

Sterilization pouches

Instructions for Use



CardinalHealth

Type I: Self-Sealing sterilization pouch

Cat. no.	Material description	Packaging	Raw material	Sterilization method
92028	Pouch Paper Self Seal 10.5in. x 28in.	100ea/bx; 6bx/cs	High Performance White Medical Grade Paper + Blue Complex Film	Steam or ETO
92114	Pouch Paper Self Seal 4in. x 11in.	200ea/bx; 4bx/cs		
92152	Pouch Paper Self Seal 12in. x 15in.	100ea/bx; 4bx/cs		
92168	Pouch Paper Self Seal 8in. x 16in.	200ea/bx; 4bx/cs		
92308	Pouch Paper Self Seal 3.5in. x 8.75in.	200ea/bx; 4bx/cs		
92309	Pouch Paper Self Seal 3.5in. x 9.875in.	200ea/bx; 4bx/cs		
92318	Pouch Paper Self Seal 13in. x 18in.	100ea/bx; 4bx/cs		
92322	Pouch Paper Self Seal 3.5in. x 22in.	200ea/bx; 4bx/cs		
92510	Pouch Paper Self Seal 5.5in. x 10in.	200ea/bx; 4bx/cs		
92515	Pouch Paper Self Seal 5in. x 15in.	200ea/bx; 4bx/cs		
92713	Pouch Paper Self Seal 7.5in. x 13in.	200ea/bx; 4bx/cs		
92923	Pouch Paper Self Seal 9.125in. x 25.5in.	100ea/bx; 6bx/cs	White High Density Polyethylene (HDPE) Tyvek® + Transparent Film	ETO
32115	Pouch Tyvek® Self Seal 10in. x 15in.	100ea/bx; 5bx/cs		
32218	Pouch Tyvek® Self Seal 12in. x 18in.	100ea/bx; 4bx/cs		
32307	Pouch Tyvek® Self Seal 3in. x 7in.	100ea/bx; 8bx/cs		
32409	Pouch Tyvek® Self Seal 4in. x 9in.	100ea/bx; 8bx/cs		
32412	Pouch Tyvek® Self Seal 4in. x 12in.	100ea/bx; 8bx/cs		
32422	Pouch Tyvek® Self Seal 4in. x 22in.	100ea/bx; 8bx/cs		
32610	Pouch Tyvek® Self Seal 6in. x 10in.	100ea/bx; 8bx/cs	100ea/bx; 8bx/cs	
32812	Pouch Tyvek® Self Seal 8in. x 12in.			

1. Packaging

Place items to be sterilized into an appropriate sized pouch. The pouch should only be filled 3/4 of the packing volume to allow proper air evacuation and sterilant penetration. Carefully press the excess air out of the pouch and ensure there is at least one (1) inch between the adhesive strip and items.



After removing the protective strip, seal the pouch by folding the adhesive strip onto the pouch. Apply pressure from the center of the adhesive, towards the edges. Repeat this motion an additional time for extra security. If you are using a double pouching method, the pouch sizes should be selected so the inner pouch can be placed inside the outer pouch without folding. The inner pouch must also be sealed. The paper side of both pouches should face the same way. For example, paper towards paper and film towards film.



2. Loading the sterilizer

If you are using several pouches at once, when placing pouches in the sterilizer make sure plastic side of sterilization pouch always faces paper side of adjacent pouch to allow proper air evacuation and sterilant penetration. If possible use a pouch rack to eliminate stacking of the sterilization pouches. Check that pouches are dry upon removal.

3. Sterilization instructions

Please refer to the following recommendations for Steam and ETO sterilization cycles.

Sterilization method	Parameter		
	Temperature setting	Time setting	Pressure setting
Steam	250°F (121°C)	≥20 minutes	≥1.2bar
	273°F (134°C)	≥4 minutes	≥2.1bar
ETO	129 - 133°F (54 - 56°C), 50%PH	≥105 minutes	-70KPA

4. Storage

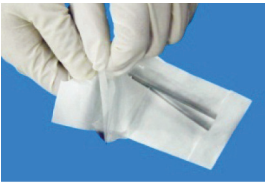
Ensure the sterile storage area is well-ventilated and provides protection against dust, moisture, insects and extreme temperature and humidity. Sterilization pouches should be stored in a cool and dry environment (temperature 59-85°F; humidity 40-70%). The items should be positioned so that packaging is not crushed, bent, compressed, or punctured so the package integrity is not otherwise compromised.

5. Shelf life

Our Pouch and Tubing products have been tested and passed five year accelerated aging testing post sterilization. They were found to have no leaks, and showed no physical damage while stored under controlled storage conditions.

6. Aseptic presentation

The sterilized pouch should be peeled off gently and opened slowly from the chevron end.



Type II: Heat-Sealing sterilization pouch

Cat. no.	Material description	Packaging	Raw material	Sterilization method	Sealing parameter
90168	Pouch Paper Heat Seal 8in. x 16in.	100ea/bx; 9bx/cs	High Performance White Medical Grade Paper + Blue Complex Film	Steam or ETO	Sealing temperature is: 334-370°F (168-188°C); Sealing pressure is: 0.441-0.637K PA; Sealing time is: 0.8-1.5s
90308	Pouch Paper Heat Seal 3in. x 8in.	200ea/bx; 5bx/cs			
90408	Pouch Paper Heat Seal 4in. x 8in.	200ea/bx; 5bx/cs			
90411	Pouch Paper Heat Seal 4.5in. x 11in.	200ea/bx; 5bx/cs			
90422	Pouch Paper Heat Seal 4in. x 22in.	200ea/bx; 5bx/cs			
90515	Pouch Paper Heat Seal 5in. x 15in.	200ea/bx; 5bx/cs			
90610	Pouch Paper Heat Seal 6in. x 10in.	200ea/bx; 5bx/cs			
90713	Pouch Paper Heat Seal 7.5in. x 13in.	200ea/bx; 5bx/cs			
90810	Pouch Paper Heat Seal 8in. x 10in.	200ea/bx; 5bx/cs			
91015	Pouch Paper Heat Seal 10in. x 15in.	100ea/bx; 5bx/cs			
91218	Pouch Paper Heat Seal 12in. x 18in.	100ea/bx; 5bx/cs			
91315	Pouch Paper Heat Seal 13in. x 15in.	100ea/bx; 5bx/cs			
91616	Pouch Paper Heat Seal 16in. x 16in.	100ea/bx; 5bx/cs			
91822	Pouch Paper Heat Seal 18in. x 22in.	100ea/bx; 5bx/cs			
37115	Pouch Tyvek® Heat Seal 10in. x 15in.	100ea/bx; 5bx/cs	White High Density Polyethylene (HDPE) Tyvek® + Transparent Film	ETO	Sealing temperature is: 257-266°F (125-130°C); Sealing pressure is: 0.343-0.49KP A; Sealing time is: 0.8-1.5s
37218	Pouch Tyvek® Heat Seal 12in. x 18in.	100ea/bx; 4bx/cs			
37307	Pouch Tyvek® Heat Seal 3in. x 7in.	100ea/bx; 10bx/cs			
37409	Pouch Tyvek® Heat Seal 4in. x 9in.	100ea/bx; 10bx/cs			
37412	Pouch Tyvek® Heat Seal 4in. x 12in.	100ea/bx; 10bx/cs			
37422	Pouch Tyvek® Heat Seal 4in. x 22in.	100ea/bx; 10bx/cs			
37610	Pouch Tyvek® Heat Seal 6in. x 10in.	100ea/bx; 10bx/cs			
37812	Pouch Tyvek® Heat Seal 8in. x 12in.	100ea/bx; 10bx/cs			

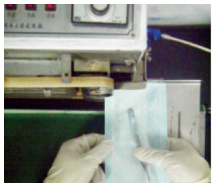
1. Packaging

Place items to be sterilized into an appropriate sized pouch. The pouch should only be filled 3/4 of the packing volume to allow proper air evacuation and sterilant penetration. Carefully press the excess air out of the pouch and ensure there is at least one (1) inch of area available around all four (4) sides of the enclosed items.



Seal the pouch with the heat-seal machine according to the appropriate sealing parameters listed in the above chart.

All parameters should be validated before using.



If you are using a double pouching method, the pouch sizes should be selected so the inner pouch can be placed inside the outer pouch without folding. The inner pouch must also be sealed. The paper side of both pouches should face the same way. For example, paper towards paper and film towards film.



2. Loading the sterilizer

If you are using several pouches at once, when placing pouches in the sterilizer make sure plastic side of sterilization pouch always faces paper side of adjacent pouch to allow proper air evacuation and sterilant penetration. If possible use a pouch rack to eliminate stacking of the sterilization pouches. Check that pouches are dry upon removal.

3. Sterilization instructions

Please refer to the following recommendations for Steam and ETO sterilization cycles.

Sterilization method	Parameter		
	Temperature setting	Time setting	Pressure setting
Steam	250°F (121°C)	≥20 minutes	≥1.2bar
	273°F (134°C)	≥4 minutes	≥2.1bar
ETO	129 - 133°F (54 - 56°C), 50%PH	≥105 minutes	-70KPA

4. Storage

Ensure the sterile storage area is well-ventilated and provides protection against dust, moisture, insects and extreme temperature and humidity. Sterilization pouches should be stored in a cool and dry environment (temperature 59 - 85°F; humidity 40 - 70%). The items should be positioned so that packaging is not crushed, bent, compressed, or punctured so the package integrity is not otherwise compromised.

5. Shelf life

Our Pouch and Tubing products have been tested and passed five year accelerated aging testing post sterilization. They were found to have no leaks, and showed no physical damage while stored under controlled storage conditions.

6. Aseptic presentation

The sterilized pouch should be peeled off gently and opened slowly from the chevron end.



Type III: Paper and Tyvek® sterilization tubing

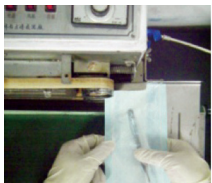
Cat. no.	Material description	Packaging	Raw material	Sterilization method
T90002	Tubing Paper 2in. width; 100ft. roll	100ft/roll; 10rolls/cs	High Performance White Medical Grade Paper + Blue Complex Film	Steam or ETO
T90003	Tubing Paper 3in. width; 100ft. roll	100ft/roll; 10rolls/cs		
T90004	Tubing Paper 4in. width; 100ft. roll	100ft/roll; 10rolls/cs		
T90006	Tubing Paper 6in. width; 100ft. roll	100ft/roll; 10rolls/cs		
T90009	Tubing Paper 9in. width; 100ft. roll	100ft/roll; 6rolls/cs		
T90012	Tubing Paper 12in. width; 100ft. roll	100ft/roll; 6rolls/cs		
T37003	Tubing Tyvek® 3in. width; 75ft. roll	75ft/roll; 10rolls/cs	White High Density Polyethylene (HDPE) Tyvek® + Transparent Film	ETO
T37004	Tubing Tyvek® 4in. width; 75ft. roll	75ft/roll; 10rolls/cs		
T37006	Tubing Tyvek® 6in. width; 75ft. roll	75ft/roll; 10rolls/cs		
T37009	Tubing Tyvek® 9in. width; 75ft. roll	75ft/roll; 6rolls/cs		

1. Packaging

Place items to be sterilized into an appropriate sized pouch. The pouch should only be filled 3/4 of the packing volume to allow proper air evacuation and sterilant penetration. Carefully press the excess air out of the pouch and ensure there is at least one (1) inch of area available around all four (4) sides of the enclosed items.



Seal the pouch with the heat-seal machine according to the appropriate sealing parameters listed in the above chart. All parameters should be validated before using.



If you are using a double pouching method, the pouch sizes should be selected so the inner pouch can be placed inside the outer pouch without folding. The inner pouch must also be sealed. The paper side of both pouches should face the same way. For example, paper towards paper and film towards film.



2. Loading the sterilizer

If you are using several pouches at once, when placing pouches in the sterilizer make sure plastic side of sterilization pouch always faces paper side of adjacent pouch to allow proper air evacuation and sterilant penetration. If possible use a pouch rack to eliminate stacking of the sterilization pouches. Check that pouches are dry upon removal.

3. Sterilization instructions

Please refer to the following recommendations for Steam and ETO sterilization cycles.

Sterilization method	Parameter		
	Temperature setting	Time setting	Pressure setting
Steam	250°F (121°C)	≥20 minutes	≥1.2bar
	273°F (134°C)	≥4 minutes	≥2.1bar
E0	129 - 133°F (54 - 56°C), 50%PH	≥105 minutes	-70KPA

4. Storage

Ensure the sterile storage area is well-ventilated and provides protection against dust, moisture, insects and extreme temperature and humidity. Sterilization pouches should be stored in a cool and dry environment (temperature 59 - 85°F; humidity 40 - 70%). The items should be positioned so that packaging is not crushed, bent, compressed, or punctured so that the package integrity is not otherwise compromised.

5. Shelf life

Our Pouch and Tubing products have been tested and passed five year accelerated aging testing post sterilization. They were found to have no leaks, and showed no physical damage while stored under controlled storage conditions.

6. Aseptic presentation

The sterilized pouch should be peeled off gently and opened slowly.



Type IV: Multiple inner pouch

Material no.	Material description	Packaging	Raw material	Sterilization method
96004	Pouch multiple inner 4 pouches sheet; 4 inner pouches, 8.9cm width per pouch	100ea/bx; 2bx/cs	High Performance White Medical Grade Paper	Steam or ETO
96008	Pouch multiple inner 8 pouches sheet; 8 inner pouches, 3.8cm width per pouch	100ea/bx; 2bx/cs	+ Blue Complex Film	

1. Packaging

Place items to be sterilized into an appropriate sized multiple inner pouches. The pouch should only be filled 3/4 of the packing volume to allow proper air evacuation and sterilant penetration. Choose the appropriate pouch or tubing and put the multiple inner pouch within it. The sterilization pouch sizes should be selected so the multiple inner pouch can be placed inside the outer pouch without folding. The paper side of both pouches should face the same way. For example, paper towards paper and film towards film.

2. Loading the sterilizer

Please refer to the packaging process for the outer pouch you have selected (e.g. refer to Paper Heat-Seal instructions if using Paper Heat-Seal outer pouch). Make sure plastic side of sterilization pouch always faces paper side of adjacent pouch. If possible, use a pouch rack to eliminate stacking of the sterilization pouches. Check that pouches are dry upon removal.

3. Sterilization instructions

Please refer to the following recommendations for Steam and ETO sterilization cycle.

Sterilization method	Parameter		
	Temperature setting	Time setting	Pressure setting
Steam	250°F (121°C)	≥20 minutes	≥1.2bar
	273°F (134°C)	≥4 minutes	≥2.1bar
ETO	129 - 133°F (54 - 56°C), 50%PH	≥105 minutes	-70KPA

4. Storage

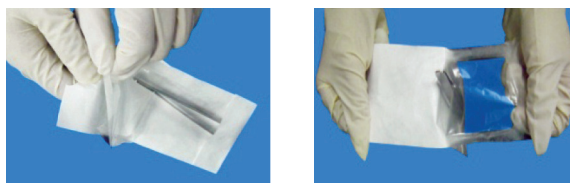
Ensure the sterile storage area is well-ventilated and provides protection against dust, moisture, insects and extreme temperature and humidity. Sterilization pouches should be stored in a cool and dry environment (temperature 59 - 85°F; humidity 40 - 70%). The items should be positioned so that packaging is not crushed, bent, compressed, or punctured so the packaging integrity is not otherwise compromised.

5. Shelf life

Our Pouch and Tubing products have been tested and passed five year accelerated aging testing post sterilization. They were found to have no leaks, and showed no physical damage while stored under controlled storage conditions.

6. Aseptic presentation

The sterilized pouch should be peeled off gently and opened slowly from the chevron end.



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