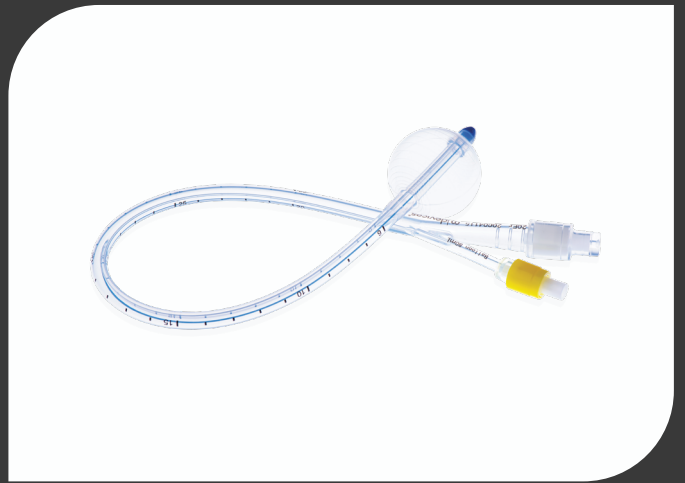


Cervical Dilating Balloon and Securement Device

PRODUCT DATA SHEET



DESCRIPTION

m|devices Cervical Dilating Balloon and Securement Device has been specifically designed to be used as a mechanical dilation device for cervical ripening. The round closed distal end meets infection control principles by maintaining a closed system and clear markings for balloon capacity on the balloon lumen and printed batch have all been considered to assist the clinician with ease of use. The Securement Device (optional) is included to apply light traction post balloon insertion.

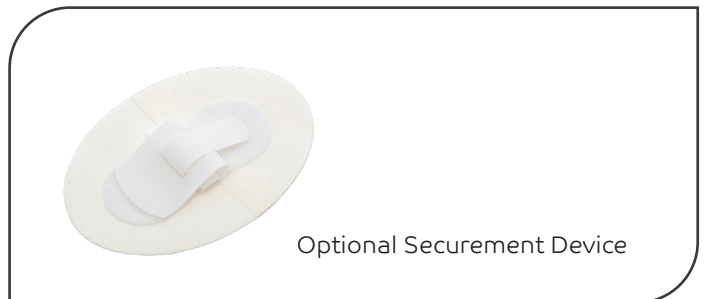
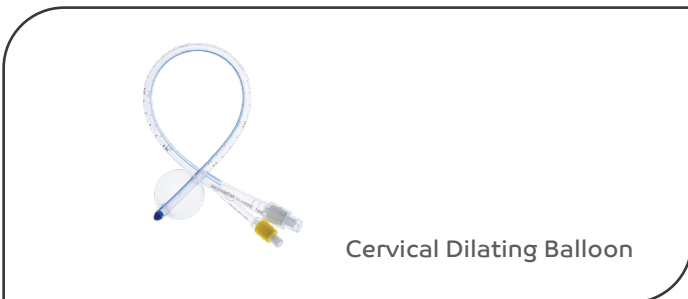
FEATURES AND BENEFITS

- Silicone material assists with an easy insertion and does not require the aid of an introducer
- Balloon lumen is distinguished by a yellow coloured valve and is clearly labeled with the maximum volume capacity.
- High contrast position markings
- Round closed end maintains infection control principles which can often be a concern with a Foley catheter, when used in this application
- Batch number printed for ease of identification
- Two step Securement Device is easy to apply to the thigh and assists in providing the light traction required

PRODUCT DATA

- 80mL balloon capacity
- Radiopaque
- Size: 20Fr, Length 40cm
- Latex/DEHP free
- Securement Device size 8.5cm X 12.5cm
- Materials:
 - Balloon Catheter: Silicone
 - Securement Device: Non-woven fabric, acrylic adhesive, glassine paper
- ARTG 307304 (Balloon) and 299241 (Securement Device)
- Shelf life: 3 years

PRODUCT PACKAGING LABEL



RE-ORDER	DESCRIPTION	SIZE	CARTON/QTY
OB010020	Cervical Dilating Balloon	80mL balloon	10
UR060001	Securement Device (8.5cm x 12.5cm)	Large	50