

**SELDINGER (ANGIOGRAPHY) NEEDLE**

- ⚠ Please read these instructions for use carefully before using this device.
- ⚠ PLEASE DO NOT USE THE DEVICE WITHOUT READING THE INSTRUCTIONS MANUAL.
- ⚠ Informing the patient and the patient consent must be obtained.
- ⚠ This product should be administered by a **physician trained in this technique**.

This instructions for use;

1. *Seldinger (Angiography) Needle package contents*
2. *Device visual and list*
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**1. Seldinger (Angiography) Needle package contents**

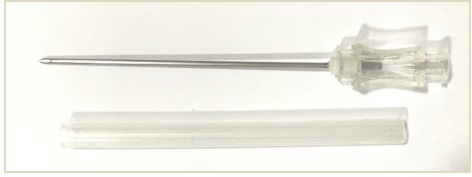
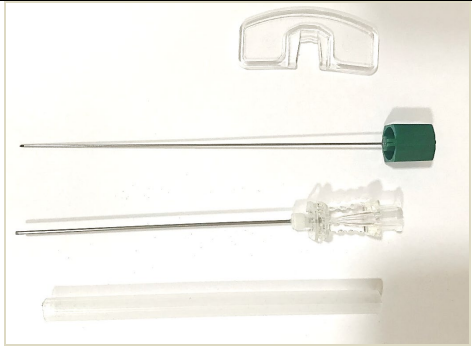

- > Seldiner Needle
- > Stylet\*
- > Wings\*

\*Optional.

**2. Device visual and list**

|            |  |  |
|------------|--|--|
| TSLD1870   | Seldinger (Anjiyografi) iğnesi, stiletsiz, kanatsız,<br>18Gx70mm |  |
| TSLD1870K  | Seldinger (Anjiyografi) iğnesi, stiletsiz, kanatlı,<br>18Gx70mm  |  |
| TSLD1870SK | Seldinger (Anjiyografi) iğnesi, stiletli, kanatlı,<br>18Gx70mm   |  |

## SELDINGER (ANGIOGRAPHY) NEEDLE

|            |   |  |
|------------|---|--|
| TSLD2170   | Seldinger (Anjiyografi) İğnesi 21G x 70 mm          |  |
| TSLD2170SK | Seldinger (Anjiyografi) İğnesi 21G x 70mm, Stiletli |  |
| TSLD2134   | Seldinger (Anjiyografi) İğnesi, 21Gx34mm            |  |

### 3. Device components material information

Stainless steel, PE, ABS

### 4. Device application

- 4.1 Used for angiography.
- 4.2 Prepare patient for the procedure according to standard technique and ensure patient will remain in proper position throughout the procedure
- 4.3 Open pack using sterile technique.
- 4.4 Remove plastic tip protector and examine needle body and tip in order to confirm its integrity.
- 4.5 If needle has a stylet, remove stylet then place it again to confirm smooth movement.
- 4.6 Start puncture to blood vessel at the application area.
  - ⚠ *If single-wall technique is preferred, the puncture should be limited to front wall of blood vessel. Attention is required in order not to injure back wall.*
- 4.7 Pull back stylet and monitor blood flow.
- 4.8 Stop advancing of needle as soon as you observe blood flow. Insert guide wire through needle.
- 4.9 Remove needle by gently pulling it backwards.
- 4.10 Dispose the needle according to medical waste regulations.

### 5. Indications

- › It is indicated for angio and vascular access interventions.

### 6. Contraindications

- › Distorted Anatomy
- › Infection at the Site of Access
- › Proximal Vascular Injury
- › Bleeding Disorders or Anticoagulation
- › Combative Patients
- › Not used in children
- › The decision on the applicability of the procedure depends on the competence of the doctor who will perform the procedure.

### 7. Side Effects

- › Hematoma

**SELDINGER (ANGIOGRAPHY) NEEDLE****8. Risks**

- › The risk of infection for practitioners
- › Low blood pressure
- › Stroke, heart attack or heart rhythm disorders
- › Allergic reaction of the contrast dye is injected in some patients
- › Excessive bleeding
- › Risk of infection
- › Blood clots
- › Heart or vessel perforation
- › Air embolism

**9. Warnings**

- › In this medical device, the interventions after application and application should be made by physicians who are experts in their fields.
- › Do not use if package is torn or damaged. These are not sterile.
- › Store in cool, dry and dust free environments.
- › After use dispose device according to medical disposal regulations.
- › Do not apply any techniques other than the approved procedure.
- › Use this medical device only for the mentioned intended purpose.
- › Do not use excessive force during the insertion of the needle, it may cause the needle cannula to bend and / or break.
- › This medical device is for single use only. Reuse or re-sterilization of the original package after opening is dangerous and can cause cross contamination, infection and trauma.
- › Any serious incident related to the device must be reported to the manufacturer and competent authority.
- › Examine this medical device for possible damage before using it (For example: curl, bending, deformity, cut or blunt tip).

**10. Symbols**

Sterilized using ethylene oxide



Keep dry



Do not re-use



Humidity limitation



Do not use if package is damaged



Batch code



Use-by date



Do not re-sterilize



Date of manufacture



Non-pyrogenic



Temperature limit



Keep away from sunlight



Consult (e IFU) instructions for use  
[www.egemen.com.tr](http://www.egemen.com.tr)

**11. Manufacturer Information**

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The instructions in this manual and all other Egemen International® (TMT Tıbbi Medikal Malz. San. Tic. Aş.) sources are for guidance purpose only. The proper use of this device should be based on clinical training of the physician.