

# Distech Protection Earloop Mask

## Blue Pleated

### TECHNICAL DATA SHEET

2115M, 2116M, 2117M, 2118M – Distech Low Barrier Protection Procedural Earloop

Face Mask (Level 1)

#### 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.



#### Material Description

Outer layer	Spun-bonded Polypropylene
Filter layer	Melt-blown Polypropylene
Inner layer	Spun-bonded Polypropylene
Earloops	Knitted Polyester
Nose-piece	Plastic covered iron
Color	Available in blue, pink, yellow and green Latex Free

#### ASTM STANDARD PERFORMANCE<sup>1</sup>

Bacterial Filtration Efficiency (BFE)	BFE @ 3.0 µm large bacteria ≥ 95%
Differential Pressure (ΔP)	ΔP < 4.0 mm of H <sub>2</sub> O/cm <sup>2</sup>
Particulate Filtration Efficiency (PFE)	≥ 95 % with 0.1µm large latex particles
Fluid Resistance	Resistant @ 80mmHg
Textile Flammability	Class I flame spread

#### Other Tests

Skin Irritation	Negligible
Skin Sensitization	Negligible
Usage	Single Use Only

Dimensions		Packaging
Length	178 mm (7")	50 masks / box 10 boxes / case 500 masks /case
Width	89 mm (3 1/2")	
Number of pleats	3 shingle pleats	
Depth of pleats	13 mm (1/2")	

**Storage** Store under cool, clean, and dry conditions. Avoid excessive heat (over 40°C or 104°F)

**Country of Origin** China

Note 1 All tests were conducted in accordance with ASTM 2100 and the results have an AQL of 4.0%.



**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					
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			
	Length of Nose-piece		100 mm		105 mm	
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				

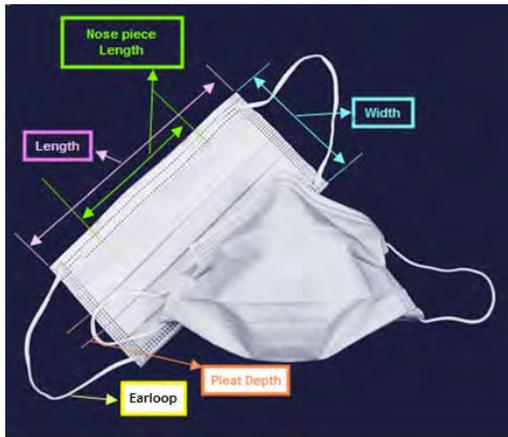
Marketing: TDS 6.3-2 Date: 10-April-2015



## TECHNICAL DATA SHEET

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

Visual  
Mask



Item Code		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)

Marketing: TDS 6.3-2

Date: 10-April-2015

