

A demonstration/instructional video of how to use the Femmeze is available to view on the MDTi website at <https://www.mdti.co.uk/femmeze>

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5. TECHNICAL SPECIFICATIONS

The FEMMEZE® pack contains:
1 x FEMMEZE® device
2 x Sachet of lubricant
1 x Instruction for use
1 x Carrying pouch

Conformity	MDD 2007/47/EC CE classification Class 1 Vagina Trainer
Autoclave cycles	100
Material Specification	Ticona Hostaform C9021 – POM Copolymer (ACETAL) Colour Pink BPA Free
Size and length of FEMMEZE® trainer	17cm x 8cm x 2.5cm
Pack dimension and weight	19cm x 12cm x 3cm 100 grams
Recommended that the product be replaced every:	5 years
Manufacturer’s standard approvals:	ISO 13485:2012

UK Help

MDTi care +44 (0)1902 778380
Monday - Friday. 9.00am to 5.00pm.
An answer phone will be available out of these hours.
Any queries or concerns about using the FEMMEZE® call MDTi Care. Calls are charged at the UK normal rate. For all web enquires please visit: www.mdti.co.uk.

6. BIBLIOGRAPHY

- Hagen, S., & Stark, D. (2011). Conservative prevention and management of pelvic organ prolapse in women. The Cochrane Library.
- Mustain, W. C. (2017). Approaches and Treatment of Intussusception, Volvulus, Rectal Prolapse, and Functional Disorders of the Colon, Rectum, and Anus: Functional Disorders: Rectocele. Clinics in colon and rectal surgery, 30(1), 63.
- Hai-Ying, C., Rojas, R. G., Hall, J. C., Atan, I. K., & Dietz, H. P. (2016). Digitation associated with defecation: what does it mean in urogynaecological patients?. International urogynecology journal, 27(2), 229-232.



FEMMEZE®
Improving dignity and self- management for women with pelvic organ prolapse (Rectocele)
Product code : 40075



User Instructions
Version 2.5 August 2018

MDTi Careline: 01902 778380
For any queries about using your Femmeze® please call
Monday-Friday, 9.00am to 5.00pm.
An answer-phone will be available out of these hours. Calls are charged.

Please read carefully before using.
Always follow instructions before use.

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Indications of Use: The Femmeze Rectocele Device is for use as a manual, reusable and removable device placed into the vagina temporarily to train back or re-align the rectum tissue to treat a rectocele. The device is used to replace the use of pessaries or the fingers.

The FEMMEZE®

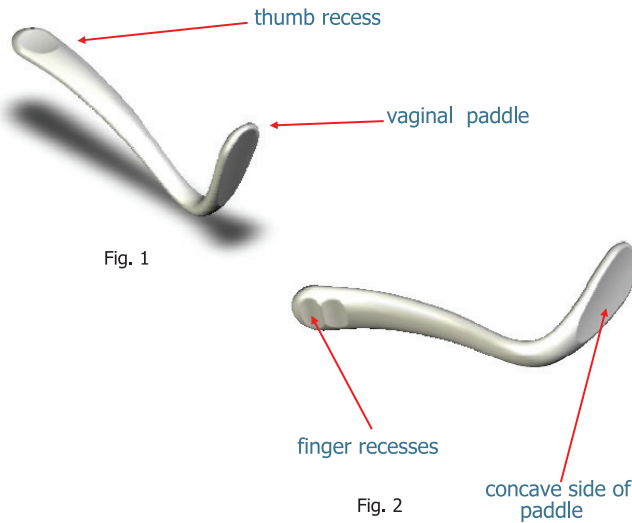
Where there is bulging of the back wall (rectocele), this can distort the position of the rectum and therefore there may be difficulty in passing stool. The rectum wall bulges into the vagina. To cope with this, some women will resort to inserting their fingers into the vagina to apply pressure to the vaginal wall, repositioning the rectocele and training the vagina back to its proper shape, to aid passing their stool. The rectocele bulges into the vagina causing narrowing, this narrowing can be temporarily positioned back using the FEMMEZE®.

1. INSTRUCTIONS FOR USE

The FEMMEZE® has been designed to be safe, easy and convenient to use whilst being able to be stored in a discreet and easily manageable pouch, which also includes space for small sachets or 50ml tube of lubricant to be accommodated.

The FEMMEZE® may be used as part of the care and self-treatment of women who are experiencing a rectocele. Rectocele (pelvic organ prolapse) is a distressing long-term condition. The rectum herniates forward through a vaginal tissue-wall tear, obstructing bowel emptying. The condition can typically be attributed to childbirth or hysterectomy. This vaginal device enables women to re-align the rectum from within the vagina to allow for more comfortable emptying.

The FEMMEZE® is shaped like a shoehorn, the paddle end of the device is inserted into the vagina whilst your thumb rests within the recess that is located at the top of the handle (Fig. 1) and with at least two fingers located within the grooves that are positioned on the reverse of the handle (Fig. 2).



This leaflet offers advice on the use and care of your FEMMEZE®. The device is a single-user device and must only be used by you.

IMPORTANT: Never attempt to insert the FEMMEZE® using a gripped hand around the handle of the device as this may result in you applying a greater pressure than that which is required in order to use the device safely and effectively.

IMPORTANT: These instructions are intended as a guide and you should seek the advice of your doctor or nurse specialist before using this device.

2. INSERTING YOUR FEMMEZE®

In order to re-align the rectum the FEMMEZE® is recommend for use rather than your fingers.

If using the device for the first time, wash it thoroughly in hot soapy water then rinse and dry it to remove all traces of soap (to avoid possible irritation).

To insert the device apply a small amount of a vaginal lubricant around the paddle of the device, gently insert into the vagina as shown in Diagram 1; push in a posterior direction repositioning the rectocele so as to permit emptying as in Diagram 2.

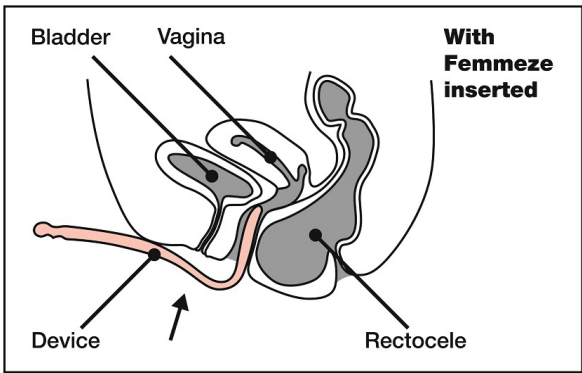


Diagram. 1

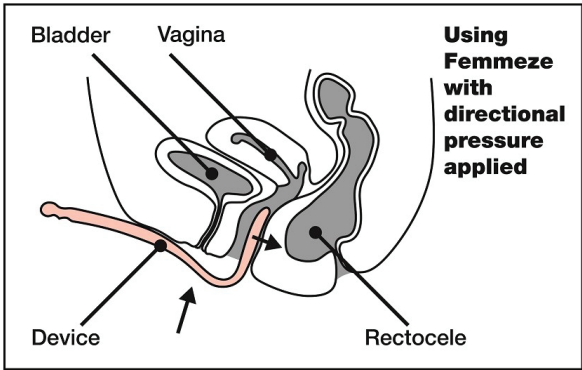


Diagram. 2

3. CARING FOR YOUR FEMMEZE®

You should check your device before it is used for any cracks or rough edges. If there is any damage to the device then it is important that you do not use and should immediately contact the manufacturer for a replacement by calling the Careline number +44 (0) 1902 778380 or email info@mdti.co.uk.

3a. CLEANING INSTRUCTIONS

This device is supplied as Non-Sterile, it is to be cleaned thoroughly all over with warm soapy water and then dried off before use or thoroughly wiped over with a sterile wipe. Before and after each use of the device ensure that you repeat the cleaning instructions. The device can also be cleaned in boiling hot water before use (allow the water to cool before removing). Do not use a disinfectant.

4. OTHER INFORMATION

IMPORTANT: This device has been designed to be used for inserting into the vagina, it should never be inserted into the rectum.

The FEMMEZE® should only be used on yourself, by yourself. No other person such as a carer or partner should assist you with its use as they may apply excessive force on the device which may cause you harm.

Contra- Indications

Stop using the device immediately if you experience any of the following:

- Unexplained bleeding
- Pain or discomfort during use, or if
- You are unable to insert it into the vagina

If you experience any of the above you should discontinue use of the device and seek medical advice.

Caution: If you are pregnant or you think you are pregnant, we cannot advise use of the Femmeze.

To use the Femmeze in the first few weeks following childbirth, we recommend that you consult with your healthcare professional to check if you can use the Femmeze.

IMPORTANT: Seek medical advice before using the device if the rectocele is visible outside the vagina or if you have any unresolved contraction of the vagina, such as may arise from pelvic radiotherapy.