Radial Artery Compression Tourniquets (Rotary) Instructions for Use

CE 0197

DMK-I-37M A/1
2024-10-8

Radial Artery Compression Tourniquets (Rotary)

Instructions for Use

Please read the instructions for use carefully before use.

Product Description:

Radial Artery Compression Tourniquets (Rotary) (hereinafter referred to as the device) is used to compress the puncture site for hemostasis following invasive procedures of the radial artery.

Device Models and Specifications

DRD/DRPD series

No.	Model	Specification/ Strap length
1	DRD17	170 mm
2	DRD19	190 mm
3	DRD21	210 mm
4	DRPD17	170 mm
5	DRPD19	190 mm
6	DRPD21	210mm

DYD series

No.	Model	Length of Band #1 L1±10%	Color of Band #1, Band #2	Application （Left hand/Right hand）
1	DYD22HZ	220mm	Black	Left hand
2	DYD26HZ	260mm	Black	Left hand
3	DYD30HZ	300mm	Black	Left hand
4	DYD22CZ	220mm	Colour	Left hand
5	DYD26CZ	260mm	Colour	Left hand
6	DYD30CZ	300mm	Colour	Left hand
7	DYD22HY	220mm	Black	Right hand
8	DYD26HY	260mm	Black	Right hand
9	DYD30HY	300mm	Black	Right hand
10	DYD22CY	220mm	Colour	Right hand
11	DYD26CY	260mm	Colour	Right hand

12	DYD30CY	300mm	Colour	Right hand

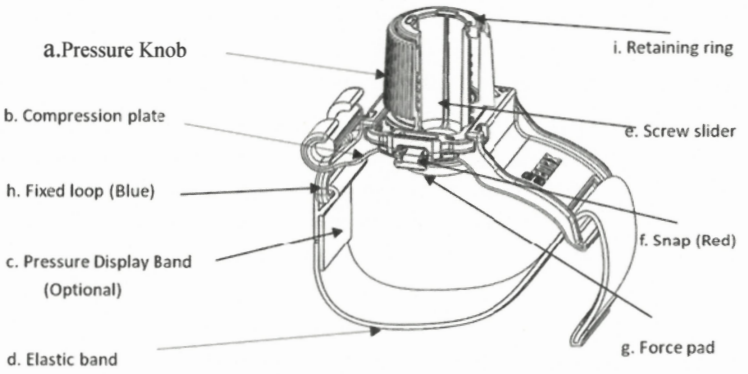
Performance Characteristics:

The device (DRD/DRPD) features include an observation window, pressure display band (Optional), safety lock etc. Elastic band is able to withstand a static tension of 20 N in the horizontal direction for 15 s, and will not break or fall off.

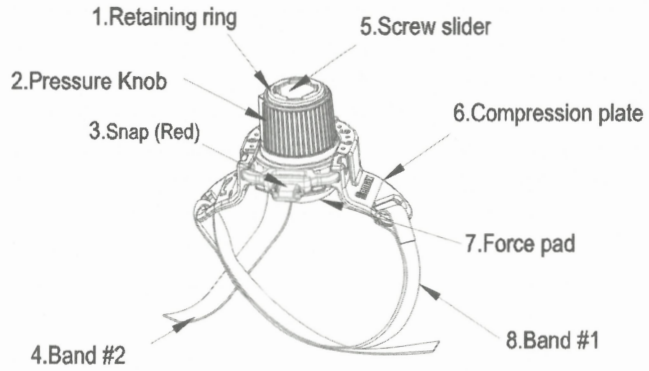
The device (DYD) features include an observation window, safety lock etc. The fixtures are able to withstand a static tension of 20 N in the horizontal direction for 15 s, and will not break or fall off.

Product Diagram:

DRD/DRPD series

No.	Components	Diagrams
a	Pressure Knob	
b	Compression plate	
c	Pressure display band (Optional)	
d	Elastic band	
e	Screw slider	
f	Snap (Red)	
g	Force pad	
h	Fixed loop (Blue)	
i	Retaining ring	

DYD series

No.	Components	Diagrams
1	Retaining ring	
2	Pressure Knob	
3	Snap (Red)	
4	Band #2	
5	Screw slider	
6	Compression plate	
7	Force pad	
8	Band #1	

Intended Purpose:

The Radial Artery Compression Tourniquets (Rotary) is used to temporarily compress the puncture site of the radial artery after percutaneous intervention; The DYD series is also intended for temporary hemostasis of distal radial artery post percutaneous puncture.

Indications for Use:

The Device (DRD/DRPD) is used to assist hemostasis on the puncture site of the radial artery, following trans-radial procedures.

The Device (DYD) is used to assist hemostasis on the puncture site of the distal radial artery, following distal trans-radial procedures.

Clinical Benefits

Temporary hemostasis of radial artery post percutaneous puncture.（DRD/DRPD）

Temporary hemostasis of distal radial artery post percutaneous puncture. (DYD)

Target Population

This product is intended for people who require temporary hemostasis of radial artery post percutaneous puncture.（DRD/DRPD）

This product is intended for people who require temporary hemostasis of distal radial artery post percutaneous puncture.(DYD)

Intended User

The Radial Artery Compression Tourniquets (Rotary) must be operated by professional medical staff.

Contraindications

a. Ulnar artery blood flow obstruction.
b. Multiple punctures of the radial artery, where the device's force pad is unable to cover all puncture sites.
c. Where patients needs to move the wrist and forearm frequently during the postoperative compression period.
d. The device is only designed for hemostasis to puncture sites of the wrist.
e. Allergy to silicone rubber.
f. Patients with abnormal platelet and coagulation function.

Possible Complications:

a. Hematoma and hemorrhage.
b. Local pain and infection.
c. Local skin and soft tissue necrosis.
d. Allergic skin reactions.
e. Arterial occlusion and peripheral vascular blood flow disorders.
f. Arterial and venous thrombosis.
g. False aneurysm.

Transportation condition:

Keep away from heavy and sunshine, keep dry.

Temperature limit：-18℃~55℃.

Humidity limitation：0~85%.

How supplied:

Contents:

One（1）Radial Artery Compression Tourniquets (Rotary)

Sterile: Sterilized with ethylene oxide gas. Non-pyrogenic.

Storage:

This product is the sterile device for single use only. The temperature is 10℃~30℃. The humidity is less than 80%. And stored in a dry, dark, cool place.

The shelf-life is 3 years.

Products/devices to be used together with the Radial Artery Compression Tourniquets (Rotary)

NO.

Precaution:

- Postoperative patients should consult their doctor immediately, if there is any abnormal phenomenon. Please follow doctor's advice.
- During the hemostasis pressure, the patient needs to straighten the wrist at the puncture site side.（DRD/DRPD）
- During the hemostasis pressure, the patient needs to straighten the palm at the puncture site side.(DYD)
- Patients are forbidden to operate the device.
- Be prepared for surgery in case an emergency arises.
- If large doses of heparin are used during the procedure, un-heparinized treatment should be carried out

before the use of the device.

- Patients with systolic blood pressure above 180mmHg should use the device with caution.
- After the device is used, it shall be disposed of according to the disposal method of disposable medical device waste.
- In cold climates, the device's force pad may become hard, but can still be used.
- The device（DRD/DRPD） is normally used on the radial artery of the forearm. When necessary, the device can be turned around and used to stop bleeding following puncture procedures to the ulnar artery and the steps are the same as for radial side.
- The device (DYD) is used only on the distal radial artery of the palm.

Warnings:

- This product is designed for single use only. DO NOT re-sterilize and/or reuse. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another.
- Use the product prior to the "Use By" date specified on the package.
- Do not use if the single package or the product has been damaged or soiled.
- The persons perform this device should be professional and trained.
- Potential biological hazards shall be aware. Please dispose products according to medical practice, local regulation and laws.
- The pressure display band of this product is reference of compression value only.
- Aseptic operation should be carried out during the procedure.

Note: any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

Instructions for use:

a) Estimate the size of the patient's wrist and select the appropriate device (DRD/DRPD) model.
Or estimate the size of the patient's palm and select the appropriate device (DYD) model.

b) Check the packaging before use. If the packaging or device is damaged, do not use.

c) Take the device out of the sterile packaging in accordance with sterile practices and specifications.

Note 1: If the device is used in the ward, you should wear sterile gloves and put on sterile towels.

Note 2: After the device has been taken out of the sterile packaging, please check the following:

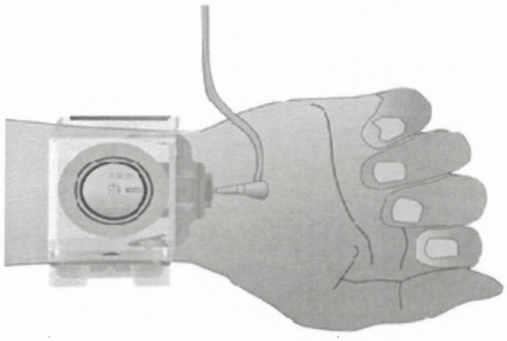
That the force pad should be attached to the compression plate and that the pressure knob rotates freely in both directions.That the elastic band anchor (blue), on the radial side, is securely connected to the compression plate.

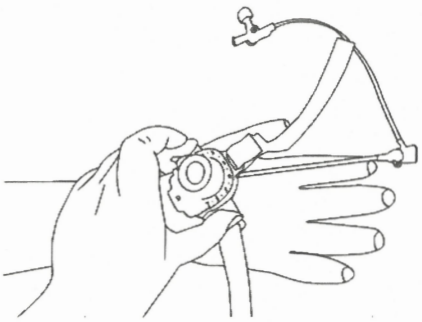
d) Before compression begins, the introducer sheath should be withdrawn 1-2 cm. Ensure there is no vasospasm.

e) The puncture site should be cleaned thoroughly.

Note: Blood and fluid at the puncture site may cause the force pad to slip away from the puncture site and cause bleeding.

f) Choosing compression point. Using the observation window to locate the position of the puncture point, then position the c force pad 3 mm, proximal to the puncture site. (If necessary, a small size of four-layer gauze can be used to cover the puncture point).



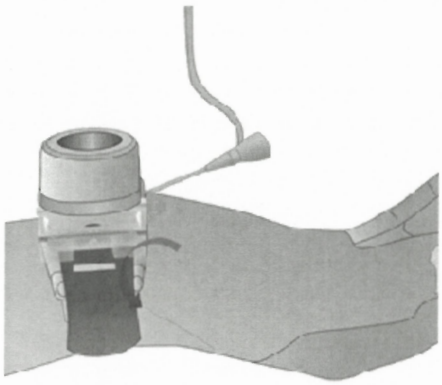


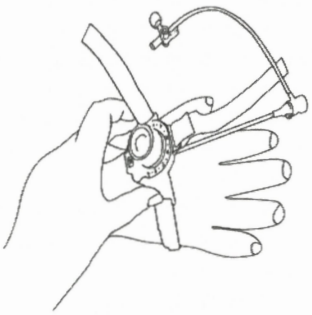
DRD/DRPD series DYD series

g) Positioning the device. The blue anchor of the elastic band should be located on the patient's radial side.(DRD/DRPD)

h) Once the force pad is correctly placed over the puncture point, secure the elastic band and ensure it is not too loose or too tight. (DRD/DRPD)

Once the force pad is correctly placed over the puncture point, pass the band #1 through the hole in the Compression plate and secure. Then secure the band #2 on the Velcro tape of the band #1 from the palm side and ensure it is not too loose or too tight. (DYD)

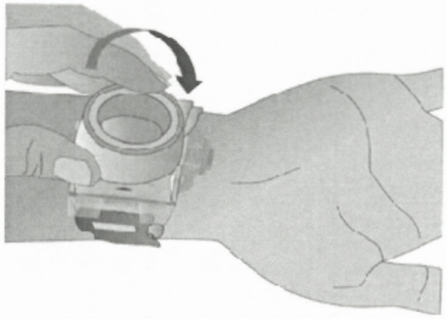


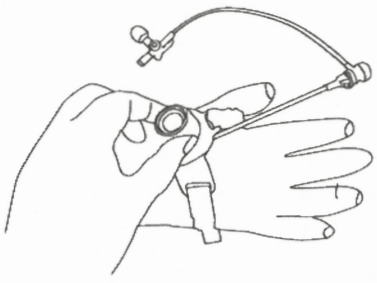


DRD/DRPD series DYD series

i) Make sure the Velcro elastic band is firmly attached and secure, to avoid bleeding caused by loosening of the elastic band.

j) Once the device has been positioned, rotate the pressure knob clockwise slowly. The pressure should be sufficient enough to allow the sheath to be removed without bleeding. Then remove the catheter or sheath.





DRD/DRPD series DYD series

k) Rotate the pressure knob clockwise to increase the pressure.

When pressurizing, the operator should carefully observe the length change of the yellow pressure display band on the radial side of the elastic band. As the pressure increases, the yellow display band will gradually widen.(DRD/DRPD)

Rotate the pressure knob clockwise to increase the pressure

No.	Model	Weight	Width of the Pressure is Extended to about	Number of turns of rotation
1	DRD17	40 - 60kg	5mm	3.25 circles (3×360°+90°) ~ 3.5 circles (3.5×360°)
2	DRD19	60 - 80kg	6mm	
3	DRD21	Over 80kg	7mm	
4	DRPD17	/	/	2.5 circles (2.5×360°) ± 45°
5	DRPD19			
6	DRPD21			
7	DYD22XX	40 - 60kg	/	2.5 circles (2.5×360°) ± 45°
8	DYD26XX	60 - 80kg		
9	DYD30XX	Over 80kg		

Warning: The yellow pressure display band on the elastic band, cannot provide accurate pressure values of the force pad. The above pressure value recommendations are only used as a reference when using the device. The purpose of these recommendations is to assist the operator in gauging the appropriate compression and to avoid excessive pressure, which may cause compression injury to the patient. Therefore, during compression of the device, please use an appropriate amount of pressure to avoid causing pain, numbness, and bleeding at the puncture site of the patient.

l) After the device compression, the operator should press the red safety lock button to lock the pressure knob. After locking the pressure knob, the pressure knob cannot be rotated. Locking the safety lock button can prevent the patient from mistakenly releasing the device and causing bleeding.

m) After all the above steps, recheck the device's position and check for any bleeding or hematoma at the puncture point. Observing the pulse of the radial artery at the proximal end is also necessary. Special attention should be paid to avoid any serious complications of muscular septal syndrome.

n) If there are signs of bleeding at the puncture site of the radial artery, release the safety lock button and continue to rotate the pressure knob clockwise until the bleeding stops. If there is serious pain or numbness, release the safety lock button and rotate the pressure knob anti-clockwise or loosening the elastic band to avoid neurovascular compression injury.

o) Decompressed steps: Once the clinical staff determine that hemostasis has been achieved, then decompression of the device is indicated. To decompress the device, pull the safety button to release and gradually rotate the pressure knob in an anti-clockwise direction.

p) If the pressure knob is released to the limit position and the patients still feels severe pain or numbness, then it is appropriate to also loosen the elastic band.

q) If the bleeding cannot be stopped according to the above procedures, the device should be terminated immediately.

r) The time to use the device for radial artery hemostasis, should be determined by the clinical staff.

s) Disposal: once the hemostasis process is finished, clean the puncture site and seal it with a sterile dressing.

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Symbols:

	Do not re-use		Max Contents
	Caution		Keep away from sunlight
	Use-by date		Keep dry
	Date of manufacture		Manufacturer
LOT	Batch code		Single sterile barrier system& Sterilized using ethylene oxide
REF	Catalogue number	EC REP	Authorized representative in the EuropeanCommunity/European Union
	Do not use if package is damaged and consult instructions for use	CE	CE Marking Of Conformity
	Consult instructions for use or consult electronic instructions for use	MD	Medical device
	Do not resterilize	UDI	Unique device identifier
℞ Only	Prescription Use Only	STERILE EO	Sterilized using ethylene oxide

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