

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 70 and 71, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p style="text-align: center;">Licensee</p> <p>1. Bronson Methodist Hospital</p>	<p>In accordance with application dated January 15, 2021,</p>	<p>4. Expiration Date: June 30, 2036</p>
<p>2. 601 John St. Kalamazoo, MI 49007</p>	<p>3. License No.: 21-13125-01 is renewed in its entirety to read as follows:</p>	<p>5. Docket No.: 030-02146 Reference No.:</p>

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
A. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As Needed	A. For use in uptake, dilution and excretion studies permitted by 10 CFR 35.100.
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As Needed	B. For use in imaging and localization studies permitted by 10 CFR 35.200.
C. Any byproduct material permitted by 10 CFR 35.300	C. Any	C. 2 curies total	C. For any use permitted by 10 CFR 35.300.
D. Any byproduct material permitted by 10 CFR 31.11	D. Prepackaged Kits	D. 10 millicuries total	D. For use in in-vitro studies.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License No.: 21-13125-01

Docket or Reference No.:
030-02146

Amendment No. 74

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|---|---|--|---|
| <p>6. Byproduct, source, and/or special nuclear material</p> <p>E. Yttrium-90 permitted by 10 CFR 35.1000</p> | <p>7. Chemical and/or physical form</p> <p>E. Microspheres (Sirtex Wilmington LLC, Model Sirtex Medical SIR-Spheres microspheres)</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>E. 3 curies total</p> | <p>9. Authorized use</p> <p>E. For use in permanent brachytherapy in a Sirtex Wilmington LLC SIR-Spheres delivery system permitted by 10 CFR 35.1000.</p> |
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CONDITIONS

10. A. Licensed material shall be used or stored at the licensee's facilities located at 601 John St., Kalamazoo, Michigan 49007.
- B. Licensed material listed in Subitem Nos. 6.A. and 6.B. shall be used at the licensee's facilities located at 408 Hazen St., Paw Paw, Michigan 49079.
- C. Licensed material listed in Subitem Nos. 6.A. through 6.C. shall be used at the licensee's facilities located at 955 S Bailey St., South Haven, Michigan 49090.
11. The Radiation Safety Officer (RSO) for this license is Louisa Ritchlin.
12. Licensed material shall only be used by, or under the supervision of:
- A. Individuals permitted to work as authorized users in accordance with 10 CFR 35.13 and 10 CFR 35.14.
- B. The following individuals are authorized users for the material and medical uses as indicated:
- | <u>Authorized User (M.D.,D.O.,etc.)</u> | <u>Material and Use</u> |
|---|---|
| George J. Balogh, M.D. | 10 CFR 31.11,10 CFR 35.100,10 CFR 35.200 |
| Ruggero Battan, M.D. | 10 CFR 35.300 |
| Joseph A. Borrello, M.D. | 10 CFR 35.100,10 CFR 35.200 |
| Theodore J. Cunningham, M.D. | 10 CFR 31.11,10 CFR 35.100,10 CFR 35.200 |
| Michael G. Doherty, M.D. | 10 CFR 35.1000 (limited to yttrium-90 as SIR-Spheres) |
| Brett J. Eliuk, D.O | 10 CFR 35.100,10 CFR 35.200 |
| Andrew Forsyth, M.D. | 10 CFR 35.1000 (limited to yttrium-90 as SIR-Spheres) |
| John A. Freeby, M.D. | 10 CFR 31.11,10 CFR 35.100,10 CFR 35.200 |
| Bruce D. Goethe, M.D. | 10 CFR 31.11,10 CFR 35.100,10 CFR 35.200 |

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Authorized User (M.D., D.O., etc.)Material and Use

Christina V. Jacobs, M.D.

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300 (limited to oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries)

Todd Johnson, M.D.

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300

Thomas A. Keller Jr., M.D.

10 CFR 35.100, 10 CFR 35.200

Arthur G. Laurell, M.D.

10 CFR 31.11, 10 CFR 35.100, 10 CFR 35.200

Craig Moore, M.D.

10 CFR 35.1000 (limited to yttrium-90 as SIR-Spheres)

Douglas D. Notman, M.D.

10 CFR 35.300

Robert Oostveen, M.D.

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300 (limited to oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries)

Michael Pack, D.O.

10 CFR 35.100, 10 CFR 35.200

Michael S. Pawlik, D.O.

10 CFR 35.100, 10 CFR 35.200

Eric William Payne, M.D.

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300 (limited to oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries)

Joel H. Reinoehl, M.D.

10 CFR 35.200

Christopher Rogers, D.O.

10 CFR 35.100, 10 CFR 35.200

Matthew A. Smetts, M.D.

10 CFR 35.1000 (limited to yttrium-90 as SIR-Spheres)

Patrick A. Sorek, M.D.

10 CFR 31.11, 10 CFR 35.100, 10 CFR 35.200

Manish K. Varma, M.D.

10 CFR 35.1000 (limited to yttrium-90 as SIR-Spheres)

Robert A. Williams, D.O.

10 CFR 35.100, 10 CFR 35.200

Douglas J. Wunderly, M.D.

10 CFR 35.100, 10 CFR 35.200

Robert Zick, M.D.

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300 (limited to iodine-131 for imaging and localization studies)

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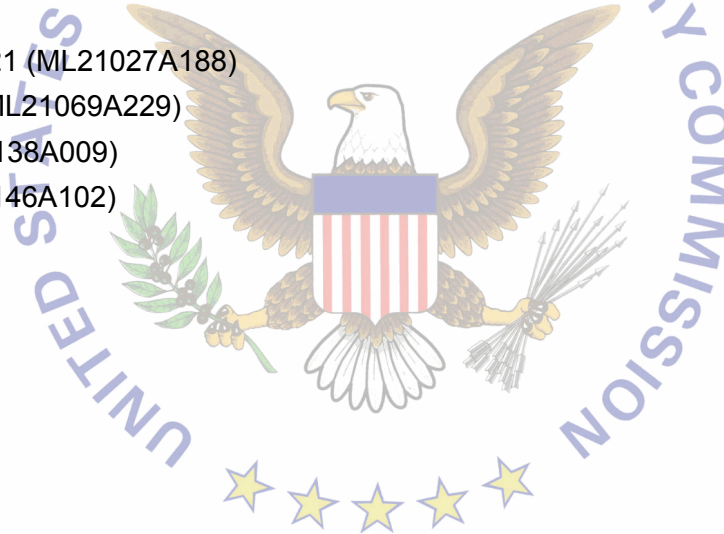
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13. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those statements, representations, and procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26 and applicable guidance updates for 10 CFR 35.1000 uses. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence impose on the licensee requirements that are more restrictive than or in addition to the regulations

- A. Application dated January 15, 2021 (ML21027A188)
- B. Letter dated February 22, 2021 (ML21069A229)
- C. Letter dated April 15, 2021 (ML21138A009)
- D. Letter dated May 17, 2021 (ML21146A102)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: June 3, 2021By: _____
Magdalena R. Gryglak
Region 3