

INTERNAL USE ONLY
--DO NOT PRINT THIS PAGE--

RM7260 Rev. 1 - Package Insert, IFU, ChitoPulse, All Sizes

Size: 8.5" x 11", folded down to 4.25" x 5.5"

MS-RM4018

 Black  PMS704  PMS185



RADIAL HEMOSTATIC DEVICE

Intended Use / Indications:

ChitoPulse™ is intended to promote hemostasis following a catheterization or other puncture into a blood vessel in a patient’s radial artery, including arterial or venous line or sheath removal, hemodialysis and in patients on anticoagulation therapy.

Description:

ChitoPulse™ is a compression device incorporating a hemostatic chitosan patch that, when positioned directly onto an access site, applies localized mechanical pressure to promote hemostasis and rapid control of bleeding. The chitosan patch acts as an adjunct to the mechanical compression provided by the adjustable strap and compression balloon to aid the control of bleeding. Using the inflation syringe, the compression applied by the device can be controlled by the user without unfastening the band, allowing gradual release of compression as hemostasis occurs. ChitoPulse™ is a single use device. Once hemostasis is achieved, the adjustable band is intended to be removed leaving the hemostatic chitosan patch in place. The hemostatic chitosan patch can be secured in place with a securement dressing and left in situ for up to 24 hrs. ChitoPulse™ also provides a barrier against bacterial penetration by a wide range of gram positive and gram negative organisms.



Cautions / Warnings:

	Caution
	Do not inject air into any other port than the air injection port of this device. This could result in embolization.
	Not intended for femoral artery compression.
	Do not use if package is damaged or contents are wet
	Keep dry
	Sterile vs. non-sterile: Sterilized using irradiation
	Prescription only. U.S. Federal law restricts this device to sale by or on the order of a physician.
	Do not resterilize
	Not made with natural rubber
	Storage conditions: best stored at room temperature Upper limit of temperature 78°F/26°C Lower limit of temperature 52°F/11°C
	Do not re-use

Precautions:

- Patients should not be left unattended while the device is in use.
- Prior to use, ensure correct alignment of the device.
- Over-inflation of balloon could cause damage to balloon, compromising the performance of the compression band. Maximum 15ml.
- Do not leave device on for inappropriately long periods of time, as tissue damage may occur.
- If there is itching, redness or swelling of the skin while using compression band, stop and treat appropriately.
- Arterial pulse distal to the compression site should be monitored to ensure the artery is not completely occluded, as arterial damage and/or thrombosis could occur.
- Air injection volume and compression time may differ according to the patient’s condition, the heparin volume, and the size of the puncture site. Check the puncture site and adjust accordingly.
- Do not to inject air into any other port other than the injection port of this device. This could result in embolization.
- Do not use the inflation syringe for other purposes than to inflate the ChitoPulse.
- Do not cleanse compression band before use as it could affect efficacy of the device.
- Use immediately after opening.
- For external use only, do not implant.
- Discard any unused portion of the product.

Contraindications:

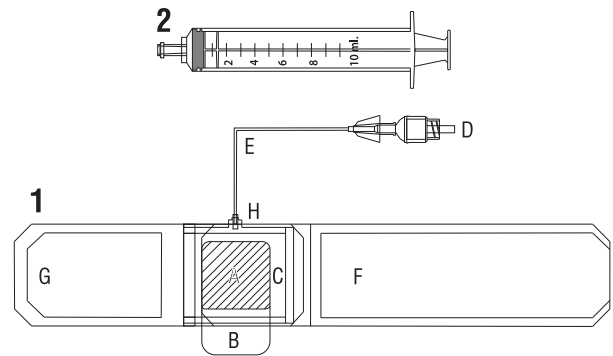
- Patients hypersensitive to the materials of compression device, which contains chitosan from shellfish. If you suspect an allergic reaction, treat appropriately.
- Patients with infection or other serious skin diseases at the site of puncture.
- For transradial catheterization only: patients with an abnormal Allen test, Barbeau test, or radial pulse, or insufficient dual arterial supply.

Adverse Events:

Potential adverse events include allergic reaction, artery occlusion, hematoma formation, recurrent bleeding, nerve damage, and pain or numbness.

1. ChitoPulse device components A through H:

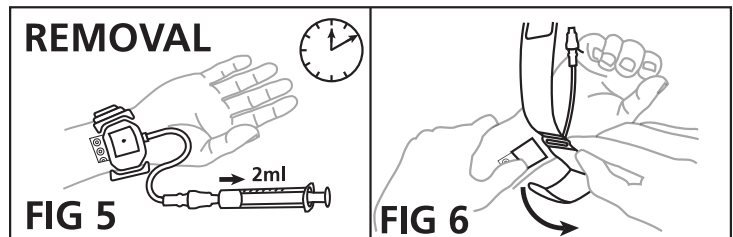
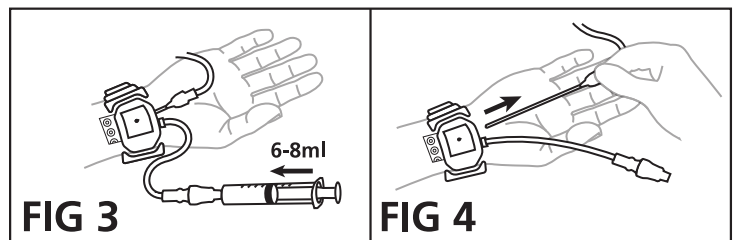
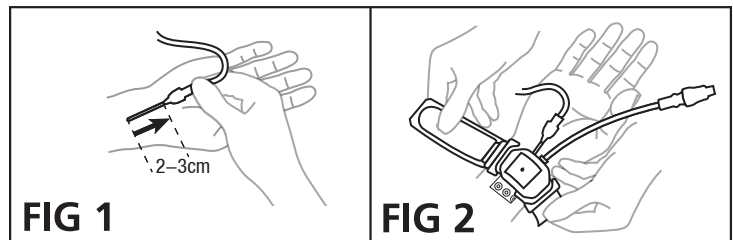
- A. 1 x 1 inch chitosan hemostatic patch
- B. Clear release tab with indicator symbol (⊙) to provide for separation of A from C, leaving A against access site
- C. 1.5 x 1.5 inch clear compression balloon
- D. Bidirectional activated luer lock valve that attaches to the syringe
- E. Air-line, tubing connection between C and D
- F. Flexible clear band with fastener loop securement
- G. Flexible band positioner with fastener hook securement
- H. 1.5 x 1.5 inch clear flat rigid support plate with positioning indicator (●)



2. Inflation Syringe (10ml)

Instructions for Use:

1. Using a sterile technique, open the foil pouch and transfer the ChitoPulse™ into the sterile field.
2. After catheterization, withdraw the sheath 2–3 cm (Figure 1).
3. Place the ChitoPulse™ around the patient’s forearm with the center of the chitosan patch (A) with indicator (●) 2–3 mm proximal to the puncture site and the flexible positioner (G) on the thumb-side of the arm (Figure 2). Fix the ChitoPulse™ securely around the forearm. Device will be positioned differently for the left or right wrist. When device is used on the right side, the air-line (E) will point to the fingers. When used on the left side, the air-line will point down the arm to the elbow.
4. Inflate the compression balloon (C) by attaching the inflation syringe (included) to the luer lock valve (D). Inject the appropriate volume of air into the compression balloon (Figure 3). Normal range: 6–8ml. Maximum: 10ml.
5. Remove the sheath (Figure 4) and confirm patent hemostasis is achieved. If bleeding is observed around the edge of the patch, add more air into the compression balloon (not to exceed 15ml) until bleeding stops.
6. At the recommended device removal time, remove 2ml’s of air every 10 minutes (Figure 5). If bleeding is observed, add more air to restore hemostasis. Remove 2ml’s after another 10 minutes. Continue this process until compression balloon is deflated.
7. Once the compression balloon is deflated and it is confirmed that there is no bleeding, un-fasten the ChitoPulse™, hold down on the clear release tab (B) with the indicator symbol (⊙) that is attached to the chitosan patch, and remove the band by slowly pulling away and slightly up from the release tab so that the chitosan patch remains on the wound (Figure 6).
8. Dispose of the used band and inflation syringe appropriately. Apply a securement dressing (not included) to secure chitosan patch in place.
9. Instruct patient to remove patch within 24 hours, by irrigating with saline or water, while gently pulling up on the corner of the patch.



Manufactured for:
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 Your feedback is important to us.
 Please go to www.tricolbiomedical.com/feedback.

Pending Pats

Size Options:

Part number	1095	1096	1097
Band length	9in / 23cm	12in / 30.5cm	15in / 38cm

