. Break the pin to activate the concentrate.
- (20) Concentrate for dialysis. Make sure that the concentrate corresponds to the patient's prescription and the dialysis machine settings. To be used in conjunction with a dialyzer.
- (21) Break the frangible pin. The frangible pin is located in the concentrate tray. Break the pin to activate the concentrate.
- (22) Concentrate for dialysis. Make sure that the concentrate corresponds to the patient's prescription and the dialysis machine settings. To be used in conjunction with a dialyzer.
- (23) Break the frangible pin. The frangible pin is located in the concentrate tray. Break the pin to activate the concentrate.
- (24) Concentrate for dialysis. Make sure that the concentrate corresponds to the patient's prescription and the dialysis machine settings. To be used in conjunction with a dialyzer.
- (25) Break the frangible pin. The frangible pin is located in the concentrate tray. Break the pin to activate the concentrate.

SoftPac C195			SoftPac C195 & BiCart		
	g/l	mmol/l		mmol/l	
NaCl	270.9	Na ⁺	140		
KCl	8.030	K ⁺	15		
CaCl ₂ · 2H ₂ O	15.58	Ca ²⁺	1.75		
MgCl ₂ · 6H ₂ O	4.524	Mg ²⁺	22.5		
		Cl ⁻	400.0		
CH ₃ COOH	8.107	CH ₃ COO ⁻	135.0		
C ₂ H ₄ O ₂	45.00	C ₂ H ₄ O ₂	243.8		
		H ⁺	135.0		

Refract water following ISO 22810-1 or equivalent to 100 °C

CE 0123 MD Vantive Health GmbH
 Manufactured by: Bieffe Medical S.p.A. Via S. Maria 14, 23025 Sondrio (SO), Italy. Made in Italy.
 Vantive Health GmbH, Burgenerstrasse 130, 4102 Glattpark (Eptingen), Switzerland. www.vantive.com
 EC REP Vantive S.r.l. via del Sereno 89, 00142 Rome, Italy.



Vantive

EASY CONNECTION

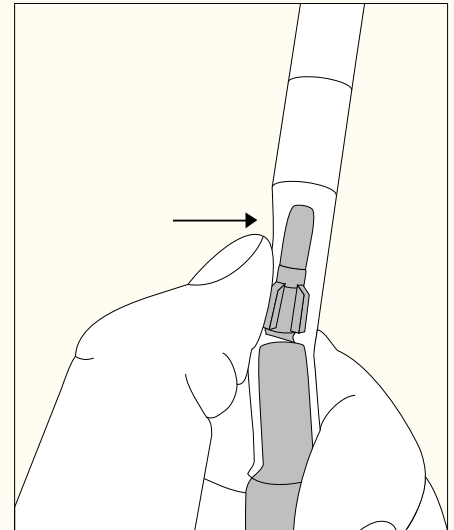
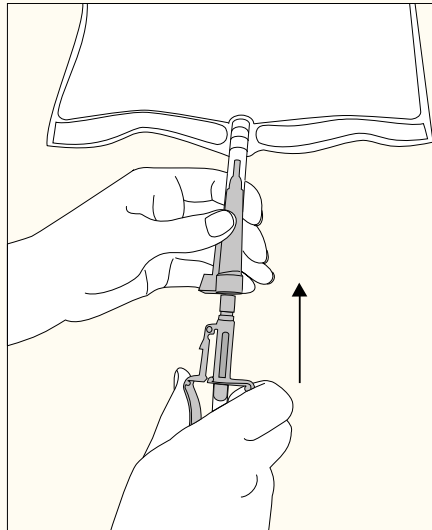
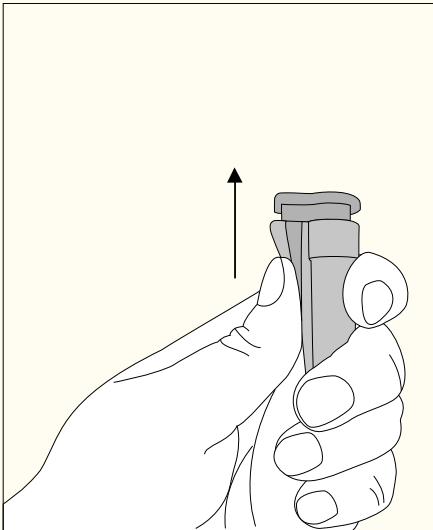
The key-way connector may reduce the risk of contamination compared to canister

DESIGNED FOR PATIENT SAFETY

SoftPac concentrate has an exclusive key-way connector designed for patient safety compatible. The key-way connector and cap keep treatment quick, clean and convenient.

Our frangible pin has been designed to improve safety. It snaps easily into place and may reduce handling complications or potential incidents.

The Vantive closed system also may reduce the risk of contamination of dialysis fluid throughout treatment.¹



Use within 24 hours after the frangible pin has been broken.



BICART

SoftPac concentrate in combination with the Vantive **BiCart** cartridge are convenient and easy to handle. In combination clinics are able to get a system designed for ultrapure dialysis fluid.^{3,4} Hygienic improvement may result in a reduced treatment related inflammation, may reduce the risk of contamination and bacterial growth^{4,5} and set the new standard in a lightweight and convenient dialysis solution.



QUICK AND CONVENIENT

Each treatment set-up can also be quick, convenient and clean due to a unique connection through the key-way connector system.

EFFICIENT HANDLING

SoftPac concentrate bags are compact and require less space than canisters and fit comfortably within clinical workflows

FITS ANY CLINIC

SoftPac concentrate is available in two sizes,¹ a 3.5-liter flexible bag for standard treatments and a 5 liter version for higher volume treatments. Both sizes are easy to place in position and attach before use due to a convenient slightly opened 3 hole and 5-hole design for the two respective sizes. These small modifications may facilitate efficient handling and preparation.

SoftPac concentrate bags are compact and require much less space than typical canisters and can be easily stored, used and disposed of.



ENVIRONMENTALLY FRIENDLY

The New **SoftPac** does not have an overwrap which leads to an easier and faster preparation for dialysis treatment.



EASIER DISPOSAL

SoftPac concentrate allows for easier disposal compared to canister. The simple design enables folding of the packaging providing less bulk for waste storage.



PVC FREE

The new **SoftPac** concentrate has been completely redesigned to eliminate the need for any PVC material in its construction. Health officials around the world are continuously implementing more directives to remove PVC from many products. Taking away the PVC material allows **SoftPac** concentrate to meet the health care demands as well as safeguarding patients.⁶

SoftPac

REF 114953

G195

5000 ml

K⁺ 1.5 mmol/l

Ca²⁺ 1.75 mmol/l

1+44

Glucose 1 g/l

Acetate 3 mmol/l

- (1) Acid concentrate for dialysis. Make sure that the composition corresponds to physician's prescription and the dialysis machine settings. To be used under medical supervision. Use only if concentrate is clear and free from visible particles. Not for infusion.
- (2) Hart konzentrat til dialyse. Sørg for, at sammensætningen stemmer overens med lægens ordination og dialysmaskinestillingerne. Skal anvendes under lægelig overvågning. Må kun anvendes, hvis konzentratet er klart (ingen synlige partikler). Ikke til infusion.
- (3) Säurekonzentrat für die Dialyse. Die Zusammensetzung muss der Verordnung des Arztes und den Einstellungen des Dialysegeräts entsprechen. Darf nur unter ärztlicher Aufsicht verwendet werden. Konzentrat darf nur verwendet werden, wenn es klar und frei von sichtbaren Partikeln ist. Nicht zur Infusion.
- (4) Οξύ συμπύκνωμα για αιμοκάθαρση. Βεβαιωθείτε ότι η σύνθεση αντιστοιχεί στη συνταγή του γιατρού και στις ρυθμίσεις του μηχανήματος αιμοκάθαρσης. Γραφήση υπό την επίβλεψη ενός γιατρού. Χρησιμοποιείται μόνο εάν το συμπύκνωμα είναι διαυγές και δεν υπάρχουν ορατά σωματίδια. Δεν χρησιμοποιείται για έγχυση.
- (5) Concentrado ácido para diálisis. Asegúrese de que la composición corresponde a la prescripción médica y a la configuración de la máquina de diálisis. Debe utilizarse bajo control médico. Utilizar únicamente si el concentrado es transparente y no se observa partícula alguna. No debe utilizarse para infusión.
- (6) Hapan konzentraatti dialyysiä varten. Varmista, että koostumus vastaa lääkärin määräystä ja dialyysilaitteen asetusta. Käytettävä lääkärin valvonnassa. Käytä vain, jos konzentraatti on limpinä eikä sisällä näkyviä hiukkasia. Ei infuusiota.
- (7) Concentrat acide pour dialyse. Vérifier que la composition est conforme à la prescription médicale et aux paramètres du générateur de dialyse. À utiliser sous surveillance médicale. Le concentré ne doit être utilisé que s'il est limpide et exempt de particules visibles. Ne pas utiliser en perfusion.
- (8) Szekeskoncentratum dialízisra. Győzjen arra, hogy az összetétel megfeleljen az orvos előírásának és a dialízisgépjel beállításainak. Orvosi felügyelet mellett használandó. Csak akkor használható, ha a koncentrátum tisztán és nem tartalmaz látható részecskéket. Nem használható infúzióhoz.
- (9) Concentrato ácido per dialisi. Accertarsi che la composizione corrisponda alla prescrizione del medico e alle impostazioni del monitor per dialisi. Da utilizzare sotto la supervisione di un medico. Utilizzare solo se il concentrato è limpido e privo di particelle visibili. Non destinato all'infusione.
- (10) Halvén készítésű koncentrátum. Jellemzően, ked szűzítés nélküli gyártású termék és dialízis géppel különállóan használható. Ne használják infúzióhoz. Ne használják infúzióhoz.
- (11) Zuurconcentraat voor dialyse. Verifieer u ervan dat de samenstelling overeenkomt met het voorschrift van de arts en de instellingen van het dialyseapparaat. Voor gebruik onder medische supervisie. Gebruik het product alleen als het concentraat helder is en er geen zichtbare deeltjes te zien zijn. Niet voor infusie.
- (12) Syrekoncentrat for dialyse. Kontroller at sammensætningen overensstemmer med lægens ordination og maskinens indstillinger. Skal bruges under tilsyn af lege. Må ikke bruges med mindre konzentratet er klart og frit for synlige partikler. Ikke til infusion.
- (13) Kisel konzentrat za dijalizu. Uverite se da sastav odgovara preskripciji lekara i podešavanjima aparata za dijalizu. Koristiti pod nadzorom lekara. Koristite samo ako je konzentrat čist i ne sadrži vidljive čestice. Nije namenjen za infuziju.
- (14) Hart konzentrat til dialys. Kontroller at sammensætningen overensstemmer med lægares ordination og dialysmaskinens indstillinger. Anvænds under lægares overvågning. Anvænds kun hvis konzentratet er klart og uden synlige partikler. Ej veest til infusion.

SoftPac G195

	g/l	mmol/l
NaCl	270.9	Na ⁺ 4635
KCl	5.030	K ⁺ 67.5
CaCl ₂ · 2H ₂ O	11.58	Ca ²⁺ 78.75
MgCl ₂ · 6H ₂ O	4.674	Mg ²⁺ 22.5
	Cl ⁻	4905.0
CH ₃ COOH	8.107	CH ₃ COO ⁻ 135.0
C ₆ H ₁₂ O ₆	45.00	C ₆ H ₁₂ O ₆ 249.8
	H ⁺	135.0

In purified water (following ISO 22550-3 or equivalent) to 1000 ml

SoftPac G195 & BiCart

	mmol/l
Na ⁺	140
K ⁺	1.5
Ca ²⁺	1.75
Mg ²⁺	0.500
Cl ⁻	109.0
CH ₃ COO ⁻	3
C ₆ H ₁₂ O ₆	5.55
HCO ₃ ⁻	34

Theoretical osmolality: 295.3 mOsmol/l



Manufactured by: **Vantive Health GmbH**, Thurgauerstrasse 130, 8042 Glattbrunn (Diplikon), Switzerland, www.vantive.com

Manufactured by: **Bierle Medical S.p.A.**, Via Solvito 94, 23035 Sondrio (SO), Italy, Made in Italy

Manufactured by: **Vantive S.r.l.**, Via del Serafico 89, 00142 Rome, Italy



Vantive

07-25-00-5100



SPECIFICATIONS	SOFTPAC / SOFTPAC CITRATE C 3.5L	SOFTPAC / SOFTPAC CITRATE G 5L
Device description ¹	The SoftPac/SoftPac Citrate products are acetic/citric acid-based acid concentrates. The products are non-sterile and available with or without glucose. Non-Pyrogenic. The products shall be diluted as indicated, 1+44 immediately before use. The dialysis machine mixes the acid concentrate with the sodium bicarbonate concentrate to produce a bicarbonate-based dialysis fluid.	
Intended purpose ¹	The SoftPac product is an acid concentrate for bicarbonate-based haemodialysis and is intended to be used together with a dry sodium bicarbonate cartridge for on-line preparation of haemodialysis, haemodiafiltration or haemofiltration fluids on compatible Vantive/Baxter/Gambro dialysis systems.	
Indication ¹	To be used in bicarbonate-based dialysis treatments for patients suffering from acute kidney injury, chronic kidney disease or acute intoxication with dialysable substances.	
Content	3.5L of acid-based concentrate to be diluted	5L of acid-based concentrate to be diluted
Dilution ratio	1+44	1+44
Volume of dialysis fluid when mixed	157 L	225 L
Duration time at 500 ml/min ²	5H15	7H30
Container material	Polyolefin medical grade	
Packaging	Cardboard box with 3 bags	Cardboard box with 2 bags
Box size	H 210 mm x L 333 mm x W 254 mm	H 210 mm x L 333 mm x W 254 mm
Box weight	Approximately 13.2 kg	Approximately 12.7 kg
Quantity per pallet	150 bags	100 bags
Shelf life	24 months	24 months
Storage condition	Store between +4°C and +30°C	

SoftPac Citrate 3.5L		SoftPac Citrate 5L		Electrolyte concentration after dilution together with a dry sodium bicarbonate cartridge							
PRODUCT CODE	PRODUCT NAME	PRODUCT CODE	PRODUCT NAME	Na ⁺ mmol/l	HCO ₃ ⁻ mmol/l	Cl ⁻ mmol/l	K ⁺ mmol/l	Ca ²⁺ mmol/l	Mg ²⁺ mmol/l	Citrate mmol/l	Glucose g/l
115753	SoftPac Citrate C140			140	34	107.8	1.0	1.41	0.5	1.0	1.0
		115824	SoftPac Citrate G150	140	34	108.0	1.0	1.51	0.5	1.0	1.0
115755	SoftPac Citrate C165	115825	SoftPac Citrate G165	140	34	108.3	1.0	1.66	0.5	1.0	1.0
115760	SoftPac Citrate C240			140	34	108.8	2.0	1.41	0.5	1.0	1.0
115761	SoftPac Citrate C250	115784	SoftPac Citrate G250	140	34	109.0	2.0	1.51	0.5	1.0	1.0
115762	SoftPac Citrate C265	115785	SoftPac Citrate G265	140	34	109.3	2.0	1.66	0.5	1.0	1.0
115763	SoftPac Citrate C275	115786	SoftPac Citrate G275	140	34	109.5	2.0	1.76	0.5	1.0	1.0
115767	SoftPac Citrate C340			140	34	109.8	3.0	1.41	0.5	1.0	1.0
115768	SoftPac Citrate C350	115789	SoftPac Citrate G350	140	34	110.0	3.0	1.51	0.5	1.0	1.0
115769	SoftPac Citrate C365	115790	SoftPac Citrate G365	140	34	110.3	3.0	1.66	0.5	1.0	1.0
115770	SoftPac Citrate C375	115791	SoftPac Citrate G375	140	34	110.5	3.0	1.76	0.5	1.0	1.0
115774	SoftPac Citrate C450			140	34	111.0	4.0	1.51	0.5	1.0	1.0
115775	SoftPac Citrate C465			140	34	111.3	4.0	1.66	0.5	1.0	1.0

SoftPac 3.5L		SoftPac 5L		Electrolyte concentration after dilution together with a dry sodium bicarbonate cartridge							
PRODUCT CODE	PRODUCT NAME	PRODUCT CODE	PRODUCT NAME	Na ⁺ mmol/l	HCO ₃ ⁻ mmol/l	Cl ⁻ mmol/l	K ⁺ mmol/l	Ca ²⁺ mmol/l	Mg ²⁺ mmol/l	Acetate mmol/l	Glucose g/l
114933	SoftPac C197			140	34	107,5	1,0	1,25	0,5	3	1
		114952	SoftPac G194	140	34	108,0	1,0	1,50	0,5	3	1
114941	SoftPac C298	114961	SoftPac G298	140	34	108,5	2,0	1,25	0,5	3	1
114948	SoftPac C395			140	34	109,5	3,0	1,25	0,5	3	1
		114965	SoftPac G394	140	34	110,0	3,0	1,50	0,5	3	1

MACHINE TYPE	DESCRIPTION	CODE	MEDICAL DEVICE
Vantive Artis AK 200 series AK 96, AK 98	Connector integrated Kit SoftPac Connector integrated. Order Hook SoftPac	K40375001 K40219002	Class I Class I
BBraun** Dialog IQ, Dialog +	SoftPac 136	1401360014 (200 / carton)	Class IIa
Fresenius** 4008, 5008	SoftPac 136	1401360014 (200 / carton)	Class IIa

The **SoftPac / SoftPac Citrate** concentrate is compatible with Vantive/Baxter/Gambro dialysis systems.

* For full availability in your local region please contact your Vantive representative.

** Refer to the **SoftPac** connector instructions for use which indicate accessories for haemodialysis can be used with most of devices and/or lines for haemodialysis.

Contact the manufacturer to select the correct configuration of the accessories which can ensure an adequate compatibility with devices and/or lines for haemodialysis.

For the safe and proper use of the devices referenced within, refer to the complete Instructions for Use.

1. SoftPac / SoftPac Citrate instructions for use.
2. Vantive Data on File.
3. Ward RA. Sem Dialysis 2004; 17:489–497.
4. Lonnemann G. Blood Purif 2004; 22:124–129.
5. Schiff H., High-Flux Dialyzers, Backfiltration, and Dialysis Fluid Quality, 2011.
6. The safety of medical devices containing DEHP plasticized PVC or other plasticizers on neonates and other groups possibly at risk (2014 update), SCHENIR.



Medical device of class IIb for **SoftPac** product.

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Medical device of class IIa for **SoftPac 136** and 130.



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