mediNiK®
Purenum

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mediNiK® Purenum

A. About the product

1. **What makes the Hydrogel method unique?**

   mediNiK® solves the problem of residual stone fragments during endoscopic removal (URS) of renal stones, which can lead to new stone formation. Both hydrogel components bind residual stones within a few minutes. The stone fragments bound by the gel can then be effectively and quickly removed using the grasping methods used in flexible URS.

2. **What is the proven benefit of the product for the patient?**

   By removing significantly more small renal stone fragments (< 1 mm) than a conventional URS without the use of mediNiK®, mediNiK® reduces the risk of recurrence for patients because recrystallization nuclei are no longer present. Nearly all < 1 mm kidney stones are a potential new seed for new, larger renal stones.

3. **Has it been proven how many renal stone fragments can be removed during surgery with mediNiK®?**

   Depending on the type and size of the renal stone, more than 1000 small fragments can be removed by mediNiK® during a single operation.

4. **Can mediNiK® also be used for percutaneous nephrolithotomy (PCNL or PNL)?**

   The certification of mediNiK® is currently valid for use only as part of a URS.

5. **Does the hydrogel stick to the equipment or tissue?**

   The unique hydrogel does not stick to surfaces. However, it may become trapped e.g. in the catch basket, even if the catch basket is open. To prepare the catch basket for the next recovery procedure, we recommend wiping the hydrogel on a coarse sterile gauze.

6. **Is mediNiK® safe? (toxicologically safe?)**

   Yes, mediNiK® is a medical product based on natural raw materials. Almost all the raw materials in the two components - K1 (basic substance) and K2 (activator) - are found in everyday foods and medical products. Its biological harmlessness has been proven in studies related to DIN EN ISO 10993.

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7. **What is the advantage of mediNiK® compared with the blood clot method?**

   mediNiK® essentially has three advantages compared with the use of autologous blood. Firstly, the high-contrast colour of mediNiK® enables it to be administered more precisely, thus securely and completely embedding the stone fragments. Secondly, gel formation is much faster than blood clotting. And thirdly, any gel left in the kidney after the procedure dissolves as a result of diuresis and cannot cause any obstruction.

8. **Are allergic reactions possible?**

   No, the data obtained to date regarding the use of mediNiK® on patients do not indicate any allergic reactions due to the administration of the hydrogel.

9. **What pack sizes are available?**

   The pack size is for 5 applications, with 5 x 5 ml (K1) + 5 x 11 ml (K2).

10. **How can I purchase mediNiK®?**

    mediNiK® is a certified medical product manufactured by Purenum GmbH; a wholly owned subsidiary of FARCO-PHARMA. The product can be ordered from FARCO-PHARMA.

11. **Is training provided for the product? Where can I get training materials?**

    To participate in training, it is best to contact Purenum directly at info@purenum.com or FARCO-PHARMA at info@farco-pharma.de.

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B. Application
Hydrogel application

12. Do I need a special ureterorenoscope?

You can use any standard ureterorenoscope without any problem.

13. How many syringes do I need per patient/application?

1 application = 2 syringes (1 x component K1 + component K2)

14. How can you tell that a sufficient amount of the basic substance K1 has been applied?

K1 is blue coloured and transparent, creating a good colour contrast on the monitor and ensuring that the stone fragments are visible. When all stone fragments are completely coated with the blue component, a sufficient amount has been applied.

15. How can I be sure that a sufficient amount of the activator K2 has been administered?

There is no need to ensure a precise mixing ratio. At least two to three times the amount of the previously introduced base substance K1 should be administered. Since overdose of the activator K2 is not possible, the entire syringe content can be injected slowly (without turbulence).

16. Is it possible to administer too much mediNiK® (K1 or K2)?

The amount of the basic substance K1 administered should be enough to completely surround all fragments according to the rule of as much as needed, but as little as possible. About 0.3 to 0.5 ml of K1 should be sufficient for one calyx, although several calices can be filled in succession before K2 is added.
On the other hand, it is not possible to apply too much of the activator K2.

17. After adding component K2, no solid hydrogel is formed, or only a small amount. Why is that?

a. The flush was not stopped before the application of K1 and K1 was therefore flushed out or diluted.

b. Component K2 was administered so quickly that component K1 was flushed out by the resulting turbulence.

c. Component K2 was administered too close to component K1, so that component K1 was flushed out.

d. Too little of the component K2 was used, no visible yellowing of the total fluid in the kidney.

e. If it is not the first application: Lack of flushing, residual component K2 was still present in the kidney.

f. Not waiting long enough for the gel to form.

18. What happens if the flush is NOT turned off before applying mediNiK®?

The basic substance K1 is flushed away or diluted by the flow resulting from the flush. The residual fragments to be retrieved are therefore insufficiently coated.

19. What happens if I do not administer a component?

If only one of the two components is applied, no gel formation will occur. Consequently, the residual fragments cannot be retrieved as expected.

20. What happens if I reverse the order of use?

If the activator K2 is applied first, during the subsequent application of base substance K1 gel formation will occur instantaneously. The residual fragments will therefore be bound weakly or not at all by the hydrogel.

21. Do I need to apply pressure to the syringes to force the components out of the syringes?

The more viscous component K1 (base substance) requires slightly more force to be applied than component K2 (activator), especially when it is administered through a catheter (which may be useful when a reusable scope is employed, for example). When administered directly through the working channel, as recommended, the amount of both components is easy to control.

If it is not possible to administer the components K1 or K2 (through a catheter), it may be because:

1) the selected catheter is too narrow.

2) there is a blockage in the catheter caused by residues of the other component that have not been flushed away.
3) The Tuohy-Borst adapter at the inlet of the working channel has been tightened too much so the catheter diameter is reduced.

22. It is difficult to plunge the syringes when they are first pressed, is this normal?

Yes, first the technical pressure point must be released by briefly depressing the syringe plunger, when the end cap is fixed, e.g., by placing the syringe on a firm surface, similarly to other FARCO-PHARMA syringes (e.g., Instillagel and Endosgel).

23. Can mediNiK® be administered a second time during surgery?

Yes, mediNiK® can even be administered several times to one patient. This requires the working channel of the endoscope and the kidney to be carefully flushed with physiological saline solution so that no residues of component K2 are present. Residual K2 would lead to immediate gel formation upon reapplication of K1 without the stone fragments being sufficiently coated.

Retrieval of renal stone fragments

24. Grasping the hydrogel with the grasper is difficult or causes the hydrogel to tear. Why is that?

It is essential to wait at least 3 minutes after administration of K2 because the gel is too soft to grasp after a shorter time. Likewise, complete closure of the catch basket will sever the hydrogel.
Grasping the hydrogel is fundamentally different from conventional grasping of stone fragments. To allow for the retrieval of larger amounts of the hydrogel (containing the bound residual fragments), it is designed to be soft. This means it can mould to the urinary tract or ureteral sheath. Therefore, the catch basket should be closed only slightly. Grasping the hydrogel is fundamental to the procedure and can be practised in advance on a model of the kidney.

25. Why does the hydrogel clot have to be pulled out „carefully“? What if I „lose“ half of it?

The hydrogel is designed to be soft so that it can mould to the urinary tract or ureteral sheath. At the juncture between the renal pelvis and the ureteral sheath

there is a narrowing. If the hydrogel is pulled through too quickly at this point, the part protruding from the catch basket may be sheared off. This part must be retrieved in a further step. Due to the gel's position directly inside the renal pelvis, it is easy to grasp and subsequently retrieve the fragments.

26. What happens if residues of mediNiK® remain in the kidney after the procedure?

Any residues of mediNiK® remaining in the kidney are not hazardous for the patient. Natural diuresis reverses the gel formation. The gel gradually becomes softer until it becomes completely liquid and the patient excretes it with the urine.

C. Following administration

27. How do I dispose of the hydrogel and syringe residues?

Component K1 and component K2 do not pose any risk to humans. Syringes can be disposed of in accordance with the hospital's internal disposal standards for the lowest waste safety level.
The catheters and the hydrogel must be disposed of separately as they come into contact with mucous membranes and/or urine and the renal stone fragments.

28. Can residues of mediNiK® be used for another operation?

No. The principle is that opened and used syringes may only be used in one patient for a single operation.

29. How can I isolate the retrieved stone fragments from the hydrogel for analysis?

There are two possibilities, in principle:

1) The stones can be mechanically removed from the hydrogel and rinsed with sufficient water.
2) The hydrogel is dissolved by placing it in a chelating agent (e.g. EDTA) so that isolated stone fragments can be sent for analysis.