

Nantong Boke Endo Medical Device Technology CO.,LTD.	Document No.: SVCE-09	Edition: A0	Page: 1/5
CE Technical Documentation	IFU	Effective Date: Jan-08-2018	



Disposable Suction Valve

Instruction for Use

Types:

BK-SA01, BK-SF06

Specification

Testing item		Specification
Package	Outer package	No damage, no pollution and well sealed
	Inner package	Appearance : Smooth seal and no leakage of seal
		Permeability test: well sealed
Packing Qty		In accordance with model requirements
Initial contaminating bacteria		No more than 100cfu/g
Sterility		Sterility assurance level SAL 10-6
Performance		Factory inspection report from the supplier

This product is manufactured in Class 100000 clean room, sterilized by ethylene oxide. The product is sterile.

Structure:

The composition of suction valve (BK-SA01)

Nantong Boke Endo Medical Device Technology CO.,LTD. CE Technical Documentation	Document No.: SVCE-09	Edition: A0	Page: 2/5
	IFU		Effective Date: Jan-08-2018

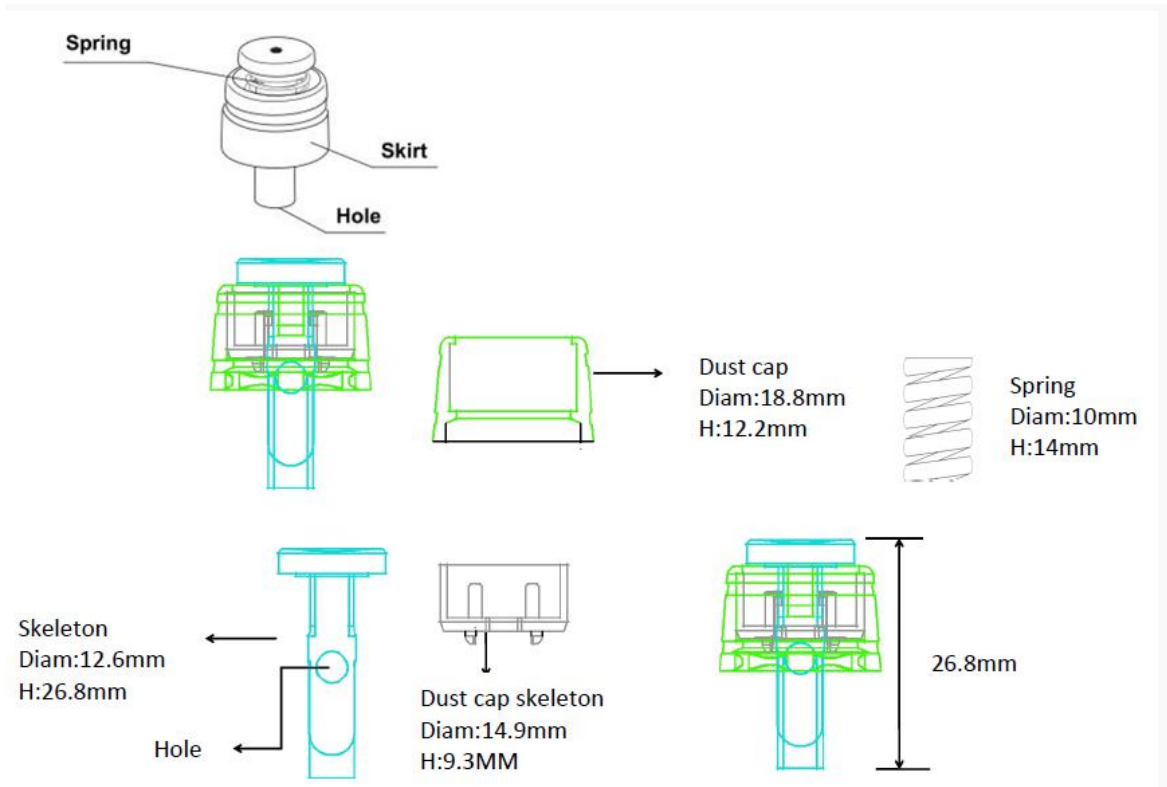


Figure 1

The composition of suction valve (BK-SF06)

Nantong Boke Endo Medical Device Technology CO.,LTD. CE Technical Documentation	Document No.: SVCE-09	Edition: A0	Page: 3/5
	IFU	Effective Date: Jan-08-2018	

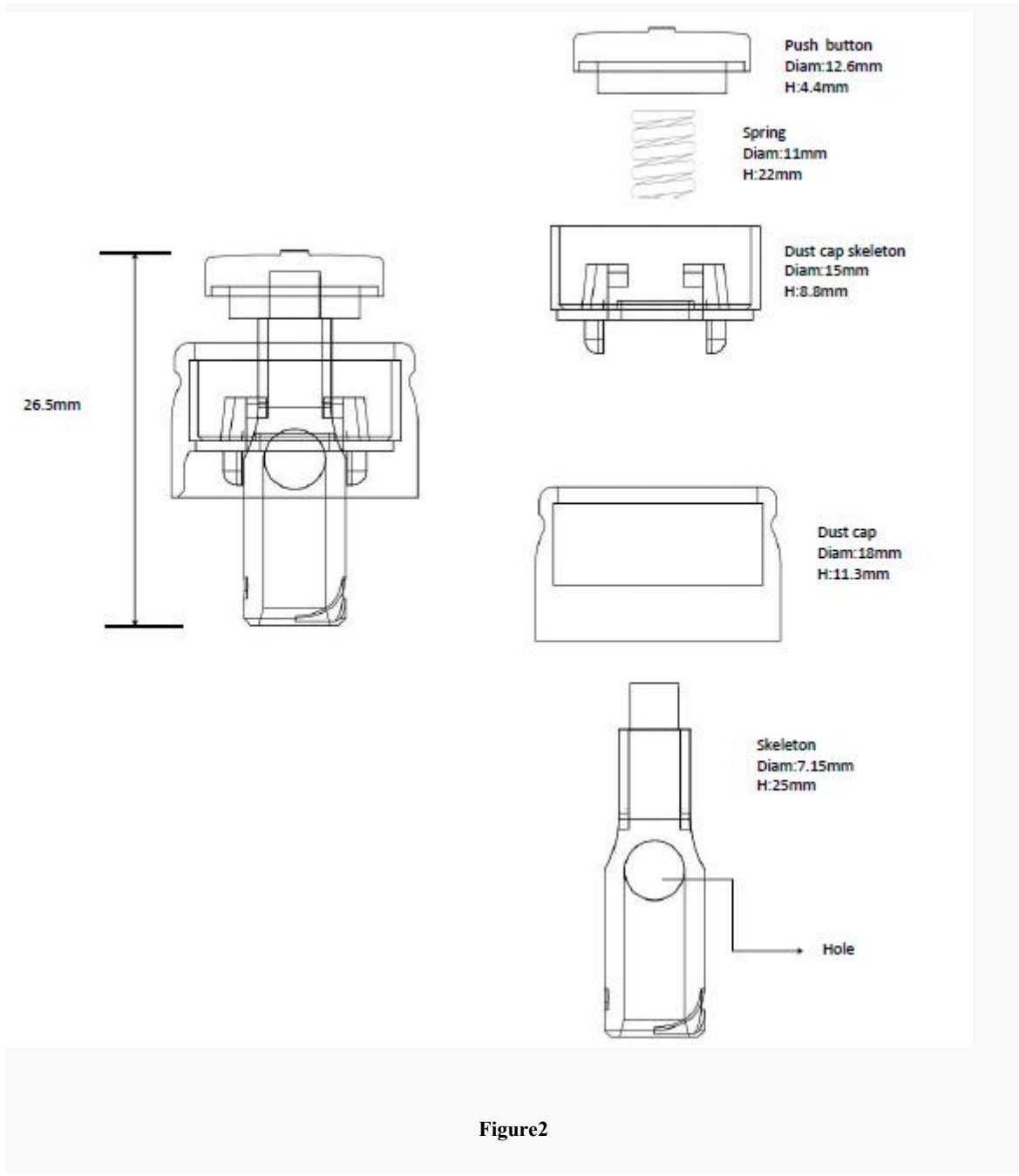


Figure2

Intended use

The product is used to control the suction function of an endoscope during GI endoscopic procedures.

Instruction for Use

- 1) Remove the suction valve from the tray.
- 2) Insert the suction valve into the suction cylinder of an endoscope (see Figure 1 above).
- 3) Twist valve slightly to seat in proper orientation within the cylinder.
- 4) Confirm that the valve fits securely and that there is no gap between the valve end cap and the endoscope.

Nantong Boke Endo Medical Device Technology CO.,LTD.	Document No.: SVCE-09	Edition: A0	Page: 4/5
CE Technical Documentation	IFU	Effective Date: Jan-08-2018	

Note: the valve should not be able to be rotated once it is fully inserted into the cylinder.

- 5) Actuate the valve by pressing and releasing a few times to confirm smooth function.

Note: Dipping in water may facilitate ease of use.

Contraindication

Contraindications include those specific to any endoscopic procedure.

Warning and Precautions

- 1) The product can be used after opening the seal. It is strictly forbidden to reuse it so as to prevent cross infection.
- 2) The product is strictly forbidden to use when the package is broken.
- 3) Make sure the holes in the air/water and suction valves are not clogged or blocked. (This could cause continuous air/CO2 flow, or inadequate suction.).
- 4) Check the product before use to make sure the package or the product itself is not damaged.
- 5) The product must be used by the medical professionals.

Shelf Life

Three years.

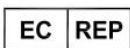
Product Disposal

After use, the products may be potential biohazards. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Symbol Description



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



Authorized representative in the European Community, Indicates the Authorized representative in the European Community



CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC



Date of manufacture, Indicates the date when the medical device was manufactured



Manufacturer, Indicates the medical device manufacturer, as defined in EU Directives 93/42/EEC



Use-by date, Indicates the date after which the medical device is not to be used



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

Nantong Boke Endo Medical Device Technology CO.,LTD.	Document No.: SVCE-09	Edition: A0	Page: 5/5
CE Technical Documentation	IFU	Effective Date: Jan-08-2018	



Do not use if package is damaged, Indicates a medical device that should not be used if the package has been damaged or opened



Sterilized using ethylene oxide.



Batch code, Indicates the manufacturer's batch code so that the batch or lot can be identified.



Fragile, handle with care, Indicates a medical device that can be broken or damaged if not handled carefully.



Keep away from sunlight, Indicates a medical device that needs protection from light sources.



Keep dry, Indicates a medical device that needs to be protected from moisture.



Reference, indicates the types



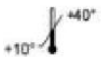
Read instructions prior to using this product



Latex free



Do not re-sterilize



Storage conditions: keep the device +10°C~+40°C



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