Product Data Sheet

DISPO MEDICAL

T.U.R. Koppelsysteem

REF: 53291

Sterile, single use, non-invasive and non-active, single or double PVC- tubing systems of various length/diameter, with spike(s), tubing clamp(s), connectors, with or without drip chamber, pillow valve or hand pump.

INTENDED USE:

Intended for washing out a body cavity or surgical sites with a stream of clear sterile fluid.

INDICATIONS FOR USE

Per the discretion of the qualified medical professional, when washing out a body cavity or surgical site with a stream of clear sterile fluid is warranted.

INTENDED PATIENT

The intended patient population is restricted to adults, based on the medical condition and other clinical considerations; the qualified medical professional needs to decide if the medical device is suitable for the intended medical procedure.

PRODUCT

PRODUCT FAMILY:	Irrigation
DURATION OF USE:	Short Term Use: continuous use between 60 minutes and 30 days.
REGULATION:	EU MDD 93/42/EEC
PRODUCT CLASSIFICATION:	Class IIa Rule 2
PRODUCT INFORMATION:	Length Tube: ±200cm Diameter Tube: Ø4.8x6.8mm Length Silicone: ±8cm Diameter Silicone: Ø5x9mm Open/close

MATERIALS

MAIN MATERIALS:	ABS - Soft PVC - PVC DEHT 553 / 753 - Silicone
LATEX:	NO
PHTHALATES, CMR, ENDOCRINE DISRUPTING SUBSTANCES (≥ 0.1% w/w):	NO
PRESENCE OF ANIMAL ORIGIN SUBSTANCES:	NO
SHELF LIFE:	≤ 36 MONTHS

CE 0344 | LATEX | STERILE EO | MD | 2 | +5° / +40°