The ParaGard® T 380A should not be inserted when one or more of the following contraindications are present:

1. Pregnancy or suspicion of pregnancy.
2. Known or suspected PID.
3. Known or suspected genital herpes.
4. Positive tuberculin test.
5. Known or suspected Bartonellosis.
6. Known or suspected gonococcal infection.
7. Known or suspected untreated gonococcal cervicitis.
8. Copper-containing IUDs should not be inserted in the presence of diagnosed genital warts. If warts are clinically suspected or confirmed, they should be treated and cleared before insertion of an IUD.
9. Untreated acute cervicitis or vaginitis, including bacterial vaginosis, until the infection is controlled.
10. known or suspected chlamydial infection.
11. Known or suspected pelvic congestion syndrome.
12. Known or suspected pelvic inflammatory disease.
13. Known or suspected tuberculosis.
14. Known or suspected syphilis.
15. Known or suspected gonorrhea.
16. Known or suspected HIV infection.
17. Known or suspected human Papillomavirus infection.
18. Known or suspected genital herpes.
19. Known or suspected genital warts.
20. Known or suspected Bartonellosis.
21. Known or suspected gonococcal infection.
22. Known or suspected untreated gonococcal cervicitis.
23. Known or suspected genital herpes.
24. Known or suspected genital warts.
25. Known or suspected Bartonellosis.
26. Known or suspected gonococcal infection.
27. Known or suspected untreated gonococcal cervicitis.
28. Known or suspected genital herpes.
29. Known or suspected genital warts.
30. Known or suspected Bartonellosis.
31. Known or suspected gonococcal infection.
32. Known or suspected untreated gonococcal cervicitis.
33. Known or suspected genital herpes.
34. Known or suspected genital warts.
35. Known or suspected Bartonellosis.
36. Known or suspected gonococcal infection.
37. Known or suspected untreated gonococcal cervicitis.
38. Known or suspected genital herpes.
39. Known or suspected genital warts.
40. Known or suspected Bartonellosis.
41. Known or suspected gonococcal infection.
42. Known or suspected untreated gonococcal cervicitis.
43. Known or suspected genital herpes.
44. Known or suspected genital warts.
45. Known or suspected Bartonellosis.
46. Known or suspected gonococcal infection.
47. Known or suspected untreated gonococcal cervicitis.
48. Known or suspected genital herpes.
49. Known or suspected genital warts.
50. Known or suspected Bartonellosis.
51. Known or suspected gonococcal infection.
52. Known or suspected untreated gonococcal cervicitis.
53. Known or suspected genital herpes.
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75. Known or suspected Bartonellosis.
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77. Known or suspected untreated gonococcal cervicitis.
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82. Known or suspected untreated gonococcal cervicitis.
83. Known or suspected genital herpes.
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86. Known or suspected gonococcal infection.
87. Known or suspected untreated gonococcal cervicitis.
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163. Known or suspected genital herpes.
164. Known or suspected genital warts.
165. Known or suspected Bartonellosis.
166. Known or suspected gonococcal infection.
167. Known or suspected untreated gonococcal cervicitis.
168. Known or suspected genital herpes.
169. Known or suspected genital warts.
170. Known or suspected Bartonellosis.
171. Known or suspected gonococcal infection.
172. Known or suspected untreated gonococcal cervicitis.
TABLE II
ParaGard® T 380A
(Intrauterine Copper Contraceptive)

GROSS ANNUAL TERMINATION AND CONTINUATION RATES
All Copper ParaGard T 380A IUD Students
Combined Population Council and WHO Studies

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<th>Rate of Item</th>
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<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
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<tr>
<td>Continuation</td>
<td>68.8</td>
<td>74.0</td>
<td>77.8</td>
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<td>85.3</td>
<td>87.9</td>
<td>85.7</td>
<td>85.3</td>
<td>88.0</td>
<td>87.0</td>
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<td>Pregnancy</td>
<td>21.4</td>
<td>17.3</td>
<td>15.7</td>
<td>9.9</td>
<td>5.4</td>
<td>4.2</td>
<td>3.9</td>
<td>3.7</td>
<td>3.7</td>
<td>4.3</td>
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<tr>
<td>Bleeding/Pain</td>
<td>8.2</td>
<td>6.9</td>
<td>6.4</td>
<td>4.5</td>
<td>3.1</td>
<td>2.6</td>
<td>2.4</td>
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<td>2.2</td>
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<td>0.2</td>
<td>0.2</td>
<td>0.2</td>
<td>0.2</td>
<td>0.2</td>
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</tbody>
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Note: n is the number of subjects in each group. Varies with the level of experience and the type of copper contraceptive used. A second generation copper IUD is the ParaGard® T380A.

TABLE III
GROSS ANNUAL RATES PER 100 CONTINUING USERS BY YEAR AND PAROUS STATUS

<table>
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<tr>
<th>Rate of Item</th>
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<th>3</th>
<th>4</th>
<th>5</th>
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<td>Parous Women</td>
<td>36</td>
<td>20</td>
<td>45</td>
<td>59</td>
<td>66</td>
<td>66</td>
<td>66</td>
<td>66</td>
<td>66</td>
<td>66</td>
</tr>
<tr>
<td>Non-Parous Women</td>
<td>36</td>
<td>20</td>
<td>45</td>
<td>59</td>
<td>66</td>
<td>66</td>
<td>66</td>
<td>66</td>
<td>66</td>
<td>66</td>
</tr>
</tbody>
</table>

Note: n is the number of subjects in each group. Varies with the level of experience and the type of copper contraceptive used. A second generation copper IUD is the ParaGard® T380A.

INSTRUCTIONS FOR USE
ParaGard® T 380A
(Intrauterine Copper Contraceptive)

1. The lowest expected and typical failure rates during the first year of continuous use are 0.3% and 0.6/100 person years, respectively.
2. Among couples who initiate use of a method (not necessarily for the first time) and use it perfectly (both consistently and correctly), the percentage who use a method for one year.
3. Among couples who use a method for one year, the percentage who use it with some error. Women who use a method for one year include women who use it continuously for at least 12 months or who use it intermittently for a shorter period but who use it consistently and correctly for at least 12 months.
4. Among couples who use a method for one year and who use it with some error, the percentage who continue to use a method for one year.
5. If appropriate, commence antibiotic prophylaxis one hour before insertion.
6. The position of the uterus should be determined during the preinsertion examination.
7. Be sure the baby is getting adequate nutrition.
8. Without spermicides.