

maxell

MEDICAL DEVICES TECHNOLOGY INTERNATIONAL LIMITED



EXTRACTS OF TECHNICAL FILE

RELATING TO THE FEMMAX PRODUCT

CONTENT

MATERIAL SUMMARY AND MANUFACTURING	3
DILATOR SIZES	4
DESIGN SPECIFICATIONS	5

MATERIAL SUMMARY AND MANUFACTURING

Material:	Polypropylene
Resin Type:	Propylene Ethylene Copolymer: 400-GA05
Melt Temperature:	165°C
Conformity	Medical Devices Directive 93/42/EC
Product Shelf life	None
Manufacturing Subcontractor	Maxell Molding Services Ltd Oaktree Place, Hortonwood 35, Telford, Shropshire, TF1 7FR
Manufacturer's certificate approvals	BS EN ISO 9001:2008 BS EN ISO 13485:2012

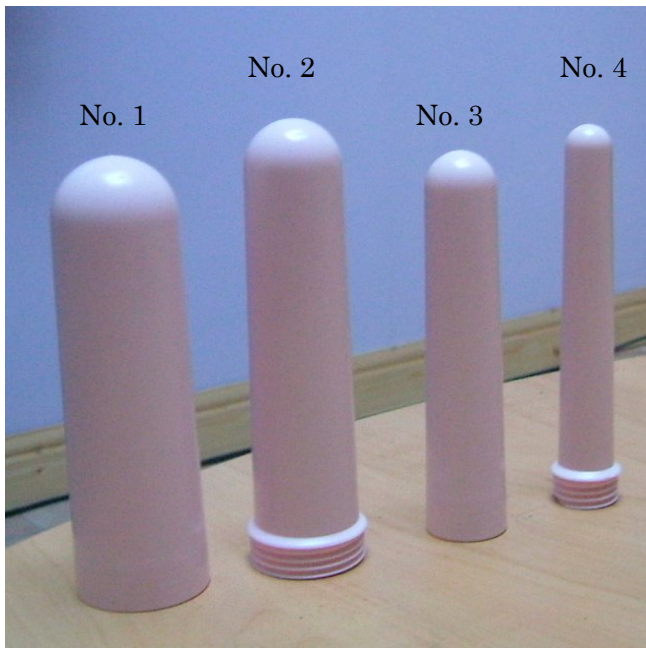
DILATOR SIZES

This product is recommended as a single user device

Dilator No	Dilation dimensions
1	35mm diameter at the tip, rising to 39mm
2	27mm diameter at the tip, rising to 31mm
3	20mm diameter at the tip, rising to 24mm
4	15 mm diameter at the tip, rising to 19mm



DESIGN SPECIFICATIONS



Shape of Dilators:	Dome ended to break down adhesions more readily, shaped in order to be clearly engaged by users as a medical device and not to be confused as a sex toy or replacement penis
Compliance:	Sizes graduate in order to allow for user comfort and enabling self treatment more readily and is fit for purpose
Colour:	Engaging to user, in order to be seen as an enabler to personal health rather than a cold clinical appliance, helps to overcome psychological barriers in the use of such devices
Screw mechanism assembly:	The design ensures that when the dilators are fitted together correctly that the user can be assured that there is less likelihood of the device causing damage to the walls of the vagina or tearing any stitches that may surround the area. The design also allows for ease of handling with a firm grip for a user who may suffer poor manual dexterity or poor coordination.
Material finish:	Waxy coating to give a tactile feel in order to reassure the user that the product will fit comfortably