CODAN

- de Allgemeiner Benutzerhinweis
- en General user information
- fr Informations générales pour l'utilisateur
- sv Allmän användarinformation
- pt Informações gerais para utilizadores
- nl Algemene gebruiksinstructies
- da Generel brugerinformation
- it Informazioni generali per l'utilizzatore
- no Generell brukerinformasjon
- es Información general para el usuario

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CE 0123

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en

General user information

for single use products in sterile packaging

Please read this information carefully before use.

Warnings and cautions

- This product is to be used by qualified medical personnel only
- This product is for single use only. Do not re-sterilise and/or re-use
- Do not use if the package is open or damaged
- Re-tighten closure plugs before use
- Do not use if protection caps are displaced
- Stress cracks could appear when used for a longer time together with solutions based on alcohol and lipids
- For administration of blood and blood components, check suitability of infusion pump before application
- For disconnectable connections, check tightness before use
- If equipped with an orange protection cap (vented), replace it with a closure plug (non-vented)
- Observe the medication manufacturer's instructions for use regarding incompatibility and the present Summary of Product Characteristics
- When applied for infusion, use fluid filter < 20 µm (according to EN ISO 8536)
- Accepted good hygiene measures and working practices should be followed at all times
- The used product has to be disposed of correctly. Specially marked containers should be used necessary. Local regulations must be observed

Re-use warnings

The re-use of the product may cause unpredicted health risks! A used product is a potential carrier of pathogens, which means a health hazard to the patient and the spreading of infectious germs within the health care facility. Reprocessing of used products compromises safety. The manufacturer cannot be held responsible for the sterility assurance of re-used products within the health care facility.

Pressure **Compatible for use under pressure and gravity - according to EN ISO 1135 & EN ISO 8536**	**Gravity** **Compatible for use under gravity only - according to EN ISO 1135 & EN ISO 8536**
EN ISO 15223 **Non-pyrogenic** Indicates a medical device that is non-pyrogenic.	ISO 7000 **Contains or presence of** Indicates the presence of identified product or substance.
EN ISO 15223 **Do not use if package is damaged** Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 7000/EN 60416 **Does not contain or no presence of** Indicates the no presence of identified product or substance.
EN ISO 15223 **Drops per millilitre** Indicates the number of drops per millilitre.	EN 15986 **Contains or presence of Phthalates** Indicates the presence of identified phthalate.
EN ISO 15223 **Liquid filter with pore size** Indicates an infusion or transfusion system of the medical device that contains a filter of a particular nominal pore size.	EN ISO 15223 **One-way valve** Indicates a medical device with a valve that allows flow in only one direction.
EN ISO 15223 **Do not re-use** Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 7000 **Pump, liquid pump**
EN ISO 15223 **Catalogue number** Indicates the manufacturer's catalogue number so that the medical device can be identified.	EN ISO 15223 **Non-sterile** Indicates a medical device that has not been subjected to a sterilization process.
EN ISO 15223 **Batch code** Indicates the manufacturer's batch code so that the batch or lot can be identified.	EN ISO 15223 **Sterilized using ethylene oxide** Indicates a medical device that has been sterilized using ethylene oxide.
EN ISO 15223 **Date of manufacture** Indicates the date when the medical device was manufactured.	EN ISO 15223 **Sterilized using irradiation** Indicates a medical device that has been sterilized using irradiation.
EN ISO 15223 **Manufacturer** Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	EN ISO 15223 **Use-by date** Indicates the date after which the medical device is not be used.

EN ISO 15223 **Humidity limitation** Indicates the range of humidity to which the medical device can be safely exposed. (e.g. between 30 % and 60 %)	EN ISO 15223 **Fragile, handle with care** Indicates a medical device that can be broken or damaged if not handled carefully.
EN ISO 15223 **Temperature limit** Indicates the temperature limits to which the medical device can be safely exposed. (e.g. between 15° C and 25° C)	EN ISO 15223 **Keep away from sunlight** Indicates a medical device that needs protection from light sources.
EN ISO 15223 **Caution** Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	EN ISO 15223 **Keep dry** Indicates a medical device that needs to be protected from moisture.
EN ISO 15223 **Consult instructions for use** Indicates the need for the user to consult the instructions for use.	ISO 639-1 **Language information** (de = German, en = English, fr = French, sv = Swedish, pt = Portuguese, nl = Dutch, da = Danish, it = Italian, no = Norwegian, es = Spanish)
EN ISO 15223 **Authorized representative in the European Community** Indicates the authorized representative in the European Community.	**For intravenous use only** I.V. = latin: intra "into" and vena "vein".
Filling/storage volume Tube volume is defined in millilitre per meter with an optional pressure definition. (e.g. 7 ml/1 m (40° C) 9 ml/1 m (40° C/2 bar))	**Not for intravenous use** I.V. = latin: intra "into" and vena "vein".
AirStop Indicates a medical device with a special AirStop filter membrane.	**Do not use for more than 24 hours**
disconnectable **Disconnectable connections**	**Tube dimensions** Indicates the tube dimension of the medical device. OD = Outer tube diameter, ID = Inner tube diameter (referring to the main line)