



## TECHNICAL DATA SHEET

### Procedure Earloop Face Mask, Level 2 Barrier Items # 2115, 2115K, 2116, 2117 and 2118

#### Intended Use

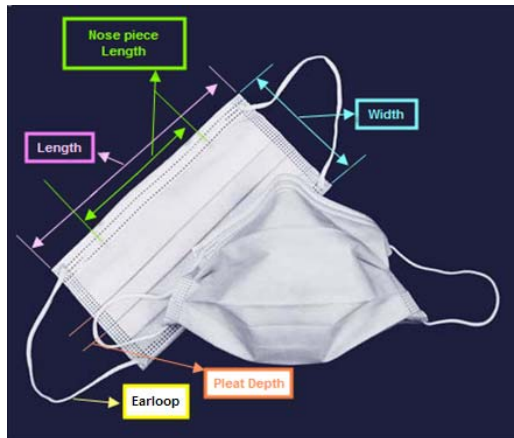
The procedure masks are intended to be worn by personnel during surgical or other medical procedures to protect both the patient and the operating personnel from transfer of microorganisms, body fluids and particulate material transfer.

Characteristic			Specification			
Description			Rectangular face masks with a shapeable nosepiece and two earloops present, one on each side, in order to hold mask in place.			
Material	Mask body Composition		<b>Outer Material</b>	Spunbond Polypropylene (SBPP)		
			<b>Filter Layer</b>	Meltblown Polypropylene (MBPP)		
			<b>Inner Material</b>	Spunbond Polypropylene (SBPP)		
	Nose-piece Composition		Aluminum / Plastic covered iron			
Elastic Band Composition		Knitted polyester				
Color			<b>Item Code</b>	<b>Color</b>		
			2115	Blue (Pantone 9440C – 9442C)		
			2115K	White		
			2116	Pink (Pantone 9021C – 9286C)		
			2117	Yellow (Pantone 600C – 601C)		
			2118	Green (Pantone 331C – 333C)		
Dimension	Body Size	Length	<b>Item 2115 K</b>		<b>Other Items</b>	
		Width	145 mm		175 mm	
	Length of Earloop		95 mm		89 mm	
	Pleat Depth		160 mm			
	Length of Nose-piece		14 mm		165 mm	
	Length of Nose-piece		100 mm		105 mm	
Bacterial Filtration Efficiency (BFE)			BFE @ 3,0 µm large Bacteria ≥ 98%			
Differential Pressure (ΔP)			ΔP < 5,0 mm of H <sub>2</sub> O/cm <sup>2</sup>			
Particulate Filtration Efficiency (PFE)			PFE @ 0,1 µm large Latex particules ≥ 98%			
Fluid Resistance			Synthetic Blood Resistant @ 120mmHg			
Flame Spread			Class I			
Packaging			<b>Item Code</b>	<b>Masks / Box</b>	<b>Boxes / Case</b>	<b>Masks / Case</b>
			2115, 2115K, 2116, 2117, 2118	50	10	500
			<b>Item Code</b>	<b>Masks / Plastic Bag</b>	<b>Plastic Bags / Case</b>	<b>Masks / Case</b>
			2115-Bulk, 2117-Bulk	500	1	500
2117-Fold	50	10				

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**Visual**  
*Mask*



Item Code	Description	Color	Specific Attributes
2115	Distech Procedure Earloop Face Masks, 50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Blue	Non-Sterile
2115-Bulk	Distech Procedure Earloop Face Masks, 500 Masks/Bag, 1 Bag/Case	Blue	Non-Sterile Bulk
2115K	Distech Procedure Earloop Face Masks, 50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	White	Non-Sterile
2116	Distech Procedure Earloop Face Masks, 50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Pink	Non-Sterile
2117	Distech Procedure Earloop Face Masks, 50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Yellow	Non-Sterile
2117-Bulk	Distech Procedure Earloop Face Masks, 500 Masks/Bag, 1 Bag/Case	Yellow	Non-Sterile Bulk
2117-Fold	Distech Procedure Earloop Face Masks, 50 Masks/Plastic Bag, 10 Plastic Bags/Case, 500 Masks/Case	Yellow	Non-Sterile Mask folded in half
2118	Distech Procedure Earloop Face Masks, 50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Green	Non-Sterile

**Regulatory**

FDA Class 2, Product Code FXX, 510(K) number K051291

Health Canada Class 1

**Storage Conditions**

Store under ambient temperature and dry conditions. Avoid excessive heat (over 40°C or 104°F)