95 | 10 | 10 | 95

10 | 135 | 155

Product quality information feedback sheet for customer

Dear customer:
The Huber Needles for single use with brand KDL manufactured according to standard. We follow the product standard, implemented "counting sampling method of lot-by lot" to identify quality status of each production lot, so all qualified products from our company has possibility of non-conforming risk for each product. So we honestly hope you could check our product before use according to "routine regulation of medical nursing" to erase product which is not qualified and avoid non-conforming single product. This work is also necessary and will bring benefit to patient. The erased product can be stored by you temporarily, we will responsible for exchange and compensation.

At the same time, to be honest, we hope you could issue your suggestion and comment for product quality, this will greatly improve our work, and improve product quality level.

Thank you for your cooperation

Zhejiang Kindly Medical Device Co.Ltd.

Annex: Comment and suggestion for the product quality of this lot:

Feedback issuer: Address: Date:

Please mail your comment, suggestion and feedback sheet together to our company, post fee will be paid back to you when we reply your feedback sheet

115

KDL®

Please read instruction for use very carefully and follow usage description Instruction for user of Huber Needles for single use

[Product name]
General name: Huber Needles for single use

[Product structure, type and model]
Product contains lock cover, female conical fitting, tubing, flow clip, tubing insert, Y-injection site, tubing, double-wing plate, needle handle, adhesive, needle tube, protective cap.
Models are identified as color of needle supporter in following sheet:

mm

Model	25G	24G	23G	22G	21G	20G	19G	18G
Outside diameter	0.5	0.55	0.6	0.7	0.8	0.9	1.1	1.2
Color	Orange	Mid-purple	Deep blue	Black	Deep green	Yellow	Milk	Pink

[Product usage and scope]
The Huber Needles is intended for infusion or injection of medicinal fluids into patients embedded with subcutaneous infusion port.

[Usage method]
Product is sterile by ETO, no pyrogen, non-toxic and sterile, can be used after openning primary package. Open primary package from peer gap, take out product and fix it onto infusion (transfusion) set, syringe or other Lure conical fittings of administration set. Then, according to clinical nursing science vein infusion operating method, the vein carries out a puncture on the human body.

[Cautions]
Product is forbidden to be used in case of primary package broken, protective cap removed, needle tip in abnormal status, exceeding expiry date. Take care when you open primary package to prevent product fall down to floor. Product is for single use only, do not use it repeatedly, Please discard it after usage.

[Warning]
This product is not stored and infusion of fat emulsion and other fat-soluble liquids and medicines. Prohibit the use of this product in polyvinyl chloride infusion is in compatible with the drug.
Re-use of single-use devices creates a potential risk of patient or user. It may lead to contamination and/or impairment of functional capability. Contamination and/or limited functionality of the device may lead to injury, illness or death of the patient.

[Storage and maintenance]
Product should be stored in clean room without corrosive gas and well ventilated.

[Identification, label and description]
On the package, "means for single use, " STERILE EO " means product sterilized by ETO.

[Validity]
Product validity is 5 years. Production lot number and expiry date are demonstrated on the package.

[Manufacturer]
Zhejiang Kindly Medical Devices Co., Ltd.
Address: No.758, 5th Binhai Road,Binhai,Industrial Park,Longwan District,325025
Wenzhou, Zhejiang Province,PRC
Tel: 0086-577-86372777 Fax: 0086-577-86374972

[Representative]
Shanghai International Holding Corp. GmbH(Europe)
Address: Eiffestrasse 80, 20537 Hamburg Germany Tel：0049-40-2513175 Fax：0049-40-255726

[Date of revision]
2019-04-21

115

描 图

旧底图总号

底图总号

日期	签字

技术要求

1、说明书文字、图案按图制版，线条美观；
2、本说明书为双面印刷；
3、说明书采用蓝色（PANTONE 287C）油墨印刷。

标记	处数	更改文件号	签 字	日 期

设计		工艺	
制图		标准化	
校对		批准	
审核		日期	

KDL一次性使用胸腔针 说 明 书

105克铜板纸

SM.CE.13

图样标记	数量	重 量	比 例
S A B			

共 张 第 张

浙江康德莱医疗器械股份有限公司