

CHIRALINE

Instruction for Use Extension Line for Single Use

- Description:** Extension line for single use. Sterile, Non-toxic, Non-pyrogenic.
- Indication for Use:** Intended use to connection and extension infusion or transfusion sets for administration liquids or blood into the circulation system by using of intravenous catheter and cannula.
- Precautions:** Always check for leaks after changing the connection.
- Cautions:** Dispose of the extension set safely, so that nobody can prick or injure themselves on it;
Discard the set after each use;
Do not clean or re-sterilize;
This device remains sterile until the package is opened or damaged;
Do not use if the sterile package has been opened or damaged;
Never use if any part is disconnected or if protective cap is disconnected.
- How to use:** Open the individual package;
Connect proximal Luer connector to infusion syringe and fix it;
Fill the line with solution. Make sure, that the line is patent and there are no air-bubbles in the infusion system;
Connect distal Luer-lock connector with vein catheter or injection needle;
Perform the infusion according to routine method.

Used symbol on blister:

 REF	Product reference		For single use only	 STERILE EO	Sterilised by Ethylene oxide
 LOT	Batch/Lot Number		Do not use if unit package is damaged	 PHT DEHP	With content or presence phthalates
	Date of Manufacturing		Keep away from sunlight		
	Use by/Expiry date		Keep away from rain		
	Manufactured by		Pyrogen free		
	See instruction for use		Temperature limitation		

- Re-sterilization:** Product is not intended for re-sterilization. Manufacturer prohibits re-sterilization.
- Reuse of product:** Product is not intended for reuse. Product intended to be used once only for a single patient. Manufacturer prohibits reuse. Because when reuse is not guaranteed sterility and purity of the product (implication - contamination, infection, injury of patient).
- Dangerous substances:** If unit package is marked with symbol „PHT-DEHP“ product contains substances called dangerous. Tubing is a part of extension set which contains dangerous substance. According external analysis in independent laboratory the tubing contains substance DEHP = bis (2-ethylhexyl) phthalate in average 26,5wt%.

DEHP has been used as a plasticizer in medical devices such as intravenous tubing and bags, catheters, dialysis bags and tubing, and blood bags and transfusion tubing, and air tubes. For this reason, concern has been expressed about leachates transported into the patient, especially for those requiring extensive infusions, e.g. newborns in intensive care nursery settings, haemophiliacs, and kidney dialysis patients. According to the European Commission Scientific Committee on Health and Environmental Risk (SCHER), exposure to DEHP may exceed the tolerable daily intake in some specific population groups, namely people exposed through medical procedures such as kidney dialysis.