INFU-SURG® PRESSURE INFUSION BAG

LATEX FREE | DISPOSABLE | SINGLE PATIENT USE | NON-STERILE | DEHP FREE | MR CONDITIONAL

DEVICE MANUFACTURING SPECIFICATIONS	
Reference Number	4005H, 4010H, 4030H
Manufacturer	Ethox Medical/SunMed LLC
Classification – US	Class I
FDA Product Code	KZD – Infusor, Pressure, for IV Bags
Registration Number	880.5420
Classification – Canada	Class 1
Classification – EU	Class IIa
CE Mark/Notified Body	CE 2797/BSI Group
Authorized Representative	Mt Promedt Consulting GmbH
EMDN	A0599 – Disposable Infusion Mechanical Systems – Accessories
GMDN Code	13100 Infusion, Regulator, Pressure
UMDNS Code	13100, Pressure Infusor
Usage	Single Patient Use
Sterile	Non-Sterile
Patient population	Newborns, Infants, Pediatric and Adult Patients
Packaging	5/Box, 25/Case
Shelf Life	4.5 Years

Description: A medical device with an inflatable bladder, a pressure gauge, and an inflation bulb. For rapid infusion of fluids to the patient, an intravenous fluid bag is placed between the sleeve and bladder, and the device is manually pressurized. The steady pressure on the bag pushes the liquid into a drip chamber to allow the fluids to flow into the patient.

Intended Purpose: The device is intended to pressurize the IV bag, which in turn deliver a variety of fluids/medications to the human body.

Area of Use: For use by trained medical professionals. The product is often used in emergency rooms, trauma units, surgical suites, post-anesthesia care, intensive care units and emergency medical services.

Contraindications: None known.

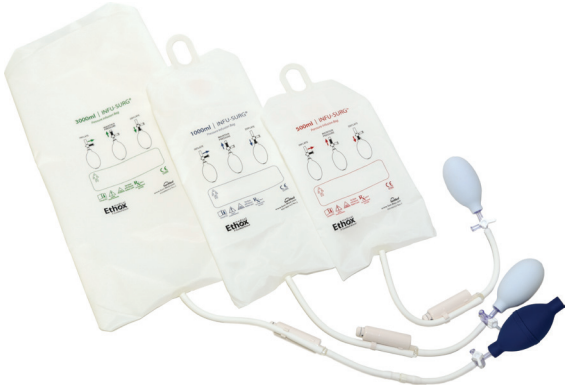
DEVICE SPECIFICATIONS

Description	Specification
Pressure Gauge Range	150 mm Hg to 300 mm Hg
Pressure Gauge Accuracy	± 15% FS
Pressure Relief	375 ± mm Hg (±15%)
Bladder Size	500 mL, 1000 mL, 3000 mL

MRI SAFETY INFORMATION

Description	Specification
Name of Device	Ethox Pressure Infusion Bag
Static Magnetic Field (T)	7-T or less
Maximum Spatial Field Gradient	19-T/m (1,900-gauss/cm)

Part Number	Size	UOM	GTIN	UOM	GTIN
4005H	500 mL	Each	10889483151839	Box	20889483161836
4010H	1000mL	Each	10889483151860	Box	20889483151867
4030H	3000 mL	Each	10889483101872	Box	20889483101879



DEVICE MATERIAL

Component	Material
Bladder	Urethane Coated Nylon
Mesh Sleeve	Nylon/Polyester
Tubing	Polyvinyl Chloride, White
Stopcock	Polycarbonate/ High-Density Polyethylene
Inflation Bulb	Plastisol, Dark and Light Blue
Body Gauge & Cylinder	Acrylonitrile Butadiene Styrene
Gauge Spring	Phosphorus Bronze
Gauge Seal	Thermoplastic Polyurethane
Hanging Hook	Acrylonitrile Butadiene Styrene

Latex: AirLife™ does not utilize latex or latex-containing material to manufacture products. To the best of our knowledge, latex does not contact components or finished goods during the manufacturing process.

Phthalates: The selected materials are Non-DEHP; DEHP was not intentionally added as part of the manufacturing process.

Mercury-Lead: The selected materials do not contain lead or mercury.

Biocompatible: Per device classification in ISO 10993-1:2018. The INFU-SURG® device is manufactured from standard materials used in medical, transportation and aerospace industries. The materials were chosen based on performance in a non-patient contact environment.

The device does not contain human blood derivatives or animal tissue.

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