

vamzdelių sistema su
vožtuvais - 1 vnt.;

- vienkartinis (simbolis ant pakuotės);
- sterilus (pažymėta simboliu);
- suderintas darbui su KT mobiliu injektoriumi Accutron CT-D;

medtronic.com

CE 0482

Instructions for use

for the double head tube systems **REF 317099-100, 317100-100, 317100-901, 317102-100, 317108-100, 317109-100, 317112-100 and 317114-100** with green check valves.

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 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 product may only be applied by trained and instructed medical staff.

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 tube systems 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 product for other purposes!

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

Symbols used on the packaging



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

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.

Safety instructions



CAUTION!

Risk of fatal or serious injuries due to air embolisms!

- Vent the syringes and the connected tubes every time after filling the injector with contrast medium or saline solution.
- Do not connect the patient to the system until you have completely vented the syringes and the connected tubes.
- Make sure before every injection that there are no air inclusions in the syringes and the connected tubes.



CAUTION!

Risk of infection!

- Make sure that the packagings of the products do not show any signs of damage.
- Do not remove the protective caps of the tube ends until you make the connections.
- Make sure that the use-by date of the consumables has not been passed.
- Observe the general hygiene principles and the special hygiene requirements of your organisation to avoid also product contamination from outside.
- Dispose of the tube system after single use on a single patient.



CAUTION!

Risk of material damage or injuries by using a reprocessed tube system.

Reprocessing the tube system may change the chemical, biological, microbiological or physical properties of the product. This leads to a loss of function of the tube system.

Do not reprocess nor reuse the tube system.



ATTENTION!

Risk of stress crack formation!

Disinfectants may damage the plastics and lead to the formation of stress cracks.
Avoid any contact with disinfectants during the connection.

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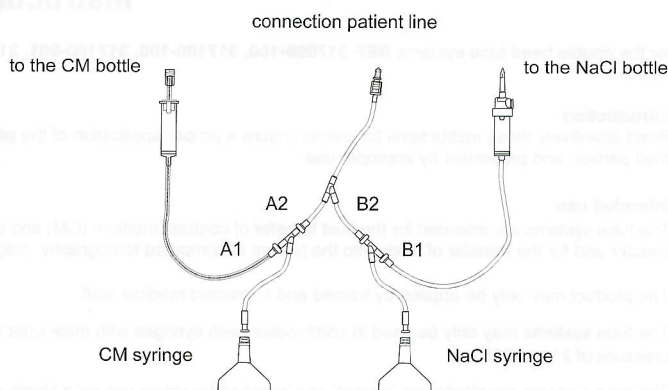
Connecting the tube system

The figure on the right shows tube system REF 317108-100 as an example of the tube systems listed above.

The tube system has four valves which function as follows:

- When you fill the CM syringe with contrast medium, valve A1 is opened and valve A2 closed.
- When you inject contrast medium out of the CM syringe, valve A1 is closed and valve A2 opened.
- The valves B1 and B2 function in the same way.

The tube marked with a green stripe is intended for the contrast medium bottle.



- Insert the syringes into the recipients as described in the instructions for use of the injector.
- Remove the protective caps from the CM syringe and CM tube end.



ATTENTION!

Risk of damage to the syringe and tube system!

When screwing on the tube system with too much force you may damage the Luer Lock thread and therefore make the syringe and tube system unusable. Therefore do not overtighten the Luer Lock thread.

- Screw the tube system onto the CM syringe with approx. one half-turn.
- Repeat the steps for the NaCl side.
- Hang the CM and NaCl bottle with the opening downwards on the bottle holder.

In the next steps connect the tube system to the CM bottle.

When using a tube system with inline drip chamber on the CM side:

- Remove the protective cap from the spike of the drip chamber.
- Press the spike into the septum of the CM bottle.
- Open the ventilating flap on the spike of the drip chamber.
- Briefly press the drip chamber together twice to fill it roughly half-full with contrast medium.

When using a tube system with inline drip chamber on the CM side and Scanbag:

- Connect the tube system to the Scanbag as described in the instructions for use of the Scanbag manufacturer.
- Briefly press the drip chamber together twice to fill it roughly half-full with contrast medium.

- Repeat the above steps on the NaCl side in order to connect the tube system to the NaCl bottle.
- Move the pistons of the syringes forward, fill the syringes with contrast medium and saline solution, vent the tube system as described in the instructions for use of the injector.
- Immediately before the examination of the patient, connect the patient line to the tube system and vent the patient line.

Post-examination work

- Remove the syringes and tubes as described in the instructions for use of the injector.
- Properly dispose of all consumables in accordance with the regulations on waste disposal and hygiene applying to the operator.