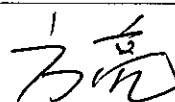

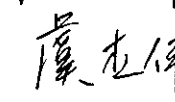


宁波新跃医疗科技股份有限公司 NINGBO XINWELL MEDICAL TECHNOLOGY CO., LTD	文件编号 File No.	RD/S-106-0003
一次性使用活组织取样钳使用说明书 IFU of Disposable Endoscopic Biopsy Forceps	版次 Ver.	A/1
	生效日期 Valid Date	2022.04.06
	页码 Page	1/19

文件更改履历 Change History				
版次 Ver.	修改内容 Change Descriptions	修改人 Author	日期 Date	修改单号 Change No.
1.0	原版 First issued	Yuanting Jin	2020.06.12	/
A/0	原版 First issued	Liang Fang	2021.05.12	ECN2021051201
A/1	1.说明书模板更新, 从 A/0 至 A/1 2.英文名“Disposable Biopsy Forceps”更改为 “Disposable Endoscopic Biopsy Forceps”; 3.“2.1 Naming rules 命名规则”中增加 not plastic default 不包塑缺省; 4.“2.4 Structural composition 结构组成”中产品结构 及名称增加更详细解释; 5.增加“Intended use 预期用途, Indications for Use 适应症, Intended users 预期使用者, Intended patient group 预期病人群体”四项; 6.“8.6.Residual ethylene oxide 环氧乙烷残留量 ”改为“产品灭菌后, 环氧乙烷残留量应不大于 4mg/ 件”; 7.“12 Precautions 注意事项”增加更详细解释; 8.“10 Contraindications 禁忌症”增加更详细解释; 9.“13 Packaging Marks 包装标志”增加部分医疗器 械标记。	Fang Liang	2022.04.06	ECN2022040602
文件批准栏 Approval Column For Document				
编制 Prepared By		日期 Date	2022.04.06	
审核 Checked By		日期 Date	2022.4.6	
批准 Approved By		日期 Date	2022.4.6	

# Instruction for Use

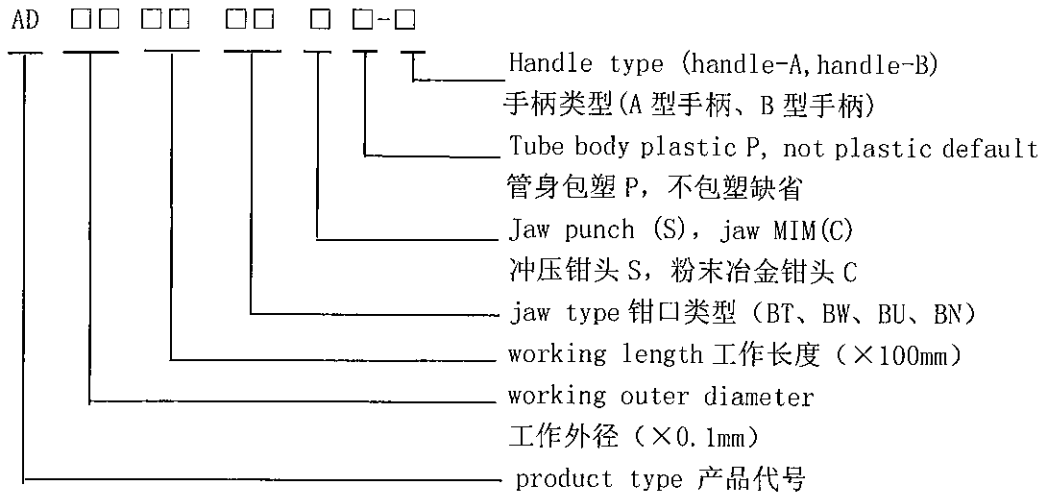
## 1 Product Name 产品名称

Disposable Endoscopic Biopsy Forceps

一次性使用活组织取样钳

## 2 Product Description 产品简介

### 2.1 Naming rules 型号命名规则



For example: AD2423BTSP-A

Indicates that the working outer diameter of the disposable endoscopic biopsy forceps (“Biopsy Forceps” for short) is  $\Phi 2.4\text{mm}$ , the working length is 2300mm, the jaws have no positioning needles, the jaws are flat, and the jaws are formed by stamping, tube The body is covered with plastic, and the handle type is A-shaped handle.

示例：AD2423BTSP-A

表示一次性使用活组织取样钳（简称“取样钳”）的工作外径为 $\Phi 2.4\text{mm}$ ，工作长度为2300mm，钳头无定位针，钳口为平口型，钳头的成型方式为冲压，管身包塑，手柄类型为A型手柄。

### 2.2 Product model specifications 产品规格型号

For the list of product models, see Table 1.

产品型号列表，见表1。

Table 1 Product model list

表1 产品型号列表

No. 序号	Type/Specifi cation 型号/ 规格	Outer diameter ×working length (mm) 工作外径×工作 长度 mm	Type 钳 口类型	Punch or MIM 冲压/粉末 冶金	Needle Yes/ No 是否带 针	Plastic coated Yes/No 是否包 塑	Hand le type 手柄 类型	maximum width of insertion part (mm) 插 入部最大宽度	channel diameter (mm) 适 用钳道内 径
1	AD1807BTS-A	Φ1.8×700	Flat 平口	Punch 冲压	No	No	A	1.95	≥Φ2.0
2	AD1807BWS-A				Yes	No	A	1.95	≥Φ2.0
3	AD1807BTSP-A				No	Yes	A	1.95	≥Φ2.0
4	AD1807BWSP-A				Yes	Yes	A	1.95	≥Φ2.0
5	AD1807BUS-A		alligat or 鳄口	Punch 冲压	No	No	A	1.95	≥Φ2.0
6	AD1807BNS-A				Yes	No	A	1.95	≥Φ2.0
7	AD1807BUSP-A				No	Yes	A	1.95	≥Φ2.0
8	AD1807BNSP-A				Yes	Yes	A	1.95	≥Φ2.0
9	AD1810BTS-A	Φ1.8×1000	Flat 平口	Punch 冲压	No	No	A	1.95	≥Φ2.0
10	AD1810BWS-A				Yes	No	A	1.95	≥Φ2.0
11	AD1810BTSP-A				No	Yes	A	1.95	≥Φ2.0
12	AD1810BWSP-A				Yes	Yes	A	1.95	≥Φ2.0
13	AD1810BUS-A		alligat or 鳄口	Punch 冲压	No	No	A	1.95	≥Φ2.0
14	AD1810BNS-A				Yes	No	A	1.95	≥Φ2.0
15	AD1810BUSP-A				No	Yes	A	1.95	≥Φ2.0
16	AD1810BNSP-A				Yes	Yes	A	1.95	≥Φ2.0
17	AD1812BTS-A	Φ1.8×1200	Flat 平口	Punch 冲压	No	No	A	1.95	≥Φ2.0
18	AD1812BWS-A				Yes	No	A	1.95	≥Φ2.0
19	AD1812BTSP-A				No	Yes	A	1.95	≥Φ2.0
20	AD1812BWSP-A				Yes	Yes	A	1.95	≥Φ2.0
21	AD1812BUS-A		alligat or 鳄口	Punch 冲压	No	No	A	1.95	≥Φ2.0
22	AD1812BNS-A				Yes	No	A	1.95	≥Φ2.0
23	AD1812BUSP-A				No	Yes	A	1.95	≥Φ2.0
24	AD1812BNSP-A				Yes	Yes	A	1.95	≥Φ2.0
25	AD1816BTS-A	Φ1.8×1600	Flat 平口	Punch 冲压	No	No	A	1.95	≥Φ2.0
26	AD1816BWS-A				Yes	No	A	1.95	≥Φ2.0
27	AD1816BTSP-A				No	Yes	A	1.95	≥Φ2.0
28	AD1816BWSP-A				Yes	Yes	A	1.95	≥Φ2.0
29	AD1816BUS-A		alligat or 鳄口	Punch 冲压	No	No	A	1.95	≥Φ2.0
30	AD1816BNS-A				Yes	No	A	1.95	≥Φ2.0
31	AD1816BUSP-A				No	Yes	A	1.95	≥Φ2.0
32	AD1816BNSP-A				Yes	Yes	A	1.95	≥Φ2.0
33	AD1818BTS-A	Φ1.8×1800	Flat 平口	Punch 冲压	No	No	A	1.95	≥Φ2.0
34	AD1818BWS-A				Yes	No	A	1.95	≥Φ2.0
35	AD1818BTSP-A				No	Yes	A	1.95	≥Φ2.0

36	AD1818BWSP-A			Yes	Yes	A	1.95	$\geq \Phi 2.0$	
37	AD1818BUS-A		alligat or 鳄口	Punch 冲压	No	No	A	1.95	$\geq \Phi 2.0$
38	AD1818BNS-A				Yes	No	A	1.95	$\geq \Phi 2.0$
39	AD1818BUSP-A				No	Yes	A	1.95	$\geq \Phi 2.0$
40	AD1818BNSP-A				Yes	Yes	A	1.95	$\geq \Phi 2.0$
41	AD1823BTS-A	$\Phi 1.8 \times 2300$	Flat 平口	Punch 冲压	No	No	A	1.95	$\geq \Phi 2.0$
42	AD1823BWS-A				Yes	No	A	1.95	$\geq \Phi 2.0$
43	AD1823BTSP-A				No	Yes	A	1.95	$\geq \Phi 2.0$
44	AD1823BWSP-A				Yes	Yes	A	1.95	$\geq \Phi 2.0$
45	AD1823BUS-A		alligat or 鳄口	Punch 冲压	No	No	A	1.95	$\geq \Phi 2.0$
46	AD1823BNS-A				Yes	No	A	1.95	$\geq \Phi 2.0$
47	AD1823BUSP-A				No	Yes	A	1.95	$\geq \Phi 2.0$
48	AD1823BNSP-A				Yes	Yes	A	1.95	$\geq \Phi 2.0$
49	AD2407BTS-A	$\Phi 2.4 \times 700$	Flat 平口	Punch 冲压	No	No	A	2.6	$\geq \Phi 2.8$
50	AD2407BWS-A				Yes	No	A	2.6	$\geq \Phi 2.8$
51	AD2407BTSP-A				No	Yes	A	2.6	$\geq \Phi 2.8$
52	AD2407BWSP-A				Yes	Yes	A	2.6	$\geq \Phi 2.8$
53	AD2407BUS-A		alligat or 鳄口	Punch 冲压	No	No	A	2.6	$\geq \Phi 2.8$
54	AD2407BNS-A				Yes	No	A	2.6	$\geq \Phi 2.8$
55	AD2407BUSP-A				No	Yes	A	2.6	$\geq \Phi 2.8$
56	AD2407BNSP-A				Yes	Yes	A	2.6	$\geq \Phi 2.8$
57	AD2410BTS-A	$\Phi 2.4 \times 1000$	Flat 平口	Punch 冲压	No	No	A	2.6	$\geq \Phi 2.8$
58	AD2410BWS-A				Yes	No	A	2.6	$\geq \Phi 2.8$
59	AD2410BTSP-A				No	Yes	A	2.6	$\geq \Phi 2.8$
60	AD2410BWSP-A				Yes	Yes	A	2.6	$\geq \Phi 2.8$
61	AD2410BUS-A		alligat or 鳄口	Punch 冲压	No	No	A	2.6	$\geq \Phi 2.8$
62	AD2410BNS-A				Yes	No	A	2.6	$\geq \Phi 2.8$
63	AD2410BUSP-A				No	Yes	A	2.6	$\geq \Phi 2.8$
64	AD2410BNSP-A				Yes	Yes	A	2.6	$\geq \Phi 2.8$
65	AD2412BTS-A	$\Phi 2.4 \times 1200$	Flat 平口	Punch 冲压	No	No	A	2.6	$\geq \Phi 2.8$
66	AD2412BWS-A				Yes	No	A	2.6	$\geq \Phi 2.8$
67	AD2412BTSP-A				No	Yes	A	2.6	$\geq \Phi 2.8$
68	AD2412BWSP-A				Yes	Yes	A	2.6	$\geq \Phi 2.8$
69	AD2412BUS-A	$\Phi 2.4 \times 1200$	alligat or 鳄口	Punch 冲压	No	No	A	2.6	$\geq \Phi 2.8$
70	AD2412BNS-A				Yes	No	A	2.6	$\geq \Phi 2.8$
71	AD2412BUSP-A				No	Yes	A	2.6	$\geq \Phi 2.8$
72	AD2412BNSP-A				Yes	Yes	A	2.6	$\geq \Phi 2.8$
73	AD2416BTS-A	$\Phi 2.4 \times 1600$	Flat 平口	Punch 冲压	No	No	A	2.6	$\geq \Phi 2.8$
74	AD2416BWS-A				Yes	No	A	2.6	$\geq \Phi 2.8$
75	AD2416BTSP-A				No	Yes	A	2.6	$\geq \Phi 2.8$

76	AD2416BWSP-A			Yes	Yes	A	2.6	$\geq \Phi 2.8$	
77	AD2416BUS-A		alligat or 鳄口	Punch 冲压	No	No	A	2.6	$\geq \Phi 2.8$
78	AD2416BNS-A				Yes	No	A	2.6	$\geq \Phi 2.8$
79	AD2416BUSP-A				No	Yes	A	2.6	$\geq \Phi 2.8$
80	AD2416BNSP-A				Yes	Yes	A	2.6	$\geq \Phi 2.8$
81	AD2418BTS-A	$\Phi 2.4 \times 1800$	Flat 平口	Punch 冲压	No	No	A	2.6	$\geq \Phi 2.8$
82	AD2418BWS-A				Yes	No	A	2.6	$\geq \Phi 2.8$
83	AD2418BTSP-A				No	Yes	A	2.6	$\geq \Phi 2.8$
84	AD2418BWSP-A				Yes	Yes	A	2.6	$\geq \Phi 2.8$
85	AD2418BUS-A		alligat or 鳄口	Punch 冲压	No	No	A	2.6	$\geq \Phi 2.8$
86	AD2418BNS-A				Yes	No	A	2.6	$\geq \Phi 2.8$
87	AD2418BUSP-A				No	Yes	A	2.6	$\geq \Phi 2.8$
88	AD2418BNSP-A				Yes	Yes	A	2.6	$\geq \Phi 2.8$
89	AD2423BTS-A	$\Phi 2.4 \times 2300$	Flat 平口	Punch 冲压	No	No	A	2.6	$\geq \Phi 2.8$
90	AD2423BWS-A				Yes	No	A	2.6	$\geq \Phi 2.8$
91	AD2423BTSP-A				No	Yes	A	2.6	$\geq \Phi 2.8$
92	AD2423BWSP-A				Yes	Yes	A	2.6	$\geq \Phi 2.8$
93	AD2423BUS-A		alligat or 鳄口	Punch 冲压	No	No	A	2.6	$\geq \Phi 2.8$
94	AD2423BNS-A				Yes	No	A	2.6	$\geq \Phi 2.8$
95	AD2423BUSP-A				No	Yes	A	2.6	$\geq \Phi 2.8$
96	AD2423BNSP-A				Yes	Yes	A	2.6	$\geq \Phi 2.8$
97	AD1807BTC-A	$\Phi 1.8 \times 700$	Flat 平口	MIM 粉末冶金	No	No	A	1.95	$\geq \Phi 2.0$
98	AD1807BWC-A				Yes	No	A	1.95	$\geq \Phi 2.0$
99	AD1807BTCP-A				No	Yes	A	1.95	$\geq \Phi 2.0$
100	AD1807BWCP-A				Yes	Yes	A	1.95	$\geq \Phi 2.0$
101	AD1807BUC-A		alligat or 鳄口	MIM 粉末冶金	No	No	A	1.95	$\geq \Phi 2.0$
102	AD1807BNC-A				Yes	No	A	1.95	$\geq \Phi 2.0$
103	AD1807BUCP-A				No	Yes	A	1.95	$\geq \Phi 2.0$
104	AD1807BNCP-A				Yes	Yes	A	1.95	$\geq \Phi 2.0$
105	AD1810BTC-A	$\Phi 1.8 \times 1000$	Flat 平口	MIM 粉末冶金	No	No	A	1.95	$\geq \Phi 2.0$
106	AD1810BWC-A				Yes	No	A	1.95	$\geq \Phi 2.0$
107	AD1810BTCP-A				No	Yes	A	1.95	$\geq \Phi 2.0$
108	AD1810BWCP-A				Yes	Yes	A	1.95	$\geq \Phi 2.0$
109	AD1810BUC-A		alligat or 鳄口	MIM 粉末冶金	No	No	A	1.95	$\geq \Phi 2.0$
110	AD1810BNC-A				Yes	No	A	1.95	$\geq \Phi 2.0$
111	AD1810BUCP-A				No	Yes	A	1.95	$\geq \Phi 2.0$
112	AD1810BNCP-A				Yes	Yes	A	1.95	$\geq \Phi 2.0$
113	AD1812BTC-A	$\Phi 1.8 \times 1200$	Flat 平口	MIM 粉末冶金	No	No	A	1.95	$\geq \Phi 2.0$
114	AD1812BWC-A				Yes	No	A	1.95	$\geq \Phi 2.0$
115	AD1812BTCP-A				No	Yes	A	1.95	$\geq \Phi 2.0$

116	AD1812BWCP-A		alligat or 鳄口	MIM 粉末冶金	Yes	Yes	A	1.95	$\geq \Phi 2.0$
117	AD1812BUC-A				No	No	A	1.95	$\geq \Phi 2.0$
118	AD1812BNC-A				Yes	No	A	1.95	$\geq \Phi 2.0$
119	AD1812BUCP-A				No	Yes	A	1.95	$\geq \Phi 2.0$
120	AD1812BNCP-A				Yes	Yes	A	1.95	$\geq \Phi 2.0$
121	AD1816BTC-A	$\Phi 1.8 \times 1600$	Flat 平口	MIM 粉末冶金	No	No	A	1.95	$\geq \Phi 2.0$
122	AD1816BWC-A				Yes	No	A	1.95	$\geq \Phi 2.0$
123	AD1816BTCP-A				No	Yes	A	1.95	$\geq \Phi 2.0$
124	AD1816BWCP-A				Yes	Yes	A	1.95	$\geq \Phi 2.0$
125	AD1816BUC-A		alligat or 鳄口	MIM 粉末冶金	No	No	A	1.95	$\geq \Phi 2.0$
126	AD1816BNC-A				Yes	No	A	1.95	$\geq \Phi 2.0$
127	AD1816BUCP-A				No	Yes	A	1.95	$\geq \Phi 2.0$
128	AD1816BNCP-A				Yes	Yes	A	1.95	$\geq \Phi 2.0$
129	AD1818BTC-A	$\Phi 1.8 \times 1800$	Flat 平口	MIM 粉末冶金	No	No	A	1.95	$\geq \Phi 2.0$
130	AD1818BWC-A				Yes	No	A	1.95	$\geq \Phi 2.0$
131	AD1818BTCP-A				No	Yes	A	1.95	$\geq \Phi 2.0$
132	AD1818BWCP-A				Yes	Yes	A	1.95	$\geq \Phi 2.0$
133	AD1818BUC-A		alligat or 鳄口	MIM 粉末冶金	No	No	A	1.95	$\geq \Phi 2.0$
134	AD1818BNC-A				Yes	No	A	1.95	$\geq \Phi 2.0$
135	AD1818BUCP-A				No	Yes	A	1.95	$\geq \Phi 2.0$
136	AD1818BNCP-A				Yes	Yes	A	1.95	$\geq \Phi 2.0$
137	AD1823BTC-A	$\Phi 1.8 \times 2300$	Flat 平口	MIM 粉末冶金	No	No	A	1.95	$\geq \Phi 2.0$
138	AD1823BWC-A				Yes	No	A	1.95	$\geq \Phi 2.0$
139	AD1823BTCP-A				No	Yes	A	1.95	$\geq \Phi 2.0$
140	AD1823BWCP-A				Yes	Yes	A	1.95	$\geq \Phi 2.0$
141	AD1823BUC-A	$\Phi 1.8 \times 2300$	alligat or 鳄口	MIM 粉末冶金	No	No	A	1.95	$\geq \Phi 2.0$
142	AD1823BNC-A				Yes	No	A	1.95	$\geq \Phi 2.0$
143	AD1823BUCP-A				No	Yes	A	1.95	$\geq \Phi 2.0$
144	AD1823BNCP-A				Yes	Yes	A	1.95	$\geq \Phi 2.0$
145	AD2407BTC-A	$\Phi 2.4 \times 700$	Flat 平口	MIM 粉末冶金	No	No	A	2.6	$\geq \Phi 2.8$
146	AD2407BWC-A				Yes	No	A	2.6	$\geq \Phi 2.8$
147	AD2407BTCP-A				No	Yes	A	2.6	$\geq \Phi 2.8$
148	AD2407BWCP-A				Yes	Yes	A	2.6	$\geq \Phi 2.8$
149	AD2407BUC-A		alligat or 鳄口	MIM 粉末冶金	No	No	A	2.6	$\geq \Phi 2.8$
150	AD2407BNC-A				Yes	No	A	2.6	$\geq \Phi 2.8$
151	AD2407BUCP-A				No	Yes	A	2.6	$\geq \Phi 2.8$
152	AD2407BNCP-A				Yes	Yes	A	2.6	$\geq \Phi 2.8$
153	AD2410BTC-A	$\Phi 2.4 \times 1000$	Flat 平口	MIM 粉末冶金	No	No	A	2.6	$\geq \Phi 2.8$
154	AD2410BWC-A				Yes	No	A	2.6	$\geq \Phi 2.8$
155	AD2410BTCP-A				No	Yes	A	2.6	$\geq \Phi 2.8$

156	AD2410BWCP-A			Yes	Yes	A	2.6	$\geq \Phi 2.8$		
157	AD2410BUC-A		alligat or 鳄口	MIM 粉末冶金	No	No	A	2.6	$\geq \Phi 2.8$	
158	AD2410BNC-A				Yes	No	A	2.6	$\geq \Phi 2.8$	
159	AD2410BUCP-A				No	Yes	A	2.6	$\geq \Phi 2.8$	
160	AD2410BNCP-A				Yes	Yes	A	2.6	$\geq \Phi 2.8$	
161	AD2412BTC-A	$\Phi 2.4 \times 1200$	Flat 平口	MIM 粉末冶金	No	No	A	2.6	$\geq \Phi 2.8$	
162	AD2412BWC-A				Yes	No	A	2.6	$\geq \Phi 2.8$	
163	AD2412BTCP-A				No	Yes	A	2.6	$\geq \Phi 2.8$	
164	AD2412BWCP-A				Yes	Yes	A	2.6	$\geq \Phi 2.8$	
165	AD2412BUC-A			alligat or 鳄口	MIM 粉末冶金	No	No	A	2.6	$\geq \Phi 2.8$
166	AD2412BNC-A					Yes	No	A	2.6	$\geq \Phi 2.8$
167	AD2412BUCP-A					No	Yes	A	2.6	$\geq \Phi 2.8$
168	AD2412BNCP-A					Yes	Yes	A	2.6	$\geq \Phi 2.8$
169	AD2416BTC-A	$\Phi 2.4 \times 1600$	Flat 平口	MIM 粉末冶金	No	No	A	2.6	$\geq \Phi 2.8$	
170	AD2416BWC-A				Yes	No	A	2.6	$\geq \Phi 2.8$	
171	AD2416BTCP-A				No	Yes	A	2.6	$\geq \Phi 2.8$	
172	AD2416BWCP-A				Yes	Yes	A	2.6	$\geq \Phi 2.8$	
173	AD2416BUC-A			alligat or 鳄口	MIM 粉末冶金	No	No	A	2.6	$\geq \Phi 2.8$
174	AD2416BNC-A					Yes	No	A	2.6	$\geq \Phi 2.8$
175	AD2416BUCP-A					No	Yes	A	2.6	$\geq \Phi 2.8$
176	AD2416BNCP-A					Yes	Yes	A	2.6	$\geq \Phi 2.8$
177	AD2418BTC-A	$\Phi 2.4 \times 1800$	Flat 平口	MIM 粉末冶金	No	No	A	2.6	$\geq \Phi 2.8$	
178	AD2418BWC-A				Yes	No	A	2.6	$\geq \Phi 2.8$	
179	AD2418BTCP-A				No	Yes	A	2.6	$\geq \Phi 2.8$	
180	AD2418BWCP-A				Yes	Yes	A	2.6	$\geq \Phi 2.8$	
181	AD2418BUC-A			alligat or 鳄口	MIM 粉末冶金	No	No	A	2.6	$\geq \Phi 2.8$
182	AD2418BNC-A					Yes	No	A	2.6	$\geq \Phi 2.8$
183	AD2418BUCP-A					No	Yes	A	2.6	$\geq \Phi 2.8$
184	AD2418BNCP-A					Yes	Yes	A	2.6	$\geq \Phi 2.8$
185	AD2423BTC-A	$\Phi 2.4 \times 2300$	Flat 平口	MIM 粉末冶金	No	No	A	2.6	$\geq \Phi 2.8$	
186	AD2423BWC-A				Yes	No	A	2.6	$\geq \Phi 2.8$	
187	AD2423BTCP-A				No	Yes	A	2.6	$\geq \Phi 2.8$	
188	AD2423BWCP-A				Yes	Yes	A	2.6	$\geq \Phi 2.8$	
189	AD2423BUC-A			alligat or 鳄口	MIM 粉末冶金	No	No	A	2.6	$\geq \Phi 2.8$
190	AD2423BNC-A					Yes	No	A	2.6	$\geq \Phi 2.8$
191	AD2423BUCP-A					No	Yes	A	2.6	$\geq \Phi 2.8$
192	AD2423BNCP-A					Yes	Yes	A	2.6	$\geq \Phi 2.8$
193	AD1807BTS-B	$\Phi 1.8 \times 700$	Flat 平口	Punch 冲压	No	No	B	1.95	$\geq \Phi 2.0$	
194	AD1807BWS-B				Yes	No	B	1.95	$\geq \Phi 2.0$	
195	AD1807BTSP-B				No	Yes	B	1.95	$\geq \Phi 2.0$	

196	AD1807BWSP-B			Yes	Yes	B	1.95	$\geq \Phi 2.0$	
197	AD1807BUS-B		alligat or 鳄口	Punch 冲压	No	No	B	1.95	$\geq \Phi 2.0$
198	AD1807BNS-B				Yes	No	B	1.95	$\geq \Phi 2.0$
199	AD1807BUSP-B				No	Yes	B	1.95	$\geq \Phi 2.0$
200	AD1807BNSP-B				Yes	Yes	B	1.95	$\geq \Phi 2.0$
201	AD1810BTS-B	$\Phi 1.8 \times 1000$	Flat 平口	Punch 冲压	No	No	B	1.95	$\geq \Phi 2.0$
202	AD1810BWS-B				Yes	No	B	1.95	$\geq \Phi 2.0$
203	AD1810BTSP-B				No	Yes	B	1.95	$\geq \Phi 2.0$
204	AD1810BWSP-B				Yes	Yes	B	1.95	$\geq \Phi 2.0$
205	AD1810BUS-B		alligat or 鳄口	Punch 冲压	No	No	B	1.95	$\geq \Phi 2.0$
206	AD1810BNS-B				Yes	No	B	1.95	$\geq \Phi 2.0$
207	AD1810BUSP-B				No	Yes	B	1.95	$\geq \Phi 2.0$
208	AD1810BNSP-B				Yes	Yes	B	1.95	$\geq \Phi 2.0$
209	AD1812BTS-B	$\Phi 1.8 \times 1200$	Flat 平口	Punch 冲压	No	No	B	1.95	$\geq \Phi 2.0$
210	AD1812BWS-B				Yes	No	B	1.95	$\geq \Phi 2.0$
211	AD1812BTSP-B				No	Yes	B	1.95	$\geq \Phi 2.0$
212	AD1812BWSP-B				Yes	Yes	B	1.95	$\geq \Phi 2.0$
213	AD1812BUS-B	$\Phi 1.8 \times 1200$	alligat or 鳄口	Punch 冲压	No	No	B	1.95	$\geq \Phi 2.0$
214	AD1812BNS-B				Yes	No	B	1.95	$\geq \Phi 2.0$
215	AD1812BUSP-B				No	Yes	B	1.95	$\geq \Phi 2.0$
216	AD1812BNSP-B				Yes	Yes	B	1.95	$\geq \Phi 2.0$
217	AD1816BTS-B	$\Phi 1.8 \times 1600$	Flat 平口	Punch 冲压	No	No	B	1.95	$\geq \Phi 2.0$
218	AD1816BWS-B				Yes	No	B	1.95	$\geq \Phi 2.0$
219	AD1816BTSP-B				No	Yes	B	1.95	$\geq \Phi 2.0$
220	AD1816BWSP-B				Yes	Yes	B	1.95	$\geq \Phi 2.0$
221	AD1816BUS-B		alligat or 鳄口	Punch 冲压	No	No	B	1.95	$\geq \Phi 2.0$
222	AD1816BNS-B				Yes	No	B	1.95	$\geq \Phi 2.0$
223	AD1816BUSP-B				No	Yes	B	1.95	$\geq \Phi 2.0$
224	AD1816BNSP-B				Yes	Yes	B	1.95	$\geq \Phi 2.0$
225	AD1818BTS-B	$\Phi 1.8 \times 1800$	Flat 平口	Punch 冲压	No	No	B	1.95	$\geq \Phi 2.0$
226	AD1818BWS-B				Yes	No	B	1.95	$\geq \Phi 2.0$
227	AD1818BTSP-B				No	Yes	B	1.95	$\geq \Phi 2.0$
228	AD1818BWSP-B				Yes	Yes	B	1.95	$\geq \Phi 2.0$
229	AD1818BUS-B		alligat or 鳄口	Punch 冲压	No	No	B	1.95	$\geq \Phi 2.0$
230	AD1818BNS-B				Yes	No	B	1.95	$\geq \Phi 2.0$
231	AD1818BUSP-B				No	Yes	B	1.95	$\geq \Phi 2.0$
232	AD1818BNSP-B				Yes	Yes	B	1.95	$\geq \Phi 2.0$
233	AD1823BTS-B	$\Phi 1.8 \times 2300$	Flat 平口	Punch 冲压	No	No	B	1.95	$\geq \Phi 2.0$
234	AD1823BWS-B				Yes	No	B	1.95	$\geq \Phi 2.0$
235	AD1823BTSP-B				No	Yes	B	1.95	$\geq \Phi 2.0$



236	AD1823BWSP-B		alligat or 鳄口	Punch 冲压	Yes	Yes	B	1.95	$\geq \Phi 2.0$
237	AD1823BUS-B				No	No	B	1.95	$\geq \Phi 2.0$
238	AD1823BNS-B				Yes	No	B	1.95	$\geq \Phi 2.0$
239	AD1823BUSP-B				No	Yes	B	1.95	$\geq \Phi 2.0$
240	AD1823BNSP-B				Yes	Yes	B	1.95	$\geq \Phi 2.0$
241	AD2407BTS-B	$\Phi 2.4 \times 700$	Flat 平口	Punch 冲压	No	No	B	2.6	$\geq \Phi 2.8$
242	AD2407BWS-B				Yes	No	B	2.6	$\geq \Phi 2.8$
243	AD2407BTSP-B				No	Yes	B	2.6	$\geq \Phi 2.8$
244	AD2407BWSP-B				Yes	Yes	B	2.6	$\geq \Phi 2.8$
245	AD2407BUS-B		alligat or 鳄口	Punch 冲压	No	No	B	2.6	$\geq \Phi 2.8$
246	AD2407BNS-B				Yes	No	B	2.6	$\geq \Phi 2.8$
247	AD2407BUSP-B				No	Yes	B	2.6	$\geq \Phi 2.8$
248	AD2407BNSP-B				Yes	Yes	B	2.6	$\geq \Phi 2.8$
249	AD2410BTS-B	$\Phi 2.4 \times 1000$	Flat 平口	Punch 冲压	No	No	B	2.6	$\geq \Phi 2.8$
250	AD2410BWS-B				Yes	No	B	2.6	$\geq \Phi 2.8$
251	AD2410BTSP-B				No	Yes	B	2.6	$\geq \Phi 2.8$
252	AD2410BWSP-B				Yes	Yes	B	2.6	$\geq \Phi 2.8$
253	AD2410BUS-B		alligat or 鳄口	Punch 冲压	No	No	B	2.6	$\geq \Phi 2.8$
254	AD2410BNS-B				Yes	No	B	2.6	$\geq \Phi 2.8$
255	AD2410BUSP-B				No	Yes	B	2.6	$\geq \Phi 2.8$
256	AD2410BNSP-B				Yes	Yes	B	2.6	$\geq \Phi 2.8$
257	AD2412BTS-B	$\Phi 2.4 \times 1200$	Flat 平口	Punch 冲压	No	No	B	2.6	$\geq \Phi 2.8$
258	AD2412BWS-B				Yes	No	B	2.6	$\geq \Phi 2.8$
259	AD2412BTSP-B				No	Yes	B	2.6	$\geq \Phi 2.8$
260	AD2412BWSP-B				Yes	Yes	B	2.6	$\geq \Phi 2.8$
261	AD2412BUS-B		alligat or 鳄口	Punch 冲压	No	No	B	2.6	$\geq \Phi 2.8$
262	AD2412BNS-B				Yes	No	B	2.6	$\geq \Phi 2.8$
263	AD2412BUSP-B				No	Yes	B	2.6	$\geq \Phi 2.8$
264	AD2412BNSP-B				Yes	Yes	B	2.6	$\geq \Phi 2.8$
265	AD2416BTS-B	$\Phi 2.4 \times 1600$	Flat 平口	Punch 冲压	No	No	B	2.6	$\geq \Phi 2.8$
266	AD2416BWS-B				Yes	No	B	2.6	$\geq \Phi 2.8$
267	AD2416BTSP-B				No	Yes	B	2.6	$\geq \Phi 2.8$
268	AD2416BWSP-B				Yes	Yes	B	2.6	$\geq \Phi 2.8$
269	AD2416BUS-B		alligat or 鳄口	Punch 冲压	No	No	B	2.6	$\geq \Phi 2.8$
270	AD2416BNS-B				Yes	No	B	2.6	$\geq \Phi 2.8$
271	AD2416BUSP-B				No	Yes	B	2.6	$\geq \Phi 2.8$
272	AD2416BNSP-B				Yes	Yes	B	2.6	$\geq \Phi 2.8$
273	AD2418BTS-B	$\Phi 2.4 \times 1800$	Flat 平口	Punch 冲压	No	No	B	2.6	$\geq \Phi 2.8$
274	AD2418BWS-B				Yes	No	B	2.6	$\geq \Phi 2.8$
275	AD2418BTSP-B				No	Yes	B	2.6	$\geq \Phi 2.8$
276	AD2418BWSP-B				Yes	Yes	B	2.6	$\geq \Phi 2.8$

277	AD2418BUS-B	alligat or 鳄口	Punch 冲压	No	No	B	2.6	$\geq \Phi 2.8$	
278	AD2418BNS-B			Yes	No	B	2.6	$\geq \Phi 2.8$	
279	AD2418BUSP-B			No	Yes	B	2.6	$\geq \Phi 2.8$	
280	AD2418BNSP-B			Yes	Yes	B	2.6	$\geq \Phi 2.8$	
281	AD2423BTS-B	Flat 平口	Punch 冲压	No	No	B	2.6	$\geq \Phi 2.8$	
282	AD2423BWS-B			Yes	No	B	2.6	$\geq \Phi 2.8$	
283	AD2423BTSP-B			No	Yes	B	2.6	$\geq \Phi 2.8$	
284	AD2423BWSP-B			Yes	Yes	B	2.6	$\geq \Phi 2.8$	
285	AD2423BUS-B	alligat or 鳄口	Punch 冲压	No	No	B	2.6	$\geq \Phi 2.8$	
286	AD2423BNS-B			Yes	No	B	2.6	$\geq \Phi 2.8$	
287	AD2423BUSP-B			No	Yes	B	2.6	$\geq \Phi 2.8$	
288	AD2423BNSP-B			Yes	Yes	B	2.6	$\geq \Phi 2.8$	
289	AD1807BTC-B	Flat 平口	MIM 粉末冶金	No	No	B	1.95	$\geq \Phi 2.0$	
290	AD1807BWC-B			Yes	No	B	1.95	$\geq \Phi 2.0$	
291	AD1807BTCP-B			No	Yes	B	1.95	$\geq \Phi 2.0$	
292	AD1807BWCP-B			Yes	Yes	B	1.95	$\geq \Phi 2.0$	
293	AD1807BUC-B		alligat or 鳄口	MIM 粉末冶金	No	No	B	1.95	$\geq \Phi 2.0$
294	AD1807BNC-B				Yes	No	B	1.95	$\geq \Phi 2.0$
295	AD1807BUCP-B				No	Yes	B	1.95	$\geq \Phi 2.0$
296	AD1807BNCP-B				Yes	Yes	B	1.95	$\geq \Phi 2.0$
297	AD1810BTC-B	Flat 平口	MIM 粉末冶金	No	No	B	1.95	$\geq \Phi 2.0$	
298	AD1810BWC-B			Yes	No	B	1.95	$\geq \Phi 2.0$	
299	AD1810BTCP-B			No	Yes	B	1.95	$\geq \Phi 2.0$	
300	AD1810BWCP-B			Yes	Yes	B	1.95	$\geq \Phi 2.0$	
301	AD1810BUC-B		alligat or 鳄口	MIM 粉末冶金	No	No	B	1.95	$\geq \Phi 2.0$
302	AD1810BNC-B				Yes	No	B	1.95	$\geq \Phi 2.0$
303	AD1810BUCP-B				No	Yes	B	1.95	$\geq \Phi 2.0$
304	AD1810BNCP-B				Yes	Yes	B	1.95	$\geq \Phi 2.0$
305	AD1812BTC-B	Flat 平口	MIM 粉末冶金	No	No	B	1.95	$\geq \Phi 2.0$	
306	AD1812BWC-B			Yes	No	B	1.95	$\geq \Phi 2.0$	
307	AD1812BTCP-B			No	Yes	B	1.95	$\geq \Phi 2.0$	
308	AD1812BWCP-B			Yes	Yes	B	1.95	$\geq \Phi 2.0$	
309	AD1812BUC-B		alligat or 鳄口	MIM 粉末冶金	No	No	B	1.95	$\geq \Phi 2.0$
310	AD1812BNC-B				Yes	No	B	1.95	$\geq \Phi 2.0$
311	AD1812BUCP-B				No	Yes	B	1.95	$\geq \Phi 2.0$
312	AD1812BNCP-B				Yes	Yes	B	1.95	$\geq \Phi 2.0$
313	AD1816BTC-B	Flat 平口	MIM 粉末冶金	No	No	B	1.95	$\geq \Phi 2.0$	
314	AD1816BWC-B			Yes	No	B	1.95	$\geq \Phi 2.0$	
315	AD1816BTCP-B			No	Yes	B	1.95	$\geq \Phi 2.0$	
316	AD1816BWCP-B			Yes	Yes	B	1.95	$\geq \Phi 2.0$	
317	AD1816BUC-B		alligat	MIM	No	No	B	1.95	$\geq \Phi 2.0$

318	AD1816BNC-B			Yes	No	B	1.95	$\geq \Phi 2.0$	
319	AD1816BUCP-B			No	Yes	B	1.95	$\geq \Phi 2.0$	
320	AD1816BNCP-B			Yes	Yes	B	1.95	$\geq \Phi 2.0$	
321	AD1818BTC-B	$\Phi 1.8 \times 1800$	Flat 平口	MIM 粉末冶金	No	No	B	1.95	$\geq \Phi 2.0$
322	AD1818BWC-B				Yes	No	B	1.95	$\geq \Phi 2.0$
323	AD1818BTCP-B				No	Yes	B	1.95	$\geq \Phi 2.0$
324	AD1818BWCP-B				Yes	Yes	B	1.95	$\geq \Phi 2.0$
325	AD1818BUC-B		alligat or 鳄口	MIM 粉末冶金	No	No	B	1.95	$\geq \Phi 2.0$
326	AD1818BNC-B				Yes	No	B	1.95	$\geq \Phi 2.0$
327	AD1818BUCP-B				No	Yes	B	1.95	$\geq \Phi 2.0$
328	AD1818BNCP-B				Yes	Yes	B	1.95	$\geq \Phi 2.0$
329	AD1823BTC-B	$\Phi 1.8 \times 2300$	Flat 平口	MIM 粉末冶金	No	No	B	1.95	$\geq \Phi 2.0$
330	AD1823BWC-B				Yes	No	B	1.95	$\geq \Phi 2.0$
331	AD1823BTCP-B				No	Yes	B	1.95	$\geq \Phi 2.0$
332	AD1823BWCP-B				Yes	Yes	B	1.95	$\geq \Phi 2.0$
333	AD1823BUC-B		alligat or 鳄口	MIM 粉末冶金	No	No	B	1.95	$\geq \Phi 2.0$
334	AD1823BNC-B				Yes	No	B	1.95	$\geq \Phi 2.0$
335	AD1823BUCP-B				No	Yes	B	1.95	$\geq \Phi 2.0$
336	AD1823BNCP-B				Yes	Yes	B	1.95	$\geq \Phi 2.0$
337	AD2407BTC-B	$\Phi 2.4 \times 700$	Flat 平口	MIM 粉末冶金	No	No	B	2.6	$\geq \Phi 2.8$
338	AD2407BWC-B				Yes	No	B	2.6	$\geq \Phi 2.8$
339	AD2407BTCP-B				No	Yes	B	2.6	$\geq \Phi 2.8$
340	AD2407BWCP-B				Yes	Yes	B	2.6	$\geq \Phi 2.8$
341	AD2407BUC-B		alligat or 鳄口	MIM 粉末冶金	No	No	B	2.6	$\geq \Phi 2.8$
342	AD2407BNC-B				Yes	No	B	2.6	$\geq \Phi 2.8$
343	AD2407BUCP-B				No	Yes	B	2.6	$\geq \Phi 2.8$
344	AD2407BNCP-B				Yes	Yes	B	2.6	$\geq \Phi 2.8$
345	AD2410BTC-B	$\Phi 2.4 \times 1000$	Flat 平口	MIM 粉末冶金	No	No	B	2.6	$\geq \Phi 2.8$
346	AD2410BWC-B				Yes	No	B	2.6	$\geq \Phi 2.8$
347	AD2410BTCP-B				No	Yes	B	2.6	$\geq \Phi 2.8$
348	AD2410BWCP-B				Yes	Yes	B	2.6	$\geq \Phi 2.8$
349	AD2410BUC-B		alligat or 鳄口	MIM 粉末冶金	No	No	B	2.6	$\geq \Phi 2.8$
350	AD2410BNC-B				Yes	No	B	2.6	$\geq \Phi 2.8$
351	AD2410BUCP-B				No	Yes	B	2.6	$\geq \Phi 2.8$
352	AD2410BNCP-B				Yes	Yes	B	2.6	$\geq \Phi 2.8$
353	AD2412BTC-B	$\Phi 2.4 \times 1200$	Flat 平口	MIM 粉末冶金	No	No	B	2.6	$\geq \Phi 2.8$
354	AD2412BWC-B				Yes	No	B	2.6	$\geq \Phi 2.8$
355	AD2412BTCP-B				No	Yes	B	2.6	$\geq \Phi 2.8$
356	AD2412BWCP-B				Yes	Yes	B	2.6	$\geq \Phi 2.8$
357	AD2412BUC-B	$\Phi 2.4 \times 1200$	alligat or	MIM 粉末冶金	No	No	B	2.6	$\geq \Phi 2.8$
358	AD2412BNC-B				Yes	No	B	2.6	$\geq \Phi 2.8$

359	AD2412BUCP-B				No	Yes	B	2.6	$\geq \Phi 2.8$			
360	AD2412BNCP-B				Yes	Yes	B	2.6	$\geq \Phi 2.8$			
361	AD2416BTC-B	$\Phi 2.4 \times 1600$	Flat 平口	MIM 粉末冶金	No	No	B	2.6	$\geq \Phi 2.8$			
362	AD2416BWC-B				Yes	No	B	2.6	$\geq \Phi 2.8$			
363	AD2416BTCP-B				No	Yes	B	2.6	$\geq \Phi 2.8$			
364	AD2416BWCP-B				Yes	Yes	B	2.6	$\geq \Phi 2.8$			
365	AD2416BUC-B				No	No	B	2.6	$\geq \Phi 2.8$			
366	AD2416BNC-B				Yes	No	B	2.6	$\geq \Phi 2.8$			
367	AD2416BUCP-B	$\Phi 2.4 \times 1800$	alligat or 鳄口	MIM 粉末冶金	No	Yes	B	2.6	$\geq \Phi 2.8$			
368	AD2416BNCP-B				Yes	Yes	B	2.6	$\geq \Phi 2.8$			
369	AD2418BTC-B				No	No	B	2.6	$\geq \Phi 2.8$			
370	AD2418BWC-B				Yes	No	B	2.6	$\geq \Phi 2.8$			
371	AD2418BTCP-B	$\Phi 2.4 \times 1800$	Flat 平口	MIM 粉末冶金	No	Yes	B	2.6	$\geq \Phi 2.8$			
372	AD2418BWCP-B				Yes	Yes	B	2.6	$\geq \Phi 2.8$			
373	AD2418BUC-B				No	No	B	2.6	$\geq \Phi 2.8$			
374	AD2418BNC-B				Yes	No	B	2.6	$\geq \Phi 2.8$			
375	AD2418BUCP-B				No	Yes	B	2.6	$\geq \Phi 2.8$			
376	AD2418BNCP-B				Yes	Yes	B	2.6	$\geq \Phi 2.8$			
377	AD2423BTC-B				$\Phi 2.4 \times 2300$	Flat 平口	MIM 粉末冶金	No	No	B	2.6	$\geq \Phi 2.8$
378	AD2423BWC-B							Yes	No	B	2.6	$\geq \Phi 2.8$
379	AD2423BTCP-B	No	Yes	B				2.6	$\geq \Phi 2.8$			
380	AD2423BWCP-B	Yes	Yes	B				2.6	$\geq \Phi 2.8$			
381	AD2423BUC-B	No	No	B				2.6	$\geq \Phi 2.8$			
382	AD2423BNC-B	Yes	No	B				2.6	$\geq \Phi 2.8$			
383	AD2423BUCP-B	No	Yes	B				2.6	$\geq \Phi 2.8$			
384	AD2423BNCP-B	Yes	Yes	B				2.6	$\geq \Phi 2.8$			

### 2.3 Product overview 产品概述

The disposable endoscopic biopsy forceps consist of a jaw head assembly, a tube body and a handle. Used with endoscope, it is mainly used to clamp living mucosa tissue under endoscope for inspection. The product has good insertability, and the jaws are flexible and sharp. The jaw head has flat mouth type, alligator mouth type, flat mouth with needle type, alligator mouth with needle type.

取样钳由钳头组件、管身和手柄组成。配合内窥镜使用，主要用于夹住内窥镜下的活粘膜组织进行检查。产品可插入性良好，爪部灵活锋利。钳头包括平口型、鳄口型、平口带针型、鳄口带针型。

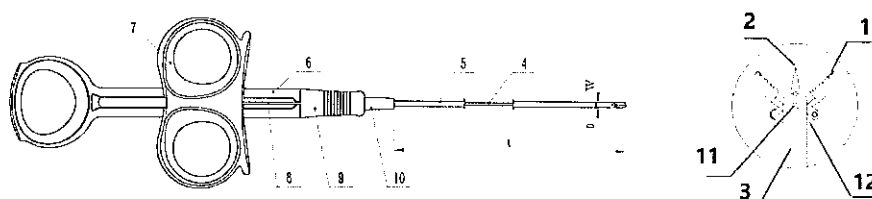
### 2.4 Structural composition 结构组成

The product consists of three parts: jaw head assembly, tube body (spring tube or plastic coated spring tube) and handle (A-type handle or B-type handle).

产品由钳头组件、管身（弹簧管或包塑弹簧管）和手柄（A型手柄或B型手柄）三部分组成

2.4.1 The structure diagram of A-type handle biopsy forceps, see Figure 1.

A 型手柄取样钳结构示意图，见图 1。



1-jaw 2-locating pin 3-support 4-stainless steel rope 5-spring tube/spring tube plastic-coating 6-shaft 7- ring 8-puller 9-protective cap 10-protective sleeve 11-pin 12-connecting rod D-outer diameter L-working length W- Maximum width of inserting part

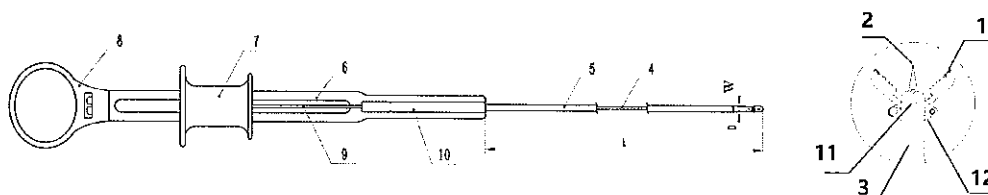
1-钳头 2-定位针 3-支撑架 4-不锈钢丝绳 5-弹簧管/包塑弹簧管 6-钳柄 7-钳环 8-拉杆 9-防护帽 10-保护套管 11-销钉 12-连杆 D-工作外径 L-工作长度 W-插入部最大宽度

Figure 1 Schematic diagram of the structure of biopsy forceps (type A handle)

图 1 一次性使用活组织取样钳 (A 型手柄) 结构示意图

2.4.2 The structure diagram of B-type handle biopsy forceps, see Figure 2.

B 型手柄取样钳结构示意图，见图 2。



1-jaw 2-locating pin 3-support 4-stainless steel rope 5-spring tube/spring tube plastic-coating 6-handle 7-ring 8-thumb ring 9-puller 10-pressure plate 11-pin 12-connecting rod D-working outer diameter L-working length W- Maximum width of inserting part

1-钳头 2-定位针 3-支撑架 4-不锈钢丝绳 5-弹簧管/包塑弹簧管 6-钳柄 7-钳环 8-拇指环 9-拉杆 10-压板 11-销钉 12-连杆 D-工作外径 L-工作长度 W-插入部最大宽度

Figure 2 Schematic diagram of the structure of biopsy forceps (type B handle)

图 2 一次性使用活组织取样钳 (B 型手柄) 结构示意图

2.4.3 The flat, flat with needle, alligator and alligator with needle forms of the tongs used in a one-off use. See Figure 3 for a schematic diagram of the jaw head.

一次性使用活组织取样钳的钳头有平口型、平口带针型、鳄口型和鳄口带针型四种形式。钳头示意图，见图 3。

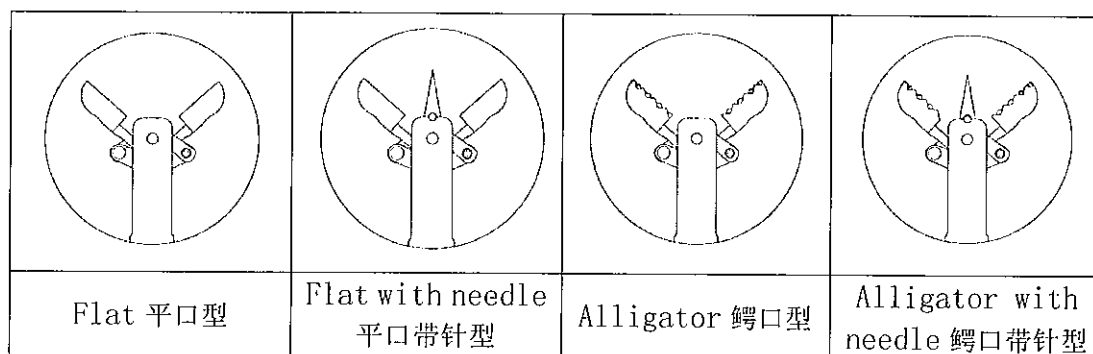


Figure 3 Schematic diagram of jaw head  
图3 钳头示意图

### 3 Intended use 预期用途

Endoscopic biopsy of the digestive tract and removal of foreign bodies.  
通过内镜对消化道的活组织取样和钳取清除异物

### 4 Indications 适应症

This product is used to clamp the living mucosa tissue under the endoscope for inspection  
产品适用于需要内镜下做活检的患者

### 5 Intended users 预期使用者

The trained medical professionals. 经培训的专业医务人员

### 6 Intended patient group 预期的病人群体

Intended patient population older than one year  
大于一岁的病人群体

### 7 Appearance 外观

7.1. The outer surface of the jaws of the biopsy forceps should be smooth, clean, and free from sharp edges, burrs and other surface defects.

取样钳钳头的外表面应光滑、清洁，无锋棱、无毛刺等表面缺陷。

7.2. The coiled body of the biopsy forceps should be tight and straight, without obvious gaps and bending; the outer surface of the plastic coating is smooth, clean, straight, and without color difference, and there should be no bubbles, pinholes and twists.

取样钳管身盘绕应紧密、平直，不应有明显的间隙和折曲；包塑层外表面光滑、清洁、平直、无色差，不应有气泡、针孔和曲折。

7.3. The handle of the biopsy forceps should be smooth and free of scars, uniform in color, and without obvious patterns and bubbles.

取样钳手柄应光洁无结疤，色泽均匀，无明显花纹和气泡。

7.4. The needle tip of the jaw with needles should not be deformed or obviously skewed. The needle tip should not protrude from the pliers when the pliers are closed.

带针钳头针尖不可有变形、明显歪斜等缺陷，钳头闭合时针尖不可凸出钳头。

7.5. The teeth of the alligator jaws are evenly arranged, the teeth are clear, the alignment is accurate, and the mesh is in place.

鳄鱼口型钳头的齿型排布均匀、齿型清晰，对位准确、啮合到位。

## 8 Performance 性能

8.1. The head of the biopsy forceps should be smooth, and the cutting edge should be complete and sharp. When the jaw head is closed, the head end to one-half of the point should be anastomosed without obvious deviation.

取样钳钳头应光滑，刃口应完整、锐利。钳头闭合时头端至二分之一处应吻合，不得有明显偏歪。

8.2. The opening angle of the two jaws of the biopsy forceps should not be less than  $90^\circ$ ; when the jaws of the needle sampling forceps are opened to  $90^\circ$ , the needle tip should be longer than the end of the forceps, and the jaws should not be exposed when closed.

取样钳钳头二片张开角度应不小于  $90^\circ$ ；带针取样钳钳头张开至  $90^\circ$  时，针尖应长于钳端，闭合时不得露出钳头。

8.3. The jaws of the biopsy forceps should be opened and closed easily and flexibly without jamming.

取样钳钳头开闭应轻松灵活，不得有卡塞现象。

8.4. Corrosion resistance 耐腐蚀性能

The outer surface of the jaws of the biopsy forceps and the metal parts shall not show signs of corrosion.

取样钳钳头及金属部件的外表面不得出现腐蚀痕迹。

8.5. Sterility requirements 无菌要求

The product is sterilized with ethylene oxide, and the product should be sterile.

产品采用环氧乙烷灭菌，产品应无菌。

8.6. Residual ethylene oxide 环氧乙烷残留量

After the product is sterilized, the residual amount of ethylene oxide should not exceed 4mg/device.

产品灭菌后，环氧乙烷残留量应不大于 4mg/件。

## 9. Directions for use 使用说明

9.1. Observe the target that needs biopsy under the endoscope, and select the biopsy forceps that matches the channel of the endoscope.

在内窥镜下观察需要活检的目标，选择与内窥镜通道相匹配的取样钳。

9.2. Pull the ring back to close the jaw head, and insert the biopsy forceps into the endoscopic biopsy channel.

后拉钳环使钳头闭合，将取样钳插入内窥镜活检通道。

9.3. Slowly push the biopsy forceps until the head of the biopsy forceps is visible under the endoscope.

缓慢推送取样钳直至在内窥镜视野下可见取样钳头部露出。

9.4. Push the ring to open the jaw head and push it to the desired biopsy tissue site.

推动钳环将钳头张开，并推至所需钳取的活检组织部位。

9.5. Pull the ring to close the jaw head around the biopsy tissue.

拉动钳环，围绕活检组织闭合钳头。

Note: If the jaw head cannot be closed completely, the endoscope and biopsy forceps can be taken out at the same time, and then the forceps heads can be manually closed, and the biopsy forceps can be withdrawn from the channel of the endoscope.

**注意：**如钳头无法完全闭合，可将内窥镜和取样钳作为一体同时取出，然后手动关闭钳头，从内窥镜通道中撤出取样钳。

9.6. Gently apply a backward pulling force on the jaw ring of the biopsy forceps to keep the jaw head in the closed state, and pull the biopsy forceps back from the endoscope channel.

在取样钳钳环处轻轻施加向后拉力以保持钳头继续处于闭合状态，从内窥镜通道中回拉取样钳。

9.7. Prepare specimens for inspection according to the country or local regulations.

按所在国家或当地的规范准备标本，以备检查。

## 10 Contraindications 禁忌症

10.1. Patients with coagulopathy

10.2. Patients with other systemic diseases who can not tolerate endoscopy and treatment.

10.3. Patients with mental diseases, unable to cooperate with endoscopy and treatment.

10.4. Physicians determine that endoscopic treatment is not appropriate after weighing the advantages and disadvantages.

10.1. 患者有凝血功能障碍的

10.2. 患者合并其他系统疾病无法耐受内镜检查 and 治疗的。

10.3. 患者合并精神系统疾病，无法配合内镜检查 and 治疗的。

10.4. 医师经利弊权衡，认定不合适进行内镜治疗的。

## 11 Potential complications 潜在并发症

Others include (but are not limited to): coagulopathy. Complications caused by disposable endoscopic biopsy forceps include (but are not limited to): minor bleeding, perforation, fever, infection, membrane tear, redness and swelling. 其他包括（但不限于）：凝血性疾病。一次性使用活组织取样钳引起的并发症包括（但不限于）：轻微出血，穿孔，发热，感染，膜撕裂、红肿。

## 12 Precautions 注意事项

12.1. Check the integrity and expiration date of the product packaging. If the packaging is damaged or the product has exceeded the expiration date, it is strictly prohibited to use!

12.2. Please read the product manual carefully before using the product. Understand the minimum endoscope channel size required to use this device through



the product label;

12.3. Before using the product, check the entire device for any abnormal phenomena such as disconnection, bending, breakage of the connection part, and failure of the jaw head to open. If you find the above conditions that affect the normal operation of the device, please do not use it.

12.4. When the biopsy forceps encounter resistance during the pushing process, the endoscope can be slightly straightened, and the biopsy forceps should not be forced through the channel of the endoscope to avoid damage to the channel of the endoscope.

12.5. If the endoscope has an auxiliary forceps lifter, the forceps lifter should be closed before pushing the biopsy forceps; if resistance is encountered during the pushing process, the forceps lifter should be opened to allow the biopsy forceps to pass and use the forceps lifter to position the biopsy forceps.

12.6. This product is a single-use sterile product. After use, please destroy it in accordance with the country's or local bio-hazardous medical waste management regulations. Repeated use is strictly prohibited.

12.7. This product must be operated by a trained physician.

12.8. Intended application site: sampling the living tissues in digestive tract and respiratory tract through endoscope

12.9. This product shall be used in combination with flexible endoscope. The model of endoscope shall be selected according to the inner diameter of applicable forceps channel specified in Table 1.

12.1. 检查产品包装的完整性和有效期，包装破损或产品超过有效期，严禁使用！

12.2. 使用产品前，请仔细阅读该产品说明书。通过产品标签了解使用本器械所需要的最小内镜通道尺寸；

12.3. 使用产品前，检查整个器械是否存在连接部位脱落、弯折、破损以及钳头无法打开等异常现象，如发现上述影响器械正常工作的情况，请勿使用。

12.4. 当取样钳在推送过程中遇到阻力，可略微伸直内窥镜，不得强行用力将取样钳推过内窥镜通道，以免损伤内窥镜道。

12.5. 若内窥镜有辅助抬钳器，在推送取样钳之前应关闭抬钳器；如推送过程中遇到阻力，应打开抬钳器，让取样钳通过，使用抬钳器定位取样钳。

12.6. 本产品为一次性使用的无菌产品，用后请按所在国家或当地的生物危险性医疗废弃物管理规范销毁，严禁重复使用。

12.7. 本品必须由过培训的医师操作。

12.8. 预期使用部位：通过内镜对消化道和呼吸道的活组织取样。

12.9. 该产品需配合软式内窥镜使用，内窥镜的型号需要根据表1中规定的适用钳道内径来选择。

### 13 Warning 警告

13.1. It is strictly forbidden to use when the package has been opened or damaged!

13.2. Only for single use!

13.3. Repeated sterilization is strictly prohibited!

13.4. It is strictly forbidden to use the product when its expiration date has expired!

13.5. Before using the device, the doctor should be familiar with the operation and use of the device.

13.6. Before using the device, the doctor should read the product instructions completely.

13.1. 包装已打开或破损时，严禁使用！

13.2. 仅供单次/单人使用！

13.3. 严禁重复灭菌使用！

13.4. 产品超过有效期时，严禁使用！

13.5. 在使用该器械之前，医生应熟悉器械操作使用。

13.6. 在使用该器械之前，医生应完整阅读产品使用说明书。

#### 14 Transportation & Storage 运输和储存条件

14.1. Avoid hard pressure, direct sunlight and rain exposure.

14.2. The product shall be stored in a well-ventilated room with relative humidity of not more than 80% and without corrosive gas.

14.1. 防止重压、阳光直射和雨水淋湿。









14.2. 产品应存放在相对湿度不超过 80%、无腐蚀气体和通风良好的室内。














#### 15 Shelf life 保存期限

Sterilized using Ethylene Oxide. Shelf life is 2 years. Manufacture date and expiration date on the product label.

产品采用环氧乙烷气体灭菌，产品有效期为 2 年。生产日期及失效日期见产品标签。

#### 16 Packaging Marks 包装标志

No.	Symbol	Meaning	No.	Symbol	Meaning
1		Manufacturer 制造商	14		Authorized representative in the European Community/ European Union 欧洲共同体/欧洲联盟授权代表
2		Date and Country of manufacture 制造日期和国家	15		Use by date 有效期
3		Batch code 批号	16		Catalogue number 产品编号
4		Sterilized using ethylene oxide 采用 EO 灭菌	17		Single sterile barrier system with protective packaging outside 单一无菌屏障系统，外部有保护性包装

5		Do not re-sterilize 不得二次灭菌	18		Do not use if package is damaged and consult instructions for use 如包装破损切勿使用, 请咨询使用说明
6		Model number 型号	19		Keep away from sunlight 保存遮光
7		Keep dry 保持干燥	20		Unique device identifier 设备唯一标识符
8		Humidity limitation 湿度极限	21		Do not re-use 不得二次使用
9		Consult instructions for use or consult electronic instructions for use 参考使用说明或参考电子使用说明	22		Caution 警告
10		Does not contain natural rubber latex 不含天然橡胶胶乳	23		Non-pyrogenic 无热原
11		Medical device 医疗器械	24		Quantity 数量
12		CE Marking CE 标识	25		This way up 向上
13		Single sterile barrier system 单一无菌屏障系统			



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