

Product Data Sheet



Product Information			
Product Code:	101048		
Product Name:	4-piece Valve Kit + Air Water Channel Cleaning Adapter		
Product Group:	Endo Procedure	Product Family:	Champion Combo Sets
Compatibility:	For Olympus® 160 / 180 / 190 / 240 / 260 / 290 / 1100 / 1200 / 1500 Series Endoscopes		
Intended Use:	The single use ANDORATE® Champion Air/Water Valve is used to control the air / water function of an endoscope during GI endoscopic procedures. The single use ANDORATE® Suction Valve is used to control the suction function of an endoscope during GI endoscopic procedures. The single use ANDORATE® Champion Biopsy Valve is used to cover the opening to the biopsy/suction channel of Olympus® gastrointestinal endoscopes. The biopsy valve provides access for endoscopic device passage and exchange, helps maintain insufflation, minimizes leakage of biomaterial from the biopsy port through the endoscopic procedure and provides access for irrigation. The single use AQUAPULSE® Auxiliary Water Connector is used in conjunction with irrigation tubing, intended to provide irrigation via irrigation fluids such as sterile water supplied to the Olympus® GI endoscope during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump. The auxiliary water connector is manufactured with a one-way valve to minimize the risk of cross contamination of the irrigation system. The ANDORATE® Air Water Channel Cleaning Adapter is intended as part of the precleaning process, to help clear the air/water channel of Olympus® GI endoscopes post procedures.		
Shelf Life:	5 Years	Sterilisation:	EO Steriliation
Product Use:	Single Use, Do not re-sterilise		
Product Material:	Not made with natural rubber latex, DEHP or animal or biological product		

Regulatory Information			
Manufacturer and Address:	GA Health Company Limited Unit 1511-13 & 15, 15/F, Tower 2, Grand Central Plaza, 138 Shatin Rural Committee Road, Shatin, N.T., Hong Kong		
EU MDR Classification:	Class Is	EMDN / CND Code:	G030899
UK MDD Classification:	Class Is	USFDA Classification:	Class II
UMDNS Code:	14325	GMDN Code:	60760
GTIN:	<u>Individual</u>	<u>Box</u>	<u>Carton</u>
	04897106955893	14897106955890	24897106955897

Storage, Transport and Disposal	
Storage:	Keep away from sunlight and keep dry Temperature: -20 to +60°C Humidity: 10-85% RH
Disposal:	After use, this product may be a potential biohazard. Handle and dispose of the product in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

Packaging Information	
Material:	PET Tray with Medical Paper Cover
Primary Packaging:	Components housed in blister tray with medical paper cover, 1 pcs per bag
Secondary Packaging:	<u>Box</u>
	Size: 274*231*250mm Qty: 60pcs Gross Weight: 1.28kg
	<u>Carton</u>
	Size: 567*477*275mm Qty: 240pcs Gross Weight: 5.12kg