

Product data sheet

317635-000

Product name EN

CT2 / MRT Set ELS

Product group

10 - Set

Rev 00 / 20.12.2022



2 ELS tipo
200 ml
švirkštai

2 x 316035-000 ELS 200 ml Syringe,
1 x 317120-000 MRS 222 MR- Tube System
1 x Patient Line 150 cm
2 x J Tube

vamzdelių sistems
su vožtuvais

150 cm paciento
linija

0,1-10 ml/s
FlowRate

Specifications

Highlights

Accutron CT-D

*Accutron HP-D

Accutron MR

Accutron MR3

*CT-Mode

Compatible Devices

Injektoriaus gamintojo patvirtinimas,
kad siūlomas rinkinys skirtas naudoti su
Accutron CT-D

3 years

Shelf life

**21 bar/
305 psi**

max. Pressure

Intended use: The intended use of the product group set as a kit results from the intended use of the individual set components.

The tube systems are intended for the fluid transfer of contrast medium (CM) and saline solution (NaCl). They are intended for the filling of syringes of a contrast medium injector and for the transfer of fluids into the patient in computed tomography, magnetic resonance imaging, and X-ray mammography.

The patient lines are intended for the fluid transfer of contrast medium (CM) and saline solution (NaCl) into the patient in computed tomography, magnetic resonance imaging, and X-ray mammography.

The 21 bar syringes - single use, are used once on a single patient for the administration of contrast media and saline solution in the radiological diagnostics of computed tomography, magnetic resonance tomography and X-ray mammography.

Accessories are used to connect several non-active medical products (patient line, tube system or syringe) or to connect a non-active medical product to the dosing chamber for the fluid transfer of contrast media and saline solution.

Application and Application frequency:

Single use device, Single use device intended for single use on a single patient.

- Valve technology Microbiologically and virologically safe.
- Self-closing. Opening pressure 170 mbar / 2,5 psi
- Drip chamber with ground filter for filling without any particles, pore size no more than 15 µm.
- Spike with microbiological ventilation filter, pore size 3 µm

Net weight (Product + Blister): 348 g

Carton weight: 1235 g

Quantity per outer carton: PU 20

Minimum order quantity = 1 full carton/ box: PU 20

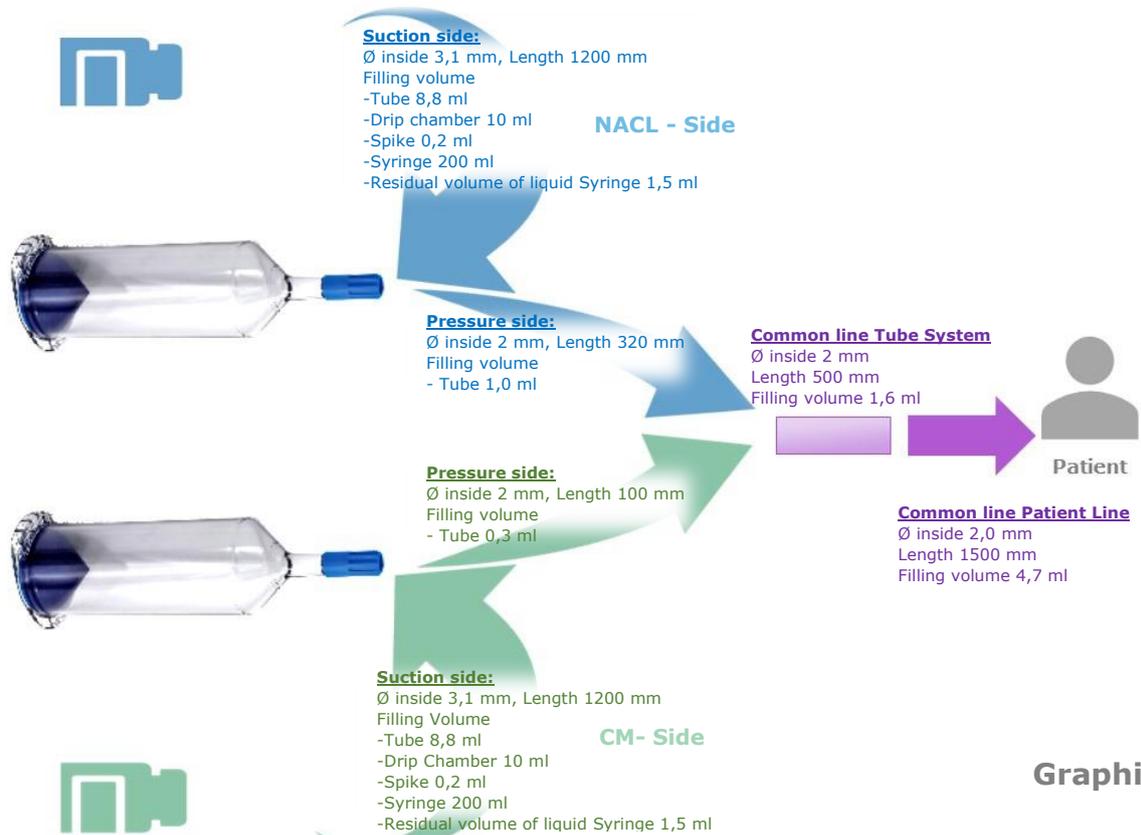
Weight Shipping unit: 8,6 kg

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Technical Specification

Functional facts



Technical Specification

Material data

Material Tube
 Tube: Polyvinylchloride, DEHP-free
 Luer-Lock Connector:
 Polycarbonate
 Protective Cap: Polypropylene
 Drip Chamber: Polyvinylchloride
 DEHP-free

Material Syringe
 Syringe: Polycarbonate
 Piston: Polycarbonate
 Seal: Polyethylene
 Protective Cap: Polypropylene

Material Accessories
 J Tube: Polyethylene

Sterile barrier system
 Peel off hard blister packaging

Materials sterile barrier system
 Tyvek Paper 64 g/m²
 Polystyrene Blister

Dimensions outer carton
 52x35x50.5 cm

CE-mark
 CE 0482

Classification (MDD)
 Class IIa

UMDNS Code
 15-265

GMDN Code
 16545

Sterilization
 ETO-Gas

Storage conditions
 Storage Temperature: -15°C-50°C
 Relative Humidity: 35%-75%
 Store in the closed carton,
 protected from direct sunlight and
 in a dry place.

HS Code
 90183900

Barcode inner blister
 (01)14250288603278(10)1234567
 89(17)yyymmdd

Barcode inner carton
 /

Barcode outer carton
 (01)34250288603272(10)1234567
 89(17)yyymmdd

Manufacturer
MEDTRON AG
Hauptstrasse 255
66128 SAARBRÜCKEN
Germany

Instructions for use

for the sets REF 317601-000, 317602, 317602-000, 317602-100, 317603-000, 317603-100, 317604, 317604-000, 317604-100, 317614-100, 317616, 317616-000, 317620-000, 317625-000, 317627, 317627-000, 317627-100, 317628, 317628-000, 317629-100, 317632-000, 317635-000, 317636-000, 317637-000, and 317638-000

Introduction

Read attentively these instructions for use to ensure a proper application of the products and a safe operation of the injector, and to avoid damages to patients, users, third parties, and properties by improper use.

Intended use

The 21 bar syringes (single-use) are used for one-time use on a single patient for the administration of contrast medium and saline solution in radiological diagnostics of computed tomography, magnetic resonance imaging and X-ray mammography.

By means of a contrast medium injector the fluids are transferred from a supply container to the syringe, then the syringe is emptied and the fluids are thus administered to the patient.

The syringe may only be used in combination with contrast medium injectors of MEDTRON AG which are limited to a maximum pressure of 21 bar/305 psi.

The tube systems are intended for the fluid transfer of contrast medium (CM) and saline solution (NaCl). They are intended for the filling of syringes of a contrast medium injector and for the transfer of fluids into the patient in computed tomography, magnetic resonance imaging, and X-ray mammography.

The tube systems may only be used in combination with syringes with male Luer Lock connection and with contrast medium injectors which are limited to a maximum pressure of 21 bar/305 psi.

The patient lines are intended for the fluid transfer of contrast medium (CM) and saline solution (NaCl) into the patient in computed tomography, magnetic resonance imaging, and X-ray mammography.

The patient lines may only be used in combination with commercially available consumables with Luer Lock connections and with contrast medium injectors which are limited to a maximum pressure of 21 bar/305 psi.

The products may only be applied by trained and instructed medical staff.

The products are single use devices and intended for single use on a single patient.

Any use above and beyond this scope is deemed to be inappropriate. Never use the products for other purposes!

MEDTRON AG ensures the suitability of the products for the intended use. Further manufacturer-specific requirements must be observed.

su numatyta atidarymo vieta

Symbols used on the packaging

pažymėtas galiojimo laikas sterilus

 vienkartinis	 Use by	 LOT	 STERILE EO	 REF	 15 µm	
Do not reuse	Use by	Batch code	Sterilisation using ethylene oxide	Order number	Liquid filter with pore size 15 µm	Manufacturer
 Do not use if package is damaged	 Store protected from direct sunlight	 Store in a dry place	 Consult instructions for use	 One-way valve. Allows flow in one direction only.	 Do not resterilise	 This side up
 Temperature range for the storage	 Do not stack more than the specified number of packages	 Pressure	 Fragile; handle with care			

Symbols used in these instructions for use



CAUTION!

This symbol indicates risks which could involve fatal or serious personal injuries or severe damage to property.



ATTENTION!

This symbol highlights risks which could involve material damage.



Note!

This symbol indicates tips and particularities regarding the handling of the products.