



# Celsius-Pak

Disposable Containers for controlled Freeze-Thaw



Celsius-Pak combines unique design in disposable container with a protective structural frame. The robustness of the assembly ensures protection, support and ease of handling. Celsius-Pak provides uniform and reproducible freeze and thaw processes for biopharmaceuticals in manufacturing and process development.

The new Celsius-Paks 1 & 2 L combines a unique design of a disposable container with an integral protective structural holder.

The new 8.3L and 16.6L Celsius-Pak Frame 2G offers and improved robustness over the first generation design by adding bumpers to withstand tip-over, adding curved cross section to grip the ice block and eliminating sharps.

Celsius-Pak are specifically designed for controlled freezing, thawing and long term frozen storage of biopharmaceuticals such as:

- Process intermediates
- Bulk drug substances
- Product in clinical phases (pre, I, II +)
- Vaccines

## Single-Use System for Controlled Freeze and Thaw Operation

Celsius-Paks are specifically designed to be used with the Celsius Freeze-Thaw Modules, the only Controlled Freeze-Thaw System in disposable containers. Celsius-Paks are constructed from S71 film, a multi-layer co-extruded high gas barrier film containing EVAM (ethylene vinyl acetate copolymer, monomaterial) as fluid contact layer and EVOH (ethylene vinyl alcohol) as gas barrier layer. Celsius-Pak frames provide protection to the contents during all processes, making the assembly robust and reliable and simplifying the handling, storage and shipping of the disposable containers.

## Security of Supply

Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing Single-Use solutions based on collaborative supplier management and customer demand planning assures a state of the art and robust supply chain that can cope with strong market growth.

## Key Features

- Single-use
- Scalable
- Robust
- Facilitated Validation
- Complete Logistical Solution
- Clean, pre-sterilized and integrity tested

## Validation

Celsius-Paks have been qualified applying the most complex and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Celsius-Pak with data representing the widest range of process fluids in a variety of processing conditions. Full compliance with ISO11137 allows sterility assurance level validation of  $10^{-6}$  for each Single-Use product over its entire shelf life. A type III drug master file (DMF) is on record with the FDA.

## Quality Assurance

Sartorius Stedim Biotech Quality Systems for Single-Use Products follow applicable ISO and FDA regulations for Medical Devices. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

## Available from Stock

The entire range of Celsius-Pak is available from stock.

<b>Specifications</b>	<b>30 mL Celsius-Pak</b>	<b>100 mL Celsius-Pak</b>	<b>1L Celsius-Pak</b>	<b>2L Celsius-Pak</b>	<b>8.3 L Celsius-Pak</b>	<b>16.6 L Celsius-Pak</b>
Inlet Port	1 on top with female Luer Lock	1 on top with female Luer Lock	MPC Quick Coupling	MPC Quick Coupling	1 on top with MPC or KPC connector and Y splitter with male Luerlock or vent filter	1 on top with MPC or Opta connector and Y splitter with male Luerlock or vent filter
Outlet Port	1 on top with female Luer Lock	1 on top with female Luer Lock	MPC Quick Coupling	MPC Quick Coupling	1 on bottom with MPC or KPC connector	1 on bottom with MPC or Opta connector
Vent Filter	-	-	20 cm <sup>2</sup> Hydrophobic Sterilizing Vent Filter	20 cm <sup>2</sup> Hydrophobic Sterilizing Vent Filter	-	-
Film	S71	S71	S71	S71	S71	S71
Sterilization	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation
<b>Materials</b>	<b>30 mL Celsius-Pak</b>	<b>100 mL Celsius-Pak</b>	<b>1L Celsius-Pak</b>	<b>2L Celsius-Pak</b>	<b>8.3 L Celsius-Pak</b>	<b>16.6 L Celsius-Pak</b>
Product Contact Layer	EVAM <sup>®1</sup>	EVAM <sup>®</sup>	EVAM <sup>®</sup>	EVAM <sup>®</sup>	EVAM <sup>®</sup>	EVAM <sup>®</sup>
Gas & Moisture Barrier Layout	EVA   EVOH   EVA <sup>2</sup>	EVA   EVOH   EVA	EVA   EVOH   EVA	EVA   EVOH   EVA	EVA   EVOH   EVA	EVA   EVOH   EVA
External Robust, Handling Layer	EVA	EVA	EVA	EVA	EVA	EVA
Fill & Drain Ports	EVA	EVA	EVA	EVA	EVA	EVA
Fill & Drain Transfer Line	N   A	N   A	Platinum-Cured Silicone or C-Flex	Platinum-Cured Silicone or C-Flex	Platinum-Cured Silicone	Platinum-Cured Silicone
Thermowell	EVA	EVA	-	-	EVA	EVA
Holder	-	-	HDPE <sup>3</sup>	HDPE	-	-
<b>Frames</b>	<b>8.3 L Celsius-Pak Frame 2G</b>		<b>16.6 L Celsius-Pak Frame 2G</b>			
Ends	HDPE		HDPE			
Plate & Rods	316 Stainless Steel		316 Stainless Steel			
Dimensions (H x W x D)	92.5 cm x 27.5 cm x 19.5 cm (36.4" x 10.8" x 7.7")		92.5 cm x 42.5 cm x 19.5 cm (36.4" x 16.7" x 7.7")			

1. Ethylene Vinyl Acetate Monomaterial

2. EVA-Ethylene Vinyl Acetate, EVOH-Ethylene Vinyl Alcohol

3. High Density Polyethylene

Specifications and material are subject to change.

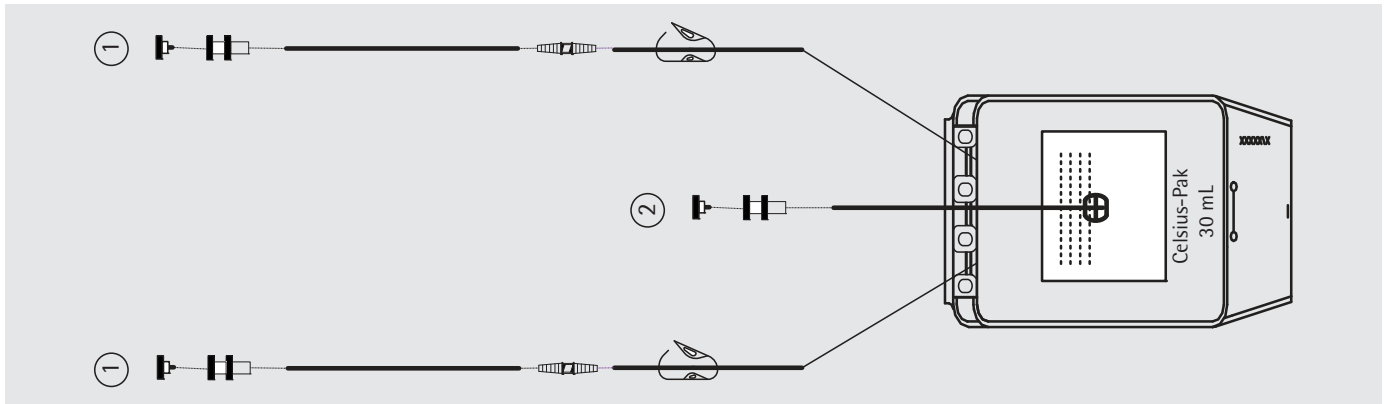
## Ordering Information

### Equipment

<b>Part Number</b>	<b>Description</b>	<b>Qty</b>
FTH-CF00016-0009	16.6L Celsius-Pak Frame 2G	1
FTH-CF00008-0015	8.3L Celsius-Pak Frame 2G	1
FTH-CF00000-0029	Celsius-Pak Frame 2G RTD Holder	1

## Ordering information

### Disposables

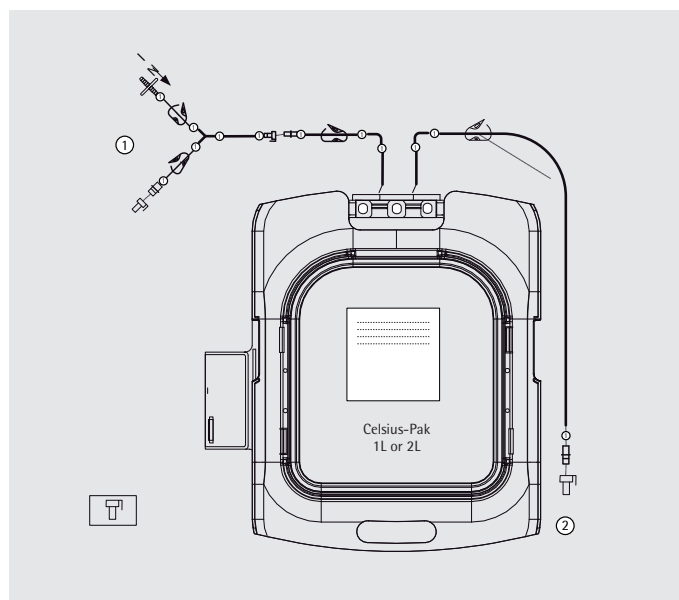


Celsius-Pak 30 mL with Thermowell & C-Flex®

Part Number	Description	Tubing	Port 1	Port 2	Qty per box
FZB114804	Celsius-Pak 30 mL with Thermowell	EVA	1/4" × 5/16" × 10 cm (4") Female LL + plug, pinch clamp	Thermowell sealed end tube 3/16" × 1/4" × 10 cm (4") Female LL + plug	10
FZB114866	Celsius-Pak 30 mL with Thermowell and C-Flex	EVA + Clear C-Flex® 374	1/8" × 1/4" × 15 cm (6") + Female LL + Plug, pinch clamp	Thermowell sealed end tube 3/16" × 1/4" × 10 cm (4") Female LL + plug	10
FDP102653	Overpouch, Celsius-Pak 30 mL	Alu Foil	N   A	N   A	250
FZB114839	Celsius-Pak 100 mL with Thermowell	EVA	1/4" × 5/16" × 10 cm (4") Female LL + plug, pinch clamp	Thermowell sealed end tube 3/16" × 1/4" × 10 cm (4") Female LL + plug	10
FZB114908	Celsius-Pak 100 mL with Thermowell, C-Flex	EVA + Clear C-Flex® 374	1/8" × 1/4" × 15 cm (6") + Female LL + Plug, pinch clamp	Thermowell sealed end tube 3/16" × 1/4" × 10 cm (4") Female LL + plug	10
FDP102667	Overpouch, Celsius-Pak 100 mL	Alu Foil	N   A	N   A	100

## Ordering information

### Disposables

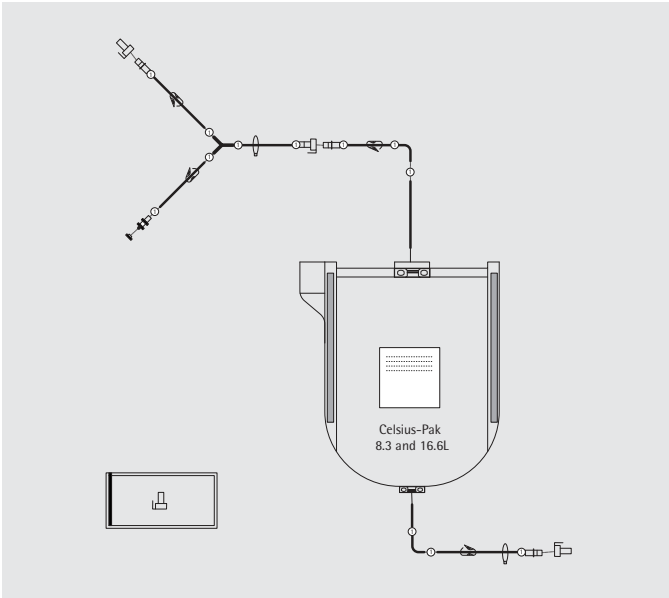


Celsius-Pak 1L or 2L with MPC

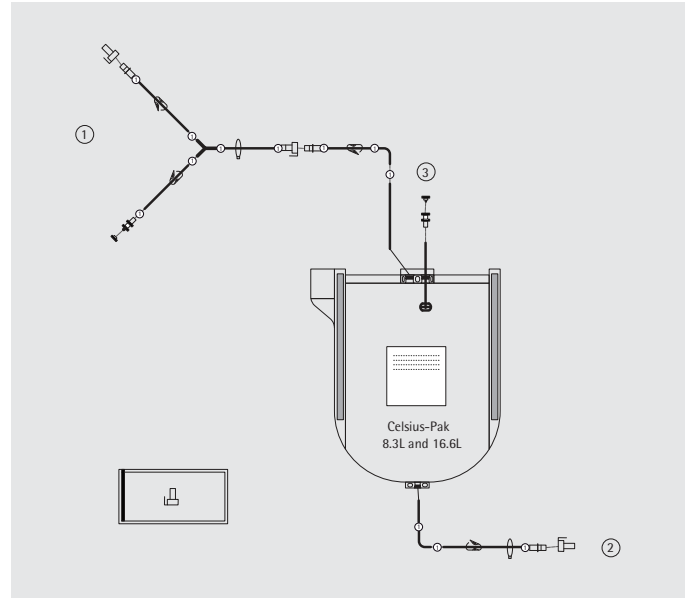
Part Number	Description	Tubing	Port 1	Port 2	Qty per box
FZB115358	Celsius-Pak, 1L, Aseptic Connection Device, Vent Filter	EVA + Silicone (pt)	EVA 3/8" × 15/32" × 4 cm (1.57") + C-Flex 1/4" × 3/8" × 30 cm (12") + Silicone (pt) 1/2" × 11/16" × 15 cm (6"), Silicone (pt) 1/4" × 3/8" L100 (L4") and Midisart vent filter	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 1/4" × 3/8" × 25 cm (10") + C-Flex 1/4" × 3/8" × 50 cm (20")	8
FZB115319	Celsius-Pak, 1L, MPC connectors, Vent Filter	EVA + Silicone (pt)	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 1/4" × 3/8" × 10 cm (4") + Silicone (pt) 1/4" × 3/8" × 10 cm (4") and Midisart vent filter + Silicone (pt) 1/4" × 3/8" × 10 cm (4") and male MPC + sealing cap	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 1/4" × 3/8" × 30 cm (12") and male MPC + sealing cap	8
FZB115366	Celsius-Pak, 2L, Aseptic Connection Device, Vent Filter	EVA + Silicone (pt)	EVA 3/8" × 15/32" × 4 cm (1.57") + C-Flex 1/4" × 3/8" × 30 cm (12") + Silicone (pt) 1/2" × 11/16" × 15 cm (6"), Silicone (pt) 1/4" × 3/8" L100 (L4") and Midisart vent filter	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 1/4" × 3/8" × 25 cm (10") + C-Flex 1/4" × 3/8" × 50 cm (20")	4
FZB115322	Celsius-Pak, 2L, MPC connectors, Vent Filter	EVA + Silicone (pt)	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 1/4" × 3/8" × 10 cm (4") + Silicone (pt) 1/4" × 3/8" × 10 cm (4") + Silicone (pt) 1/4" × 3/8" × 10 cm (4") and Midisart vent filter + Silicone (pt) 1/4" × 3/8" × 10 cm (4") and male MPC + sealing cap	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 1/4" × 3/8" × 30 cm (12") and male MPC + sealing cap	4

## Ordering information

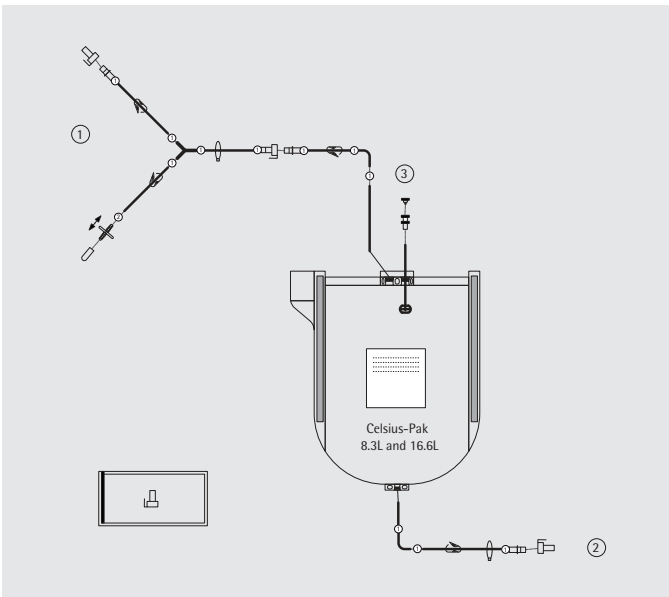
### Disposables



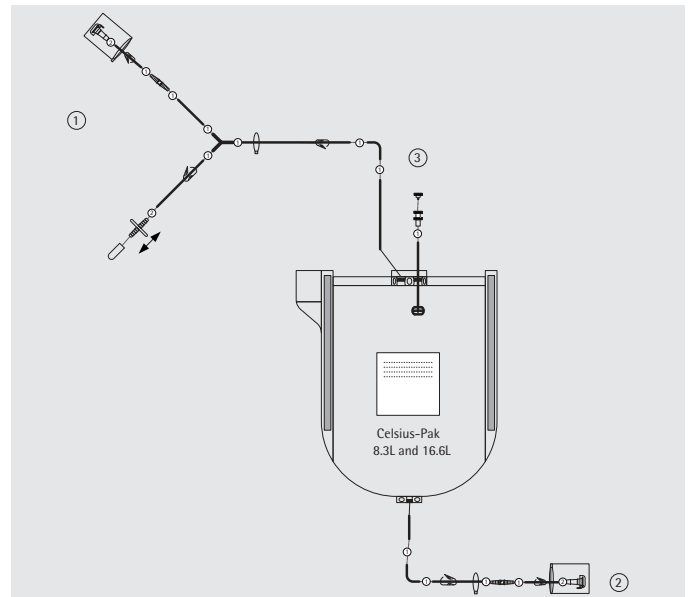
Celsius-Pak 8.3L or 16.6L without thermowell



Celsius-Pak 8.3L or 16.6L with thermowell



Celsius-Pak 8.3L or 16.6L with vent filter



Celsius-Pak 8.3L or 16.6L with thermowell, aseptic connection device and vent filter

## Ordering information

### Disposables

Part Number	Description	Tubing	Port 1	Port 2	Port 3	Qty per box
FZB115327	Celsius-Pak, 8.3L, without Thermowell	EVA + Silicone (pt)	EVA 3/8" × 15/32" × 10 cm (4") + Silicone (pt) 3/8" × 5/8" × 40 cm (15.8") + Silicone (pt) 3/8" × 5/8" × 50 cm (20") + Silicone (pt) 1/4" × 3/8" × 10 cm (4") and female LL + cap + Silicone (pt) 3/8" × 5/8" × 10 cm (4") and male MPC + sealing cap	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 3/8" × 5/8" × 200 cm (79") and male MPC + sealing cap	–	12
FZB114851	Celsius-Pak, 8.3L, Thermowell	EVA + Silicone (pt)	EVA 3/8" × 15/32" × 10 cm (4") + Silicone (pt) 3/8" × 5/8" × 40 cm (15.8") + Silicone (pt) 3/8" × 5/8" × 50 cm (20") + Silicone (pt) 1/4" × 3/8" × 10 cm (4") and female LL + cap + Silicone (pt) 3/8" × 5/8" × 10 cm (4") and male MPC + sealing cap	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 3/8" × 5/8" × 200 cm (79") and male MPC + sealing cap	–	12
FZB115370	Celsius-Pak, 8.3L, Thermowell, Aseptic Connection Device, Vent Filter	EVA + Silicone (pt)	EVA 3/8" × 15/32" × 10 cm (4") + Silicone (pt) 3/8" × 5/8" × 75 cm (30") + Silicone (pt) 3/8" × 5/8" × 15 cm (6") and Midisart vent filter + Silicone (pt) 3/8" × 5/8" × 10 cm (4") + Silicone (pt) 1/2" × 11/16" × 15 cm (6") and female aseptic connector	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 3/8" × 5/8" × 110 cm (43") and female aseptic connector	3/16" × 1/4" × 43 cm (17") + Female LL + plug (thermowell sealed end tube)	12
FZB115334	Celsius-Pak, 8.3L, Thermowell, Vent Filter	EVA + Silicone (pt)	EVA 3/8" × 15/32" × 10 cm (4") + Silicone (pt) 3/8" × 5/8" × 30 cm (12") + Silicone (pt) 3/8" × 5/8" × 60 cm (23.6") + Silicone (pt) 1/4" × 3/8" × 10 cm (4") and Midisart vent filter + Silicone (pt) 3/8" × 5/8" × 10 cm (4") and male MPC + sealing cap	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 3/8" × 5/8" × 175 cm (69") and male MPC + sealing cap	3/16" × 1/4" × 43 cm (17") + Female LL + plug (thermowell sealed end tube)	12
FZB115373	Celsius-Pak, 16.6L, without Thermowell	EVA + Silicone (pt)	EVA 3/8" × 15/32" × 10 cm (4") + Silicone (pt) 3/8" × 5/8" × 40 cm (15.8") + Silicone (pt) 3/8" × 5/8" × 50 cm (20") + Silicone (pt) 1/4" × 3/8" × 10 cm (4") and female LL + cap + Silicone (pt) 3/8" × 5/8" × 10 cm (4") and male MPC + sealing cap	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 3/8" × 5/8" × 200 cm (79") and male MPC + sealing cap		6
FZB114861	Celsius-Pak, 16.6L, Thermowell	EVA + Silicone (pt)	EVA 3/8" × 15/32" × 10 cm (4") + Silicone (pt) 3/8" × 5/8" × 40 cm (15.8") + Silicone (pt) 3/8" × 5/8" × 50 cm (20") + Silicone (pt) 1/4" × 3/8" × 10 cm (4") and female LL + cap + Silicone (pt) 3/8" × 5/8" × 10 cm (4") and male MPC + sealing cap	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 3/8" × 5/8" × 200 cm (79") and male MPC + sealing cap		6
FZB115289	Celsius-Pak, 16.6L, Thermowell, Aseptic Connection Device, Vent Filter	EVA + Silicone (pt)	EVA 3/8" × 15/32" × 10 cm (4") + Silicone (pt) 3/8" × 5/8" × 75 cm (30") + Silicone (pt) 3/8" × 5/8" × 15 cm (6") and Midisart vent filter + Silicone (pt) 3/8" × 5/8" × 10 cm (4") + Silicone (pt) 1/2" × 11/16" × 15 cm (6") and female aseptic connector	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 3/8" × 5/8" × 110 cm (43") and female aseptic connector	3/16" × 1/4" × 43 cm (17") + Female LL + plug (thermowell sealed end tube)	6
FZB115377	Celsius-Pak, 16.6L, Thermowell, Vent Filter	EVA + Silicone (pt)	EVA 3/8" × 15/32" × 10 cm (4") + Silicone (pt) 3/8" × 5/8" × 30 cm (12") + Silicone (pt) 3/8" × 5/8" × 60 cm (23.6") + Silicone (pt) 1/4" × 3/8" × 10 cm (4") and Midisart vent filter + Silicone (pt) 3/8" × 5/8" × 10 cm (4") and male MPC + sealing cap	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 3/8" × 5/8" × 175 cm (69") and male MPC + sealing cap	3/16" × 1/4" × 43 cm (17") + Female LL + plug (thermowell sealed end tube)	6



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