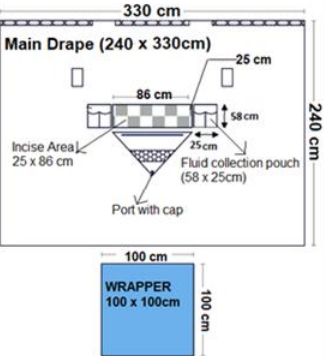


Product Specifications Sheet

Specification Sheet No	SSN-FT1580-028		
Product Name	Surgical Drapes		
Product Description	Femoral Nailing vertical Isolation Drape		
Range	365 Healthcare		
Manufacturer	Xuchang Zhengde Environstar Medical Products Co.,Ltd.		
Material	Transparent PE material, Blue PE material antistatic single		
Sterilisation	EO Sterile		
Issue Date	24 th July 2025	Version No	R01



The diagram illustrates the components and dimensions of the Surgical Drapes. The main drape is 240 cm wide and 330 cm long. It features a central incise area measuring 25 cm by 86 cm, which is covered by a fluid collection pouch measuring 58 cm by 25 cm. A port with a cap is located at the bottom center of the incise area. A separate wrapper, measuring 100 cm by 100 cm, is shown below the main drape.

Intended use	To be used to drape the patient to isolate a site from other areas of the patient's body or to contribute to reducing the risk of cross contamination.
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Packaging							
Product code	Colour	Items	Description	Dimension (cm)	Items Per Packs	Qty – Inner	Qty – Shipper Carton
82-020365	Transparent	Vertical Isolation Drape	Main drape	240 x 300 (±2)	1	10	20
			Fluid Collection pouch large	97 x 49 (±1)			
			Fluid Collection pouch small	58 x 25 (±0.5)			
			Incise Area	25 x 86 (±0.5)			
		Wrap	Wrapper	100 x 100 (±1)			

Quality Certification	ISO 13485:2016		
Device Classification	Class Is	Rule	1
Conformity Route	Medical Devices Regulation (EU) 2017/745		
Storage conditions	Store in a cool dry place away from heat and direct sunlight		
Shelf life	5 years if stored as recommended		
Contraindications/Warnings	None		
Markings	365 Healthcare, Ref, Product name in 11 languages, Dimension, Images, Quantity Barcodes, Lot, Manufacture date, Expiry date, CE Mark, Single use, Latex free, Medical device, EO Sterile, Do not use if package is damaged, keep dry, keep away from sunlight, Manufacturer Name & Address, EC-REP		
Additional information	This product is latex free.		
Medical Device and Reporting System: Incidents caused by this device must be reported immediately to our offices.			

The information provided within this Specification Sheet is correct as of last revision but it is subject to change without notice.

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Document Reference	Document Name	Reviewed By	Approved By	Revision Number	Issue Date
DMS 04-004	Product Specification Sheet	Jack Wong	Racheal Begg	R02	03 rd April 2024

Amendment Record

This procedure is reviewed to ensure its continuing relevance to the system and process that it describes. A record of contextual additions or omissions is given below. This revision history lists all changes to this document, the date of each revision, and the reason for each revision.

Revision Number	Revision Date	Reason for Revision	Updated by
R01	24/07/2025	1 st version	Jack Wong

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