DRAMIŃSKI
TECHNOLOGY

DRAMIŃSKI *OPU*

System for ultrasound guidance of ovum pick up procedure

USER MANUAL

Issue 1.2_062026

Manufactured by:

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Dramiński S.A. has established and maintained a full quality management system in accordance with the requirements of EN ISO 9001. The system is periodically audited by a notifying body TUV Rheinland LGA Products GmbH, Tillystrasse 2, 90431 Nuremberg, Germany, which is involved in compliance assessment.

We wish you a lot of success in taking care of patients. We are sure that our device will help you serve them well.
DRAMIŃSKI S.A. will accept all the comments and enquiries of your customers concerning the device and the user manual with great interest.

Contact us by calling at: + 48 89 675 26 00
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1. Introduction

1.1. Information about the user manual

In particular parts the user manual describes the structure, accessories of the device, preparation for operation, functions and operation of the system.

Familiarizing yourself with the content of the user manual will not substitute even a basic course on ultrasonography and Ovum Pick Up procedure (OPU). It is recommended that the user of the device underwent a proper training in authorized educational unit.

1.2. Warnings, comments and symbols used in the user manual

Regarding the necessity to underline important information in the user manual, the following ways of highlighting are used:

Warning!

In order to draw special attention regarding the patient or operator safety.

Attention! – in order to draw attention to protection of the device or its proper operation.

Bold text – in order to draw attention to important fragments in the user manual or to make it more legible.

Descriptions at technical drawings and figures – in order to make detection of the smallest details easier.

The symbols used in the user manual do not fully inform about safety, that is why it is necessary to read about the guidelines (Part 2) and follow them!

Symbols used in the text:
[text] – means the name of the button of the ultrasound scanner

1.3. Preliminary information about Ovum Pick Up

The Ovum Pick Up (OPU) procedure is based on inserting a needle via the wall ov vagina to the follicle in order to aspire its content together with the egg cell.

The obtained material is subjected to incubation and estimation by an embryologist. Then it can be used for in-vitro insemination.

In order to collect as much material as possible from all the follicles on the ovary, the procedure is performed under ultrasound guidance.

The system described in this user manual allows to present a distinct image of the ovary and to insert an aspiration needle into it. Thanks to this, the procedure is repeatable and effective.

1.4. General information about the device

DRAMIŃSKI OPU is designed to be used on bovine and horses. It does not mean, however, that it cannot be used on other species of animals.

The system dimensions were designed so that it could be used on young heifers.

The system is made of plastic, stainless steel and aluminium. Its construction enables easy and effective disinfection and quick assembly.

The elements used in the system enable using standard injection needles.

The DRAMIŃSKI OPU is only compatible with ultrasound scanners manufactured by DRAMIŃSKI S.A.

2. Patient and user safety

Warning!

Patient and user safety depends on following of the guidelines mentioned below!

1. The DRAMIŃSKI OPU system should only be used by qualified veterinary personnel.
2. It is necessary to disinfect the system and the probe before each examination. More information concerning disinfection is in the part Disinfection of this user manual.
3. The probe and the system should be disinfected separately.
4. It is necessary to remember not to use agents which can irritate the vaginal mucosa. It is always necessary to follow instructions of the manufacturer of the disinfection agent.
5. The DRAMIŃSKI OPU is designed for vaginal examinations and procedures.

6. It is absolutely crucial to follow the assembly and disassembly instructions of the device.
7. It is necessary to take full precautions after the needle has been put onto the guide. Lack of attention can cause an injury with the needle.
8. In order to assembly the device it is necessary to use only the original parts delivered by the manufacturer.
9. The user is recommended to perform periodic inspections of the system for any possible mechanical damages.
10. If any mechanical damages are revealed, it is necessary to contact an authorized service representative.
11. It is necessary to follow recommendations regarding temperature of operation and storage of the device.
12. The user is forbidden to modify the device.
13. After the period of exploitation, because of the risk to the environment, the device and the accessories should undergo the process of utilization by specially qualified units in accordance with the applicable law or be sent back to the manufacturer.

3. Construction

The system is made of plastic, stainless steel and aluminium. The extension consists of two parts in which there is a place for an ultrasound probe, a needle guide and a steel sleeve stabilizing the needle path. The both parts of the extension are connected with each other with the use of screws and magnets. There is also a detachable handle which makes operation of the extension easier.

The extension is designed to cooperate with the needles up to 70 mm long.

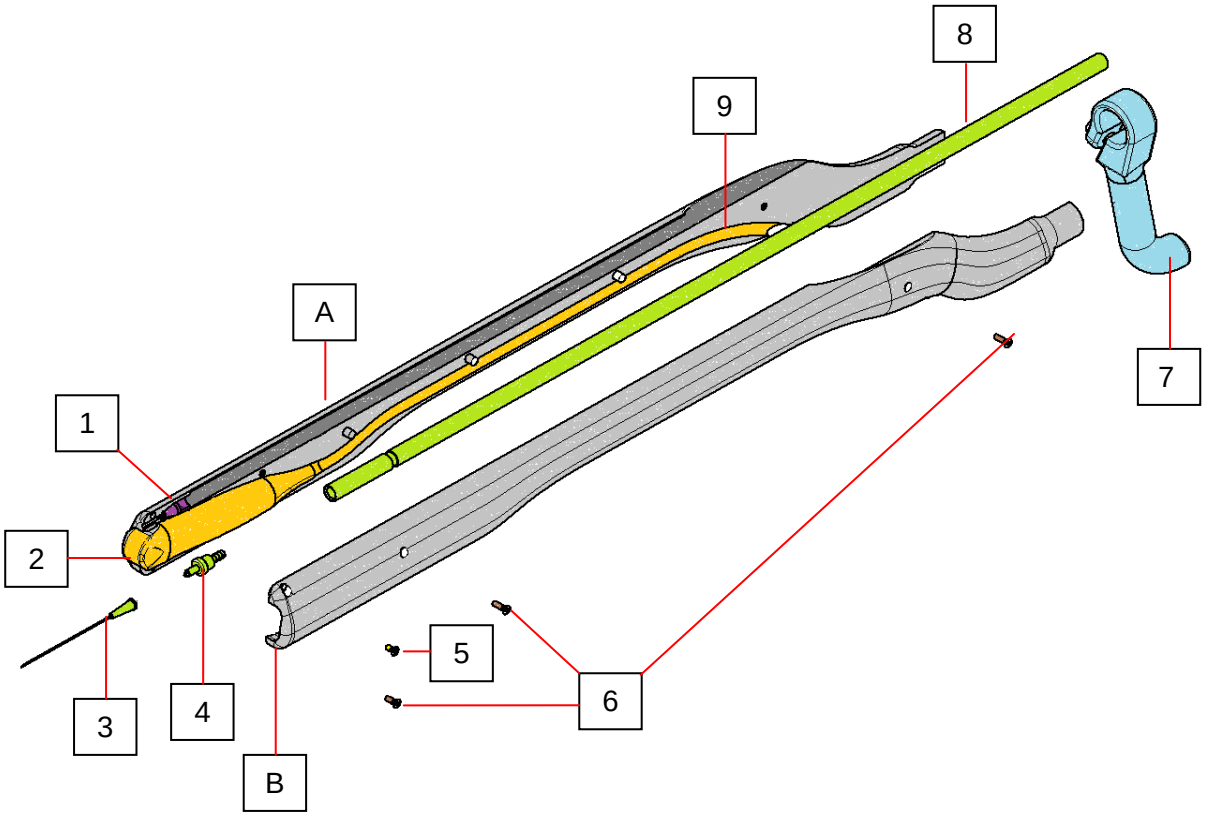


Fig. 1 Construction scheme of the DRAMIŃSKI OPU

3.1. The set content

No	Element
A, B	Extension – part A and B
1	Sleeve stabilizing the needle path
2	Probe
3	Needle*
4	Needle - tubing connector
5	Short screw 3x6 (1 item)
6	Long screws 3x8 (3 items)
7	Handle
8	Guide
9	The probe's cable
10	Cross-head screwdriver
11	Imbus

Table 1. Components of the DRAMIŃSKI OPU

* a needle is not part of the set. It is recommended to use needles with the parameters of 18-20G, 70mm.

4. Technical data

Length	625 mm
Width at the probe end	30 mm
Height at the probe end	42 mm
Weight (with the probe)	< 600 g
Radius of the probe	136 °
Probe's protection rating	IPX7
Type of recommended needles	20-18G / 70 mm
Recommended diameter of aspiration pump tubing	2 or 4 mm
Dedicated ultrasound scanners	DRAMIŃSKI 4Vet, DRAMIŃSKI 4Vet mini

Table 2. Technical data

5. Preparation for operation

5.1. Assembling the elements of the set

Warning!

Before operation make sure that each of the elements of the OPU is properly disinfected.

Attention! The short screw 3x6 is used for front upper hole of the casing.

Attention! Stop tightening the screw when you feel the slight resistance.

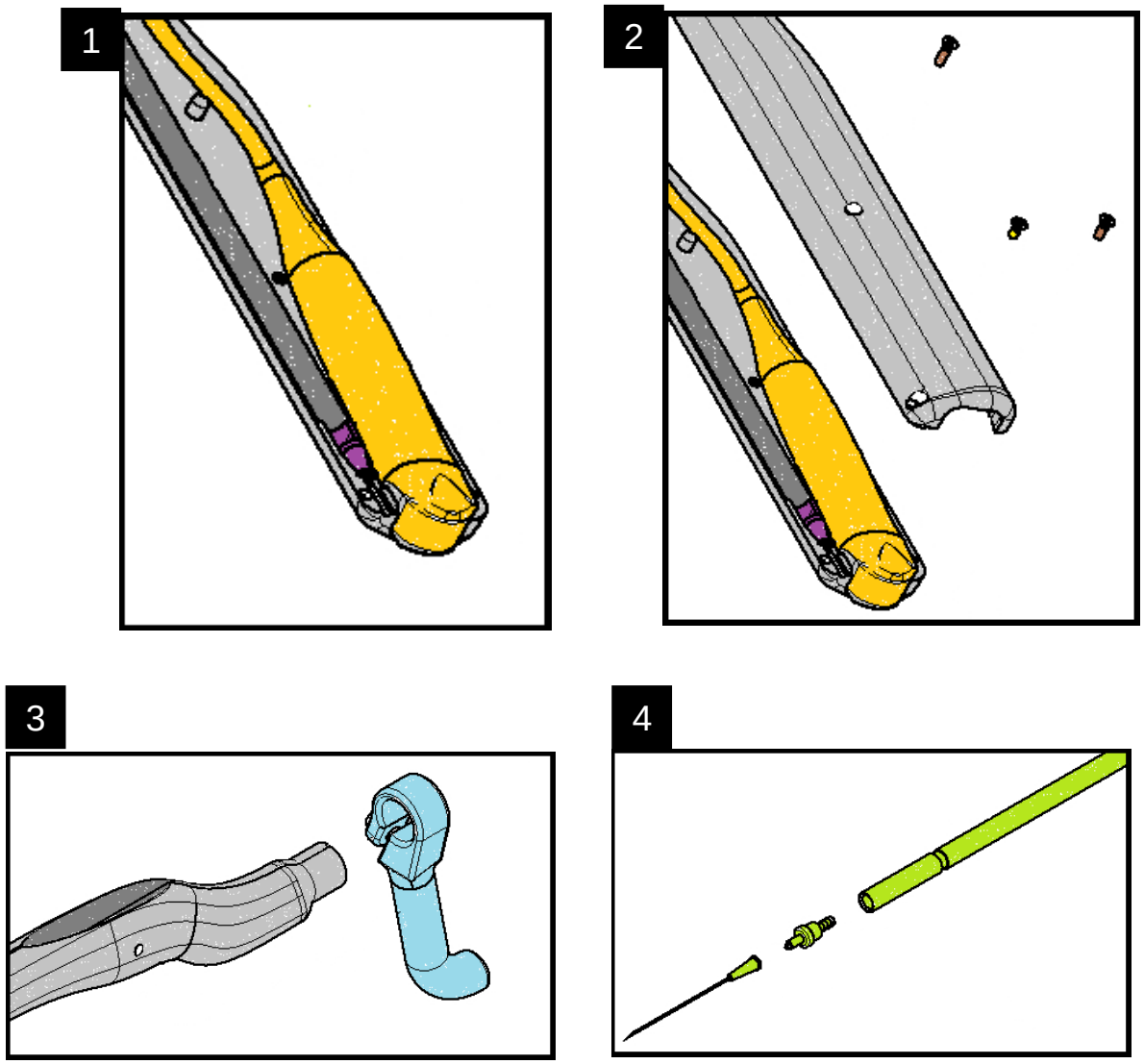


Fig. 2 Preparation of the OPU to operation

Attention! When all the elements are assembled, connect the probe in accordance with the ultrasound scanner user manual.

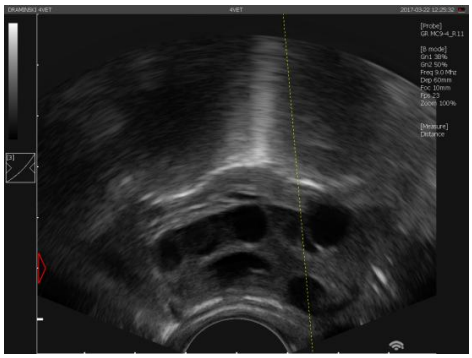
Attention! In order to better protect a patient against pathogens, it is recommended to use disposable foil cover on the whole system.

5.2. Switching on the needle path on the ultrasound scanner

The needle path is a dotted line marked on the ultrasound image which helps to foresee the path of the needle in a patient's body. The actual needle path can be a little bit different from the shown by the line.

Attention!

If the needle on the image deviates significantly from the path, it is necessary to check whether the needle has not been bent.



In order to switch on the needle path on the **4Vet / 4Vet Slim** ultrasound scanner, press [Needle]. On the screen there appears an approximate needle path marked by a yellow dotted line.

In order to switch on the needle path on **4Vet mini**:

1. Press  ;
2. Choose [Measurement] > [Needle On/Off];
3. Using the arrows on the keyboard select YES.

On the screen there appears the needle path marked by a yellow dotted line.

6. Maintenance of the system

When finished working with the system, disassemble the system, wash the elements properly and disinfect them.

Attention!
The probe must be disinfected separately. Use dedicated agents which do not contain alcohol.

Attention! Always follow the instructions of the manufacturer of the disinfection agent.

Attention! The probe protection rating is IPX7. It is not recommended to immerse the places in which the cable goes out of the probe in disinfectant. To disinfect the cable use paper towel soaked with disinfectant.

Disinfectants recommended to disinfect the probe:

Name	Active substance
Cidex	Phthalaldehyde
Cidex	Glutaraldehyde

Table 3. Recommended agents to disinfect the head.

Attention! It is necessary to remember not to use disinfectants which can irritate vagina mucosa.

The carrying case should be cleaned externally with water and detergent. The foam insert should be vacuumed regularly and cleaned with water and a mild detergent. A disinfectant solution, e.g. Virkon S, may be used for disinfection. Before using the carrying case, make sure that the foam insert is completely dry.

7. Warranty

The manufacturer gives 12-month warranty within which it guarantees troublefree operation of the device operated in accordance with the attached user manual.

In the case of a malfunction, not caused by a user, the manufacturer is obliged to repair the delivered device within the period of time not longer than 14 working days starting from the day when the device was delivered to the service (Wiktora Steffena 21, 11-036 Sząbruk, Poland) and to send the repaired device back at the expense of the manufacturer.

Mechanical damages, damages which appear as a result of improper use, storage and unauthorized repairs are not covered by the warranty.

The warranty comes into force on the basis of a purchase invoice. For any complaints regarding the device it is necessary to inform Dramiński about the malfunction as soon as it has been detected.

To submit a warranty claim, the following steps must be taken:

1. Notify DRAMIŃSKI S.A. of the device malfunction immediately after it occurs.
2. Send the device to the Service Department (no later than before the warranty expiration date) or deliver it in person together with the proof of purchase, which should include the seller's and purchaser's details, the date and place of purchase, the device name, and its serial number.
3. A description of the malfunction must be enclosed with the device sent to the Service Department to ensure efficient diagnosis and repair of the damage:

- Before shipping, the ultrasound device, carrying case, and all included accessories must be cleaned and disinfected (*in accordance with the Cleaning and Disinfection section),
- Please pay particular attention when packaging the device to ensure that it is properly secured, as the manufacturer shall not be held liable for any damage incurred during transport.

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