

Inamed Corporation  
PMA P020056  
McGhan Silicone-Filled Breast Implants

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**Core Clinical Study**  
Confirmed and Suspected Ruptures

CORE STUDY - AUGMENTATION

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Confirmed Implant Ruptures Reported in PMA

Patient ID	Date of Rupture Confirmation	Timing of Suspected Rupture Onset	Implant Status	Details (symptoms and screening method with results)
Right Implant	10/20/99	8/1/99 (estimated)	Confirmed ruptured at explant	<ul style="list-style-type: none"> <li>▪ Implanted 5/13/99</li> <li>▪ Capsular contracture, Baker grade IV, noted on 10/4/99</li> <li>▪ Full capsulectomy on 10/20/99 revealed gel on implant surface</li> <li>▪ Explant done same day (10/20/99)</li> </ul>
Left Implant	7/13/00	12/6/99 (estimated)	Confirmed ruptured at explant	<ul style="list-style-type: none"> <li>▪ Implanted 5/1/99</li> <li>▪ Lump found by breast exam on 10/18/99 suspected to be rupture</li> <li>▪ Mammogram and sonogram on 11/16/99 ruled out rupture (was swollen lymph node)</li> <li>▪ Explant 7/13/00 for asymmetry and capsular contracture revealed evidence of rupture</li> </ul>

CORE STUDY - RECONSTRUCTION

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Confirmed Implant Ruptures Reported in PMA

Patient ID	Date of Rupture Confirmation	Timing of Suspected Rupture Onset	Implant Status	Details (symptoms and screening method with results)
Left Implant	9/17/02	3/17/01 (estimated)	Confirmed ruptured at explant	<ul style="list-style-type: none"> <li>▪ Implanted 10/18/99</li> <li>▪ MRI obtained on 8/16/02</li> <li>▪ MRI indicated evidence of rupture</li> <li>▪ Explanted 9/17/02</li> <li>▪ Note: previously reported in PMA as unconfirmed rupture</li> </ul>
Right Implant	11/1/02	4/12/01 (estimated)	Confirmed ruptured at explant	<ul style="list-style-type: none"> <li>▪ Implanted 12/16/99</li> <li>▪ MRI obtained 8/9/02</li> <li>▪ MRI indicated evidence of rupture</li> <li>▪ Explanted 11/1/02</li> <li>▪ Note: previously reported in PMA as unconfirmed rupture</li> </ul>
Right Implant	9/17/02	4/17/01 (estimated)	Confirmed ruptured at explant	<ul style="list-style-type: none"> <li>▪ Implanted 12/14/99</li> <li>▪ MRI obtained 8/20/02</li> <li>▪ MRI indicated evidence of rupture</li> <li>▪ Explanted 9/17/02</li> <li>▪ Note: previously reported in PMA as unconfirmed rupture</li> </ul>
Right Implant	9/16/02	10/27/00 (estimated)	Confirmed ruptured at explant	<ul style="list-style-type: none"> <li>▪ Implanted 5/19/99</li> <li>▪ MRI obtained 4/8/02</li> <li>▪ MRI indicated evidence of rupture</li> <li>▪ Explanted 9/16/02</li> <li>▪ Note: previously reported in PMA as unconfirmed rupture</li> </ul>

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Confirmed Implant Ruptures Reported in PMA (cont.)

Patient ID	Date of Rupture Confirmation	Timing of Suspected Rupture Onset	Implant Status	Details (symptoms and screening method with results)
Left Implant	7/26/02	3/16/01 (estimated)	Confirmed ruptured at explant	<ul style="list-style-type: none"> <li>▪ Implanted 2/9/00</li> <li>▪ MRI obtained 4/22/02</li> <li>▪ MRI indicated evidence of rupture</li> <li>▪ Explanted 7/26/02</li> </ul>
Right Implant	11/13/02	6/20/01 (estimated)	Confirmed ruptured at explant	<ul style="list-style-type: none"> <li>▪ Implanted 6/12/00</li> <li>▪ MRI obtained 6/28/02</li> <li>▪ MRI indicated evidence of rupture</li> <li>▪ Explanted 11/13/02</li> <li>▪ Note: previously reported in PMA as unconfirmed rupture</li> </ul>
Right Implant	8/9/02	5/6/01 (estimated)	Confirmed ruptured at explant	<ul style="list-style-type: none"> <li>▪ Implanted 4/7/00</li> <li>▪ Patient complained of asymmetry on 6/4/02</li> <li>▪ Ultrasound obtained 6/4/02</li> <li>▪ Ultrasound indeterminate for rupture</li> <li>▪ Explanted 8/9/02</li> </ul>

Confirmed Implant Ruptures Reported in PMA

Patient ID	Date of Rupture Confirmation	Timing of Suspected Rupture Onset	Implant Status	Details (symptoms and screening method with results)
Left Implant	4/23/01	4/18/01	Confirmed ruptured at explant	<ul style="list-style-type: none"> <li>▪ Implanted 11/18/99</li> <li>▪ Patient reported significant change in implant feel on 4/18/01, PI suspected rupture</li> <li>▪ Explanted 4/23/01</li> </ul>
Left Implant	7/17/02	11/14/00 (estimated)	Confirmed ruptured at explant	<ul style="list-style-type: none"> <li>▪ Implanted 4/20/99</li> <li>▪ MRI obtained 6/12/02</li> <li>▪ MRI indicated rupture</li> <li>▪ Explanted 7/17/02</li> </ul>
Left Implant	9/24/02	6/22/01 (estimated)	Confirmed ruptured at explant	<ul style="list-style-type: none"> <li>▪ Implanted 5/16/00</li> <li>▪ MRI obtained 7/29/02</li> <li>▪ MRI indicated evidence of rupture</li> <li>▪ Explanted 9/24/02</li> <li>▪ Note: previously reported in PMA as unconfirmed rupture</li> </ul>
Right Implant	10/11/02	12/6/00 (estimated)	Confirmed ruptured at explant	<ul style="list-style-type: none"> <li>▪ Implanted 4/7/99</li> <li>▪ MRI obtained 8/8/02</li> <li>▪ MRI indicated evidence of rupture</li> <li>▪ Explanted 10/11/02</li> <li>▪ Note: previously reported in PMA as unconfirmed rupture</li> </ul>

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Suspected Implant Ruptures Reported in PMA

Patient ID	Timing of Suspected Rupture Onset	Implant Status	Details (symptoms and screening method with results)	Proposed Action Plan to Confirm Rupture
Left Implant	1/9/01 (estimated)	Unconfirmed	<ul style="list-style-type: none"> <li>▪ Implanted 1/4/00</li> <li>▪ MRI obtained 1/15/02</li> <li>▪ MRI indeterminate</li> <li>▪ Second MRI obtained 2/10/03</li> <li>▪ MRI indicated no evidence of rupture</li> </ul>	No further follow-up planned.
Left Implant	12/3/00 (estimated)	Unconfirmed	<ul style="list-style-type: none"> <li>▪ Implanted 11/22/99</li> <li>▪ MRI obtained 12/15/01</li> <li>▪ MRI indeterminate</li> <li>▪ Second MRI obtained 2/22/03 (MRI report obtained after 3/27/03 data extract)</li> <li>▪ MRI indicated no evidence of rupture</li> </ul>	No further follow-up planned.

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Suspected Implant Ruptures Reported in PMA

Patient ID	Timing of Suspected Rupture Onset	Implant Status	Details (symptoms and screening method with results)	Proposed Action Plan to Confirm Rupture
Left Implant	10/7/00 (estimated)	Unconfirmed	<ul style="list-style-type: none"> <li>▪ Implanted 3/1/99</li> <li>▪ MRI obtained 5/17/02</li> <li>▪ MRI indicated evidence of rupture</li> <li>▪ Second MRI obtained 3/4/03</li> <li>▪ MRI indicated evidence of rupture</li> <li>▪ Patient asymptomatic</li> </ul>	No follow-up planned. Doctor believes implant is folded, not ruptured.
Left Implant	12/25/00 (estimated)	Unconfirmed	<ul style="list-style-type: none"> <li>▪ Implanted 5/24/99</li> <li>▪ MRI obtained 7/29/02</li> <li>▪ MRI indicated evidence of rupture</li> <li>▪ Patient asymptomatic</li> </ul>	Additional MRI planned for July of 2003, one year after first MRI.

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Suspected Implant Ruptures Reported in PMA

Patient ID	Timing of Suspected Rupture Onset	Implant Status	Details (symptoms and screening method with results)	Proposed Action Plan to Confirm Rupture
Left Implant	2/21/01 (estimated)	Unconfirmed	<ul style="list-style-type: none"><li>▪ Implanted 1/31/00</li><li>▪ MRI obtained 3/15/02</li><li>▪ MRI indicated evidence of rupture</li><li>▪ Patient asymptomatic</li></ul>	No follow-up planned. Doctor believes implant is folded, not ruptured.

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Confirmed Implant Ruptures - Updated Data

Patient ID	Date of Rupture Confirmation	Timing of Suspected Rupture Onset	Implant Status	Details (symptoms and screening method with results)
Left Implant	9/6/02	2/14/02 (estimated)	Confirmed ruptured at explant	<ul style="list-style-type: none"><li>▪ Implanted 7/1/99</li><li>▪ MRI obtained 8/31/02</li><li>▪ MRI indicated evidence of rupture</li><li>▪ Explanted 9/6/02*</li></ul>

\*Case report form documenting explant was received after the 3/27/03 data extract, so patient appears on Table 159 as unconfirmed rupture status

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Confirmed Implant Ruptures - Updated Data

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Patient ID	Date of Rupture Confirmation	Timing of Suspected Rupture Onset	Implant Status	Details (symptoms and screening method with results)
Right Implant	12/6/02	5/13/01 (estimated)	Confirmed ruptured at explant	<ul style="list-style-type: none"><li>▪ Implanted 12/9/99</li><li>▪ MRI done 11/14/02*</li><li>▪ MRI indicated evidence of rupture</li><li>▪ Explanted 12/6/02</li></ul>

\*MRI report obtained after the 3/27/03 data extract, so timing of suspected rupture onset has not yet been adjusted to reflect an earlier indication of rupture, based on the MRI date

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Confirmed Implant Ruptures - Updated Data

Patient ID	Date of Rupture Confirmation	Timing of Suspected Rupture Onset	Implant Status	Details (symptoms and screening method with results)
Right Implant	1/13/03	12/23/00 (estimated)	Confirmed ruptured at explant	<ul style="list-style-type: none"><li>▪ Implanted 3/31/99</li><li>▪ MRI obtained 6/18/02*</li><li>▪ MRI indicated rupture</li><li>▪ Explanted 1/13/03</li></ul>

\*MRI report obtained after the 3/27/03 data extract, so timing of suspected rupture onset has not yet been adjusted to reflect an earlier indication of rupture, based on the MRI date

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Suspected Implant Ruptures - Updated Data

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There were no suspected implant ruptures identified after PMA submission among Augmentation patients.

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Suspected Implant Ruptures - Updated Data

Patient ID	Timing of Suspected Rupture Onset	Implant Status	Details (symptoms and screening method with results)	Proposed Action Plan to Confirm Rupture
Left implant	6/28/01 (estimated)	Unconfirmed	<ul style="list-style-type: none"> <li>▪ Implanted 12/17/99</li> <li>▪ Rupture suspected at follow up visit 1/8/03 due to change in breast shape</li> <li>▪ MRI obtained on 1/29/03</li> <li>▪ MRI indicated no evidence of rupture</li> <li>▪ Patient evidenced change in breast shape</li> </ul>	No further follow-up planned.
Left implant	6/18/01 (estimated)	Unconfirmed	<ul style="list-style-type: none"> <li>▪ Implanted 4/10/00</li> <li>▪ MRI obtained on 8/27/02</li> <li>▪ MRI indicated evidence of rupture</li> <li>▪ Second evaluation of MRI films (after notification that implant was a double lumen) indicated no evidence of rupture</li> </ul>	No further follow-up planned.
Right implant	6/18/01 (estimated)	Unconfirmed	<ul style="list-style-type: none"> <li>▪ Implanted 4/10/00</li> <li>▪ MRI obtained on 8/27/02</li> <li>▪ MRI indicated evidence of rupture</li> <li>▪ Second evaluation of MRI films (after notification that implant was a double lumen) indicated no evidence of rupture</li> </ul>	No further follow-up planned.

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Suspected Implant Ruptures - Updated Data

Patient ID	Timing of Suspected Rupture Onset	Implant Status	Details (symptoms and screening method with results)	Proposed Action Plan to Confirm Rupture
Right Implant	9/28/00 (estimated)	Unconfirmed	<ul style="list-style-type: none"> <li>▪ Implanted 6/10/99</li> <li>▪ Ultrasound obtained 9/20/01*</li> <li>▪ Ultrasound indicates no evidence of rupture</li> <li>▪ Patient asymptomatic on right side</li> <li>▪ Explanted 1/18/02 by another (unknown) surgeon due to suspected rupture</li> <li>▪ Rupture status of implant unknown</li> </ul>	N/A
Left Implant	9/28/00 (estimated)	Unconfirmed	<ul style="list-style-type: none"> <li>▪ Implanted 6/10/99</li> <li>▪ Ultrasound obtained 9/20/01*</li> <li>▪ Ultrasound indicates evidence of rupture</li> <li>▪ Patient had nodules in left breast</li> <li>▪ Explanted 1/18/02 by another (unknown) surgeon due to suspected rupture</li> <li>▪ Rupture status of implant unknown</li> </ul>	N/A

\*ultrasound report obtained after the 3/27/03 data extract, so timing of suspected rupture onset has not yet been adjusted to reflect an earlier indication of rupture, based on the ultrasound date