



Disposable Needle Guides

for Endocavity or General Purpose Biopsy

User Manual

Thank you for purchasing our product. Please read this manual carefully before using it, and use it strictly in accordance with the requirements of the product manual. After reading, keep it in a safe place for future reference.

1. Product name

Disposable Needle Guides for endocavity or general purpose biopsy.

2. Models

According to the purpose, products can be divided into nine types:

- 1) Endocavity needle guides (Denoted by DE)
- 2) General purpose needle guides (out-of-plane) (Denoted by DG)
- 3) General purpose needle guides (in-plane) (Denoted by DGC)
- 4) Endocavity biopsy kit (Denoted by DEK)
- 5) General purpose biopsy kit (out-of-plane) (Denoted by DGK)
- 6) General purpose biopsy kit (in-plane) (Denoted by DGCK)
- 7) Gel and probe cover kit (Denoted by DPK)
- 8) Ultrasound probe cover

The product configuration is as follows.

Model	Configuration and Quantity					
	Basic Accessories	Qty	Basic Accessories	Qty	Basic Accessories	Qty
DE	Needle guide (endocavity)	1 set	/	/	/	/
DG	Needle guide (out-of-plane)	1 set	/	/	/	/
DGC	Needle guide (in-plane)	1 set	/	/	/	/
DEK	Needle guide (endocavity)	1 set	20g gel	1 bag	5X30cm latex cover, rubber bands	1 set

DGK	Needle guide (out-of-plane)	1 set	20g gel	1 bag	10X50cm TPU cover, rubber bands	1 set
DGCK	Needle guide (in-plane)	1 set	20g gel	1 bag	14X50cm TPU cover, rubber bands	1 set
DPK	/	/	20g gel	1 bag	ultrasound probe cover, rubber bands	1 set

2.1 31 DE/DEK model details as follows

Model	Gauge Size	Compatible Transducers (endocavity use ultrasound transducer)
DE-001 DEK-001	16-18G	【Mindray】 65EC10EA, 65EC10EB, 6CV1(s), 6CV1P, CB10-4(s), CB10-4P, CB10-4E, CB10-4A, V10-4(s), V10-4B(s), V10-4BP, V11-3Ws, V11-3(E), V11-3B(E), V11-3W(E), E9-3, V11-3HE, V11-3HU; 【GE Healthcare】 IC5-9; 【Wisonic】 EV10-4; 【Samsung】 EC4-9IS, EC4-9ES, ER4-9ES; 【Landwind】 EC4-9; 【Zoncare】 6E1CD; 【VINNO】 G4-9E, X4-9E
DE-002 DEK-002	16-18G	【GE Healthcare】 E8C, E8C-RS, E8CS, E8CS-RC, E8CS-RS, E8CS-SC, IC5-9H, E72, E721, MTZ, MZ; 【Samsung】 VR5-9; 【ECM】 E610P
DE-003 DEK-003	16-18G	【Philips】 C8-4v, C9-3v, C10-3v, C9-4v (ClearVue)
DE-004 DEK-004	16-18G	【GE Healthcare】 IC9, IC9-RS
DE-005 DEK-005	16-18G	【Hitachi-Aloka】 UST-984-5, UST-981-5, UST-9112, C41B; 【Mindray】 V11-3HB

DE-006 DEK-006	16-18G	【Esaote】 EC123, SE3133, EC1123, SE3123
DE-007 DEK-007	16-18G	【Esaote】 EC1123, SE3123; 【Siemens】 EC1123
DE-008 DEK-008	16-18G	【Canon/Toshiba】 PVF-641VT, PVM-651VT, PVQ-641V, PVN-661VT, PVT-661VT; 【Siemens】 EC9-4 (ACUSON S1000, S2000, S3000 and SONOLINE Antares)
DE-009 DEK-009	16-18G	【Hitachi-Aloka】 EUP-V33W, EUP-V53W, EUP-CC531, EUP-CC531s, CC41R, CC41R1
DE-010 DEK-010	16-18G	【Hitachi-Aloka】 EUP-V73W, C41V1
DE-011 DEK-011	16-18G	【Philips】 C9-4v (Affiniti30, Affiniti50, Affiniti70, SPARQ, InnoSight)
DE-012 DEK-012	16-18G	【Samsung】 ER4-9/10ED, EV4-9/10ED, EVN4-9, ER4-9; 【Ultrasonix】 EC9-5/10; 【Alpinion】 EN3-10; 【ECM】 E610R
DE-013 DEK-013	16-18G	【Canon/Toshiba】 PVT-781VT, PVU-781VT, PVT-781VTE, PVU-781VTE
DE-014 DEK-014	16-18G	【Siemens】 MC9-4, EC9-4W, 9MC3, 9EC4; 【Konica-Minolta】 EC9-3
DE-015 DEK-015	16-18G	【GE Healthcare】 RIC5-9-D, RIC6-12-D, RIC5-9W-RS, RIC5-9A-RS, RIC5-9-RS, RIC5-9H; 【Mindray】 DE10-3, DE10-3E, DE10-3U, DE10-3WU; 【Samsung】 V5-9, EV3-10B
DE-016 DEK-016	16-18G	【SonoScape】 6V7
DE-017 DEK-017	16-18G	【Philips】 BP10-5ec, C9-4ec (HD7XE & HD9); 【Samsung】 NEV4-9ES, NER4-9ES, E3-12A; 【Alpinion】 E3-10H; 【BK】 8819, E10C4
DE-018 DEK-018	16-18G	【Hitachi-Aloka】 UST-9118, UST-9124

DE-019 DEK-019	16-18G	【SonoScape】 6V3
DE-020 DEK-020	16-18G	【Siemens】 EC-10C5, EC9-4 (CUSONX500;SONOLINE G20, G50, G60S), EV9-4 (ACUSON X500); 【SuperSonic】 SE12-3; 【ECM】 E610A
DE-021 DEK-021	16-18G	【Siemens】 EC9-4, EV9-4 (SONOLINE G40, X150, X300); 【Samsung】 EA2-11B; 【Terason】 8EC4A
DE-022 DEK-022	16-18G	【Philips】 C9-5ec
DE-023 DEK-023	16-18G	【Philips】 C10-4ec
DE-024 DEK-024	16-18G	【Welld】 8EC4A; 【Qsono】 E10-4Cs; 【SonoStar】 6E1C; 【Zoncare】 TC10; 【Youkey】 E10-4Ks; 【Karchun】 EC9-4; 【Sonomedic】 E10-4Cs; 【DAWEI】 C4-9A, EV9-4; 【Unimaging】 EV9-4; 【FocusFusion】 EC9-4
DE-025 DEK-025	16-18G	【SonoScape】 6V1; 【KAIXIN】 6.5C11H1A; 【SIUI】 V6L11C, V6L11K, V6L11F, V5H11, V6LA
DE-026 DEK-026	16-18G	【EDAN】 E10-3B
DE-027 DEK-027	16-18G	【Samsung】 EC4-9/10ED, EC4-9/13CD, EC4-9/10R, EC4-9ED; 【Alpinion】 EV3-10, EV3-10H; 【Neusoft】 EV3-10X, EC3-10X
DE-028 DEK-028	16-18G	【Siemens】 EV10-5, EC10-5w
DE-029 DEK-029	16-18G	【GE Healthcare】 BE9C, BE9CS, BE9CS-RS, BE9CS-D
DE-030 DEK-030	16-18G	【BK】 8808e, 8818, E14C4t
DE-031 DEK-031	16-18G	【Mindray】 DE11-3U, DE11-3P, DE11-3s, DE11-3E, DE11-3, DE11-3WE, DE11-3Ws

2.2 6 DG model details as follows

Model	Components	Needle Size	Biopsy Depth	Compatible Transducers
DG-A01	DG-B011	20-21G	5mm	general ultrasound transducer
	DG-B012	20-21G	10mm	
	DG-B013	20-21G	15mm	
	DG-B015	20-21G	25mm	
	DG-B017	20-21G	35mm	
DG-B011	DG-B011	20-21G	5mm	
DG-B012	DG-B012	20-21G	10mm	
DG-B013	DG-B013	20-21G	15mm	
DG-B015	DG-B015	20-21G	25mm	
DG-B017	DG-B017	20-21G	35mm	

2.3 3 DGK model details as follows

Model	Biopsy Depth	Needle Size	Compatible Transducers
DGK-A01	5mm, 10mm, 15mm, 25mm, 35mm	20-21G	general ultrasound transducer
DGK-A02	15mm, 25mm, 35mm	20-21G	
DGK-A03	5mm, 10mm, 15mm	20-21G	

2.4 17 DGC and 3 DGCK model details as follows

Model	Needle Guides	Needle Size	Compatible Transducers
DGC-01 DGCK-01	10G/10F,11G/9F,12G/8F,13G/7F, 14G/6F,15G,16G,17G,18G,19G,20G, 21G,22G,23G-the above 14 needle guides in one pack	10-23G/ 6-10F	general ultrasound transducer
DGC-0101 DGCK-0101	10G/10F,12G/8F,14G/6F,16G,18G, 20G,22G-the above 7 needle guides in one pack	6F/8F/10F 10/12/14/16/ 18/20/22G	

DGC-0102 DGCK-0102	11G/9F,13G/7F,15G,17G,19G,21G, 23G-the above 7 needle guides in one pack	7F/9F 11/13/15/17/ 19/21/23G	general ultrasound transducer
DGC-0210	10G/10F	10G/10F	
DGC-0211	11G/9F	11G/9F	
DGC-0212	12G/8F	12G/8F	
DGC-0213	13G/7F	13G/7F	
DGC-0214	14G/6F	14G/6F	
DGC-0215	15G	15G	
DGC-0216	16G	16G	
DGC-0217	17G	17G	
DGC-0218	18G	18G	
DGC-0219	19G	19G	
DGC-0220	20G	20G	
DGC-0221	21G	21G	
DGC-0222	22G	22G	
DGC-0223	23G	23G	

2.5 7 DPK model details as follows

Model	Ultrasound Probe Cover Size	Compatible Transducers
DPK-14X50	14X50cm TPU cover	general ultrasound transducer
DPK-14X100	14X100cm TPU cover	
DPK-14X150	14X150cm TPU cover	
DPK-10X50	10X50cm TPU cover	
DPK-10X100	10X100cm TPU cover	
DPK-10X150	10X150cm TPU cover	
DPK-5X30	5X30cm latex cover	endocavity ultrasound transducer

2.6 7 JFC/JYB model details as follows

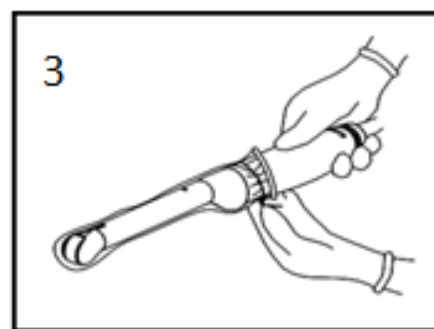
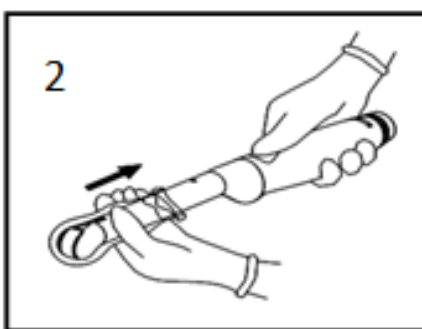
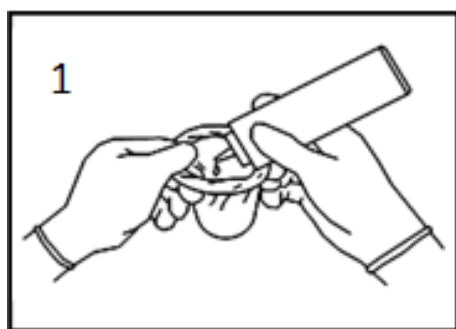
Model	Ultrasound Probe Cover Size	Compatible Transducers
JFC 14X50	14X50cm TPU cover	general ultrasound transducer
JFC 14X100	14X100cm TPU cover	
JFC 14X150	14X150cm TPU cover	
JFC 10X50	10X50cm TPU cover	
JFC 10X100	10X100cm TPU cover	
JFC 10X150	10X150cm TPU cover	
JYB 5X30	5X30cm latex cover	endocavity ultrasound transducer

3. Instructions for use

3.1 DE/DEK

3.1.1 Preparations

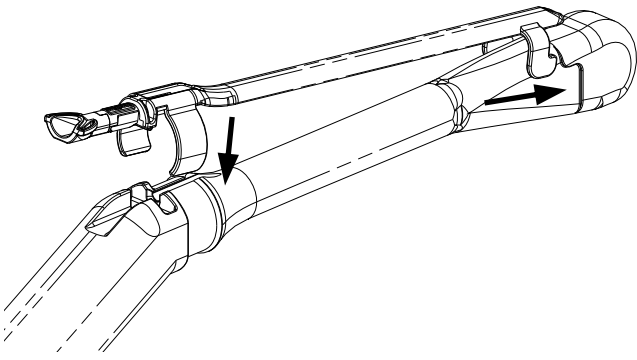
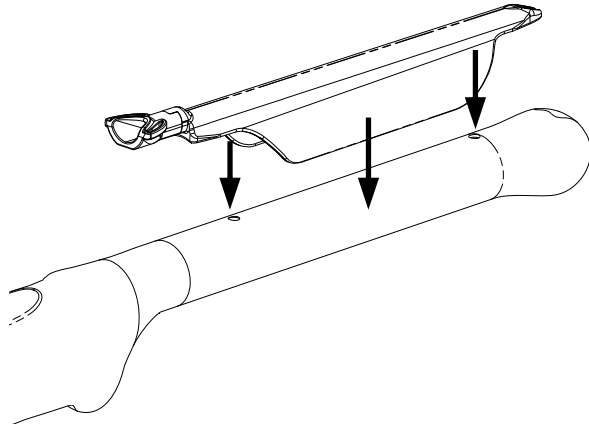
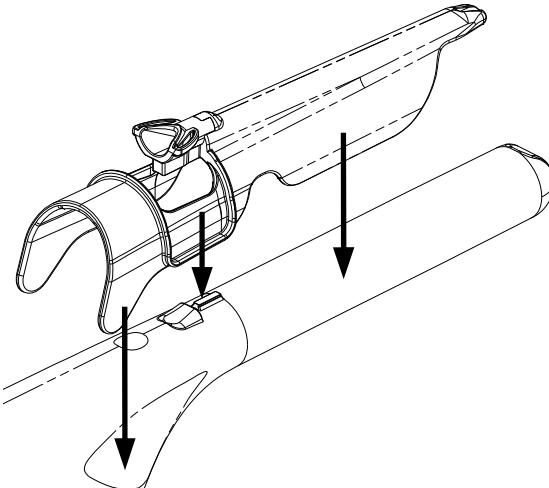
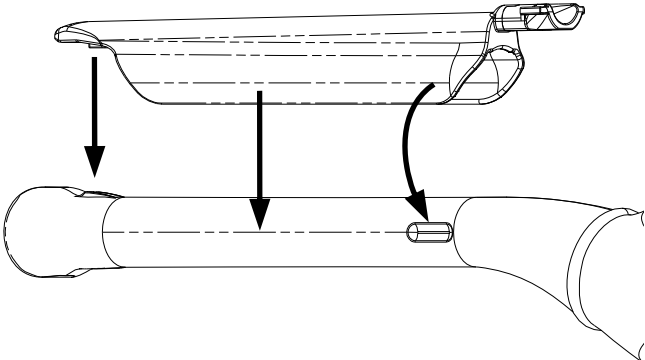
Place an appropriate amount of gel inside cover and/or on transducer surface. (Notice: imaging may be poor if no gel is used). Insert transducer into cover and pull cover tightly over transducer surface, removing wrinkles and air bubbles, and secure cover with bands.



3.1.2 Instructions for attaching disposable needle guide

Align the locating features of disposable needle guide with the transducer, and press down to secure it to the transducer. After confirming

disposable needle guide has been firmly attached, the biopsy needle can be inserted into the needle guide tube for biopsy.

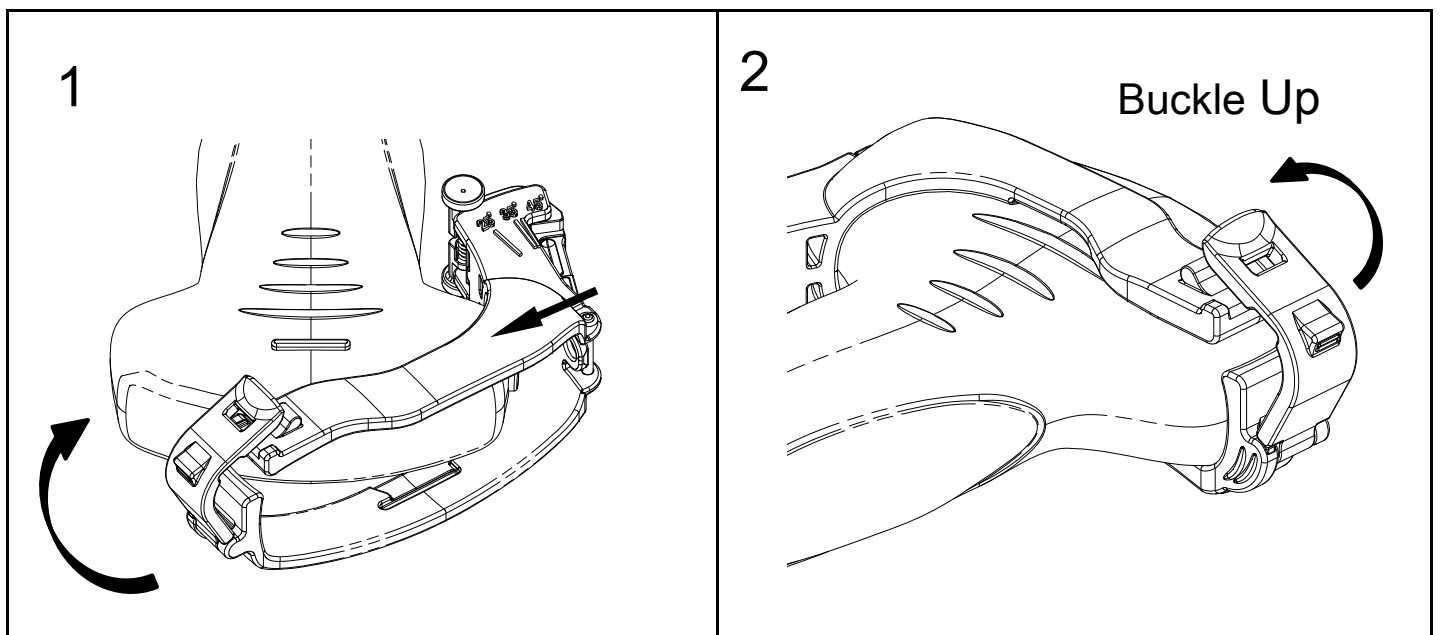
	
For DE/DEK-002,003,005,008, 009,010,013,014,016,018,019,023, 024,025,026,029,031. The front part is attached by hook, and back part is tightened by elastic snap-in.	For DE/DEK-001,004,006,007,011, 012,015,017,020,021,028. Insert the front and back side by locating holes, middle part is tightened by elastic snap-in.
	
For DE/DEK-022. Attached by middle protrusion, avoid whirling by both flat back sides; front part is tightened by elastic snap-in.	For DE/DEK-027,030. Attached by front and back side groove, middle part is tightened by elastic snap-in.

3.2 DGC/DGCK

3.2.1 Preparations

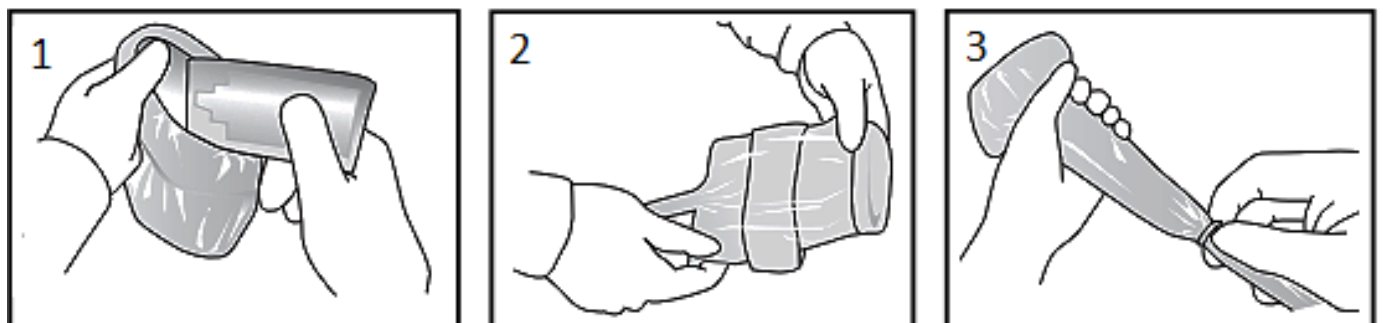
3.2.1.1 Align the reusable bracket

Align the reusable bracket with the locating features on the transducer, and make sure it is securely installed. (Note: reusable bracket is purchased separately by the user)



3.2.1.2 Insert transducer into cover

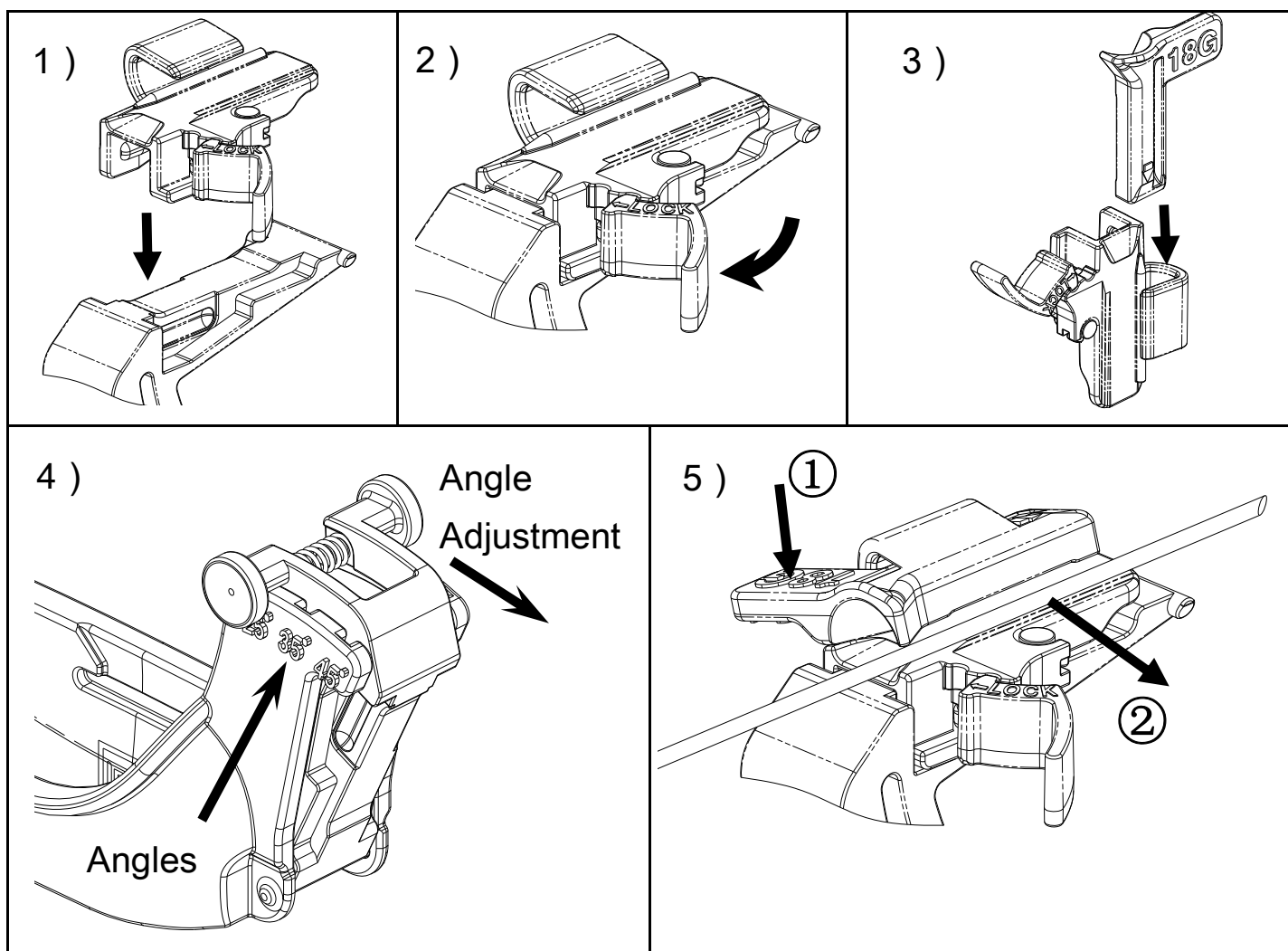
Place an appropriate amount of gel inside cover and/or on transducer surface. (Notice: imaging may be poor if no gel is used). Insert transducer into cover and pull cover tightly over transducer surface, removing wrinkles and air bubbles, and secure cover with bands.



3.2.2 Instructions for attaching the needle guide

According to the puncture site, select needle guide with corresponding depth specification and attach it to the transducer or reusable biopsy bracket, checking whether it is stuck to prevent it falling off.

Select a sufficiently long biopsy needle with matching size according to the surgical site depth, and insert the needle into the needle tube, guiding to the target point. After completing the biopsy, the transducer can be removed to elastically release the needle from the needle tube and biopsy bracket, and then the needle guide and the cover are removed and discarded.

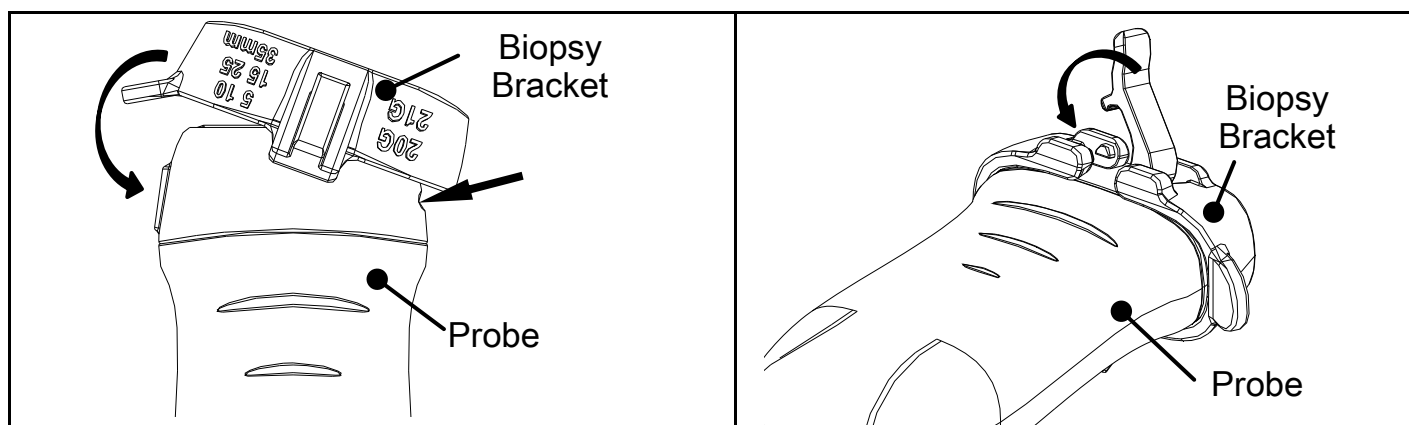


3.3 DG/DGK

3.3.1 Preparations before assembling

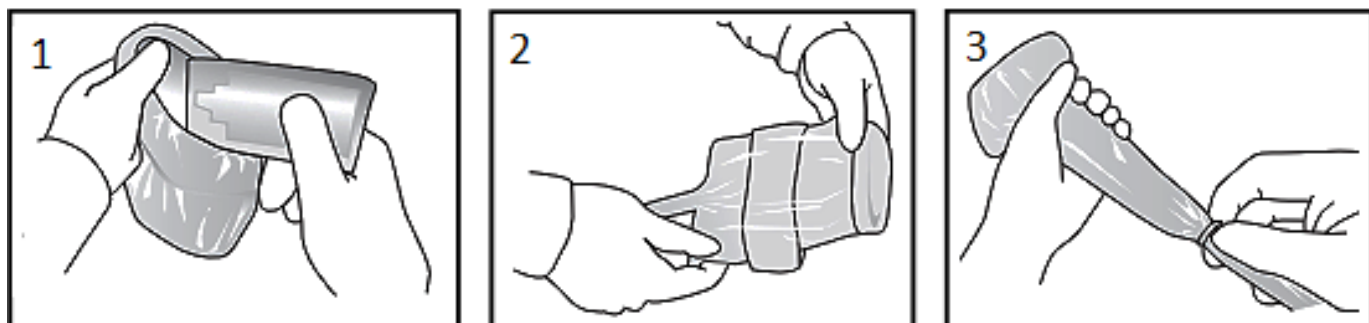
3.3.1.1 Align the reusable bracket

Align the reusable bracket with the locating features on the transducer, checking if it is securely installed. (Note: reusable biopsy bracket are non-sterile, should be purchased separately by the user and used under instruction)



3.3.1.2 Insert transducer into cover

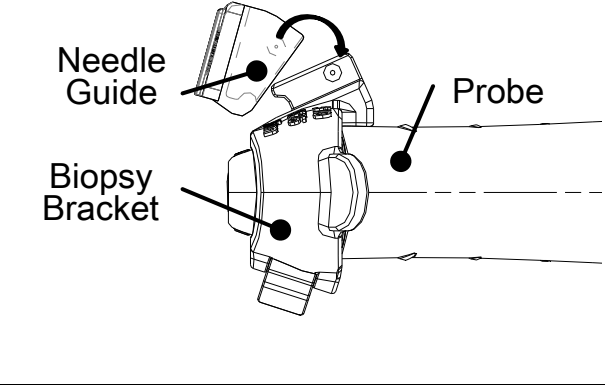
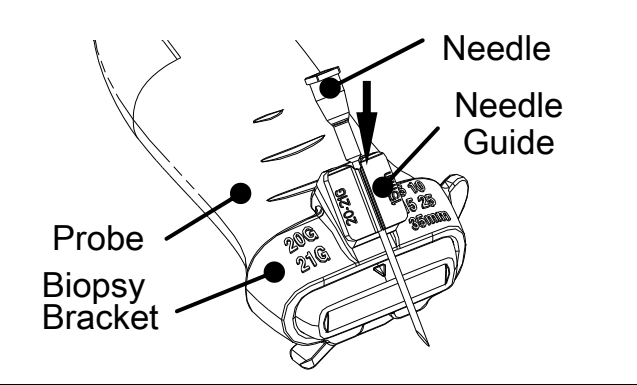
Place an appropriate amount of gel inside cover and/or on transducer surface. (Notice: imaging may be poor if no gel is used). Insert transducer into cover and pull cover tightly over transducer surface, removing wrinkles and air bubbles, and secure cover with bands.



3.3.2 Instructions for attaching the needle guide

According to the puncture site, select needle guide with corresponding depth specification and attach it to the transducer or reusable biopsy bracket, checking whether it is stuck to prevent it falling off.

Select a sufficiently long biopsy needle with matching size according to the surgical site depth, and insert the needle into the needle tube, guiding to the target point. After completing the biopsy, the transducer can be removed to elastically release the needle from the needle tube and biopsy bracket, and then the needle guide and the cover are removed and discarded.

			
Biopsy Guide Depth		Depth between skin reference line and biopsy point	
5mm		3-7 mm	
10mm		8-2 mm	
15mm		13-17 mm	
25mm		23-27 mm	
35mm		33-37 mm	

3.4 Other models

Other models are used as accessories during preparation and before assembly.

4. Precautions

- a) The product can be used only by a doctor or under the supervision of a doctor. He/she must have been trained and has a comprehensive understanding of the ultrasound diagnostic system.
- b) Before using the product for the first time, perform needle path verification in the water to verify system and needle guide relationships. Do not use the needle guide if the needle is not in the path as expected.
- c) Do not use the needle guide with fracture or deformation.
- d) When using the product, make sure the transducer is inserted into a cover, and then attach the needle guide to the cover. The cover must be sterile and can only be used once. If the package of cover is damaged or exceeds the expiration date, do not use it to avoid cross contamination.
- e) Place an appropriate amount of gel inside transducer cover and/or on transducer surface. Imaging may be poor without using gel. Make sure there is no defect with the transducer cover and pull the transducer cover tightly over transducer surface, avoiding wrinkles or bubbles.
- f) The needle guide must be securely mounted without significant shaking.
- g) Make sure the needle used matches the biopsy and the needle guide. The model of the needle guide need to be checked before using, and it's forbidden to use the one without clear label.

- h) Use needle with appropriate length to reach the region of interest.
- i) It's forbidden to reuse the disposable needle guide. After the biopsy, the disposable needle guides and other consumables such as the transducer cover and biopsy needle need to be discarded and processed by hospital medical waste center.
- j) The needle guide can only match the non-sterile reusable bracket manufactured by our company. Do not use if you find it mismatch.

5. Warning

Sterile procedures must be strictly followed when using the needle guides.

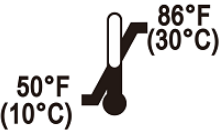
6. Transportation and storage

Disposable needle guide should be stored at the relative humidity of no more than 85%, and temperature range of 10° to 30°. Transport environment should be with the relative humidity of no more than 85% and the temperature range of -40° to 55°.

7. Validity period

Please note that the sterilization validity period of this product is 3 years. The specific production date/sterilization date can be found in the product packaging.

8. Instructions for the graphics and symbols on the label

	Do not use if package is damaged		Sterilized by ethylene oxide
	Do not reuse		Storage temperature limitation
	Keep away from sunlight		Consult instructions for use
	Batch code		Irradiation sterilization
	Date of Manufacture		Use-by date
	Manufacturer		

9. Registration and contact information

Registration/Manufacturing Enterprise:

JingFang Precision Medical Device (Shenzhen) Co., Ltd.

After-sale services supplier:

JingFang Precision Medical Device (Shenzhen) Co., Ltd.

Registration/Production address:

3/F, Bldg C, Jinwei Yuan, Crossing at Qingsong West Road and Qinglan 2nd Road, Julongshan, Grand Industrial Zone, Longtian Street, Pingshan District, 518118 Shenzhen, China

Tel : +86-755-2759 7952

E-mail: sales@innofine.cn / Website: www.innofine.cn



Shanghai International Holding Corp. GmbH (Europe)

Address : Eiffestrasse 80, 20537 Hamburg, Germany

R_x Only

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

H-TY18-D0-0006(B) Date : Mar.23, 2022



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