Remove kidney stones completely

Filling hydrogel mediNiK from Purenum

mediNiK from [Purenum](https://purenum.com/home-en.html) is a hydrogel used to remove kidney stone fragments. The kit consists of two components. Together, they form a hydrogel that also enables the removal of previously inaccessible fragments. A ViscoTec Hygienic Dispenser 2VPHD12-3D is used for the development of the production process as well as initial dosing of the newly approved product - in a semi-automatic dosing system for syringe filling. In the clean room, the empty syringes are directly connected to the pump outlet via a Luer Lock connection. Filling therefore takes place via the syringe outlet. During this process, the liquid pushes the plunger in front of it. Due to the direct coupling of the syringe to the pump, accurate filling is achieved and only a very small air bubble is trapped.

**EU certified medical device**

mediNiK is certified as a medical device in the EU. The certificate issued in May 2021 allows distribution in the EU. It has a validity period of three years, with production being inspected annually. Currently, mediNiK is only available in selected, specialized hospitals. Approval for the USA is planned for the second half of 2022.

Challenges encountered in the dosing of the hydrogel

The high demands placed on a medical product and its production must therefore also be met when dosing the hydrogel. The design of the dosing equipment must be GMP-compliant. This means that only FDA-compliant materials are used to manufacture the dosing pump. The equipment must be easy to disassemble, clean and sterilize. In addition, both a corresponding test certificate and preparatory documentation for IQ/OQ certification must be available for quality verification.

For mediNiK's dosing process, the filling quantities can be flexibly and precisely adjusted from 3 to 9 ml. Stringent dosing and repeat accuracies are basic prerequisites for successful development and subsequent validation of the manufacturing process. "By using the dispenser from ViscoTec, the syringes could be filled very effectively with mediNiK despite the small batch size," comments Manfred Peschka, Managing Director of Purenum. In addition to a simple and practicable process for filling the medical product, other advantages of ViscoTec's dosing technology include quick availability of the dosing system, easy handling and cleaning, and flexibility. The 2VPHD12-3D also performs well when the material properties and/or filling quantities still change.

How mediNiK works

Large kidney stones are crushed in surgery to break them into fragments of different sizes. Large fragments of the stone can be removed with a conventional grasper. However, smaller fragments cannot be grasped with this instrument and usually remain in the kidney. This is where the hydrogel comes into play. With its help, the intangible fragments are combined into a larger, elastic conglomerate and can therefore be extracted with the gripper: The blue component K1 flows around the fragments. The yellow component K2 is then added. The two components do not have to maintain a rigid mixing ratio. The contact of the two liquids alone forms a gel that binds the small stone fragments inside. The different colors of the two components facilitate the work of the urologist. In the video, it is easy to see that the gel containing the fragments can simply be grasped at one end and retrieved safely, i.e. through the airlock. For the subsequent analysis of the kidney stones, the hydrogel can be easily and quickly dissolved again. <https://www.youtube.com/watch?v=1QrZ9_Dw_Nk>

**About Purenum GmbH**

Purenum GmbH is a spin-off from the Fraunhofer Institute for Manufacturing Technology and Advanced Materials (IFAM) in Bremen. Purenum GmbH was founded in 2017 and started R&D operations in mid-2018 after successfully raising investor financing and funding. The core team consists of Prof. Dr. Ingo Grunwald and Dipl.-Ing. Manfred Peschka MBA.

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Images:

Ein Bild, das Wand, drinnen enthält.

Automatisch generierte Beschreibung

Horizontal arrangement of the ViscoTec Hygienic Dispenser 2VPHD12-3D in the laminar flow box, feeding via open cartridge.

Ein Bild, das drinnen, Ausguss, Zahnbürste, Hand enthält.

Automatisch generierte Beschreibung  
*Filling of component 1 (blue) via Luer Lock elbow at the dispenser outlet.*

Ein Bild, das drinnen enthält.

Automatisch generierte Beschreibung

Filling of component 2 (yellow). The vertical syringe arrangement minimizes the air bubbles being trapped during filling.

**ViscoTec – Perfectly dosed!**

ViscoTec Pumpen- u. Dosiertechnik GmbH manufactures systems required for conveying, dosing, applying, filling, and emptying medium to high-viscosity fluids. The headquarter is in Töging a. Inn (Bavaria). ViscoTec has subsidiaries in the USA, in China, Singapore, India and in France and employs about 290 people worldwide. Numerous sales partners all over the world complete the international distribution network. Next to technically sophisticated solutions to even the most complicated application, ViscoTec is the single point of contact to deliver all components for a complete system: From emptying to preparing and to dosing. This guarantees successful interaction of all components. All fluids showing a viscosity of up to 7.000.000 mPas can be conveyed and dosed almost pulsation-free and with extremely low shear. ViscoTec offers comprehensive consulting for every application and, if required, extensive tests will be carried out in close cooperation with the customer. The dosing pumps and systems are perfectly adapted to their respective application whether it is the food sector, the e-mobility industry, the aerospace field, the medical technology, the pharmaceutical industry, electronics manufacturing or many other branches.

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