

Bruksanvisning Tvåkanals-spekulum



Varning och säkerhetsföreskrifter

Läs följande innan användning

WARNING! För att undvika och minimera risken för personskador och brand Se följande instruktioner.

1. Produkten är avsedd att användas till Digitalt Multi-instrument VOT-2
 2. Produkten är avsedd för att användas i kombination med utrustning som Gedoc tillhandahåller.
 3. Produkten är avsedd för engångsbruk och får inte användas flera gånger. Följ hänvisningar hur tvåkanalsspekulum ska användas innan användning i denna manual.
 4. Får ej användas i kontakt med eller i närheten av brandkällor eller v arma ytor.
 5. Följ hänvisning om transport/förvaring och driftförhållanden noga.
 6. Produkten får inte vara skadad eller sprucken innan användning.
 7. Produkten får inte användas till annat än som beskrivs.
 8. Produkten är avsedd att användas till undersökningar av utbildad vårdgivare till patienter. Ej avsedd för lekmän
-

1. INTRODUKTION



Läs alltid bruksanvisningen före användning.

1.1 ALLMÄN INFORMATION

Produkten är en medicinteknisk produkt med CE-märkning i enlighet med MDR (EU) 2017/745. Enligt detta regelverk skall tillverkaren rapportera alla olyckor och incidenter som involverar dennes produkter. All information angående våra produkter skall därför skyndsamt rapporteras till GEDOC AB.

1.2 AVSEDD ANVÄNDNING

Tvåkanals-spekulum är avsedd att användas på Digitalt multi-instrument VOT-2. Tvåkanals-spekulum är ett tillbehör (hållare) i kombination med avsedd utrustning.

1.3 AVSEDDA ANVÄNDARE

Produkten är avsedd att användas till undersökningar för utbildade vårdgivare till patienter.

1.4 AVSEDD ANVÄNDARMILJÖ

Produkten är avsedd att användas i vårdmiljöer inom Otoskopi.

1.5 BIVERKNING OCH RISKER VID ANVÄNDNING

Vid felaktig användning eller hantering kan följande biverkningar eller risker förekomma:

Lokal irritation i hörselgången. får ej komma i kontakt med hörselgången.

Obehag eller smärta vid införsel.

Risk för skada på hörselgångens slemhinna om spekulumet är skadat, deformerat eller används felaktigt.

Alla allvarliga händelser i samband med produkten ska rapporteras till tillverkaren omedelbart.

2. ANVÄNDNING



1. Tvätta händerna nogga och använd handdesinfektion innan användning.



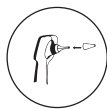
4. Använd tillbehör i främmande kropp kit eller annan utrustning som Gedoc tillhandahåller. Klart att använda för undersökning på patient.



2. Ta tvåkanals-spekulum (hållaren) från den förslutna påsen.



5. Ta av spekulum (örontratten) efter användning.



3. Sätt på spekulumet (örontratten) på kameramodulen för otoskopi hela vägen in. notera att tvåkanals-spekulum ej är avsedd för övriga kameramoduler.



5. Kassera det använda tvåkanals-spekulumet och sortera som plastavfall.

2.1 RENGÖRINGS- OCH HANTERINGSINSTRUKTIONER

Produkten är avsedd för engångsbruk och ska inte rengöras, steriliseras eller återanvändas på något sett. Återanvändning kan medföra risk för infektion, produktförsämring eller skada.

Använd inte tvåkanals-spekulum (hållare) om det är skadat.

2.2 KONTRAIKATIONER

Ska inte användas i följande fall:

- Allergi mot plast eller misstänkt överkänslighet.
- Tidigare trauma eller kirurgiska ingrepp i hörselgången där användning av spekulum kan orsaka ytterligare skada.

3. PRODUKTBESKRIVNING

Tvåkanals-spekulum av PLA medical grade plast. För engångsbruk för hygien och säkerhet. Passar till kameramodul för otoskopi i kombination med utrustning som GEDOC tillhandahåller.

4. Förvaring, transport & driftförhållande

Följ hänvisningar nedan.

Förvaringsförhållanden

Omgivningstemperatur

10°C till 30°C

Relativ luftfuktighet

Minimum 10% RH, Maximum 85% RH, Icke Kondensering

Atmosfäriskt tryck

Min 70 kPa, Max 106 kPa

Transportförhållanden

Omgivningstemperatur

10°C till 30°C

Relativ luftfuktighet

Minimum 10% RH, Maximum 95% RH, Icke Kondensering

Atmosfäriskt tryck

Min 70 kPa, Max 106 kPa

Driftförhållanden

Omgivningstemperatur

10°C till 30°C

Relativ luftfuktighet

Minimum 10% RH, Maximum 85% RH, Icke Kondensering

Atmosfäriskt tryck

Min 70 kPa, Max 106 kPa

5. MÄRKNING OCH SYMBOLFÖRKLARING

Förpackningen är märkta med produkt namn, antal, tillverkningsdatum, utgångsdatum, EAN-nummer/UDI-DI-PI, Lot nummer, ref-nummer, tillverkare.

6. ÖVRIG INFORMATION















6.1 ÖVRIG INFORMATION

förväntad livslängd på produkten är 5 år från tillverkningsdatum.

6.2 KÄLLSORTERING & ÅTERVINNING

Förpackningen och tvåkanals-spekulum sorteras som plastavfall.

5.1 SYMBOLFÖRKLARING

| | |
|---|--|
|  CE-märkt enligt Medical Device Regulation (EU) 2017/745 |  Läs bruksanvisningen |
|  CE-märkt enligt Medical Device Regulation (EU) 2017/745 |  Relativ luftfuktighet |
|  VARNING! |  Max/min temperatur |
|  För engångsbruk |  LOT nummer |
|  Ej steril |  Tillverkare |
|  Hållbarhetsdatum |  Tillverkningsdatum |
|  Artikelnummer |  Unique Device Identification |

KONTAKT

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mellan 08.00-16-00

Vi reserverar oss för eventuella felskrivningar

Disposable Biopsy Forceps

Product Specification

(Please read this manual carefully before operation)

Jiangxi Zhuoruihua Medical Equipment Co., Ltd.

December 2018

Dear user:

Thank you for using the products produced by our company. Please read

the product's " Product Specification" carefully before using this product, which will guide you to store and use this product correctly and effectively.

Table of Content

| | |
|---|-----------|
| I. Range of application and precautions | 3 |
| 1. Range | 4 |
| 2. Classification, naming and description of model specifications | 4 |
| 3. Technical indicators | 15 |
| 4. Basic matters for users to pay attention to | 15 |
| 5. Matters that users must pay attention to | 15 |
| 6. Inspection before using the product | 15 |
| 7. The mechanism of this product | 16 |
| 8. The working mechanism and environment requirements of this product.. | 16 |
| II. Operating procedures | 16 |
| 1. Preoperation check | 16 |
| 2. Operation | 16 |
| III. Storage | 17 |
| IV. Disposal of waste | 17 |
| Contact Information | 18 |

I. Range of application and precautions

1. Range

The disposable biopsy forceps are suitable for entering the natural cavity of the human body under a soft endoscope and clamping the living tissue. (The clamped living tissue is used for subsequent histological examination). The operation time is more than 1 hour and no more than 24 hours.

Contraindications:

1. Endoscopic contraindications;
2. Those who have not corrected the coagulation disorder.

2. Identification description

1) Product identification description



Batch number



See instructions



Production Date



Manufacturer



One-time use only



Cannot be sterilized



valid until



EO sterilization



Model



Do not use damaged

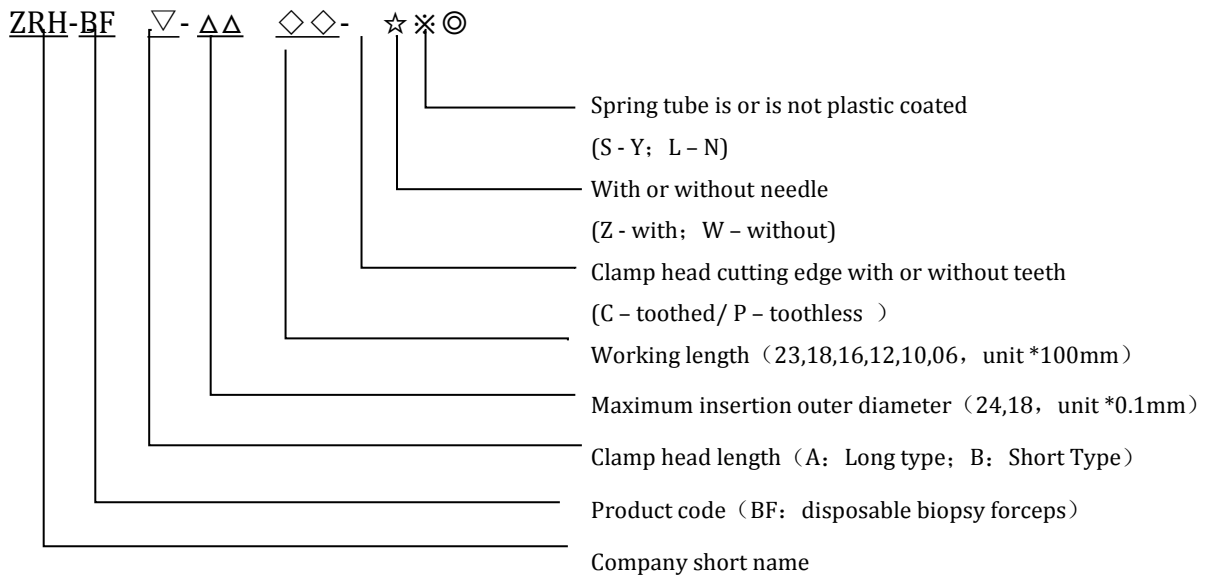


Avoid direct sunlight



Keep dry

2) Product naming rules



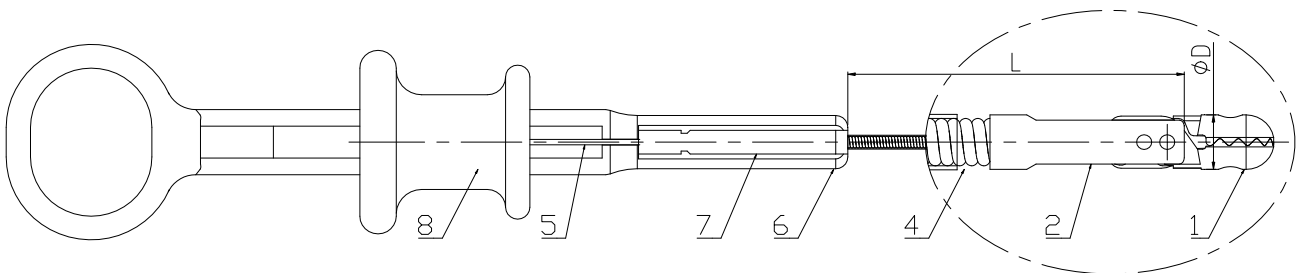
Example: ZRH is the company short name, BF is the product code of the disposable biopsy forceps, A means the long type clamp head, and 24 means the maximum insertion outer diameter is 2.4mm. 23 indicates that the working length is 230 cm, C indicates that the cutting edge of the jaw has teeth (i.e. toothed), Z indicates that there is a needle, and S indicates that the spring tube is plastic coated.

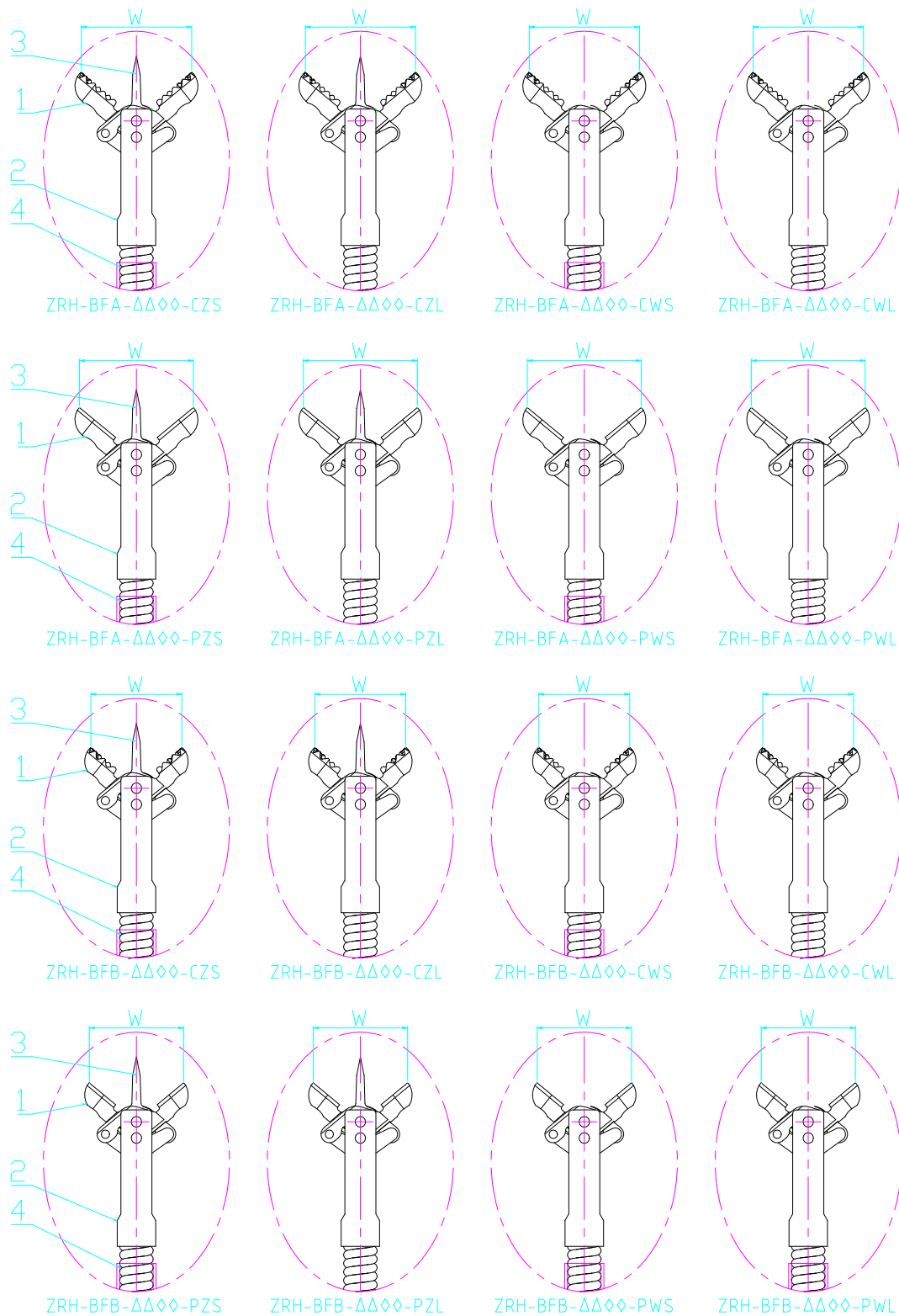
3) Product model and specifications

The type of disposable biopsy forceps is distinguished by: length of the clamp head (A long, B short), cutting edge shape of the clamp head (C toothed, P toothless), with or without needle (Z has a needle, W has no needle), the spring tube has no plastic (S is plastic coated, L not plastic coated), to distinguish.

The size of the disposable biopsy forceps is differentiated by the maximum insertion diameter (ΦD) and working length (L).

The structure and type specification of the disposable biopsy forceps are shown in Figure 1-1.





$\Delta\Delta = 24/18$ (maximum insertion outer diameter ΦD), $\diamond\diamond = 23/18/16/12/10/06$ (Working length L)

1. Clamping head, 2. Clamping seat, 3. Needle (or no needle),

4. Spring tube (or plastic-coated spring tube), 5. Catheter 6. Handle, 7. Bead, 8. Slip ring

Figure 1-1: Schematic diagram of the structure and type specifications of the disposable biopsy forceps A list of

model specifications for disposable biopsy forceps, as shown in Table 1-1.

Table 1-1 Product Model Specifications

| Serial number | Product number | Maximum clamping head size W (+0.7/-0.2) (mm) | Maximum insertion outer diameter ΦD (+0.10/-0.15) (mm) | Working length L (+8/-10) (mm) | Cutting edge of clamping head (C: Teethed / P: Flat) | Needle (Z: With / W: Without) | Spring tube W/ or W/O plastic coat (S: With / L: Without) | |
|---------------|------------------|--|---|---|---|----------------------------------|--|---|
| 1 | ZRH-BFA-2423-CZS | 6 | 2.4 | 2300 | Y | Y | Y | |
| 2 | ZRH-BFA-2423-CZL | | | | Y | Y | N | |
| 3 | ZRH-BFA-2423-CWS | | | | Y | N | Y | |
| 4 | ZRH-BFA-2423-CWL | | | | Y | N | N | |
| 5 | ZRH-BFA-2423-PZS | | | | N | Y | Y | |
| 6 | ZRH-BFA-2423-PZL | | | | N | Y | N | |
| 7 | ZRH-BFA-2423-PWS | | | | N | N | Y | |
| 8 | ZRH-BFA-2423-PWL | | | | N | N | N | |
| 9 | ZRH-BFA-2418-CZS | | | 1800 | Y | Y | Y | |
| 10 | ZRH-BFA-2418-CZL | | | | Y | Y | N | |
| 11 | ZRH-BFA-2418-CWS | | | | Y | N | Y | |
| 12 | ZRH-BFA-2418-CWL | | | | Y | N | N | |
| 13 | ZRH-BFA-2418-PZS | | | | N | Y | Y | |
| 14 | ZRH-BFA-2418-PZL | | | | N | Y | N | |
| 15 | ZRH-BFA-2418-PWS | | | | N | N | Y | |
| 16 | ZRH-BFA-2418-PWL | | | | N | N | N | |
| 17 | ZRH-BFA-2416-CZS | | | | 1600 | Y | Y | Y |
| 18 | ZRH-BFA-2416-CZL | | | | | Y | Y | N |

| | | | | | | | |
|----|------------------|--|--|--|---|---|---|
| 19 | ZRH-BFA-2416-CWS | | | | Y | N | Y |
| 20 | ZRH-BFA-2416-CWL | | | | Y | N | N |
| 21 | ZRH-BFA-2416-PZS | | | | N | Y | Y |
| 22 | ZRH-BFA-2416-PZL | | | | N | Y | N |
| 23 | ZRH-BFA-2416-PWS | | | | N | N | Y |
| 24 | ZRH-BFA-2416-PWL | | | | N | N | N |
| 25 | ZRH-BFA-2412-CZS | | | | Y | Y | Y |
| 26 | ZRH-BFA-2412-CZL | | | | Y | Y | N |
| 27 | ZRH-BFA-2412-CWS | | | | Y | N | Y |
| 28 | ZRH-BFA-2412-CWL | | | | Y | N | N |
| 29 | ZRH-BFA-2412-PZS | | | | N | Y | Y |
| 30 | ZRH-BFA-2412-PZL | | | | N | Y | N |
| 31 | ZRH-BFA-2412-PWS | | | | N | N | Y |
| 32 | ZRH-BFA-2412-PWL | | | | N | N | N |
| 33 | ZRH-BFA-2410-CZS | | | | Y | Y | Y |
| 34 | ZRH-BFA-2410-CZL | | | | Y | Y | N |
| 35 | ZRH-BFA-2410-CWS | | | | Y | N | Y |
| 36 | ZRH-BFA-2410-CWL | | | | Y | N | N |
| 37 | ZRH-BFA-2410-PZS | | | | N | Y | Y |
| 38 | ZRH-BFA-2410-PZL | | | | N | Y | N |
| 39 | ZRH-BFA-2410-PWS | | | | N | N | Y |
| 40 | ZRH-BFA-2410-PWL | | | | N | N | N |
| 41 | ZRH-BFA-2406-CZS | | | | Y | Y | Y |
| 42 | ZRH-BFA-2406-CZL | | | | Y | Y | N |
| 43 | ZRH-BFA-2406-CWS | | | | Y | N | Y |
| 44 | ZRH-BFA-2406-CWL | | | | Y | N | N |

| | | | | | | | | |
|----|------------------|---|-----|------|------|---|---|---|
| 45 | ZRH-BFA-2406-PZS | | | | N | Y | Y | |
| 46 | ZRH-BFA-2406-PZL | | | | N | Y | N | |
| 47 | ZRH-BFA-2406-PWS | | | | N | N | Y | |
| 48 | ZRH-BFA-2406-PWL | | | | N | N | N | |
| 49 | ZRH-BFA-1823-CZS | 5 | 1.8 | 2300 | Y | Y | Y | |
| 50 | ZRH-BFA-1823-CZL | | | | Y | Y | N | |
| 51 | ZRH-BFA-1823-CWS | | | | Y | N | Y | |
| 52 | ZRH-BFA-1823-CWL | | | | Y | N | N | |
| 53 | ZRH-BFA-1823-PZS | | | | N | Y | Y | |
| 54 | ZRH-BFA-1823-PZL | | | | N | Y | N | |
| 55 | ZRH-BFA-1823-PWS | | | | N | N | Y | |
| 56 | ZRH-BFA-1823-PWL | | | | N | N | N | |
| 57 | ZRH-BFA-1818-CZS | | | | 1800 | Y | Y | Y |
| 58 | ZRH-BFA-1818-CZL | | | | | Y | Y | N |
| 59 | ZRH-BFA-1818-CWS | | | Y | | N | Y | |
| 60 | ZRH-BFA-1818-CWL | | | Y | | N | N | |
| 61 | ZRH-BFA-1818-PZS | | | N | | Y | Y | |
| 62 | ZRH-BFA-1818-PZL | | | N | | Y | N | |
| 63 | ZRH-BFA-1818-PWS | | | N | | N | Y | |
| 64 | ZRH-BFA-1818-PWL | | | N | | N | N | |
| 65 | ZRH-BFA-1816-CZS | | | 1600 | | Y | Y | Y |
| 66 | ZRH-BFA-1816-CZL | | | | | Y | Y | N |
| 67 | ZRH-BFA-1816-CWS | | | | Y | N | Y | |
| 68 | ZRH-BFA-1816-CWL | | | | Y | N | N | |
| 69 | ZRH-BFA-1816-PZS | N | Y | | Y | | | |
| 70 | ZRH-BFA-1816-PZL | N | Y | | N | | | |

| | | | | | | | | |
|----|------------------|--|--|------|------|---|---|---|
| 71 | ZRH-BFA-1816-PWS | | | | N | N | Y | |
| 72 | ZRH-BFA-1816-PWL | | | | N | N | N | |
| 73 | ZRH-BFA-1812-CZS | | | 1200 | Y | Y | Y | |
| 74 | ZRH-BFA-1812-CZL | | | | Y | Y | N | |
| 75 | ZRH-BFA-1812-CWS | | | | Y | N | Y | |
| 76 | ZRH-BFA-1812-CWL | | | | Y | N | N | |
| 77 | ZRH-BFA-1812-PZS | | | | N | Y | Y | |
| 78 | ZRH-BFA-1812-PZL | | | | N | Y | N | |
| 79 | ZRH-BFA-1812-PWS | | | | N | N | Y | |
| 80 | ZRH-BFA-1812-PWL | | | | N | N | N | |
| 81 | ZRH-BFA-1810-CZS | | | | 1000 | Y | Y | Y |
| 82 | ZRH-BFA-1810-CZL | | | | | Y | Y | N |
| 83 | ZRH-BFA-1810-CWS | | | Y | | N | Y | |
| 84 | ZRH-BFA-1810-CWL | | | Y | | N | N | |
| 85 | ZRH-BFA-1810-PZS | | | N | | Y | Y | |
| 86 | ZRH-BFA-1810-PZL | | | N | | Y | N | |
| 87 | ZRH-BFA-1810-PWS | | | N | | N | Y | |
| 88 | ZRH-BFA-1810-PWL | | | N | | N | N | |
| 89 | ZRH-BFA-1806-CZS | | | 600 | Y | Y | Y | |
| 90 | ZRH-BFA-1806-CZL | | | | Y | Y | N | |
| 91 | ZRH-BFA-1806-CWS | | | | Y | N | Y | |
| 92 | ZRH-BFA-1806-CWL | | | | Y | N | N | |
| 93 | ZRH-BFA-1806-PZS | | | | N | Y | Y | |
| 94 | ZRH-BFA-1806-PZL | | | | N | Y | N | |
| 95 | ZRH-BFA-1806-PWS | | | | N | N | Y | |
| 96 | ZRH-BFA-1806-PWL | | | | N | N | N | |

| | | | | | | | |
|-----|------------------|------|-----|------|---|---|---|
| 97 | ZRH-BFB-2423-CZS | 5 | 2.4 | 2300 | Y | Y | Y |
| 98 | ZRH-BFB-2423-CZL | | | | Y | Y | N |
| 99 | ZRH-BFB-2423-CWS | | | | Y | N | Y |
| 100 | ZRH-BFB-2423-CWL | | | | Y | N | N |
| 101 | ZRH-BFB-2423-PZS | | | | N | Y | Y |
| 102 | ZRH-BFB-2423-PZL | | | | N | Y | N |
| 103 | ZRH-BFB-2423-PWS | | | | N | N | Y |
| 104 | ZRH-BFB-2423-PWL | | | | N | N | N |
| 105 | ZRH-BFB-2418-CZS | | | 1800 | Y | Y | Y |
| 106 | ZRH-BFB-2418-CZL | | | | Y | Y | N |
| 107 | ZRH-BFB-2418-CWS | | | | Y | N | Y |
| 108 | ZRH-BFB-2418-CWL | | | | Y | N | N |
| 109 | ZRH-BFB-2418-PZS | | | | N | Y | Y |
| 110 | ZRH-BFB-2418-PZL | | | | N | Y | N |
| 111 | ZRH-BFB-2418-PWS | | | | N | N | Y |
| 112 | ZRH-BFB-2418-PWL | | | | N | N | N |
| 113 | ZRH-BFB-2416-CZS | | | 1600 | Y | Y | Y |
| 114 | ZRH-BFB-2416-CZL | | | | Y | Y | N |
| 115 | ZRH-BFB-2416-CWS | | | | Y | N | Y |
| 116 | ZRH-BFB-2416-CWL | | | | Y | N | N |
| 117 | ZRH-BFB-2416-PZS | | | | N | Y | Y |
| 118 | ZRH-BFB-2416-PZL | | | | N | Y | N |
| 119 | ZRH-BFB-2416-PWS | N | N | | Y | | |
| 120 | ZRH-BFB-2416-PWL | N | N | | N | | |
| 121 | ZRH-BFB-2412-CZS | 1200 | Y | Y | Y | | |
| 122 | ZRH-BFB-2412-CZL | | Y | Y | N | | |

| | | | | | | | | | |
|-----|------------------|--|--|---|-----|------|---|---|---|
| 123 | ZRH-BFB-2412-CWS | | | | Y | N | Y | | |
| 124 | ZRH-BFB-2412-CWL | | | | Y | N | N | | |
| 125 | ZRH-BFB-2412-PZS | | | | N | Y | Y | | |
| 126 | ZRH-BFB-2412-PZL | | | | N | Y | N | | |
| 127 | ZRH-BFB-2412-PWS | | | | N | N | Y | | |
| 128 | ZRH-BFB-2412-PWL | | | | N | N | N | | |
| 129 | ZRH-BFB-2410-CZS | | | | Y | Y | Y | | |
| 130 | ZRH-BFB-2410-CZL | | | | Y | Y | N | | |
| 131 | ZRH-BFB-2410-CWS | | | | Y | N | Y | | |
| 132 | ZRH-BFB-2410-CWL | | | | Y | N | N | | |
| 133 | ZRH-BFB-2410-PZS | | | | N | Y | Y | | |
| 134 | ZRH-BFB-2410-PZL | | | | N | Y | N | | |
| 135 | ZRH-BFB-2410-PWS | | | | N | N | Y | | |
| 136 | ZRH-BFB-2410-PWL | | | | N | N | N | | |
| 137 | ZRH-BFB-2406-CZS | | | | Y | Y | Y | | |
| 138 | ZRH-BFB-2406-CZL | | | | Y | Y | N | | |
| 139 | ZRH-BFB-2406-CWS | | | | Y | N | Y | | |
| 140 | ZRH-BFB-2406-CWL | | | | Y | N | N | | |
| 141 | ZRH-BFB-2406-PZS | | | N | Y | Y | | | |
| 142 | ZRH-BFB-2406-PZL | | | N | Y | N | | | |
| 143 | ZRH-BFB-2406-PWS | | | N | N | Y | | | |
| 144 | ZRH-BFB-2406-PWL | | | N | N | N | | | |
| 145 | ZRH-BFB-1823-CZS | | | 4 | 1.8 | 2300 | Y | Y | Y |
| 146 | ZRH-BFB-1823-CZL | | | | | | Y | Y | N |
| 147 | ZRH-BFB-1823-CWS | | | | | | Y | N | Y |
| 148 | ZRH-BFB-1823-CWL | | | | | | Y | N | N |

| | | | | | | | | |
|-----|------------------|--|--|------|------|---|---|---|
| 149 | ZRH-BFB-1823-PZS | | | | N | Y | Y | |
| 150 | ZRH-BFB-1823-PZL | | | | N | Y | N | |
| 151 | ZRH-BFB-1823-PWS | | | | N | N | Y | |
| 152 | ZRH-BFB-1823-PWL | | | | N | N | N | |
| 153 | ZRH-BFB-1818-CZS | | | 1800 | Y | Y | Y | |
| 154 | ZRH-BFB-1818-CZL | | | | Y | Y | N | |
| 155 | ZRH-BFB-1818-CWS | | | | Y | N | Y | |
| 156 | ZRH-BFB-1818-CWL | | | | Y | N | N | |
| 157 | ZRH-BFB-1818-PZS | | | | N | Y | Y | |
| 158 | ZRH-BFB-1818-PZL | | | | N | Y | N | |
| 159 | ZRH-BFB-1818-PWS | | | | N | N | Y | |
| 160 | ZRH-BFB-1818-PWL | | | | N | N | N | |
| 161 | ZRH-BFB-1816-CZS | | | | 1600 | Y | Y | Y |
| 162 | ZRH-BFB-1816-CZL | | | | | Y | Y | N |
| 163 | ZRH-BFB-1816-CWS | | | | | Y | N | Y |
| 164 | ZRH-BFB-1816-CWL | | | | | Y | N | N |
| 165 | ZRH-BFB-1816-PZS | | | N | | Y | Y | |
| 166 | ZRH-BFB-1816-PZL | | | N | | Y | N | |
| 167 | ZRH-BFB-1816-PWS | | | N | | N | Y | |
| 168 | ZRH-BFB-1816-PWL | | | N | | N | N | |
| 169 | ZRH-BFB-1812-CZS | | | 1200 | Y | Y | Y | |
| 170 | ZRH-BFB-1812-CZL | | | | Y | Y | N | |
| 171 | ZRH-BFB-1812-CWS | | | | Y | N | Y | |
| 172 | ZRH-BFB-1812-CWL | | | | Y | N | N | |
| 173 | ZRH-BFB-1812-PZS | | | | N | Y | Y | |
| 174 | ZRH-BFB-1812-PZL | | | | N | Y | N | |

| | | | | | | | | | | |
|-----|------------------|---|---|---|------|-----|------|---|---|---|
| 175 | ZRH-BFB-1812-PWS | | | | N | N | Y | | | |
| 176 | ZRH-BFB-1812-PWL | | | | N | N | N | | | |
| 177 | ZRH-BFB-1810-CZS | | | | 1000 | Y | Y | Y | | |
| 178 | ZRH-BFB-1810-CZL | | | | | Y | Y | N | | |
| 179 | ZRH-BFB-1810-CWS | | | | | Y | N | Y | | |
| 180 | ZRH-BFB-1810-CWL | | | | | Y | N | N | | |
| 181 | ZRH-BFB-1810-PZS | | | | | N | Y | Y | | |
| 182 | ZRH-BFB-1810-PZL | | | | | N | Y | N | | |
| 183 | ZRH-BFB-1810-PWS | | | | | N | N | Y | | |
| 184 | ZRH-BFB-1810-PWL | | | | | N | N | N | | |
| 185 | ZRH-BFB-1806-CZS | | | | | 600 | Y | Y | Y | |
| 186 | ZRH-BFB-1806-CZL | | | | | | Y | Y | N | |
| 187 | ZRH-BFB-1806-CWS | | | | Y | | N | Y | | |
| 188 | ZRH-BFB-1806-CWL | | | | Y | | N | N | | |
| 189 | ZRH-BFB-1806-PZS | | | | N | | Y | Y | | |
| 190 | ZRH-BFB-1806-PZL | | | | N | | Y | N | | |
| 191 | ZRH-BFB-1806-PWS | | | | N | | N | Y | | |
| 192 | ZRH-BFB-1806-PWL | | | | N | | N | N | | |
| 193 | ZRH-BFA-1023-CZS | | | | 4 | 1.0 | 2300 | Y | Y | Y |
| 194 | ZRH-BFA-1023-CZL | | | | | | | Y | Y | N |
| 195 | ZRH-BFA-1023-CWS | Y | N | Y | | | | | | |
| 196 | ZRH-BFA-1023-CWL | Y | N | N | | | | | | |
| 197 | ZRH-BFA-1023-PZS | N | Y | Y | | | | | | |
| 198 | ZRH-BFA-1023-PZL | N | Y | N | | | | | | |
| 199 | ZRH-BFA-1023-PWS | N | N | Y | | | | | | |
| 200 | ZRH-BFA-1023-PWL | N | N | N | | | | | | |

| | | | | | | | |
|-----|------------------|--|--|------|---|---|---|
| 201 | ZRH-BFA-1018-CZS | | | 1800 | Y | Y | Y |
| 202 | ZRH-BFA-1018-CZL | | | | Y | Y | N |
| 203 | ZRH-BFA-1018-CWS | | | | Y | N | Y |
| 204 | ZRH-BFA-1018-CWL | | | | Y | N | N |
| 205 | ZRH-BFA-1018-PZS | | | | N | Y | Y |
| 206 | ZRH-BFA-1018-PZL | | | | N | Y | N |
| 207 | ZRH-BFA-1018-PWS | | | | N | N | Y |
| 208 | ZRH-BFA-1018-PWL | | | | N | N | N |
| 209 | ZRH-BFA-1016-CZS | | | 1600 | Y | Y | Y |
| 210 | ZRH-BFA-1016-CZL | | | | Y | Y | N |
| 211 | ZRH-BFA-1016-CWS | | | | Y | N | Y |
| 212 | ZRH-BFA-1016-CWL | | | | Y | N | N |
| 213 | ZRH-BFA-1016-PZS | | | | N | Y | Y |
| 214 | ZRH-BFA-1016-PZL | | | | N | Y | N |
| 215 | ZRH-BFA-1016-PWS | | | | N | N | Y |
| 216 | ZRH-BFA-1016-PWL | | | | N | N | N |
| 217 | ZRH-BFA-1012-CZS | | | 1200 | Y | Y | Y |
| 218 | ZRH-BFA-1012-CZL | | | | Y | Y | N |
| 219 | ZRH-BFA-1012-CWS | | | | Y | N | Y |
| 220 | ZRH-BFA-1012-CWL | | | | Y | N | N |
| 221 | ZRH-BFA-1012-PZS | | | | N | Y | Y |
| 222 | ZRH-BFA-1012-PZL | | | | N | Y | N |
| 223 | ZRH-BFA-1012-PWS | | | | N | N | Y |
| 224 | ZRH-BFA-1012-PWL | | | | N | N | N |
| 225 | ZRH-BFA-1010-CZS | | | 1000 | Y | Y | Y |
| 226 | ZRH-BFA-1010-CZL | | | | Y | Y | N |

| | | | | | | | | | |
|-----|------------------|------|---|---|-----|------|---|---|---|
| 227 | ZRH-BFA-1010-CWS | | | | Y | N | Y | | |
| 228 | ZRH-BFA-1010-CWL | | | | Y | N | N | | |
| 229 | ZRH-BFA-1010-PZS | | | | N | Y | Y | | |
| 230 | ZRH-BFA-1010-PZL | | | | N | Y | N | | |
| 231 | ZRH-BFA-1010-PWS | | | | N | N | Y | | |
| 232 | ZRH-BFA-1010-PWL | | | | N | N | N | | |
| 233 | ZRH-BFA-1006-CZS | | | | Y | Y | Y | | |
| 234 | ZRH-BFA-1006-CZL | | | | Y | Y | N | | |
| 235 | ZRH-BFA-1006-CWS | | | | Y | N | Y | | |
| 236 | ZRH-BFA-1006-CWL | | | | Y | N | N | | |
| 237 | ZRH-BFA-1006-PZS | | | N | Y | Y | | | |
| 238 | ZRH-BFA-1006-PZL | | | N | Y | N | | | |
| 239 | ZRH-BFA-1006-PWS | | | N | N | Y | | | |
| 240 | ZRH-BFA-1006-PWL | | | N | N | N | | | |
| 241 | ZRH-BFA-1023-CZS | | | 4 | 1.5 | 2300 | Y | Y | Y |
| 242 | ZRH-BFA-1023-CZL | | | | | | Y | Y | N |
| 243 | ZRH-BFA-1523-CWS | | | | | | Y | N | Y |
| 244 | ZRH-BFA-1523-CWL | | | | | | Y | N | N |
| 245 | ZRH-BFA-1523-PZS | | | | | | N | Y | Y |
| 246 | ZRH-BFA-1523-PZL | | | | | | N | Y | N |
| 247 | ZRH-BFA-1523-PWS | N | N | | | Y | | | |
| 248 | ZRH-BFA-1523-PWL | N | N | | | N | | | |
| 249 | ZRH-BFA-1518-CZS | 1800 | Y | | | Y | Y | | |
| 250 | ZRH-BFA-1518-CZL | | Y | | | Y | N | | |
| 251 | ZRH-BFA-1518-CWS | | Y | | | N | Y | | |
| 252 | ZRH-BFA-1518-CWL | | Y | | | N | N | | |

| | | | | | | | | |
|-----|------------------|--|--|------|------|---|---|---|
| 253 | ZRH-BFA-1518-PZS | | | | N | Y | Y | |
| 254 | ZRH-BFA-1518-PZL | | | | N | Y | N | |
| 255 | ZRH-BFA-1518-PWS | | | | N | N | Y | |
| 256 | ZRH-BFA-1518-PWL | | | | N | N | N | |
| 257 | ZRH-BFA-1516-CZS | | | 1600 | Y | Y | Y | |
| 258 | ZRH-BFA-1516-CZL | | | | Y | Y | N | |
| 259 | ZRH-BFA-1516-CWS | | | | Y | N | Y | |
| 260 | ZRH-BFA-1516-CWL | | | | Y | N | N | |
| 261 | ZRH-BFA-1516-PZS | | | | N | Y | Y | |
| 262 | ZRH-BFA-1516-PZL | | | | N | Y | N | |
| 263 | ZRH-BFA-1516-PWS | | | | N | N | Y | |
| 264 | ZRH-BFA-1516-PWL | | | | N | N | N | |
| 265 | ZRH-BFA-1512-CZS | | | | 1200 | Y | Y | Y |
| 266 | ZRH-BFA-1512-CZL | | | | | Y | Y | N |
| 267 | ZRH-BFA-1512-CWS | | | | | Y | N | Y |
| 268 | ZRH-BFA-1512-CWL | | | | | Y | N | N |
| 269 | ZRH-BFA-1512-PZS | | | N | | Y | Y | |
| 270 | ZRH-BFA-1512-PZL | | | N | | Y | N | |
| 271 | ZRH-BFA-1512-PWS | | | N | | N | Y | |
| 272 | ZRH-BFA-1512-PWL | | | N | | N | N | |
| 273 | ZRH-BFA-1510-CZS | | | 1000 | Y | Y | Y | |
| 274 | ZRH-BFA-1510-CZL | | | | Y | Y | N | |
| 275 | ZRH-BFA-1510-CWS | | | | Y | N | Y | |
| 276 | ZRH-BFA-1510-CWL | | | | Y | N | N | |
| 277 | ZRH-BFA-1510-PZS | | | | N | Y | Y | |
| 278 | ZRH-BFA-1510-PZL | | | | N | Y | N | |

| | | | | | | | | | | |
|-----|------------------|------|---|-----|---|-----|------|---|---|---|
| 279 | ZRH-BFA-1510-PWS | | | 600 | N | N | Y | | | |
| 280 | ZRH-BFA-1510-PWL | | | | N | N | N | | | |
| 281 | ZRH-BFA-1506-CZS | | | | Y | Y | Y | | | |
| 282 | ZRH-BFA-1506-CZL | | | | Y | Y | N | | | |
| 283 | ZRH-BFA-1506-CWS | | | | Y | N | Y | | | |
| 284 | ZRH-BFA-1506-CWL | | | | Y | N | N | | | |
| 285 | ZRH-BFA-1506-PZS | | | | N | Y | Y | | | |
| 286 | ZRH-BFA-1506-PZL | | | | N | Y | N | | | |
| 287 | ZRH-BFA-1506-PWS | | | | N | N | Y | | | |
| 288 | ZRH-BFA-1506-PWL | | | | N | N | N | | | |
| 289 | ZRH-BFA-3023-CZS | | | | 5 | 3.0 | 2300 | Y | Y | Y |
| 290 | ZRH-BFA-3023-CZL | | | | | | | Y | Y | N |
| 291 | ZRH-BFA-3023-CWS | Y | N | Y | | | | | | |
| 292 | ZRH-BFA-3023-CWL | Y | N | N | | | | | | |
| 293 | ZRH-BFA-3023-PZS | N | Y | Y | | | | | | |
| 294 | ZRH-BFA-3023-PZL | N | Y | N | | | | | | |
| 295 | ZRH-BFA-3023-PWS | N | N | Y | | | | | | |
| 296 | ZRH-BFA-3023-PWL | N | N | N | | | | | | |
| 297 | ZRH-BFA-3018-CZS | 1800 | Y | Y | | | | Y | | |
| 298 | ZRH-BFA-3018-CZL | | Y | Y | | | | N | | |
| 299 | ZRH-BFA-3018-CWS | | Y | N | | | | Y | | |
| 300 | ZRH-BFA-3018-CWL | | Y | N | | | | N | | |
| 301 | ZRH-BFA-3018-PZS | | N | Y | Y | | | | | |
| 302 | ZRH-BFA-3018-PZL | | N | Y | N | | | | | |
| 303 | ZRH-BFA-3018-PWS | | N | N | Y | | | | | |
| 304 | ZRH-BFA-3018-PWL | | N | N | N | | | | | |

| | | | | | | | | |
|-----|------------------|--|--|------|------|---|---|---|
| 305 | ZRH-BFA-3016-CZS | | | 1600 | Y | Y | Y | |
| 306 | ZRH-BFA-3016-CZL | | | | Y | Y | N | |
| 307 | ZRH-BFA-3016-CWS | | | | Y | N | Y | |
| 308 | ZRH-BFA-3016-CWL | | | | Y | N | N | |
| 309 | ZRH-BFA-3016-PZS | | | | N | Y | Y | |
| 310 | ZRH-BFA-3016-PZL | | | | N | Y | N | |
| 311 | ZRH-BFA-3016-PWS | | | | N | N | Y | |
| 312 | ZRH-BFA-3016-PWL | | | | N | N | N | |
| 313 | ZRH-BFA-3012-CZS | | | | 1200 | Y | Y | Y |
| 314 | ZRH-BFA-3012-CZL | | | | | Y | Y | N |
| 315 | ZRH-BFA-3012-CWS | | | Y | | N | Y | |
| 316 | ZRH-BFA-3012-CWL | | | Y | | N | N | |
| 317 | ZRH-BFA-3012-PZS | | | N | | Y | Y | |
| 318 | ZRH-BFA-3012-PZL | | | N | | Y | N | |
| 319 | ZRH-BFA-3012-PWS | | | N | | N | Y | |
| 320 | ZRH-BFA-3012-PWL | | | N | | N | N | |
| 321 | ZRH-BFA-3010-CZS | | | 1000 | Y | Y | Y | |
| 322 | ZRH-BFA-3010-CZL | | | | Y | Y | N | |
| 323 | ZRH-BFA-3010-CWS | | | | Y | N | Y | |
| 324 | ZRH-BFA-3010-CWL | | | | Y | N | N | |
| 325 | ZRH-BFA-3010-PZS | | | | N | Y | Y | |
| 326 | ZRH-BFA-3010-PZL | | | | N | Y | N | |
| 327 | ZRH-BFA-3010-PWS | | | | N | N | Y | |
| 328 | ZRH-BFA-3010-PWL | | | | N | N | N | |
| 329 | ZRH-BFA-3006-CZS | | | 600 | Y | Y | Y | |
| 330 | ZRH-BFA-3006-CZL | | | | Y | Y | N | |

| | | | | | | | |
|-----|------------------|--|--|--|---|---|---|
| 331 | ZRH-BFA-3006-CWS | | | | Y | N | Y |
| 332 | ZRH-BFA-3006-CWL | | | | Y | N | N |
| 333 | ZRH-BFA-3006-PZS | | | | N | Y | Y |
| 334 | ZRH-BFA-3006-PZL | | | | N | Y | N |
| 335 | ZRH-BFA-3006-PWS | | | | N | N | Y |
| 336 | ZRH-BFA-3006-PWL | | | | N | N | N |

4) Main parts of the product (product and human contact parts) material

Table 1-2 Main parts (product and human contact parts) material table

| Serial number | Part Name | Material |
|---------------|-----------------------------|----------------------------------|
| 1 | Clamping head | 05Cr17Ni4Cu4Nb (GB/T 20878-2007) |
| 2 | Clamping seat | Y12Cr18Ni9 (GB/T 20878-2007) |
| 3 | Needle | 06Cr19Ni10 (GB/T 20878-2007) |
| 4 | Spring tube | 07Cr19Ni10 (GB/T 20878-2007) |
| | Spring tube plastic coating | PE (Polyethylene) |

3. Technical indicators

- 1) The product clamp should be smooth, and the cutting edge or teeth should be complete and sharp. When the clamp head is closed, the head end should be anastomosed to one-half, and there should be no obvious hemiplegia.
- 2) The opening angle of the product pliers should be no less than 90°; when the pliers with the needle product is opened the most, the tip should be longer than the end of the pliers, and the pliers should not be exposed when closed.
- 3) The product clamping head should be opened and closed easily and flexibly, and there should be no jamming.
- 4) The product spring tube coil should be tight and straight, and there should be no obvious gap and bending.
- 5) The connection of each weld and joint of the product should be firm.
- 6) This product is a sterile product.

4. Basic matters for users to pay attention to

- 1) The user must be a medical professional with some experience in the clinical diagnosis and treatment of the endoscope;
- 2) The user must know the model and specifications of the endoscope and the inner diameter of the clamp to match the specifications in this model series.

5. Matters that users must pay attention to

- 1) If the outer diameter of the largest insertion part of this product is greater than or equal to the inner diameter of the endoscope clamp, do not use this product, otherwise it will damage the endoscope clamp;
- 2) This product is a special accessory for endoscopes and cannot be used alone. It must not be modified or used for other purposes.

6. Inspection before using the product

- 1) Check whether the sealing of the small package of the product is tight and there is no damage, and there should be no foreign objects visible in the bag;
- 2) Check whether the label and certificate are complete and complete; pay attention to the date of manufacture of the product and the effective period of sterilization;
- 3) If the package is damaged or the product parts are damaged, please contact the company immediately to exchange

7. The mechanism of this product

Operate the slip ring on the handle of the product to open or close the two clamp heads, push forward to open the clamping head, and pull back to close the clamping head to bite the living tissue.

8. The working mechanism and environment requirements of this product

1) The product is inserted into the endoscope clamp. Under the observation and monitoring of the endoscope, the slip ring on the handle is pushed forward, the jaw is opened, and the back-clamp loop closes the clamping head to clamp the living tissue. (The clamped living tissue is used for subsequent histological examination).

2) Working environment requirements: temperature 10-40 Celsius degree, relative humidity 30-85%, air pressure 700-1060hPa.

II. Operating procedures

1. Preoperation check

1) Understand the structure and specifications of the adapter, and select the product specifications that match it;

2) Prepare personal protective equipment: masks, surgical gowns, surgical gloves, cleaning equipment;

3) Check the product: If it is defective, please do not use it, you should replace it with a new one.

a) The small package of this product should be complete, the seal should be sealed; the product should be within the validity period;

b) Operate the slip ring on the handle of the product, the clamp head should be open and closed flexible, can be completely closed, the parts of the clamp head should be smooth and clean, and there should be no sharp edges or burrs;

c) Check the cutting edge of the product clamp head, it should be flat, no surface defects such as curling and burr;

d) Check the product spring tube, which should be straight and free of flexing.

2. Operation

1) Wear appropriate protective equipment during operation to isolate contaminants from the patient.

2) Disassemble the inner packaging of this product, carefully remove the product, and remove the protective cover of the clamp head.

3) Pull the slip ring back to close the jaws and carefully insert the product into the endoscope clamp until the jaws are visible in the endoscope.

4) Push the slip ring to open the clamp head, operate the endoscope to position the product to be sampled, and then pull the slip ring to close the clamp head and clamp the mucosal tissue;

5) Keep the rear pull-slip ring to keep the clamp head closed, and pull out the product from the endoscope; place the clamp head in the collection device, push the slip ring forward to open the clamp head, and place the living tissue sample in the clamp head In the collection device, the product is finally taken away.

III. Storage

This product is valid for 3 years, the production date and batch number are listed in the label.

1. Pre-storage inspection

The product should be checked before stored. Make sure that the sterile package is in good condition, and is not damaged and wet. The product should be intact.

2. Storage requirements

2.1 The product should be stored in a clean place. Do not store it under direct sunlight. Make sure that the product is not damaged by the surrounding objects.

2.2 Do not let the product touch organic solvents, ionizing radiation or ultraviolet light. The stock product should be used in turn in order, so that the product can be used before the expiration date indicated on the packaging label.

3. storage standard

Ambient temperature: $-40^{\circ}\text{C} \sim 70^{\circ}\text{C}$

Environmental humidity: 10% \sim 95%

Atmospheric pressure: 700hPa \sim 1060hPa

IV. Disposal of waste

1. Waste management

After the product is used, it should be isolated and managed as medical device waste, and should not be stored at will.

2. Disposal of waste

After the product is used, the product and packaging should be disposed of in accordance with the regulations of the hospital, administrative department and/or local government.

Warning: After using this product, it should be managed and disposed according to relevant regulations! Cannot be reused or used after sterilized!

VI、 Contact information



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