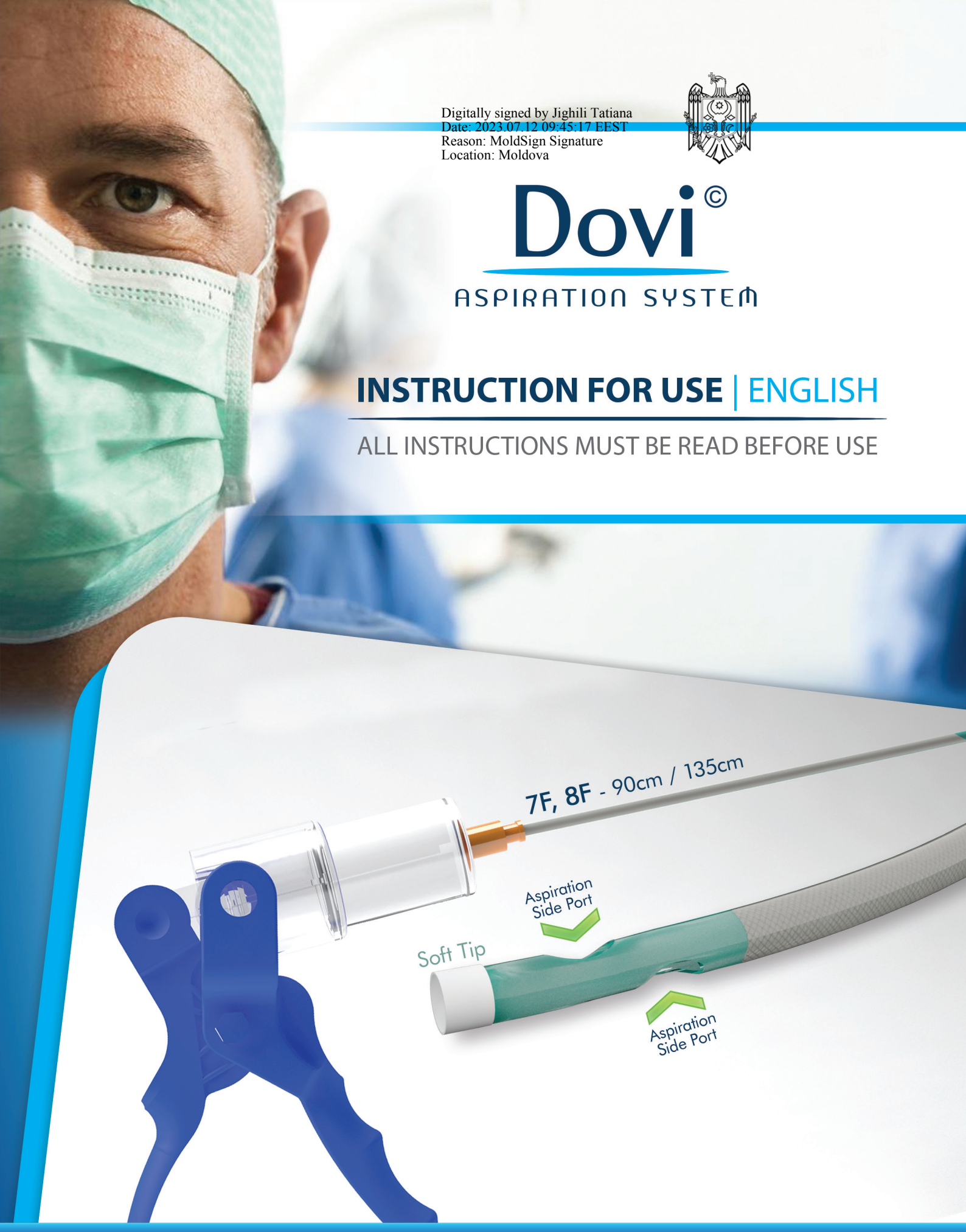
Dovi©

ASPIRATION SYSTEM

INSTRUCTION FOR USE | ENGLISH

ALL INSTRUCTIONS MUST BE READ BEFORE USE



INVAMED
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Dovi©
ASPIRATION SYSTEM

INSTRUCTIONS FOR USE

1. PRODUCT NAME
Product name Dovi Aspiration System

2. DEVICE DESRIPTION
The Aspiration System product is a motorized thrombo-aspiration catheter with a motor-pump unit. MEDDEV 2.7.1 and "EU Directive" 93/42 / EEC is a Class III Medical-Surgical product, which can be used in body. The aspiration system is an effective method for acute venous and arterial occlusions. It has a wide lumen and atraumatic tip with , rounded, closed distal end structure with two side holes preventing tissue absorption. The aspiration system has a surface that provides accessibility and a suitable hardness that prevents bending. The " Aspiration System" is disposable. There are two product varieties that are advanced directly and advanced through the guidewire. Aspiration system provides effective and safe aspiration. Thanks to this technology, it opens both the vascular lumen and prevents migration of the thrombus material to the distant. Thanks to the aspiration system, intervenes the thrombus and the thrombus inside the vein is cleansed actively and rapidly separately. It does not do unnecessary blood withdrawal and only the thrombus is aspirated.

REFERENCE NO	PRODUCT NAME	DIAMETER	LENGHT
ATA00014	Invamed Aspiration System II (Peripheral, Thromboaspiration Catheter, Advanced Directly, with Motor)	7F	90 cm

3. MANNER OF INTRODUCTION
Sterile : Aspiration System product is sterilized with ethylene oxide. It is non-pyrogenic.
Ingredients : Invamed Aspiration System
Storage : Keep in dry, dark, controlled room temperature. Do not expose organic solvents to ionizing radiation or ultraviolet light.

4. INDICATIONS
Product is indicated for removal of thrombus in both coronary and peripheral arteries and pulmonary arteries. It is used for lumen opening and aspiration of peripheral vessel, in acute, sub-acute phase and also in acute occlusions over chronic phase and patients with life threatening due to massive pulmonary embolism.

5. CONTRAINDICATIONS
- General disorder (Glasgow Coma Scale 3)

6. WARNINGS
It is disposable. Don't reuse or re-sterilize Reuse or re-sterilization processes may cause structural changes on the device and chemical residues, failure of the device or causing to the patient as a result of failure of it. Reuse or re-sterilization processes may result in infection, permanent disease / disability or death.

Don't use after the "date of expiry" on the package.

7. PRECAUTIONS
Invamed Thrombectomy System must only be used by doctors expert in usage of the product or similar interventional techniques. Producer will not be responsible for the damages arising from the uses other than those specified in this user guide.
- Principles, clinical practices and associated risks must be fully learned before using this product.
- Do not use if the packaging is opened or damaged.
- Check whether the system is working before using it; make sure that the catheter size and shape are appropriate for the procedure.
- Do not try to pass the Invamed Trombectomy System catheter through a smaller introduser sheath as indicated on the label.
- Do not use for procedures other than those specified in the Instructions for Use.
- Do not resterilize the product as it may damage the performance and increase the risk of cross contamination due to improper rework.
- When to a catheter exposed vascular system, the procedure should be performed under careful fluoroscopic observation or angiographic imaging.
- If you encounter difficulties during the process, determine the reason for the difficulty before continuing.

8. ADVERS EFFECTS

- Interventional complications
- Emboli
- Bleeding
- Infection
- Paralysis
- Vascular perforation, rupture or damage
- Mortality

9. REQUIRED MATERIALS

- Invamed Aspiration System
- Intraducer set in appropriate size with the system
- Guide wire (for OTW system)
- Aspiration motor unit

10. APPLICATION

Prior to the administration of the Dovi Aspiration System, all necessary equipment will be used for the procedure should be carefully monitored for defects. Check the package to ensure that it is not damaged during shipping, make sure the system is in working condition and if the sterile barrier is intact.

In order to prepare product for use,apply following steps:

1. Remove the Dovi Aspiration System from the sterile package according to sterile techniques.
2. Check the tip of the product catheter.
3. Wash the catheter with heparinized saline.
4. All vessels in treatment zone must be mapped in detailly.
5. Local anesthesia should be applied when the entry point is determined.
6. Seldinger entry technique should be performed with suitable introducer sheet.
7. Aspiration catheter is advanced through the appropriate intraducer set to the treatment zone over the guide wire.
8. Activate aspiration motor unit and start aspiration.
9. Always control with angiography / fluoscopy, until thrombus is removed.

WARNING: Trombectomy catheter should be withdrawn if any resistance is encountered while catheter is being advanced. It may cause damage or perforation.

11. SHELF LIFE

If kept under the specified conditions, the product has a expiry life of 3 year after production date. It is not used after the date of expiration.

12. DISPOSION

Dispose the product according to the standard institutional processes for medical waste, including disposable devices contacting with blood.

13. WARRANTY DISCLAIMER AND SETTLEMENT LIMITATION

For the Invamed product/products described in this issue, there is no express or implied warranty including the intended warranty without having any limitation from the point of view of marketability or fit for specific purpose. Under no circumstances, Invamed shall not be responsible for and direct, casual or consequential damage other than those clearly indicated in the specific law. Nobody has authority for representing or guarantying the Invamed other than those specifically specified in this document. With this issue, the definitions or specifications in the Invamed printed material have only the purpose of generally defining the product on the production date and they do not mean any open guarantee. Invamed shall not be responsible for any direct, incidental or consequential damage originated from re-use of the product.

DESCRIPTION OF LABEL / MARKING

Sterilized by ethylene oxide.

Pay attention to label warnings.

Read instructions before use

Fragile

Single use only. Cannot be u: second time.

Caution: Federal Law restricts this device to sale by or on the order of a physician

Dispose according to the medical

Keep away from sunlight

Keep at the temperature of 5 - 24C°

May create potential biological waste after use

Do not use if the product is damaged or package is already

Keep in dry place

Cannot be re-sterilized.

Non-pyrogen

Expiration date

Production date

Lot Number

Catalogue Number

Manufacturer

INVAMED

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