



## DESCRIPTION

Angiodroid The CO<sub>2</sub> (code ANG00001) Injector is a CE marked medical device that allows CO<sub>2</sub> injections at given pressures and volumes into vascular cavities.

CO<sub>2</sub> acts as contrast medium during an angiography exam, offering high benefits as well as low complications when compared to the iodinated contrast. The user can set Volume and Pressure values of the injection, to obtain radiological images with a good diagnostic value.

Angiodroid The CO<sub>2</sub> Injector is an automatic digital injector that guarantees a stable level of CO<sub>2</sub> injection pressure and an extremely accurate dose volume setting, as well as a sophisticated control system to avoid contamination with air.

Angiodroid The CO<sub>2</sub> Injector is a multi-functional angiographic device which can be connected directly to the catheter to start the injection.

Basic UDI-DI: 805647933 0515 6V

## ANGIODROID THE CO<sub>2</sub> INJECTOR LIFETIME:

- 10 years

## PRINCIPAL FEATURES

- Digital volume doses setting
- Digital injection pressure setting
- Fast automatic reload for repeatable injections
- High accuracy of the set injection pressure
- High accuracy of the set volume doses
- Dual microcontroller to ensure high performance and high safety
- Remote controller to start the injection
- Possibility to save injection settings for different body districts
- Touch screen console

Angiodroid The CO<sub>2</sub> Injector allows to perform high quality angiography using a correct setting of the parameters, also in patients with critical diseases such as renal failure, diabetes and hypersensitivity to iodinated contrast material.



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angiodroid

**INTENDED USE:** Angiodroid The CO<sub>2</sub> Injector is a device that allows the CO<sub>2</sub> dosage at specific volumes and pressures, and the injection of CO<sub>2</sub> into vascular cavities with the purpose to perform angiography.

- **Intended Users** → Angiodroid The CO<sub>2</sub> Injector is intended to be used only by healthcare professionals suitably trained. Angiodroid The CO<sub>2</sub> Injector has three main application fields:
  - interventional radiology
  - vascular surgery
  - interventional cardiology
- **Intended Population** → The device is intended for use in the execution of peripheral vessel angiography and is mainly aimed at adult, nephropathic and diabetic patients. Children are not excluded as the patient's pediatric age is not reported as a contraindication in the literature.
- **Intended Use Environment** → Angiodroid The CO<sub>2</sub> Injectors intended for use in hospitals, clinics and other medical facilities where power is supplied via a MV/LV cubicle. The device is intended for use in a covered and protected place with medical care near the patient. Ambient temperature between + 5°C and + 35°C. Relative humidity between 30% and 75%. Pressure range: 700 hPa – 1060 hPa

## INVESTIGABLE DISTRICTS

- abdominal aorta
- lower limbs
- haemodialysis fistula
- renal arteries
- pelvic arteries
- hepatic arteries
- peripheric venous system

## POSSIBLE SIDE EFFECTS CAUSED BY THE USE OF CO<sub>2</sub> AS A CONTRAST MEDIUM:

- Nausea
- Pain
- Dizziness
- Tachycardia
- Iatrogenic acidosis
- Transient paraesthesia (pins and needles, feeling cold, burning)

## CONTRAINDICATIONS TO USE OF CO<sub>2</sub> AS A CONTRAST MEDIUM:






- Supradiaphragmatic arterial studies
- Lung failure
- Presence of interatrial or interventricular communication
- Pulmonary arteriovenous malformation
- Nitric oxide anaesthesia


## PRECAUTIONS TO BE TAKEN IN CO<sub>2</sub> ANGIOGRAPHY

- Maximum dose per injection: 100 mL.
- 2 (two) minutes must pass between consecutive injections.
- Avoid the reflux of CO<sub>2</sub> into the aortic artery above the diaphragm and into the brachial and/or radial artery in the arm: CO<sub>2</sub> bubbles may rise towards the cerebral arteries, resulting in neurological damage for the patient.
- Avoid reflux of CO<sub>2</sub> in the upper and/or lower mesenteric artery: CO<sub>2</sub> bubbles may cause a vapour-lock and then ischaemia.
- In case of venous CO<sub>2</sub> overdose (gas in the right ventricle or pulmonary trunk), place the patient in the right lateral recumbent position.
- If CO<sub>2</sub> stagnation occurs (e.g. in an aortic aneurysm), change the patient's position to allow gas to flow into distal districts.
- If the patient experiences strong leg pains, change its position.
- If the patient experiences abdominal pains, check for bubbles in the mesenteric artery. In this case move the patient by lifting them sideways in order to move the bubble.

## WARNINGS

Angiodroid The CO<sub>2</sub> Injectors can be used with a medical grade CO<sub>2</sub> cylinder that complies with the specifications of the European Pharmacopoeia (EP) – Monograph 01/2008:0375, with a purity level equal or higher than 99.5%.

- Any transmission with mobile radio equipment must be avoided and cell phones must be switched off. 
- Only personnel trained and authorized by the manufacturer may remove the covers of the unit to access the internal parts. Do not open the unit there are no usable parts and there are dangerous voltages inside. 
- Before connecting the unit to the mains, make sure that the socket has a protective earth and that the network will maintain the correct supply voltage as indicated on the label of the Injector. 
- Always move the device perpendicularly to the short side and avoid collisions with obstacles. 
- Angiodroid The CO<sub>2</sub> Injector is a MR Unsafe device: is known to pose hazards in all MRI environments. 
- The MRI Compatibility are not evaluated for this device.

- Angiodroid The CO<sub>2</sub> Injector should only be used in accordance with the safety instructions contained in its User Manual and should not be used for any other purpose except as intended.
- As any active device, Angiodroid The CO<sub>2</sub> Injector must be used appropriately with periodic checks and maintenance. Perform routine maintenance periodically as indicated by the manufacturer.
- Periodically clean the equipment following manufacturer instruction.
- Products used for cleaning and disinfection, including those used for patients, could create gaseous and explosive mixtures. For this reason, it is recommended using only products in accordance with the rules applied.
- This equipment is not suitable for use in the presence of ANAESTHETIC MIXTURES THAT ARE FLAMMABLE IN AIR, OXYGEN OR NITROUS OXIDE. 
- Connect Angiodroid The CO<sub>2</sub> Injector to a power outlet behind the uninterruptible power supply to prevent the equipment from locking during the circuit priming phase.
- Do not connect the machine to multiple mains sockets, but only to a suitable ground terminal power socket that is part of an electrical system that complies with the regulations in force.
- Isolation from the mains is done by disconnecting the detachable plug. Do not position the appliance in a way that makes it difficult to disconnect the detachable plug.
- After positioning the system, apply the parking brakes.
- Do not tip the appliance upside down.
- The floor on which the device may be placed must ensure a capacity of 400Kg/m<sup>3</sup>.

## STORAGE AND TRANSPORT CONDITIONS:

- Ambient temperature between -5 °C and +50 °C
- Keep dry
- Pressure range: 700 hPa - 1060 hPa



## ACCESSORIES

In order to reach its intended use Angiodroid The CO<sub>2</sub> Injector must be used with:

- **Single Use Adaptor for Angiodroid The CO<sub>2</sub> Injector code CO200001**: The single use adaptor acts as a connection between the injector and the vascular catheter.  
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- **Angiodroid Procedural Kit code ANG-CO2-0003**: sterile disposable kit consisting of:
  - Single Use Adaptor for Angiodroid The CO<sub>2</sub> Injector
  - 2-ways manifoldBasic UDI-DI: 805647933 0539 7B



Single Use Adaptor for Angiodroid The CO<sub>2</sub> Injector and Angiodroid Procedural Kit are disposable, sterile and non-sterilizable accessories.



STERILE EO



## ACCESSORIES STORAGE AND TRANSPORT CONDITIONS:

- Temperature between +5 °C and +40 °C
- Keep dry
- Keep away from sunlight



## ACCESSORIES SHELF LIFE:

- 36 months (3 years)

