

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>

**Instructions for Use are available on the MDTi website at <https://www.mdti.co.uk/femmeze> for the following languages:**

**Francaise (French)  
Deutsche (German)  
Italiana (Italian)  
Espanola (Spanish)  
Nederlands (Dutch)  
Suomalainen (Finnish)**



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## 5. TECHNICAL SPECIFICATIONS

The FEMMEZE® pack contains:

1 x FEMMEZE® device  
2 x Sachet of lubricant  
1 x Carrying pouch

<b>Conformity</b>	MDR 2017/745 Classification Class 1R Vagina Trainer
<b>Autoclave cycles</b>	100
<b>Material Specification</b>	Ticona Hostaform C9021 – POM Copolymer (ACETAL) Colour Pink BPA Free
<b>Size and length of FEMMEZE® trainer</b>	17cm x 8cm x 2.5cm
<b>Pack dimension and weight</b>	19cm x 12cm x 3cm 100 grams
<b>Recommended that the product be replaced every:</b>	5 years
<b>Manufacturer's standard approvals:</b>	13485:2016

### 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](http://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

Additional languages available, please see back of leaflet

Version 2.8 Oct 2024

**MDTi Careline: 01 902 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 re-align the rectum tissue. The device can be used to replace the use of fingers.

## The FEMMEZE®

Rectocele (pelvic organ prolapse) is a distressing long-term condition. The rectum herniates forward through a vaginal tissue-wall tear, into the vagina obstructing bowel emptying.

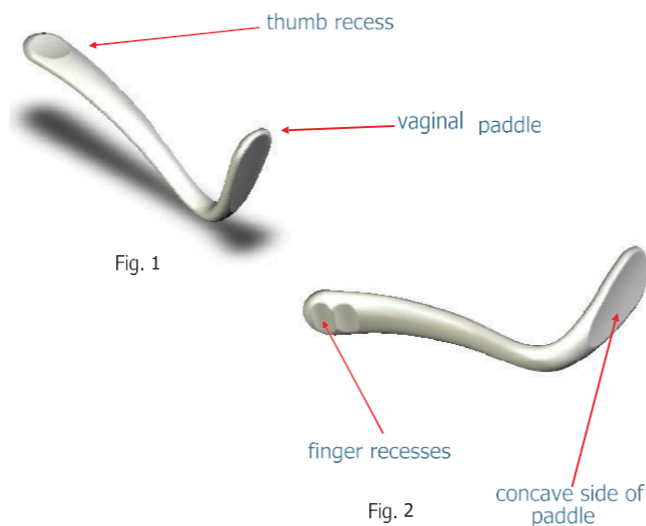
Where there is bulging of the back wall (rectocele), this can distort the position of the rectum and therefore there may be difficulty in passing stool. To cope with this, some women will resort to inserting their fingers into the vagina to apply pressure to the vaginal wall, repositioning the rectocele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

## 1. INSTRUCTIONS FOR USE (IFU)

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 to hold small sachets or 50ml tube of lubricant.

The FEMMEZE® may be used as part of the care and self-management of women who are experiencing a rectocele.

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 IFU offers advice on the use and care of your FEMMEZE®. The device is a single-user device.

**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 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®

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.

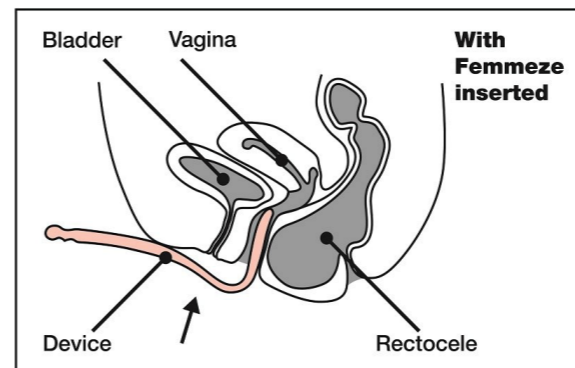


Diagram. 1

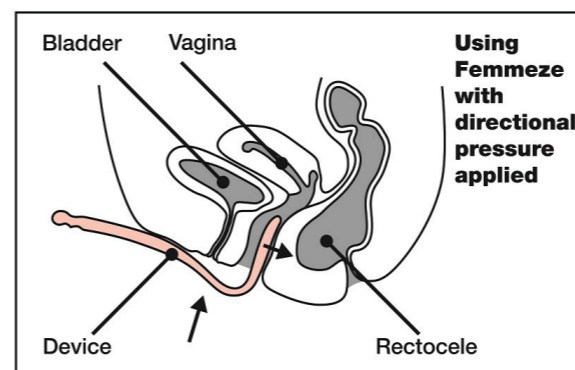


Diagram. 2

## 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 cleaned 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.

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