

Ningbo Medsun Medical Co., Ltd.

Lancing Device CE Technical Documentation

IFU of Lancing Device

CE002-11

Revision History

Current version	Issue date	Effective date	Previous version	Contents changed
02/00	2020-04-20	2020-04-20	01/00	Update according to MDR (EU) 2017/745

Approval Sheet

Performed by	Name	Signature	Date
Author	Lei Shi	Shi Lei	2020-04-20
Reviewer	Ping Liu	Liu Ping	2020-04-20
Approver	Zhicheng Chen	Chen Zhicheng	2020-04-20

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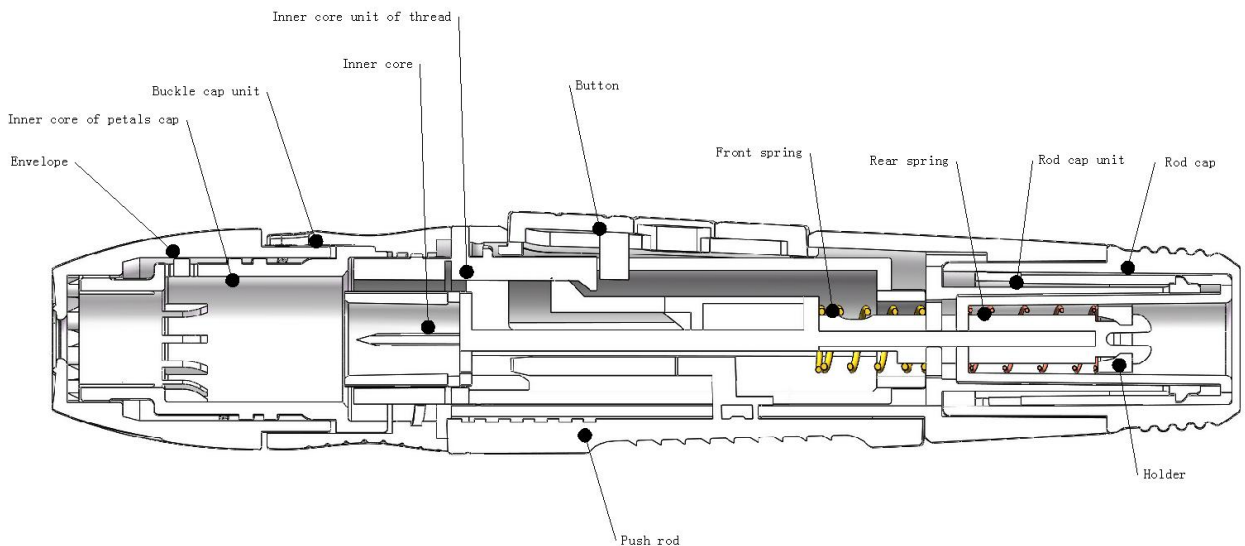
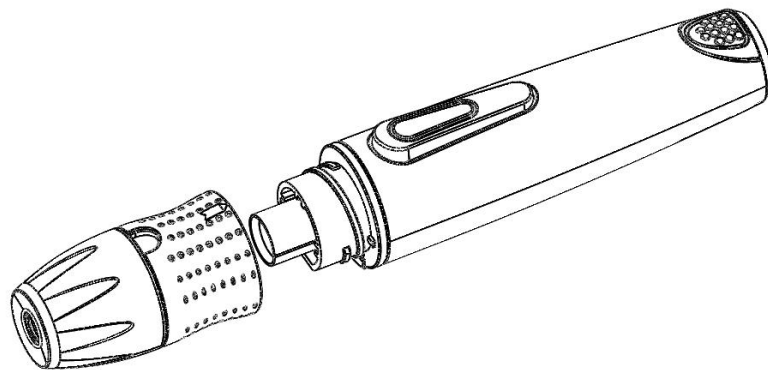
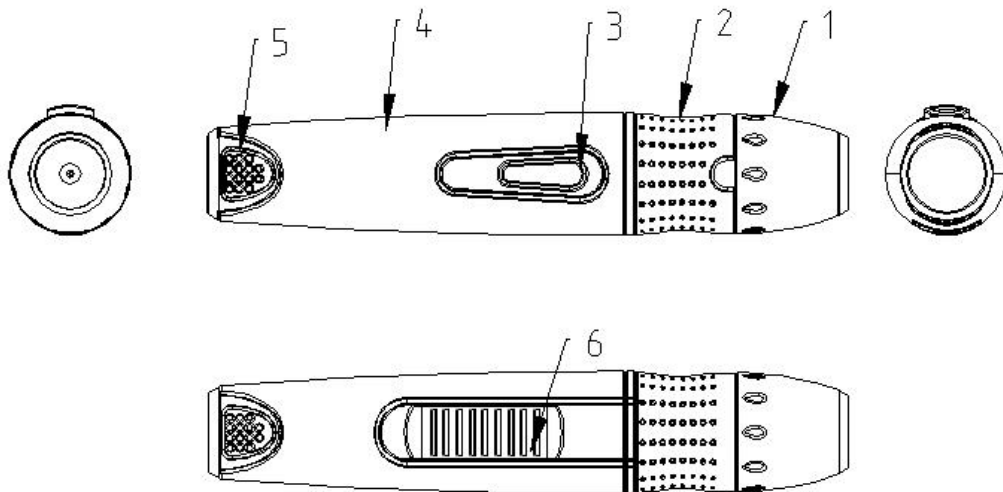
[Product Name]:



Lancing Device

[Specification and component]:

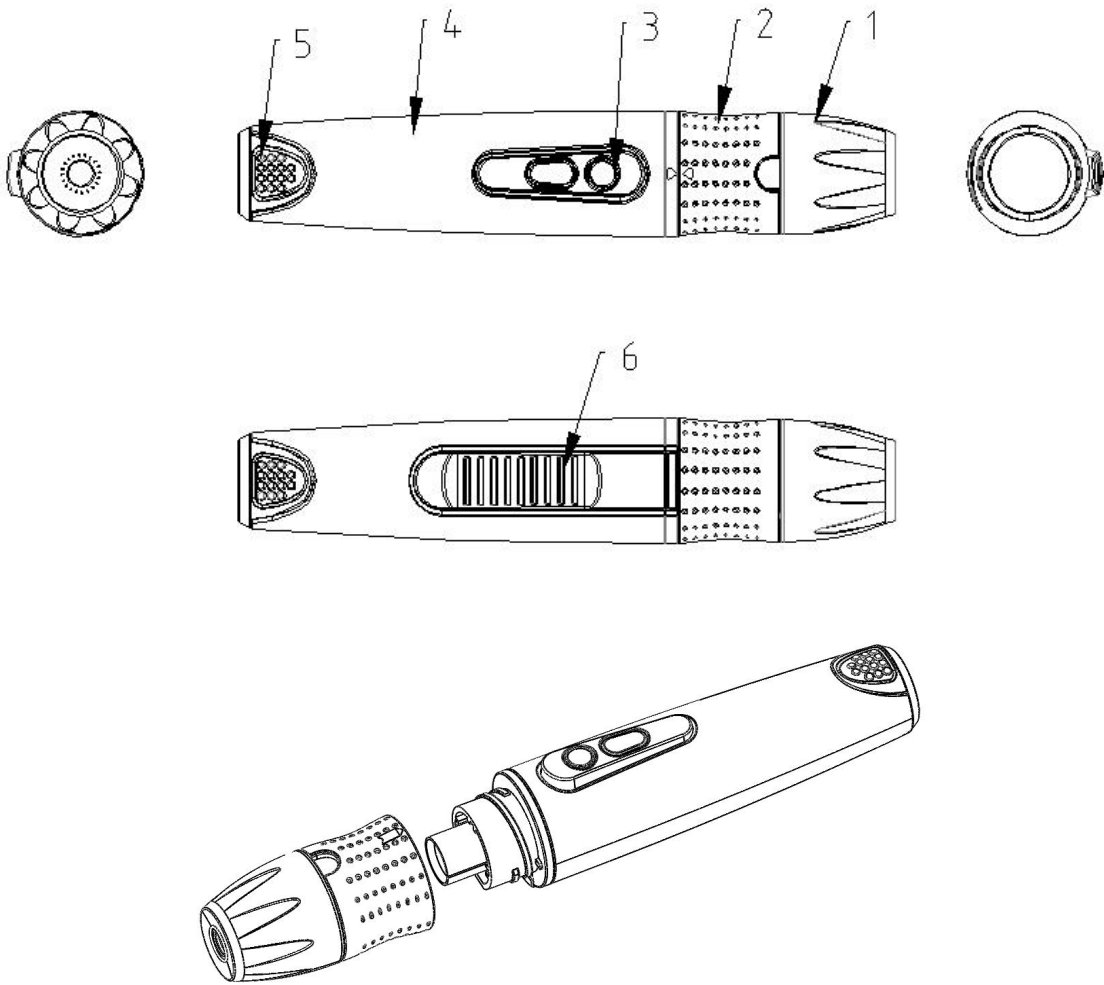
CX11A: Envelope, Inner core, Push rod, Rod cap unit, Rod cap, Holder, Front spring, Rear spring, Button, Cap, Inner core of cap, Threaded cap unit, Inner core unit of thread



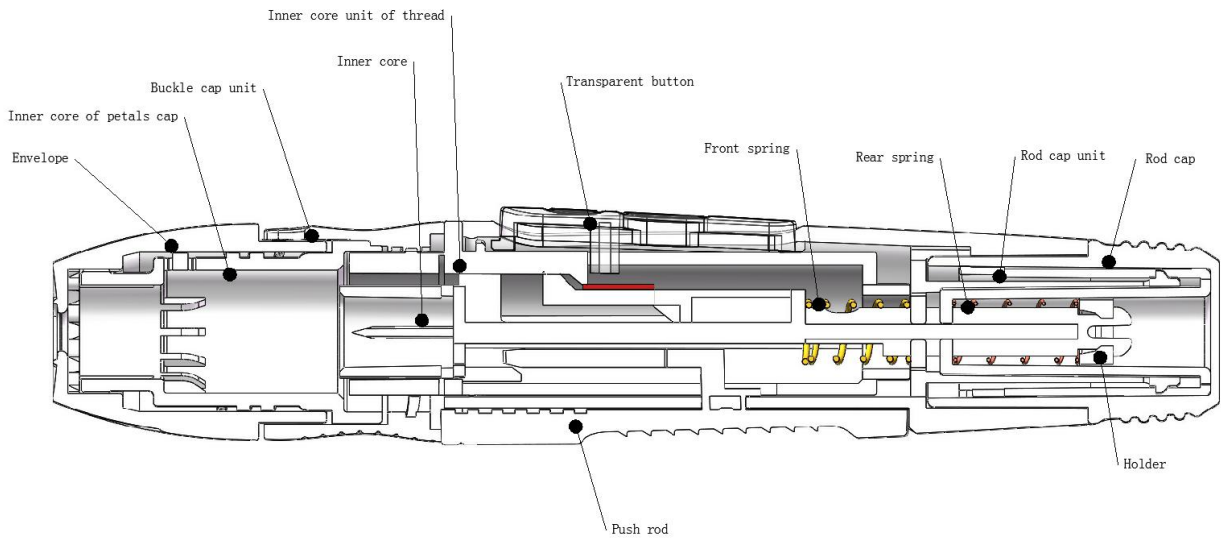
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Lancing Device (CX11-A)

CX11B1 Envelope, Inner core, Push rod, Rod cap unit, Rod cap, Holder, Front spring, Rear spring, Transparent button, Petals cap, Inner core of petals cap, Threaded cap unit, Inner core unit of thread

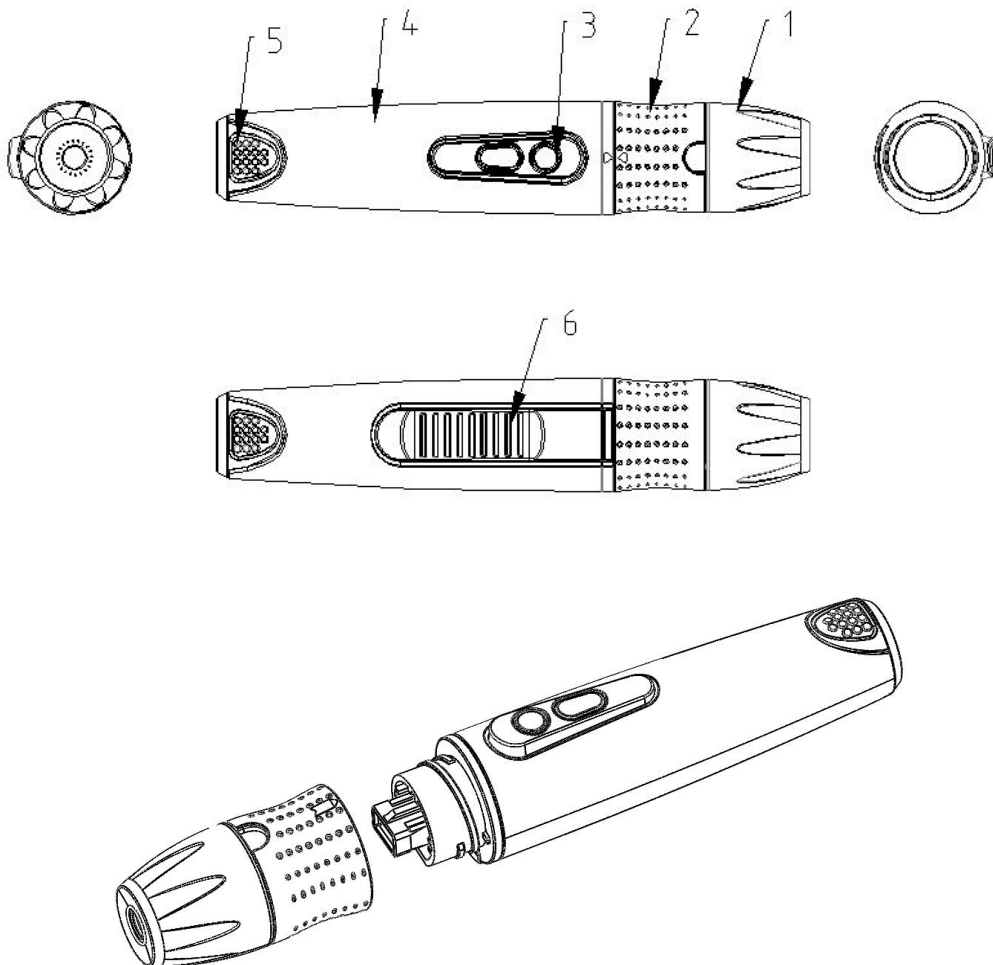


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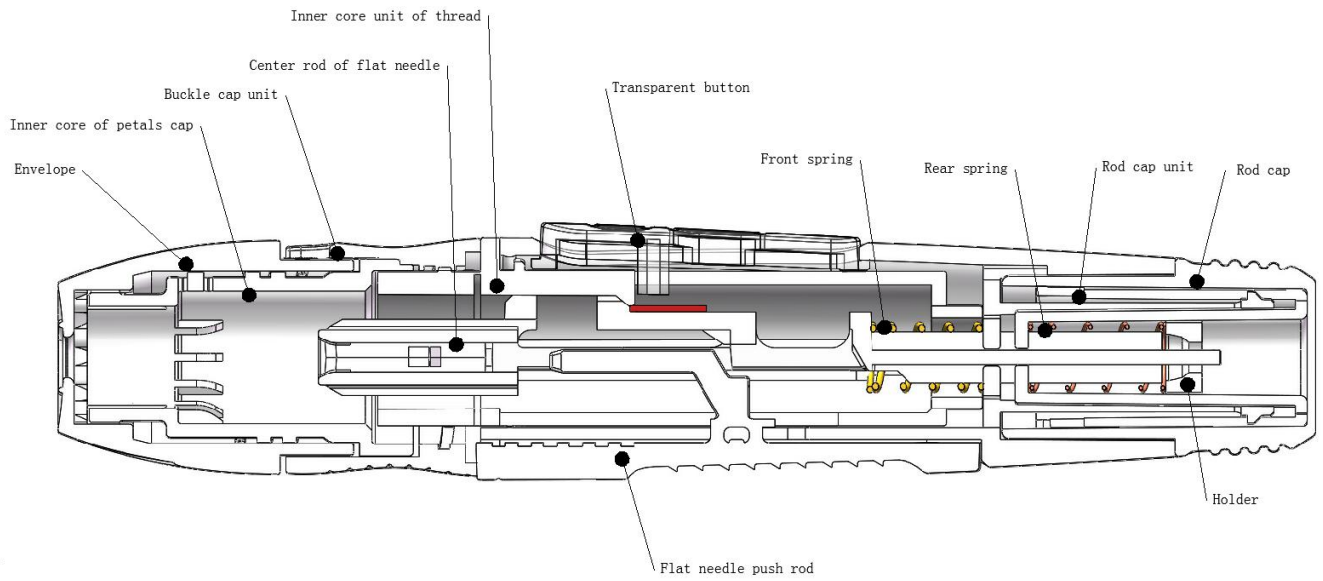


Lancing Device (CX11B1)

CX11B2 Envelope, Center rod of flat needle, Flat needle push rod, Rod cap unit, Rod cap, Holder, Front spring, Rear spring, Button, Cap, Inner core of cap, Threaded cap unit, Inner core unit of thread

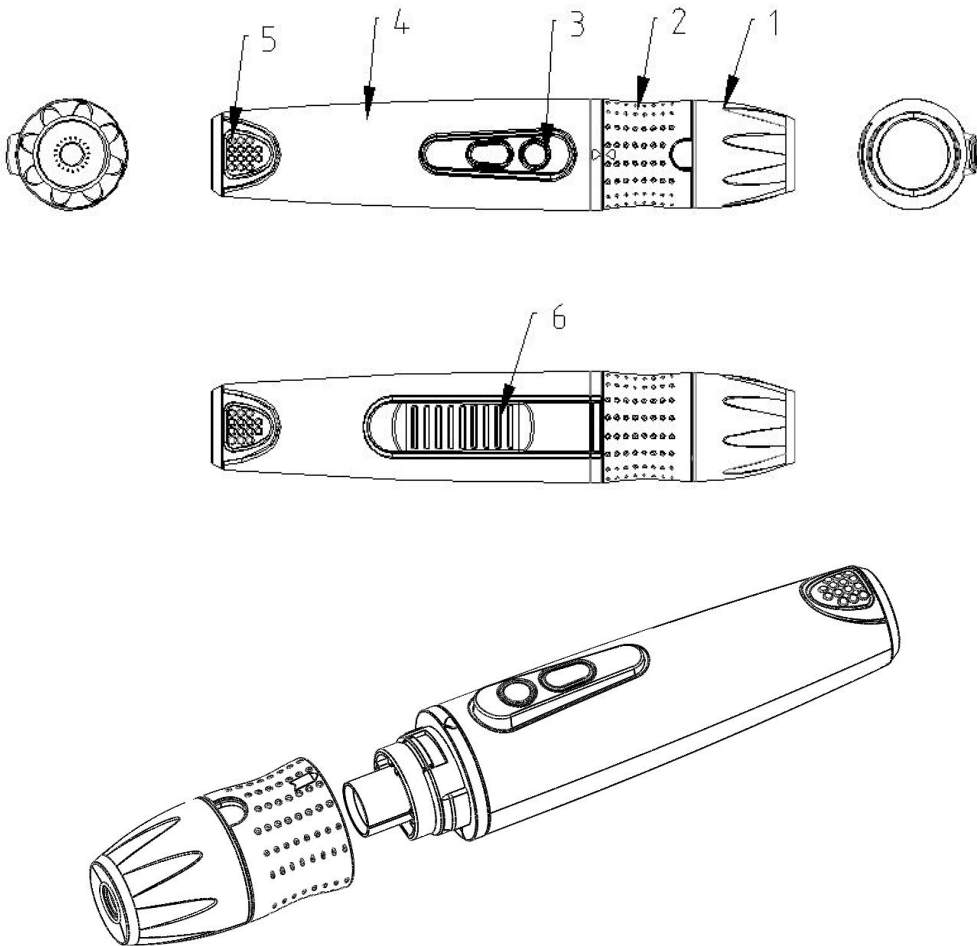


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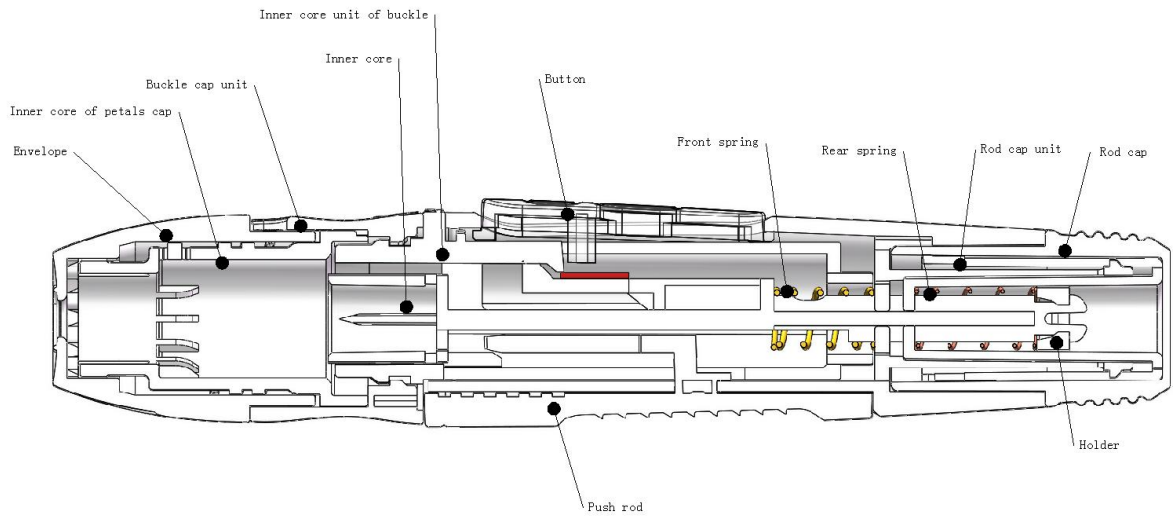


Lancing Device (CX11B2)

CX11C1 Envelope, Inner core, Push rod, Rod cap unit, Rod cap, Holder, Front spring, Rear spring, Button, Cap, Inner core of cap, Buckle cap unit, Inner core unit of buckle

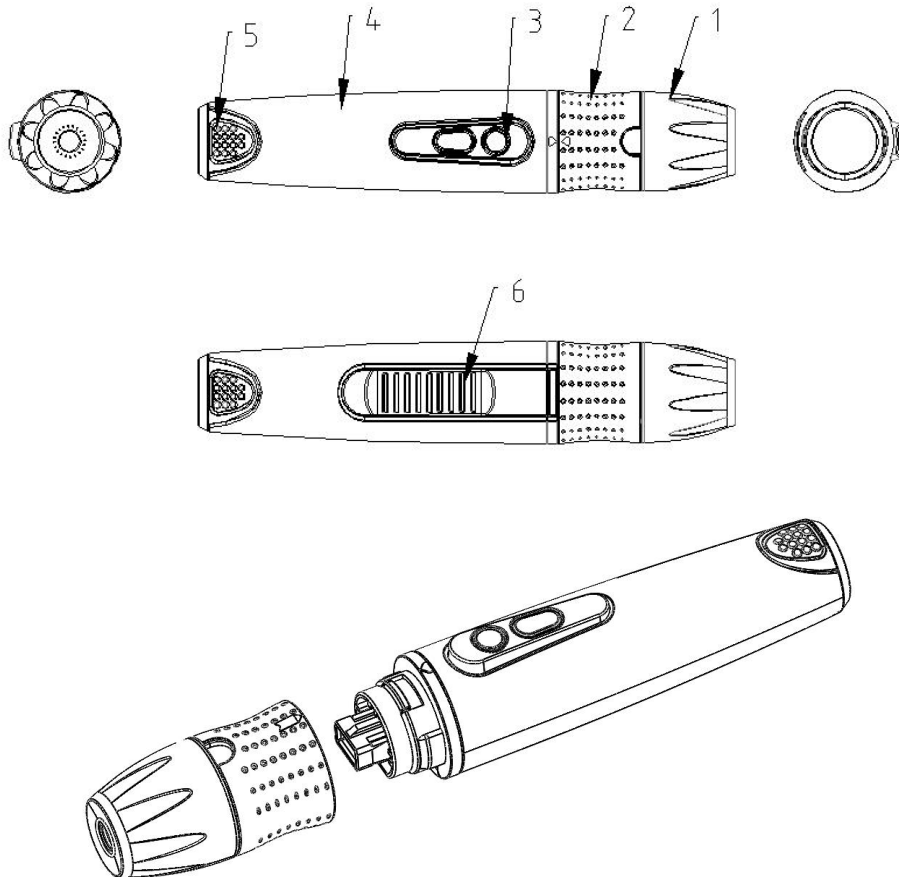


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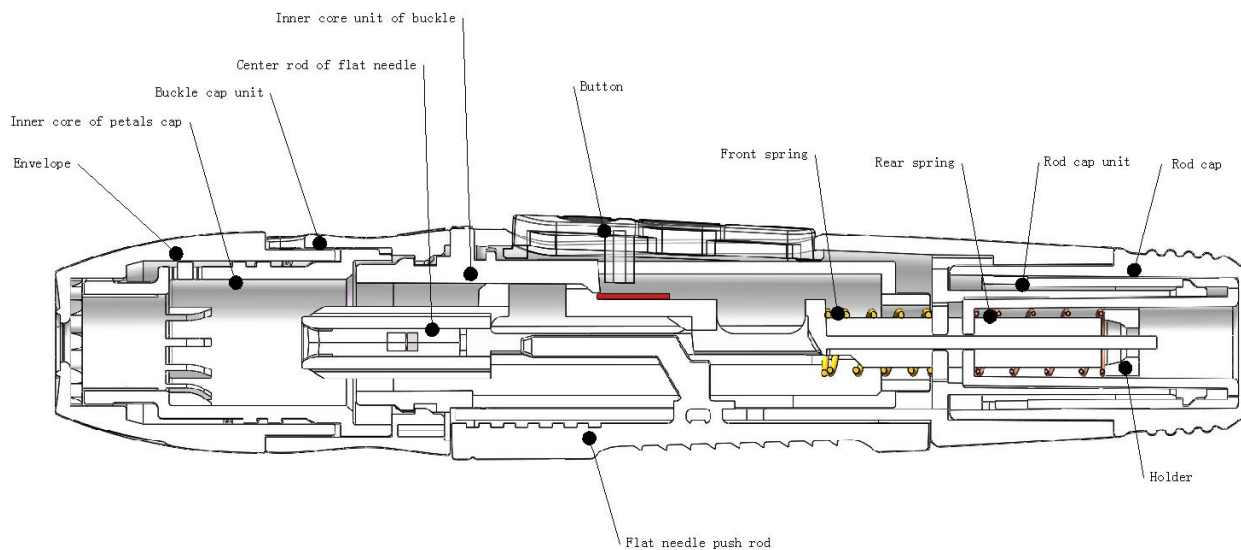


Lancing Device (CX11C1)

CX11C2 Envelope、Center rod of flat needle、 Flat needle push rod、 Rod cap unit、 Rod cap、 Holder、 Front spring、 Rear spring、 Button、 Cap、 Inner core of cap、 Buckle cap unit、 Inner core unit of buckle



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Lancing Device (CX11C2)

[Intended Use]:

Intended purpose: Lancing Device is used to collect capillary blood for clinical examination, together with disposable lancet.

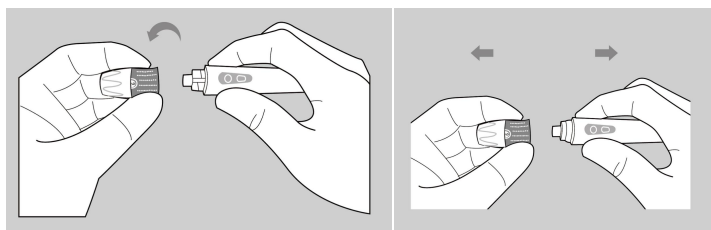
Intended position: Contact with patient's skin, and blood collection is usually finger tip.

Intended population: no specific, all gender, all races and all age.

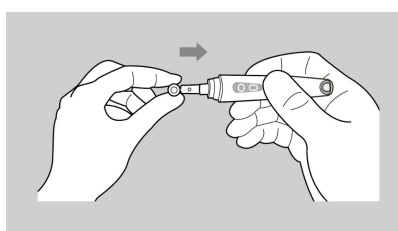
[The combination of the device with product]:

The combination of Lancing Device is disposable lancet.

[Operating Procedure]:

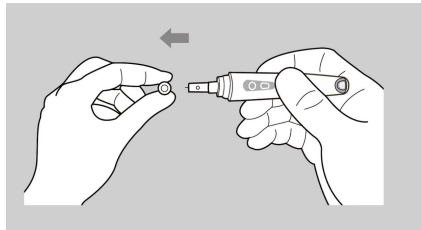


- 1) Rotate the cap for Model CX11-A and CX11-B or pull open the cap for Model CX11-C.

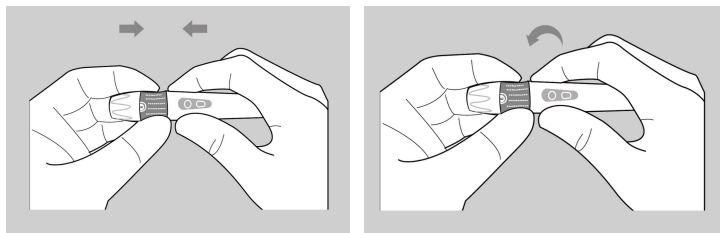


- 2) Insert a new lancet into the bottom of the holder.

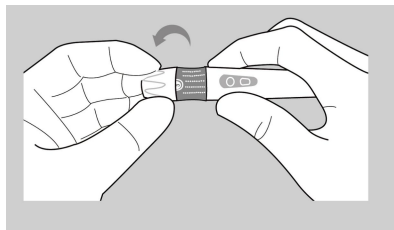
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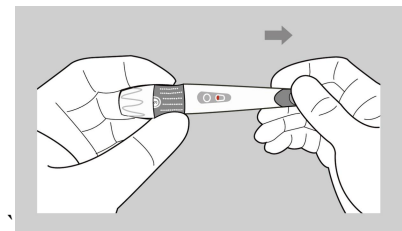
3) Rotate the protective cap of lancet until it falls off completely.



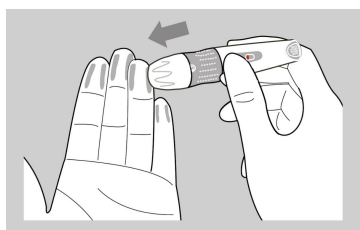
4) Rotate the cap tightly for Model CX11-A and CX11-B or push the cap tightly for Model CX11-C.



5) Rotate the cap to adjust the puncture depth of lancing device from deep to shallow. Rotate counterclockwise by 6→5.5→5→4.5→4→3.5→3→2.5→2→1.5→1. Since the skin thickness of human fingers is different, choose according to individual needs to reduce the discomfort of blood collection. We recommend depth 3 as the best depth.



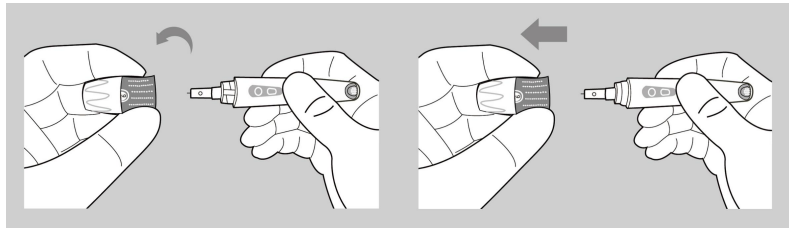
6) Hold the end of the lancing device, pull it back, release it after hearing the click, and then button displays red which means can prepare to collect blood.



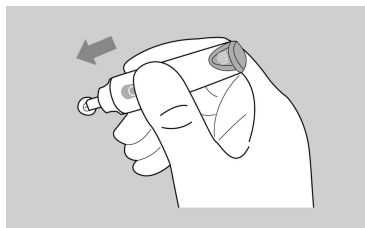
7) Point the cap of the lancing device at the blood collection position of the finger and press the

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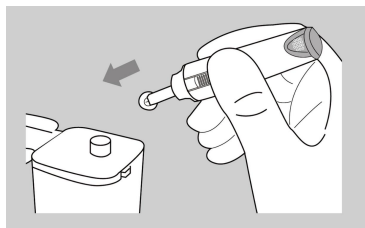
button to collect blood.



- 8) After the blood collection, rotate the cap for Model CX11-A and CX11-B or pull open the cap for Model CX11-C.



- 9) Insert the tip of lancet into the unscrewed cap to lancet.



- 10) Push the ejection button to discard the used lancet into special collection box for discarded sharp objects.

[Contraindications]:

No known contraindication.

[Caution]  :

- Lancing Device is only for personnel; never share it with other people.
- Before use, please clean the hands thoroughly to avoid infection.
- In order to get better blood samples, it is recommended to massage the blood collection site to increase blood circulation.
- Avoid sticking oil, dirt, debris and other liquids on the lancing device and lancets.
- Lancet only for single use, please do not re-use and discard it into special collection box for discarded sharp objects.



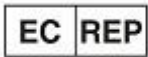










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- f) Please follow the steps as shown in the picture. Care should be taken in loading and unloading lancets to avoid puncture.

[Maintenance]:

- a) The product shall be prevented from extrusion;
- b) The packaged product should be stored in the room with relative humidity not exceeding 80%, no corrosive gases and good ventilation;
- c) The product shall be prevented from sunlight;
- d) The lancing device should be cleaned after use. Wipe the surface of the envelope, inner and outer surface of cap with 75% alcohol.

[Symbols]:

	Manufacturer		CE mark
	Authorised Representative in the European community		Batch code
	Caution		Date of manufacture
	Use by		Consult instructions for use
	Keep dry		Keep away from sunlight
	Upward		Handle with care
	Limit of stacking layers		

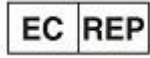


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