ReadyToProcess Single-Use Products

MADE IN CHINA

ReadyCircuit[™] assemblies are part of the ReadyToProcess[™] product platform of single-use components. Configure an assembly to meet specific needs by simply connecting 2D or 3D ReadyCircuit bags to other ReadyToProcess consumables such as filters (Fig 1). ReadyCircuit assemblies bring simplicity and speed to bioprocessing, thus enabling biopharmaceutical companies, contract manufacturing organizations (CMOs), and biotech start-ups to accelerate product development and reduce costs of initial investments. In addition, single-use ReadyCircuit assemblies can help reduce production batch change-over time, as well as costs for cleaning and cleaning validation. Since November 2018, Cytiva has collaborated with a Chinese healthcare technology supplier, Wego Pharmaceutical, to produce single-use products in China to supply customers throughout Asia Pacific. These products are manufactured according to Cytiva's global quality standards.

ReadyCircuit bags and tubing assemblies deliver:

- Quick configuration and assembly of a wide range of sterile, fluid-processing circuits.
- Flexibility of single-use technology.
- Reduction in need of cleaning and cleaning validation.
- Possibility to develop products without large capital investments in manufacturing systems.

Advantages for your application

ReadyCircuit assemblies offer distinct advantages in many applications such as aseptic clarification and purification of vaccines, monoclonal antibodies, recombinant proteins, and plasmids, aseptic cell processing, operations in environments where terminal sterilization is not feasible, production for preclinical to clinical phase II trials, processing in areas where the risk of cross-contamination is high, and Fast Track drug development processes.



Fig 1. Typical ReadyCircuit assembly with ReadyToProcess filters, ReadyMate™ Disposable Aseptic Connectors (DAC), and tubing.

Product configurations

Scale-up capability is offered by ReadyCircuit bags, for maintained continuity in your development efforts. Bag types include:

- Sample bags for small-volume applications.
- Horizontal pillow bag (50 L).
- 2D pillow bags (1, 5, 10, and 20 L) for vertical or horizontal use on mobile carts (Fig 2).
- 3D bags (50, 100, 200, and 500 L) for large-scale production.

ReadyCircuit bags have inlet and outlet ports and are supplied sterile with ReadyMate connectors or seal ended. Port configuration varies with bag type. 3D storage bags can be transported in ReadyToProcess XL bins (Fig 3).





Fig 2. ReadyToProcess single-use 2D storage bags. Right: sealed end, left: ReadyMate.



Fig 3. ReadyToProcess XL bins for 3D storage bags. From left to right: 500 L, 200 L, and 100 L bins. 1000 L bin not shown.

Fortem film

ReadyToProcess bags manufactured in China include Fortem™ film. Development with Sealed Air enabled us to apply the full range of both companies' expertise in material science to define and optimize the critical quality attributes of this singleuse platform bioprocess film. Fortem film is exceptionally well characterized, with specific analytical work done to identify and control degradative products. It has been developed in accordance with the latest industry guidance, in particular the BioPhorum Operations Group (BPOG) extractables testing protocol. It has also been qualified extensively using new methodologies for film failure, including demanding tests for flexural fatigue, weldability, and abrasion resistance. The film's architecture is comprised of a nylon outer layer that resists damage throughout the many rigors of bioprocessing conditions (Fig 4). It contains two internal gas barrier layers for maintaining pH stability during liquid storage and transportation and provides a controlled environment for cell culture applications. The contact layer is composed of linear low-density polyethylene (LLDPE) with a low extractables profile and strong weldability characteristics. The result is one film that is designed specifically for bioprocessing requirements to deliver consistent performance from beginning to end.



Fig 4. Ten-layer structure of Fortem film.

The 10-layer film is only $330 \ \mu m$ thick, with an outer layer of nylon, a double ethylene vinyl alcohol gas barrier, double polyethylene interior layer, and contact layer of LLDPE.

Ease of use

Most ReadyCircuit assemblies use ReadyMate connectors. These connectors enable you to make aseptic system connections in a matter of seconds. The genderless design facilitates connection, reduces complexity of inventory, and creates flexibility in the assembly of single-use flow paths. Features include:

- Genderless. Mates without adapters and reduces inventory.
- **Simple.** No special tools or training are required for aseptic connection in less than 60 seconds.
- **Self-contained.** Single-use aseptic connections are easily made in nonhooded environments.
- Robust. Fits sanitary clamps for permanent, high-pressure applications; gamma stable.

Specifications

Specifications for ReadyCircuit products made in China are listed in Table 1.

Table 1. General specifications for ReadyCircuit assemblies

Operation temperature	Processing temperature (liquid temperature) = 2°C to 45°C Operating temperature (ambient temperature) = 2°C to 45°C
Storage temperature	Storage of unfilled products (All Bag Assemblies) Temperature = Ambient Storage of 2-D bags filled with process fluids: Temperature = -80°C to 45°C Storage of 3-D bags filled with process fluids: Temperature = 2°C to 45°C
Material conformity	All polymeric materials in contact with process fluid • USP <88> Class VI, Biological reactivity, <i>inVivo</i> • USP <87> Biological reactivity, <i>in Vitro</i> • ISO 10993-4: Selection of tests for interaction with blood • Animal free or in compliance with EMA/410/01 Rev. 3
Sterility	Validated sterile at a SAL of 10-6 per ISO/AAMI/ASTM 11137-2:2013
Endotoxin	< 0.125 EU/mL endotoxin as determined by the LAL test, daily process sample tested USP <85> Bacterial Endotoxins
Particulate Matter	Fluid path rinses meet the current limits of USP <788> Particulate Matter in Injections, daily process sample

Production dimensions and materials

Volume					
	250 mL	1 L	5L 1	0/20 L	50 L
Length (mm)	175	312	485	594	686
Width (mm)	134	171	268	332	463



Ports	Description
1	1/4in x1/2in x2ft c-flex 374, Sealed end/ReadyMate
2	1/4in x1/2in x2ft c-flex 374, Sealed end/ReadyMate
3	3/16in x3/8in x2in silicon with needless CLAVE™

1 L	Ports	Description
	1	1/4in x1/2in x2ft c-flex 374, Sealed end/ReadyMate
	2	N/A
	3	1/4in x1/2in x2ft c-flex 374, Sealed end/ReadyMate
4	4	3/16in x3/8in x2in silicon with needless CLAVE™



Ports	Description
1	3/8in x5/8in x2ft C-Flex 374, Sealed end/ReadyMate
2	N/A
3	3/8in x5/8in x2ft C-Flex 374, Sealed end/ReadyMate
4	3/16in x3/8in x2in silicon with needleless Clave



Ports	Description
1	1/2in x3/4in x2ft C-Flex 374, Sealed end/ReadyMate
2	N/A
3	1/2in x3/4in x2ft C-Flex 374, Sealed end/ReadyMate
4	3/16in x3/8in x2in silicon with needleless Clave



Ports	Description
1	1/2in x3/4in x2ft C-Flex 374, Sealed end/ReadyMate
2	1/2in x3/4in x2ft C-Flex 374, Sealed end/ReadyMate
3	3/16in x3/8in x1ft silicon with needleless Clave

3D storage bag

Volume	50 L	100 L	200 L	500 L	1000 L
Length (mm)	516	516	643	846	1049
Width (mm)	508	508	635	838	1041
Height (mm)	213	481	610	813	940

50/100/200/500 L

(2x Inlet + 1x Outlet + 1x Sampling Port)



Ports	Description
1	1/2in x3/4in x3ft C-Flex 374, Sealed end/ReadyMate
2	1/2in x3/4in x3ft C-Flex 374, Sealed end/ReadyMate
3	1/2in x3/4in x2ft C-Flex 374, Sealed end/ReadyMate
4	1/4in x7/16in x1.5ft C-Flex 374 with needleless Clave

50/100/200/500 L



Ports	Description
1	1/2in x3/4in x3ft C-Flex 374, Sealed end/ReadyMate
2	1/2in x3/4in x2ft C-Flex 374, Sealed end/ReadyMate
3	1/4in x7/16in x1.5ft C-Flex 374 with needleless Clave

1000 L (2x Inlet + 1x Outlet + 1x Sampling Port)



Ports	Description
1	1/2in x 3/4in x3ft C-Flex 374, Sealed end 3/4in x1 1/8in x3ft C-Flex 374, ReadyMate
2	1/2in x 3/4in x3ft C-Flex 374, Sealed end 3/4in x1 1/8in x3ft C-Flex 374, ReadyMate
3	1/2in x 3/4in x3ft C-Flex 374, Sealed end 3/4in x1 1/8in x3ft C-Flex 374, ReadyMate
4	1/4in x7/16in x1.5ft C-Flex 374 with needleless Clave

1000 L (1x Inlet + 1x Outlet + 1x Sampling Port)



Ports	Description
1	1/2in x 3/4in x3ft C-Flex 374, Sealed end 3/4in x1 1/8in x3ft C-Flex 374, ReadyMate
2	1/2in x 3/4in x3ft C-Flex 374, Sealed end 3/4in x1 1/8in x3ft C-Flex 374, ReadyMate
3	1/4in x7/16in x1.5ft C-Flex 374 with needleless Clave

3D storage bags – for ReadyKart

Volume	100 L	200 L
Length (mm)	610	610
Width (mm)	509	509
Height (mm)	416	784

100/200 L	Ports	Description
A	1	1/2in x3/4in x3ft C-Flex 374, Sealed end/ReadyMate
\$1	2	1/2in x3/4in x3ft C-Flex 374, Sealed end/ReadyMate

Ordering information

2D storage bags

	Description			Bag	g configur	ation				
Product				Sampling		Tubing			Unit/	
code	Hanging/pillow bags	Volume	Fluid port	port	Туре	I.D.	Length	Connector	box	
29260177	1L 2x0.25 IN PORT 2FT CF 5PK (RM)	1 L 1x inlet port 1 needleless	C-Flex	0.25 in	2 ft	ReadyMate DAC	5			
29294704	1L 2x0.25 IN PORT 2FT CF 5PK (SE)	2 - - - - - - -	1x outlet port Clave sample		374	374 (6 mm)	(610 mm)	Seal ended		
29260179	5L 2x0.375 IN PORT 2FT CF 5PK (RM)	5 L	5 L			0.375 in	-	ReadyMate DAC		
29295532	5L 2x0.375 IN PORT 2FT CF 5PK (SE)				(9 mm)		Seal ended			
29260181	10L 2x0.5 IN PORT 2FT CF 5PK (RM)	10 L	10 L		0.5 in		ReadyMate DAC			
29296422	10L 2x0.5 IN PORT 2FT CF 5PK (SE)	2 3 4 5 5 6 7 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8				(12 mm)		Seal ended		
29260183	20L 2x0.5 IN PORT 2FT CF 5PK (RM)	20 L				0.5 in	-	ReadyMate DAC		
29297577	20L 2x0.5 IN PORT 2FT CF 5PK (SE)				(12 mm	(12 mm)) Seal ended	Seal ended		
29260185	250mL 2x.25IN PORT 1 FT CF 5PK (RM)	250 mL	mL		0.	0.25 in	0.25 in	-	ReadyMate DAC	
29299884	250mL 2x.25IN PORT 1 FT CF 5PK (SE)	*			(6 mm)		Seal ended			
29260187	50L 2x0.5IN PORT 2FT CF 5PK (RM)	50 L	-			0.5 in	-	ReadyMate DAC		
29297579	50L 2x0.5IN PORT 2FT CF 5PK (SE)					(12 mm)		Seal ended		

3D storage bags

	Description	Bag configuration							
Product				Sampling		Tubing			Unit/
code	3D bag assemblies	Volume	Fluid port	port	Туре	I.D.	Length	Connector	box
29260255	50L 3x0.5IN CF 3FT 5PK (RM)	50 L	3	1 needleless	C-Flex	0.5 in	3 ft	ReadyMate DAC	5
29312993	50L 2x0.5IN CF 3FT 5PK (RM)		2	Clave sample port	374	(12 mm)	(914 mm)		
29313203	50L 3x0.5IN CF 3FT 5PK (SE)		3					Seal ended	
29313205	50L 2x0.5IN CF 3FT 5PK (SE)		2						
29260256	100L 3x0.5in CF 3FT 5PK (RM)	100 L	3					ReadyMate DAC	
29314300	100L 2x0.5IN CF 3FT 5PK (RM)		2						
29314322	100L 3x0.5IN CF 3FT 5PK (SE)		3					Seal ended	
29314849	100L 2x0.5IN CF 3FT 5PK (SE)		2						
29260257	200L 3x0.5IN CF 3FT 4PK (RM)	200 L	3					ReadyMate DAC	4
29315051	200L 2x0.5IN CF 3FT 4PK (RM)		2						
29315188	200L 3x0.5IN CF 3FT 4PK (SE)		3					Seal ended	
29315192	200L 2x0.5IN CF 3FT 4PK (SE)		2						
29260258	500L 3x0.5IN CF 3FT 2PK (RM)	500 L	3					ReadyMate DAC	2
29315198	500L 2x0.5IN CF 3FT 2PK (RM)		2						
29315207	500L 3x0.5IN CF 3FT 2PK (SE)		3					Seal ended	
29315324	500L 2x0.5IN CF 3FT 2PK (SE)		2						
29260354	1000L 3x0.75IN CF 3FT 1PK (RM)	1000 L	3			0.75 in (18 mm)		ReadyMate DAC	1
29315658	1000L 2x0.75IN CF 3FT 1PK (RM)		2)		
29315661	1000L 3x0.5IN CF 3FT 1PK (SE)		3			0.5 in		Seal ended	
29315681	1000L 2x0.5IN CF 3FT 1PK (SE)		2			(12 mm)			

3D storage bags – for ReadyKart

	Description			Bag	g configur	ation			
Product	3D bag assemblies			Sampling . port	Tubing				Unit/
code		Volume	Fluid port		Туре	I.D.	Length	Connector	box
29260189	100L 2x0.5IN PORT 3FT CF 5PK (RM)	100 L	2	1 needleless	C-Flex	0.5 in	3 ft	ReadyMate DAC	5
29298665	100L 2x0.5IN PORT 3FT CF 5PK (SE)			Clave sample port	374	(12 mm)	(914 mm)	Seal ended	
29260253	200L 2x0.5IN PORT 3FT CF 4PK (RM)	200 L				0.5 in		ReadyMate DAC	4
29298855	200L 2x0.5IN PORT 3FT CF 4PK (SE)					(12 mm)		Seal ended	

WAVE Cellbag container (basic)

		Bag configuration				
Product code	Bag description	Volume Ports Description				
CB500ML722-01-08PK-CN	Cellbag™, 500mL, 722F, Basic	500 mL	1, 3, 5, 7	Air inlet filter	8	
			2, 4, 6, 8	3/16 in x 3/8 in x 2 in silicone, needleless sampling		
CB0001L722-01-08PK-CN	Cellbag, 1L, 722F, Basic	1 L	1, 5	1/8 in x 1/4 in x 39 in C-Flex, female Luer	_	
			2,6	3/16 in x 3/8 in x 2 in silicone, needleless sampling		
			3,7	Air outlet filter, check valve		
			4, 8	Air inlet filter		
CB0002L722-01-08PK-CN	Cellbag, 2L, 722F, Basic	2 L	1	1/8 in x 1/4 in x 39 in C-Flex, female Luer		
			2	3/16 in x 3/8 in x 2 in silicone, needleless sampling		
			3	Air inlet filter		
			4	Air outlet filter, check valve		
CB0010L722-01-05PK-CN	Cellbag, 10L, 722F, Basic	10 L	1	1/8 in x 1/4 in x 39 in C-Flex, female Luer	5	
			2	1/4 in x 7/16 in x 39 in C-Flex, female MPC		
			3	3/16 in x 3/8 in x 2 in silicone, needleless sampling		
			4	Air inlet filter		
			5	Air outlet filter, check valve		
CB0020L722-01-05PK-CN	Cellbag, 20L, 722F, Basic	20 L	1	1/8 in x 1/4 in x 39 in C-Flex, female Luer		
			2	1/4 in x 7/16 in x 39 in C-Flex, female MPC		
			3	3/16 in x 3/8 in x 2 in silicone, needleless sampling		
			4	Air inlet filter		
			5	Air outlet filter, check valve		
CB0050L722-01-05PK-CN	Cellbag, 50L, 722F, Basic	50 L	1	1/8 in x 1/4 in x 39 in C-Flex, female Luer		
			2	1/4 in x 7/16 in x 39 in C-Flex, female MPC		
			3	3/16 in x 3/8 in x 2 in silicone, needleless sampling		
			4	Air inlet filter		
			5	Air outlet filter, check valve		

Related literature

Date files	Product code
ReadyCircuit bags and tubing assemblies	28960644
ReadyKart™ mobile processing station	28960648
ReadyMate Disposable Aseptic Connectors	28937902
Operating manuals	
ReadyCircuit bags and tubing assemblies	28960646
ReadyKart mobile processing station	28960647
ReadyMate Disposable Aseptic Connectors	28938570
ReadyToProcess bins	29077794
Quick reference guide	
Getting started with ReadyCircuit components	29293762

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