Design ValidationReport for CVC Kits

(Model CVC-01, CVC-02, CVC-03, CVC-04)

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Revision History

Revision	Description of change	Date
A.0	First release	30/11/2017

1 Test purpose

The purpose of this study was to provide documented evidence that the central venous kits (Models: CVC-01, CVC-02, CVC-03, CVC-04) could meets the user's needs and requirements as evidenced by the testing and/or activities performed on finished devices.

2 Responsible personal and responsibility

Name	Title	Responsibility scope
Dai Wei	R&D Manager	Protocol discussion and review
Tu Yinchun	Manufacture Manager	Protocol discussion and review
Qiu Lijuan	RA engineer	Regulatory standards analysis
Zuo Chao	QA Manager	Lead and organize product design validation and draft design validation protocol.
Luo Youcheng	Test engineer	Responsible for simulated tests.

3 Reference

3.1 Shunmei Medical Risk Management File (SM-FXGL-CVC-02)

3.2 Design Requirement Specification for CVC kits (SM-DRS-CVC)

3.3 Design Verification for CVC kits (SM-DVP-CVC)

3.4 Design Validation Protocol for CVC kits (SM-DVaP-CVC)

3.5 ISO 780:2015, Packaging -- Distribution packaging -- Graphical symbols for handling and storage of packages

3.6 ISO 2859-1:1999, Sampling procedures for inspection by attributes -- Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

3.7 ISO 11135:2014, EO sterilization validation and routine control of medical devices

3.8 BS EN ISO 8536-4:2013, Infusion equipment for medical use -- Part 4: Infusion sets for single use, gravity feed

3.9 ISO 9626:2016, Stainless steel needle tubing for the manufacture of medical devices -- Requirements and test methods

3.10 ISO 10555-1:2013, Intravascular catheters -- Sterile and single-use catheters -- Part 1: General requirements

3.11 ISO 10555-3:2013, Intravascular catheters -- Sterile and single-use catheters -- Part 3: Central venous catheters

3.12 ISO 11070:2014, Sterile single-use intravascular introducers, dilators and guidewires

4 Sample Configuration

All parts used to manufacture the test samples must meet the manufacturing requirements. All equipment used during the manufacture and evaluation of these test samples must be properly calibrated. All production personnel must be properly trained. Any deviations to these procedures must be documented and agreed to by representatives from product development, quality, and manufacturing.

4.1 CVC Kit

Final CVC Kit which have been sterilized are required for characterization and reliability testing. These devices will be placed within an APET plastic tray and TYVEK 1073B paper, sealed, and sterilized via two (2) ethylene oxide (EO) cycles.

4.2 Sample Configuration

For all CVC kit configurations, test units will be tested as shown in table 1.They cover a whole range of the products and representing the worse case.

Table 1, CVC Kit Test Configurations

CVC		Introducer Needle	Guide Wire	Dilator	Kit Lot.	Build Quantity	Required Quantity per protocol
Single Lumen	8F, 30cm	18G	0.89mm	8Fr	SM617461	10	≥10
Single Lumen	24G, 20cm	21G	0.30mm	4Fr	SM617461	10	≥10
Double Lumen	4F, 13cm	20G	0.36mm	4Fr	SM617461	10	≥10
Double Lumen	12F, 30cm	18G	0.97mm	12Fr	SM617461	10	≥10
Triple Lumen	4F, 30cm	20G	0.36mm	4Fr	SM617461	10	≥10
Triple Lumen	12F, 30cm	18G	0.97mm	12Fr	SM617461	10	≥10
Quad Lumen	8.5F, 30cm	18G	0.89mm	9Fr	SM617461	10	≥10

4.3 Manufacture

4.3.1 Assembly

The catheters were assembled per the sequence described on their appropriate procedures and all lot specific information and traceability were recorded.

4.3.2 Packaging

All catheters were sealed within APET plastic tray and TYVEK 1073B paper and packaged sufficiently to ensure that they were damaged during transport. The packaging methods and components were documented.

4.3.3 Sterilization

All test specimens, once assembled, were subjected to two (2x) ethylene oxide sterilization cycle (the first sterilization LN is 17111311 and the second sterilization LN is 17112111) using the process currently validated for CVC kit.

4.4 General Test

4.4.1 Visual Inspection (n=all)

All CVC kitswere inspected at 2.5x to verify that the catheters and accessories was free from extraneous matter, surface defects, and any obvious drops, and the tip of the catheters is smooth, rounded, tapered or similarly finished.As for multilumen catheters, all catheters were inspected to verify that each lumen can be identified as specification.

Acceptance Criteria:

The CVC and accessories must be free of extraneous matter, surface defects, and any obvious drops.

The CVC and accessories shall be free of cracks, breaks, rough edges, burrs, and any abnormal coloration.

The tip of catheter and/or accessories should be smooth, rounded, tapered or similarly finished.

As for multilumen CVC, each lumen shall be identified as specification.

The needle point shall appear sharp and free from feather edges, burrs, and hooks.

The outer surface of effective length of introducer needle should be clean and have no impurities.

Result: Pass

All CVC kits were free of extraneous matter, cracks, breaks, rough edges, burrs and any abnormal coloration. The tip of catheter and accessories were smooth, rounded, tapered or similarly finished. As for multilumen CVC, each lumen could be identified as specification. The needle point appeared sharp and free from feather edges, burrs, and hooks.The outer surface of effective length of introducer needle was clean and had no impurities.

4.5 In-vitro Design Validation Tests

The following testing was conducted to confirm CVC kit meets the user's needs and requirements as evidenced by the testing and/or activities performed on finished devices.

4.5.1 Simulated Use (CVC kit; n=10pcs/configurations)

A total of ten (10) pcs CVC kits per each configuration per Table 1were subjected to simulated use testing. Each device was prepared for use according to the IFU. The CVC kits have been tested according to following steps:

a. The scalpel should be convenient to take to cut the skin of puncture site, if used.

b. The syringe can be well connected with introducer needle to flushing dilator, central venous catheter, etc., without obstruction, and/or to inject liquid. And the mark on the syringe is clear and volume is proper.

c. The introducer needle tube should be straight, the surface is smooth, no burs and flaking, or other defects; the tip should be sharp to conveniently punch into the vessel. And the connector of needle should be compatible with the syringe for injection or flushing, etc., no leakage.

d. The guide wire should be compatible with the introducer needle, can be inserted smoothly to the targeted site without kinking, twist, or distortion under the guidance of advancer of guide wire. And the mark(if has) is clear to ensure that the physician can be judge the insertion length and inserted site.

e. The introducer needle can be smoothly withdrawn from the guide wire without influence to the inserted guide wire. After withdraw and visual inspection, the introducer needle shall be still complete.

f. The dilator shall be compatible with the guide wire and can be inserted through the guide wire to dilate the puncture vessel. And it can be withdrawn smoothly without influence to guide wire. After withdraw and visual inspection, the dilator shall be still complete.

g. The CVC shall be compatible with the guide wire and can be inserted smoothly to the targeted site along the guide wire.

h. After CVC insertion, the guide wire can be withdrawn smoothly without influence to CVC, and the guide wire is complete, no deformation after visual inspection.

i. The injection cap can be well connected with the CVC.

j. The catheter clamp can well fix the CVC and keep the CVC in the original position and easy to suture with patients' skin during operation.

k. After the fixation of CVC, the connection parts of CVC and connection part between CVC and injection cap shall be leak-proof for infusion. And the injection cap can be easily puncture to connect with joint use device. And liquid can flow through CVC smoothly and the device can be used for infusion, central venous pressure monitoring and blood sampling during operation.

After the testing, all test devices were inspected in 20X microscope and the results were documented.

Acceptance Criteria:

All individual devices shall be compatible with corresponding connecting device.

There is not any resistance while inserting and/or withdrawing the devices.

There is not any damage after the testing.

Result: Pass

All individual devices, including CVC catheter, guide wire, dilator, introducer needle, syringe and etc, were compatible with corresponding connecting device. All test devices had subjected to have the simulated tests successfully from step a to step k as follows.

a) The scalpel was convenient to take.

b) The syringe was well connected with introducer needle to flushing dilator, central venous catheter, etc., without obstruction, and/or to inject liquid. And the mark on the syringe was clear and volume was proper.

c) The introducer needle tube was straight, the surface was smooth, no burs and flaking, or other defects; the tip was sharp to conveniently punch into the vessel. And the connector of needle was compatible with the syringe for injection or flushing, etc., no leakage.

d) The guide wire was compatible with the introducer needle, can be inserted smoothly to the targeted site without kinking, twist, or distortion under the guidance of advancer of guide wire. And the mark(if has) was clear to ensure that the physician can be judge the insertion length and inserted site.

e) The introducer needle was smoothly withdrawn from the guide wire without influence to the inserted guide wire. After withdraw and visual inspection, the introducer needle was still complete.

f) The dilator was compatible with the guide wire and was inserted through the guide wire to dilate the puncture vessel. And it was withdrawn smoothly without influence to guide wire. After withdraw and visual inspection, the dilator was still complete.

g) The CVC was compatible with the guide wire and was inserted smoothly to the targeted site along the guide wire.

h) After CVC insertion, the guide wire was withdrawn smoothly without influence to CVC, and the guide wire was complete, no deformation after visual inspection.

i) The injection cap was well connected with the CVC.

j) The catheter clamp can well fix the CVC and keep the CVC in the original position and easy to suture with patients' skin during operation.

k) After the fixation of CVC, the connection parts of CVC and connection part between CVC and injection cap was leak-proof for infusion. And the injection cap was easily puncture to connect with joint use device. And liquid can flow through CVC smoothly and the device was used for infusion, central venous pressure monitoring and blood sampling during operation.

As above, allindividual devices were compatible with corresponding connecting device.And there is not any resistance while inserting and/or withdrawing the devices. There was not any damage on the test devices after the testing.

5 Conclusion

The CVC kit has successfully met the acceptance criteria required for the in-vitro design validation tests. The product design is considered validated to meet the user's needs and requirement for vascular applications.