HemCon ChitoPULSE™

Transradial Catheterizations	Endovascular Aneurism Repair	PTRA: Percutaneous Transluminal Rotational Atherectomy
DCA: Direct Coronary Atherectomy	Intracoronary Stents	PTCA: Percutaneous Transluminal Coronary Angioplasty
PCI: Percutaneous Coronary Intervention	Intravascular Angioplasty	
	Coronary Brachytherapy	

Positive Outcomes. STAT.

RADIAL HEMOSTATIC DEVICE FOR TRANSRADIAL CARDIAC CATHETERIZATION AND INTERVENTIONAL RADIOLOGY

HemCon ChitoPulse™ is a unique radial hemostatic device combining air pressure and hemostatic technology to securely control bleeding following transradial catheterizations.

- **Cost effective:** Supports cost savings initiative with competitive price point and dependable results.
- **Fast hemostasis:** Applies localized mechanical pressure through compression band and balloon, with an adjunct chitosan patch to promote hemostasis and rapid control of bleeding[1-4].
- **Dependable:** Designed to support radial artery patency with ideal pressure; balloon retains inflation; includes adjunct hemostatic chitosan patch for added protection; works on anticoagulated patients.
- **Easy to Use:** Familiar look and feel; follow standard protocol for radial compression bands. Has unique leave behind chitosan-patch for 24 hour continued protection.
- **Safe:** Allows gradual release of compression as hemostasis occurs; provides a barrier against bacterial penetration by a wide range of gram-positive and gram-negative organisms.

Proven technology of HemCon chitosan patch works as an adjunct to hemostasis

HemCon by Tricol BIOMEDICAL INC

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HemCon ChitoPULSE™

INDICATION FOR USE

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.

HOW HEMCON CHITOPULSE WORKS

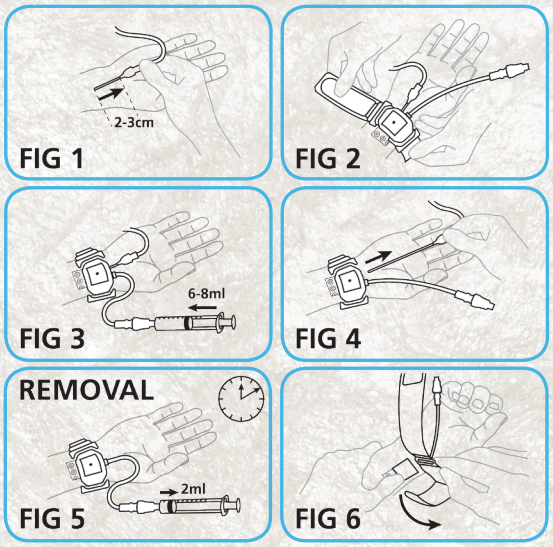
ChitoPulse is a compression device incorporating a hemostatic chitosan patch that, when positioned directly onto an access site, applies localized mechanical pressure to promote hemostasis and rapid control of bleeding. The chitosan patch acts as an adjunct to the mechanical compression provided by the 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. Once hemostasis is achieved, the adjustable band is intended to be removed leaving the hemostatic chitosan patch in place.

APPLICATION GUIDE

Consult package insert for complete instructions for use, including cautions and precautions.

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 with indicator 2-3 mm proximal to the puncture site and the flexible positioner 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 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 by attaching the inflation syringe (included) to the luer lock valve. 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 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.



BARRIER TO BACTERIA

ChitoPulse also provides a barrier against bacterial penetration by a wide range of gram positive and gram negative organisms, including many clinically relevant organisms such as MRSA, VRE, and *C. difficile*.

ORDER INFORMATION

Product	Part Number	Configuration
HemCon ChitoPulse, 9 inch	*1095*	*5/bx, 50/cs*
HemCon ChitoPulse, 12 inch	*1096*	*5/bx, 50/cs*
HemCon ChitoPulse, 15 inch	*1097*	*5/bx, 50/cs*

FDA 510K: K170958
Tax ID: 81-2091181

MMF-258 Rev. 1 (US) 10/17

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1. *Susumu Oozawa, et al. "A New Hemostasis Tool after Percutaneous Angioplasty: The HemCon Pad Hemostasis Device." J Vasc Med Surg 2014, 1:125.*
2. *Mat Nor, O. et al. "Achieving haemostasis of femoral artery puncture post angiographic procedures by manual compression. A comparison study between gauze pad and HemCon pad." ECR2013.*
3. *Arbel MD et al. "Usage of Chitosan for Femoral (USF) Haemostasis After Percutaneous Procedures: Comparative Open Label Study." EuroIntevention 2010; Apr ; 6 (9):1104-9.*
4. *Pavcnik, Dusan P. et al. "Hemostatic Efficacy of Chitosan Based Bandage for Closure of Percutaneous Arterial Access Sites An Experimental Study in Heparinized Sheep". (Oregon Health & Sciences University). 2009.*