

Brachytherapy

Catheter Ablation

EP: Electrophysiology

Intracoronary Stents

Intravascular Angioplasty

Endovascular Aneurism
Repair

DCA: Direct Coronary
Atherectomy

PCI: Percutaneous
Coronary Intervention

PTRA: Percutaneous
Transluminal Rotational
Atherectomy

PTCA: Percutaneous
Transluminal Coronary
Angioplasty



Positive Outcomes. STAT.

HEMOSTATIC PATCH FOR CARDIAC CATHETERIZATION AND INTERVENTIONAL RADIOLOGY

HemCon Patch PRO is ideally suited for diagnostic and interventional catheterization with a robust, easily conformable design.

- **Cost effective:** Lower cost than other alternatives.
- **Less hands-on time:** Shortens compression time - 5 to 10 minutes diagnostic¹⁻⁵, 10 to 15 minutes interventional²⁻⁶.
- **Fast hemostasis and ambulation:** Controls severe bleeding quickly; suggested ambulation protocol is 2 hours^{6,7}; easily removable with water within 48 hours.
- **Dependable:** Maintains structural integrity that won't crack, crumble or shed in wound; creates a strong clot; provides localized support of clotting.
- **Safe:** Works independently of the clotting cascade; provides antibacterial barrier against 24 microorganisms, including MRSA, VRE, and *C. difficile*; no known contra-indications.

HemCon Patch PRO controls bleeding following femoral PTCA procedure.



INDICATION FOR USE

The HemCon Patch PRO is a hemostatic dressing for the external, temporary control of severely bleeding wounds, intended for emergency use. The HemCon Patch PRO also controls bleeding in patients following hemodialysis and is indicated for the control of bleeding from the skin at percutaneous needle access, vascular access, and percutaneous catheter access sites.

HOW HEMCON BANDAGES WORK

HemCon products are made from chitosan, a naturally occurring polysaccharide. Chitosan is positively charged, attracting negatively-charged red blood cells and platelets. This ionic interaction creates a supportive, primary seal at the wound site independent to the clotting cascade to control all degrees of bleeding.



APPLICATION GUIDE

1. Remove sheath following hospital protocol.
2. Allow a small amount of blood, approximately the size of a nickel (2cm), to surround the puncture site.
3. DO NOT cleanse the puncture site or moisten with saline solution. Blood is required to facilitate the unique adhesion process.
4. With the printed side facing up, place the HemCon Patch PRO directly on the puncture site.
5. Hold digital pressure across the entire vascular access tract until bleeding is controlled.
6. Patch will have adhered where blood was present.
 - If it did not adhere, but hemostasis was achieved, patch can be held in place to act as an antibacterial barrier with an appropriate dressing.
 - If it did not adhere, and hemostasis was not achieved, repeat application with a new patch.
7. After bleeding has stopped, secure the HemCon Patch PRO with an appropriate dressing.
8. Recheck the wound for potential bleeding as necessary.

REMOVAL INSTRUCTIONS

- The HemCon Patch PRO can remain in place up to 48 hours.
- To remove the patch, irrigate with sterile water or saline while gently pulling up on the corner of the patch.
- Instruct discharged patients to soak the patch in the shower, and then gently peel off the patch.

REDUCTION OF MICROORGANISMS

The HemCon Patch PRO was tested for reduction of microorganisms against the following species. The log reduction data demonstrates the antibacterial barrier effect.

Organism	Gram Stain	Log Reduction
<i>Escherichia coli</i> ATCC 8739	-	>5.2
<i>Klebsiella pneumoniae</i> ATCC 4352	-	>5.3
<i>Streptococcus pyogenes</i> ATCC 19615	+	>5.5
<i>Staphylococcus aureus</i> (MRSA) ATCC 33591	+	>4.0
<i>Staphylococcus epidermidis</i> ATCC 12228	+	>5.2
<i>Salmonella choleraesuis</i> ATCC 10708	-	>5.1
<i>Pseudomonas aeruginosa</i> ATCC 9027	-	>4.3
<i>Enterococcus faecalis</i> (VRE) ATCC 51299	+	>5.4
<i>Enterococcus faecalis</i> ATCC 700802	+	>5.4
<i>Serratia marcescens</i> ATCC 13880	-	5.0
<i>Stenotrophomonas maltophilia</i> ATCC 12714	-	>5.1
<i>Streptococcus mutans</i> ATCC 25175	+	>5.2
<i>Clostridium difficile</i> ATCC 9689	+	>5.6
<i>Streptococcus pneumoniae</i> ATCC 10015	+	5.8
<i>Shigella</i> species ATCC 11126	-	>5.4
<i>Enterobacter aerogenes</i> ATCC 13048	-	>5.0
<i>Proteus mirabilis</i> ATCC 4630	-	>5.2
<i>Proteus vulgaris</i> ATCC 12454	-	>4.8
<i>Citrobacter freundii</i> ATCC 8090	-	>4.3
<i>Enterobacter cloacae</i> ATCC 13047	-	>4.2
<i>Acinetobacter baumannii</i> ATCC 15308	-	>4.2
<i>Moraxella catarrhalis</i> ATCC 8193	-	>4.1
<i>Micrococcus luteus</i> ATCC 49732	+	4.9
<i>Vibrio cholerae</i> ATCC 11558	-	>4.9

Data on file at Tricol. *in vitro* study. Log reduction at 24 hours in colony forming units (CFUs) using Antibacterial AATCC Test Method 100-2004. Only single strains of most species have been studied. The clinical utility of these results is unknown. Testing was performed by an independent, certified, contract laboratory.

ORDER INFORMATION

Part Number	Part Number	Configuration
HemCon Patch PRO, 1.5in x 1.5in	1004	10/bx, 100/cs
HemCon Patch PRO, 2in x 2in	1005	10/bx, 100/cs

FDA 510K: K080818
Tax ID: 81-2091181

MMF-224 Rev. 4 (US) 04/18

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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." *ECR* 2013.

3. Arbel MD et al. "USage of Chitosan for Femoral (USF) Haemostasis After Percutaneous Procedures: Comparative Open Label Study." *EuroIntervention* 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.

5. HemCon Patch PRO Suggested Protocol (MMF-185) (Tricol Biomedical). 2014.

6. Cath Lab Case Study of HemCon Bandages (St. Elizabeth Medical Center). 2008

7. Post-Procedural Ambulation Guidelines Following Catheterization (MMF-151) (Tricol Biomedical). 2009.