# Commercial Materials Review Cover Sheet

(Refer to the Commercial Materials Review Policy and SOP documents for details.)

**To be completed by the RA Coordinator:**
Control Number: RE-US-0854E-1224-G
Approval Date: 3/21/2024
*(Note: To be completed after receiving all necessary approvals)*
Expiration Date: 12/31/2024

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**To be completed by the originating department:**

1. Material Title: _Current ICD-10 Diagnosis Codes for Atrial Fibrillation _____
2. Submission Date: 3/6/2024
3. Requested by Date (should allow for 10 business days): 3/22/2024
4. Suggested Expiration Date (usually 6 months – 1 year): 12/31/2024
   (Expiry Date cannot exceed 2 years.)

**Origin**

5. Originating Department: _Healthcare Economics / Reimbursement_____
6. Originator's Name: __Jim Kerins _____

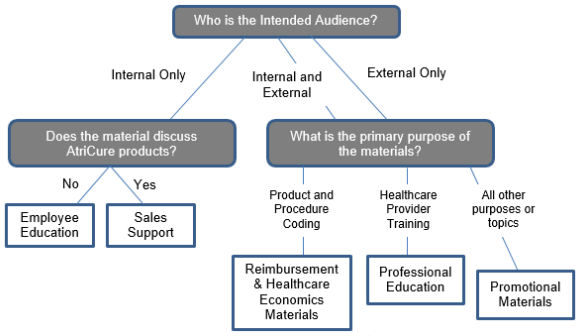
**Context**

7. Is the request to amend or review expired or current material? ☒ Yes ☐ No
   If yes, provide the CMR number of the previous version of the material and include the previous material with this submission. Previous CMR number: RE-US-0854D-0324-G _
8. What departments were consulted during the creation or peer-review of the material? __None_____
9. Are there any departments, in addition to Marketing and Regulatory Affairs, which need to participate in the review and approval of this material?

   ___No_____
   _____

AtriCure

## Audience and Usage




10. Intended Use for Material: (Select only one; see definitions in Policy)
    - ☐ Employee Education Materials
    - ☐ Professional Education Materials
    - ☐ Promotional Materials
    - ☐ Reimbursement and Healthcare Economics Materials
    - ☐ Sales Support Materials
    - ☐ Platform/System Use Only

    If material is for internal use only, has an identifier (e.g. footer, watermark) been added to the material? ☐ Yes ☒ No ☐ N/A
11. Intended Audience for Material: __Providers (physicians, hospitals) _____
12. Intended Geography for Use: ☒ U.S. Only ☐ EU Only ☐ Global
13. Is translation required? ☐ Yes ☒ No
    If Yes, what language(s): _____
14. Method of Distribution: ☒ AtriHub ☐ AFConnect ☐ Print Portal ☒ E-Mail ☐ YouTube ☐ Social Media ☐ Website: _____ ☐ Other: _____
15. Tags (For AtriHub Search Relevance): _ICD10, Diagnosis Codes, AF Dx _____

## Products

16. List the product(s), if any, discussed in the material, including the product number(s): _____
17. Are any of these products involved in an ongoing clinical trial? ☐ Yes ☒ No ☐ N/A
    If Yes, which trial(s):
18. Does the material involve the dissemination of scientific information? ☐ Yes ☒ No
19. Does the material discuss specific procedure instructions? ☐ Yes ☒ No
20. Are case studies or depictions of medical procedures included in the material? ☐ Yes ☒ No

21. Is the material, either published scientific literature or based on a review of scientific literature? ☐ Yes ☒ No
22. If yes to 21, was a copy of the literature and completed Form-621 sent to the PS&S Department (pcomplaints@atricure.com) ☐ Yes ☐ No

**Notes for Material Submission:**

- Videos should have transcripts of the actual content of the material.
- If the material is a literature paper that contains adverse events, send a copy, and completed Form-621, to the PS&S department (pcomplaints@atricure.com).

# Commercial Materials Review Cover Sheet

**To be Completed by the Approvers After Review:**

| Approver Department | Approver Individual | Review Decision | Comments Below? | Date |
|---|---|---|---|---|
| Regulatory Affairs | Tony Blank<br>Tony Blank (Mar 21, 2024 12:52 EDT) | ☑ Approved<br>☐ Approved with Changes<br>☐ Rejected | ☐ Yes<br>☑ No | 21/03/24 |
| Marketing Communications | Valerie Storch-Willhaus<br>Valerie Storch-Willhaus (Mar 21, 2024 10:59 CDT) | ☑ Approved<br>☐ Approved with Changes<br>☐ Rejected | ☐ Yes<br>☑ No | 21/03/24 |
| | | Approved<br>Approved with Changes<br>Rejected | Yes<br>No | |
| | | Approved<br>Approved with Changes<br>Rejected | Yes<br>No | |

## Final Verification and Release

Performed by: Aleesha Griffin

Date Performed: 3/21/2024

Date Communicated to Originator: 3/21/2024

### Review Feedback

1. **Regulatory Affairs**
   Approver Name: Tony Blank
   Date: 21/03/24
   Feedback:
   none

2. **Marketing**
   Approver Name: Valerie Storch-Willhaus
   Date: 21/03/24
   Feedback:
   na

3. **[Other Department Name]**
   Approver Name:
   Date:
   Feedback:

# Commercial Materials Review Cover Sheet

Attachment A: Originator's Commercial Material for External/Internal Customer Checklist

| Review Item | Verified? |
|---|---|
| Common name half size of Brand name (per FDA Guidance Document) ? | |
| Brief Indications statement (US only) provided for all AtriCure devices depicted ? | |
| All claims substantiated with sourced data? | |
| Cited device specifications noted on promotion material is properly sourced? | |
| Rx Only symbol conspicuous? | |
| Does not claim FDA Approved (510k devices only)? | |
| Does not use words such as "safer", "superior" or unsupported clinical outcomes? | |
| Images, illustrations, videos depict use consistent with cleared/approved intended uses? | |
| If bench testing provided, must disclose and state conspicuously *"Data on file with AtriCure and available upon request. Bench Test results may not necessarily be indicative of clinical performance."* | |
| Video presentations must bear control number, contain trademark, Rx Only etc… | |
| Case studies, quotations, testimonials, statements, or paraphrases of statements by 3rd parties must include statement *"Results from case studies are not predictive of results in other cases. Results in other cases may vary."* | |
| **Sales support** materials include statements with confidential mark, for internal use only<br>*"Confidential. For Internal Use Only. Do Not Copy, Display or Distribute Externally."* | |
| **Sales support** material citing discussions of unapproved uses must include disclaimer, *"This material provided describes unapproved uses and is intended to provide general information, including opinions and recommendations, contained herein for educational purposes only. "* | |
| **Case studies/testimonials** can't be used to make claims that company could not make itself. | |

# RE-US-0854E-1224-G_20240305 ICD10 DxCodes CMR Coversheet

Final Audit Report 2024-03-21

| | |
|---|---|
| Created: | 2024-03-21 |
| By: | Aleesha Griffin (AGriffin@atricure.com) |
| Status: | Signed |
| Transaction ID: | CBJCHBCAABAANP8EaxiUXs-F66rkAVYWyMqIue4oLrBn |

## "RE-US-0854E-1224-G_20240305 ICD10 DxCodes CMR Cover sheet" History

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