

OB020000

Cervical Dilating
Balloon Introducer



INSTRUCTION FOR USE

DESCRIPTION

m|devices Cervical Dilating Balloon Introducer has been designed with clinicians to assist with the insertion of the m|devices Cervical Dilating Balloon.

The malleable nylon material allows the clinician to manipulate a structured shape for a simple and efficient insertion of the Cervical Dilating Balloon.

The J-loop handle allows the clinician to secure the Introducer within the Cervical Dilating Balloon once in place to minimize movement.

Removal of the Introducer is to simply reverse bend the J-loop handle and the Introducer can be quickly removed from the Cervical Dilating Balloon.

FOR USE BY A QUALIFIED CLINICIAN. THE BELOW IS ONLY A SUGGESTION AND FACILITY PROTOCOL MUST BE FOLLOWED FOR ALL CLINICAL PROCEDURES WHERE THIS PRODUCT IS USED.

CAUTION

- Single Use Only.
- DO NOT use if the package or product has been damaged or contaminated.
- DO NOT store at extreme temperatures and humidity, avoid direct sunlight.

STEPS

1. Advance the Cervical Dilating Balloon Introducer through the white coloured valve on the Cervical Dilating Balloon. Advance until the end of the introducer sits against the tip of the Cervical Dilating Balloon.
2. Once in place, bend the J-loop handle to secure the Introducer to the Cervical Dilating Balloon. This will prevent the Introducer from sliding out of the Cervical Dilating Balloon when in use.
3. Now that the Introducer is secure, the Cervical Dilating Balloon can be moulded/curved into the desired shape to assist with the insertion procedure.
Please refer to the complete Instructions for Use on the insertion procedure provided with the m|devices Cervical Dilating Balloon and follow your facility protocol to insert the Cervical Dilating Balloon.
4. The Introducer should be removed from the Cervical Dilating Balloon once the tip of the Cervical Dilating Balloon reaches the internal uterine opening (Internal os), before the Cervical Dilating Balloon is advanced any further and the full insertion procedure has been completed.
5. To remove the Introducer from the Cervical Dilating Balloon; gently reverse bend the J-loop handle to release the Introducer from the Cervical Dilating Balloon and gently slide completely out.
6. Dispose of the Introducer as per facility protocol.

PRECAUTIONS

- Ensure the Cervical Dilating Balloon Introducer has been removed from the Cervical Dilating Balloon prior to advancing past the Internal os. The Cervical Dilating Balloon Introducer should never be introduced any further than this anatomical position.
- If obstruction is felt at any time during the insertion when using the Cervical Dilating Balloon Introducer, cease the use of the Cervical Dilating Balloon Introducer.
- Clinical judgement must be utilized throughout this procedure and only be performed by a qualified trained clinician on the procedure for cervical ripening using m|devices Cervical Dilating Balloon Introducer with m|devices Cervical Dilating Balloon.

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