

SPECIFICATIONS

ROMED FOLEY BALLOON CATHETERS 100% SILICONE

REF: FCAS-



Applicable harmonized standard: EN 1616:1997
Medical device conform MDD 93/42/EEC

SCOPE

This ROMED Standard specifies dimensional and performance requirement for sterile, single-use, flexible urethral balloon-retention catheter of the Foley type with Nelaton tip, funnel end and Luer valve. Two way catheters have two eyes and three way catheters have three eyes. The product is manufactured in silicone and is sterilized for single-use only. Length 40 cm.

MATERIALS

Silicone

Auxiliary material:

A. Silicone bond

B. Sulfuration does double two four, double two five

C. Silicone colour cream

Medical BaSO₄

Transparent. Radio opaque line through the length of the tube for X-ray visualisation.

STERILISATION

The catheters are sterilised by EtO gas. Sterility is guaranteed for a period of 5 years if package remains unopened.

GAUGE SIZE

The size of the catheter shall be designated by the Charrière gauge system and by the equivalent nominal external diameter of the shaft expressed in millimetres.

Note: The Charrière gauge system of measurement is based on the external diameter of the catheter gauge in steps of third of a millimetre, the Charrière gauge size being three times the external diameter expressed in millimetres.

TIP

For catheter size 16 Fr and above, the tip is reinforced.

DRAINAGE EYES

Catheter shall have one pair of drainage eyes which shall be located at an angle of 180 relative to one another, the eyes shall be opposite.

USE

For short term use (less than 30 days). We recommend that the Romed Foley catheters 100% silicone should not remain in the body for longer than 28 days.

Patients who need to have a indwelling catheter for longer than 30 days can have their catheter replaced by a medical professional.

BALLOON

Balloon capacities shall be as given in the table below.

Type	Size (Fr or Ch.)	Balloon capacity (ml/cc)
2-way standard	12-30	10-30
FCAS10-12	2 Way 10 ml 100% silicon size 12	o.d. 4.0
FCAS10-14	2 Way 10 ml 100% silicon size 14	o.d. 4.7
FCAS10-16	2 Way 10 ml 100% silicon size 16	o.d. 5.3
FCAS10-18	2 Way 10 ml 100% silicon size 18	o.d. 6.1
FCAS10-20	2 Way 10 ml 100% silicon size 20	o.d. 6.7
FCAS10-22	2 Way 10 ml 100% silicon size 22	o.d. 7.3
FCAS20-16	2 Way 20 ml 100% silicon size 16	o.d. 5.3
FCAS20-18	2 Way 20 ml 100% silicon size 18	o.d. 6.1
FCAS30-20	2 Way 30 ml 100% silicon size 20	o.d. 6.7
FCAS30-22	2 Way 30 ml 100% silicon size 22	o.d. 7.3

Foley catheters are phthalates free.

PACKING

Packed per piece, 10 pieces in an inner box, 10 inner boxes in an export carton.