

**PROHEALTH MORELAND SURGERY CENTER  
COMPLIANCE GUIDANCE AND CHECKLIST FOR REQUEST OF NEW OR  
NON-APPROVED MEDICAL DEVICES**

**Instructions:**

**Requestor and Other Contributors:** Please fill out information in highlighted tables and also to guide you through your analysis of this device. Please complete all items in area(s) pertaining to you. Your timeliness is appreciated as this form is needed to be presented at the committee level. After completion please return form to Corinna Kiefer, Materials Manager at: [corinna.kiefer@phci.org](mailto:corinna.kiefer@phci.org) or you may fax to 262-928-4334. Thank you!

**Information in outlined boxes need to be filled out by requesting person(s):**

1. Device Name: [Click here to enter text.](#)
2. Requested By: [Click here to enter text.](#) Phone: [Click here to enter text.](#)
3. Physician Sponsor (include specialty): [Click here to enter text.](#) Phone: [Click here to enter text.](#)
4. Date of Request: [Click here to enter a date.](#)
5. Brief Description: [Click here to enter text.](#)  
Cat# [Click here to enter text.](#) Mfr. [Click here to enter text.](#)  
Packaging (i.e. cs/10bx/5ea): [Click here to enter text.](#)  
U/M: [Click here to enter text.](#) Cost: [Click here to enter text.](#)  
Sales Rep Name: [Click here to enter text.](#) Phone: [Click here to enter text.](#)
6. Describe advantage of device vs.current MSC device(s): [Click here to enter text.](#)
7. Which objective is this device expected to achieve:  
 Cost Reduction  Improved Clinical Outcomes  Strategic Direction
8. If known, please provide contact information for up to two other facilities that are currently using this device.  
  
Contact Person: [Click here to enter text.](#) Phone # [Click here to enter text.](#)  
Name of Facility: [Click here to enter text.](#)  
  
Contact Person: [Click here to enter text.](#) Phone # [Click here to enter text.](#)  
Name of Facility: [Click here to enter text.](#)
9. This device is:  New Technology  Not currently on the MSC approved list
10. Does this device contain:  Latex  Mercury  Neither
11. Is the product labeled Single Use?  Yes  No
12. Is this device FDA approved:  Yes  No If yes, when: [Click here to enter text.](#)

13. Which CPT and ICD-9 procedure codes will be used?
14. Is this device reimbursable?  Yes  No  
If yes, please provide all reimbursement codes including, but not limited to, CPT, HCPCS, Pass through, C-codes: [Click here to enter text.](#)
15. Do new charges need to be developed in connection with the device ([Procedures and/or Device Charges](#))?  Yes  No If Yes, please provide description, price, Relative Value Unit, (RVU), CPT/HCPCS and revenue code. [Click here to enter text.](#)
16. What physician(s) (include the specialty) will be using this device? [Click here to enter text.](#)
17. Is there special training required?  Yes  No  
If yes, is training for physicians and/or staff?  Physicians  Staff  
Is this provided at no cost to MSC?  Yes  No  NA  
Cost to MSC per person: [Click here to enter text.](#)  
Comments: [Click here to enter text.](#)
18. Is there special privileging/credentialing required?  Yes  No  
For whom:  Physicians  Staff  
Is this provided at no cost to MSC?  Yes  No  NA  
Cost to MSC per person: [Click here to enter text.](#)  
Comments: [Click here to enter text.](#)
19. Is there an approved product in house now performing the same function?  Yes  No  
If no, please verify with team lead and confirm here:  Confirmed  Not confirmed  
In Custom Pack?  Yes  No  
If yes, what product would this replace?  NA  
Item # [Click here to enter text.](#) Cat: [Click here to enter text.](#) Par Cart: [Click here to enter text.](#)  
Location: [Click here to enter text.](#)  
If this replaces more than one product, please list all that apply? [Click here to enter text.](#)
20. Is consignment of this device an option?  Yes  No
21. Are there complementary products (reloads, applicators, etc.) needed?  Yes  No  
If yes, please comment, including catalog #, description, packaging, and cost: [Click here to enter text.](#)
22. Is this product line covered by a GPO agreement with Novation?  Yes  No  NA  
If yes, please list: [Click here to enter text.](#) Contract# [Click here to enter text.](#)
23. Are there any additional expenses that might be incurred with use of this device?  
 Yes  No  
If yes, please comment: [Click here to enter text.](#)
24. [Has Materials Manager \(Corinna Kiefer X84321\) been contacted](#) to assist in costing out the device?  Yes  No If yes, please provide date of contact:

This page begins a checklist to be used to ensure that all areas/departments affected have been contacted:

**PROHEALTH CARE  
COMPLIANCE CHECKLIST FOR REQUEST OF NEW OR NON-APPROVED  
MEDICAL DEVICES**

Tasks/elements	Y	N	NA	Notes
<b>LEGAL</b>				
<ul style="list-style-type: none"> <li>Legal sign-off?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Click here to enter text.
LEGAL SUMMARY/DATA SENT TO TECH COORDINATOR? <a href="mailto:richard.blattner@phci.org">richard.blattner@phci.org</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Click here to enter text.
<b>COMPLIANCE</b>				
<b>Contracts/Letters/Agreements</b> <ul style="list-style-type: none"> <li>Signed and in place <u>before</u> start of procedure, etc?               <ul style="list-style-type: none"> <li>Equipment Leasing Contact ext 84924</li> </ul> </li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Click here to enter text.
<b>Medical Staff Office</b> <ul style="list-style-type: none"> <li>Is Physician credentialed to use device?</li> <li>Conflicts of Interest?</li> <li>Questions: <a href="#">Contact Med Staff Services (Jane Smeaton x82261)</a></li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Click here to enter text.
<b>Department</b> <ul style="list-style-type: none"> <li>Is staff trained for use of device?</li> <li>Have P&amp;Ps been written to support the new device?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Click here to enter text.
<b>Infection Control</b> <ul style="list-style-type: none"> <li>Has Infection Control been contacted? <a href="#">Contact Mary Ellen French x83278)</a></li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Click here to enter text.
<b>Vendor/Rep</b> <ul style="list-style-type: none"> <li>Existing Vendor Mate Account</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Click here to enter text.
COMPLIANCE SUMMARY/DATA SENT TO TECH COORDINATOR? <a href="mailto:richard.blattner@phci.org">richard.blattner@phci.org</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Click here to enter text.
<b>FINANCE</b>				
<b>Reimbursement</b> <ul style="list-style-type: none"> <li>Has reimbursement been addressed for all payors?               <ul style="list-style-type: none"> <li>Indication Implications addressed?</li> </ul> </li> <li>Are there Medicare coverage guidelines for this device? (NCD and/or LCD)? If yes, do you have an ABN process? Do you need assistance in review of the ABN usage?</li> <li>Commercial medical policies addressed?</li> <li>Questions: <a href="#">Contact Managed Care (William Jones x84019)</a></li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Click here to enter text.

<b>Revenue</b> • Revenue impact addressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>Click here to enter text.</b>
<b>Expenses</b> • Expense impact addressed? ○ Technology acquisition costs?	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<b>Click here to enter text.</b>
<u>Departments are responsible to:</u> • Have charges in within 24 hours and any corrections within the next 48 hours. (Charges are to be in and correct within 3 days.) Reports will be used to monitor this. • Departments are to develop a daily charge reconciliation process insuring their charges are complete. • Charge problems identified will be directed back to the department for research.	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<b>Click here to enter text.</b>
<b>Charge master</b> • Do new charges need to be developed in connection with the device? (need description, price, Relative Value Unit, (RVU), CPT and revenue code.) • Will these devices be used at both OMH and WMH? • Questions: <a href="#">Contact Chargemaster Coordinator (Dawn Holecek x82021)</a>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<b>Click here to enter text.</b>
<b>FINANCE SUMMARY/DATA SENT TO TECH COORDINATOR?</b> <a href="mailto:richard.blattner@phci.org">richard.blattner@phci.org</a>	<input type="checkbox"/>	<input type="checkbox"/>		<b>Click here to enter text.</b>
<b>MATERIALS MANAGEMENT</b>				
<b>Purchasing</b> • Priced lower than current product(s)? • Trial use agreement? • Trial pricing only? • Post-trial pricing established?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<b>Click here to enter text.</b>
<b>Biomed</b> • Has Biomed been contacted? <a href="#">Contact BioMed (Eamon Ridgeway x84731)</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>Click here to enter text.</b>
<b>MATERIALS MANAGEMENT SUMMARY/DATA SENT TO TECH COORDINATOR?</b> <a href="mailto:richard.blattner@phci.org">richard.blattner@phci.org</a>	<input type="checkbox"/>	<input type="checkbox"/>		<b>Click here to enter text.</b>
<b>CLINICAL/OPERATIONAL</b>				
• Have clinical outcomes been				<b>Click here to</b>

<ul style="list-style-type: none"> <li>researched? <input type="checkbox"/></li> <li>• Sufficient data on clinical outcomes and/or adverse events? <input type="checkbox"/></li> <li>• Referrals affected? <input type="checkbox"/></li> <li>• Clinician incentives understood? <input type="checkbox"/></li> <li>• Training/credentialing addressed? <input type="checkbox"/></li> <li>• Staffing impact? <input type="checkbox"/></li> <li>• Staff efficiency addressed? <input type="checkbox"/></li> <li>• Patient convenience impact addressed? <input type="checkbox"/></li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>enter text.</b>
<b>CLINICAL/OPERATIONAL SUMMARY/DATA SENT TO TECH COORDINATOR?</b> <a href="mailto:richard.blattner@phci.org">richard.blattner@phci.org</a>	<input type="checkbox"/>	<input type="checkbox"/>		<b>Click here to enter text.</b>
<b>INFORMATION TECHNOLOGY</b>				
<ul style="list-style-type: none"> <li>• IT implications addressed? <input type="checkbox"/></li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>		<b>Click here to enter text.</b>
<b>IT SUMMARY/DATA SENT TO TECH COORDINATOR?</b> <a href="mailto:richard.blattner@phci.org">richard.blattner@phci.org</a>	<input type="checkbox"/>	<input type="checkbox"/>		<b>Click here to enter text.</b>
<b>MISCELLANEOUS</b>				
<b>Marketing</b> <ul style="list-style-type: none"> <li>• Should marketing be informed? <input type="checkbox"/></li> <li>    ○ If so, have they been contacted? <input type="checkbox"/></li> <li>• Device unique or new to region? <input type="checkbox"/></li> <li>• Differentiator? <input type="checkbox"/></li> <li>• Product life cycle addressed? <input type="checkbox"/></li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>Click here to enter text.</b>

<b>Formulated: 8/24/15 by Richard Blattner</b>
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