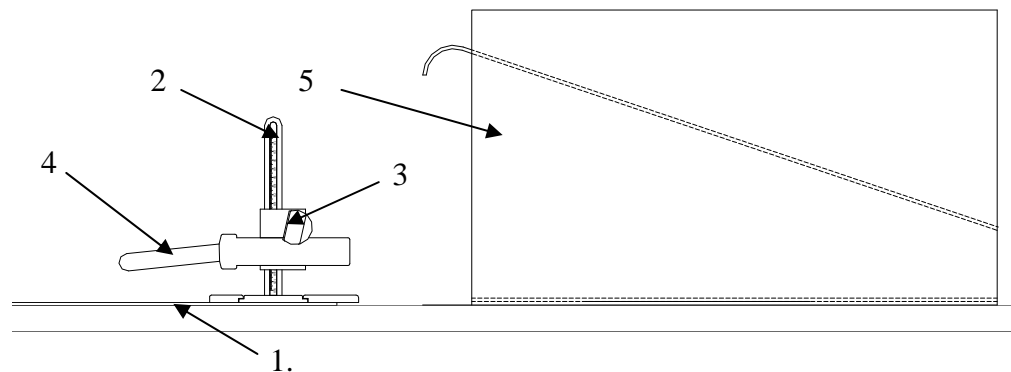


**Manufacturer:** AB Mimator  
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# Rectafix<sup>®</sup>

## Instructions for use

**Equipment:** Rectafix<sup>®</sup> model R 100



The Rectafix system consists of a baseplate with guide rails (1), a vertical column with a mm-scale (2), a locking mechanism (3) and a rectal rod with shaft (4). In addition the system has a leg rest (5) that is designed for comfortable and reproducible support of the legs during treatment.

**Intended use:** Rectafix is intended to be used only for fixation of the rectum of patients undergoing external beam therapy of the prostate in such a way that the radiation dose to the rectal tissue is minimized. By doing that the risk for serious side effects in the rectum (rectal toxicity) is significantly reduced.  
Rectafix shall only be used by doctors and nurses who have been properly trained in the use of the system.  
Rectafix is intended to be used in radiation therapy clinics in normal hospital environment..

**Indexing:** Rectafix can be used together with the most common indexing systems on the market: (Varian: Ref # 20VARSUB10 or Civco: Ref # MTIL3151M ) or other similar systems. The base plate and the leg rest are provided with holes for the indexing bars.

**CE-mark:** Rectafix is CE-marked as a medical device in class I according to the Medical Device Directive, Council Directive 93/42/EEC and its corresponding national legislations within the EEC.

**Trademark:** Rectafix<sup>®</sup> is a registered trademark and it is the property of AB Mimator.



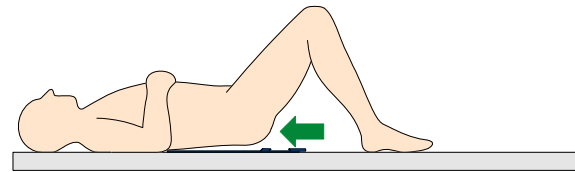
# Instructions for use of the Rectafix®

## Preparations:

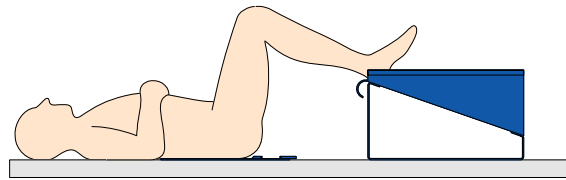
1. Prepare the patient before the first procedure by explaining the purpose of the treatment and the different steps in the process. Explain the use of the Rectafix system, how it is operated and that it reduces the risk for side effects significantly. Let the patient choose if he wants to have Rectafix during his treatments.
2. Prescriberescribe an enema e.g. Microlax Enema so the patient has cleared the rectum before both the planning CT, simulation and treatment. That reduces the risk for problems during the procedures.

## During CT, simulation or treatment:

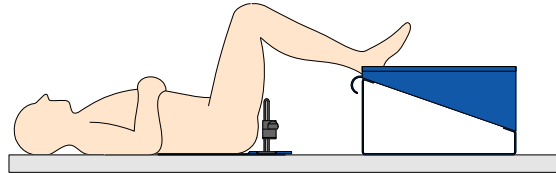
3. Let the patient lie down on the treatment table in the normal position and lift the back so the base plate can be inserted in a suitable position. The perineum should be approx. 5 cm away from the vertical column. Indexing can also be used for a reproducible positioning.



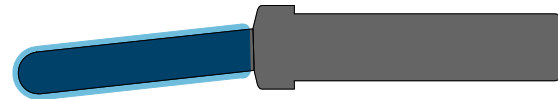
4. Put the leg rest some distance away from the base plate so that the patient can put his heels on it with the thigh bones almost vertical and the anus easily accessible.



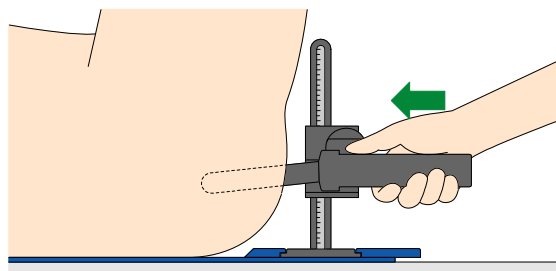
5. Insert the vertical column with locking mechanism in the baseplate rail and move it some distance away to make it is easy to insert the rectal rod. Evacuate gases if needed.



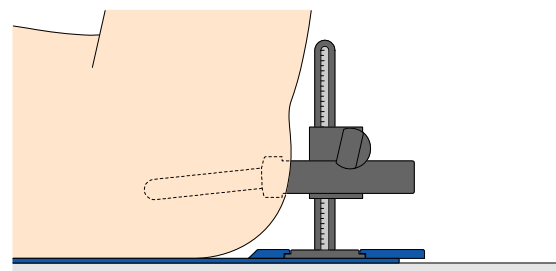
6. Apply a lubricating gel on the rectal rod to make the insertion easier. It is also possible to apply a condom on it and apply the lubricating gel on that.



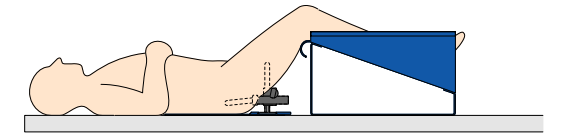
7. Insert the rectal rod into the anus and talk with the patient to make sure that he does not feel any pain or discomfort during this procedure.



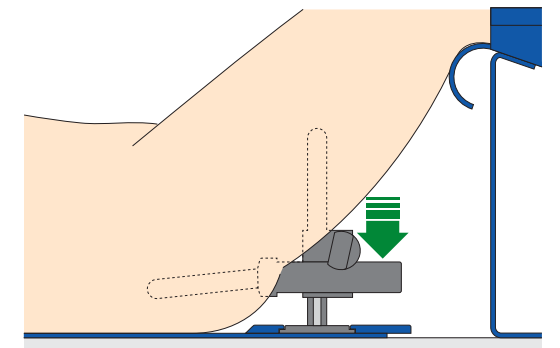
8. Loosen the locking mechanism by turning the vertical locking knob counterclockwise. Move the vertical column closer so that the rectal rod shaft fits into the slot in the locking mechanism. The rectal rod shall be inserted so far that the thick end of the shaft stops against the anus and it is locked in place with the D-shaped knob.



9. Move the leg rest closer to the patient so both legs can rest comfortably in the leg rest channels with the knees on the rounded edge and the feet resting on the sides of the leg rest channels. If an indexing bar is used the position of it in the holes in the leg rest is recorded during the first procedure and repeated at each following instance.



10. Press the rectal rod and locking mechanism as far down as possible (or to the vertical position that was recorded during the planning CT procedure). Talk with the patient to make sure that he does not feel any pain or discomfort during this procedure. Tighten the vertical locking knob to lock the locking mechanism and rectal rod in this position. Record this vertical position if it is the first time the rectal rod is used for this patient (e.g. imaging for treatment planning) so that all the coming setups can be identical.

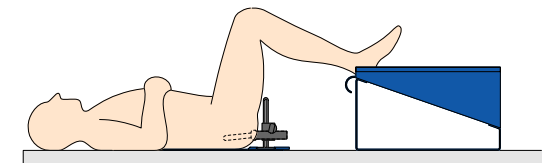


11. Position the patient with the normal table motions and alignment tools and treat according to the treatment plan.

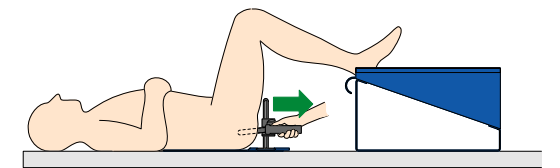
## After CT, simulation or treatment:

12. Move the treatment table to a convenient working height.

13. Ask the patient to lift his legs, move the leg rest a short distance away so the patient can put his heels on it with the thigh bones almost vertical and the anus easily accessible. (The same position as in 4).



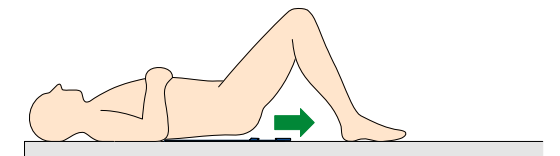
14. Unlock the rectal rod from the locking mechanism, pull it out and place it in a kidney dish.



15. Remove the vertical column by moving it out on the side and remove the leg rest from the treatment table.

16. Ask the patient to lift his back and remove the baseplate.

17. Let the patient sit up and leave the treatment table.



18. Give the patient some paper to remove the excess lubricating gel and clean himself before dressing.

19. Wipe the rectal rod clean with paper, remove the condom if you have used one and sterilize the rectal rod in the autoclave before using it again.

20. Clean the base plate and leg rest surfaces with alcohol before using it for the next patient.