

SPECIFICATIONS
ROMED SILICONE EXTERNAL MALE CATHETERS
REF: ECSIL-M, ECSIL-L, ECSIL-XL



Medical device conform MDR (EU) 2017/745

Product description

Disposable silicone external catheter is used for male external catheterization due to urinary incontinence. It shall be used together with urine drainage bag, and collect urine. The external catheter is made from medical silicone material, it consist of connecting tube, supporting tube and sheath with self-adhesive back part. The materials used are fully biocompatible.

External male catheters, transparent, silicone, with self-adhesive back part			
Item number	ECSIL-M	ECSIL-L	ECSIL-XL
Inside diameter	28 ±1mm	31 ±1mm	35 ±1mm
Full length	122 – 164 mm		
Length of connecting tube	32 ±4mm		
Length of adhesive area	45 ±5mm		
Diameter connector side	10 ±1mm		
Thickness front part	0.5 ±0.1 mm		
Thickness back part	0.15 ±0.08 mm		
Thickness connector part	0.9 – 1.3 mm		

Material description		
<i>Part</i>	<i>Materials</i>	<i>Function</i>
External catheter	Silicone	Male external urinary catheterization
Self-adhesive	Mixture of ethyl acetate, 2-propanol, heptane, toluene and 2,4-pentanedione	Fasten the silicone external catheter on the penis

Physical properties	
<i>Item</i>	<i>Test result</i>
Hardness	50 ± 5 Shore A
Tensile strength	8 ± 2 MPa
Elongation at break	200 – 600%
Permanent set	1 – 5%
Tearing strength	20 ± 5 kN/m
Linear shrinkage	1.7 – 2.2%

Packing

Per piece in a plastic bag, 30 pieces in an inner box, 12 inner boxes (=360 pieces) in an export carton.