

*Efficacy*

**11 Women should be advised of the low failure rate of IUDs, i.e. around 1% (Grade C).**

**12 IUDs containing at least 300 mm<sup>2</sup> of copper should be used as they have the lowest failure rates (Grade A).**

**✓ IUDs such as T-Safe Cu380A represent a reversible alternative to female sterilisation.**

There are few systematic reviews of randomised trials that allow a direct comparison of pregnancy rates with different devices. Factors such as a woman's sexual activity and age may be important in determining efficacy but are often not investigated fully in clinical trials. Experience of the inserter may also be important.<sup>31</sup>

WHO states that an IUD (in particular the T-Safe<sup>®</sup> Cu380A) is a very effective method, with 0.6-0.8 pregnancies per 100 women in the first 12 months of use.<sup>4</sup> Three of the largest WHO randomised trials investigated T-Safe<sup>®</sup> Cu220C, Multiload<sup>®</sup> Cu250, Nova-T<sup>®</sup> and T-Safe Cu380A devices in parous women recruited from 24 centres in 14 countries.<sup>32</sup> The T-Safe Cu380A had the lowest cumulative pregnancy rate. A follow-up study included 7159 woman-years for the T-Safe Cu380A and 17 098 woman-years for the T-Safe

Cu220C.<sup>33</sup> The T-Safe Cu380A had a significantly lower cumulative pregnancy rate after 8 years (2.2 per 100 women). Indirect comparisons with 10-year failure rates for tubal sterilisation<sup>34</sup> (1.9 per 100 women) suggest that T-Safe Cu380A may be an effective alternative to sterilisation. The WHO studies included parous women only. The 1-year failure rate for T-Safe Cu380A in nulliparous women was 1 per 100 women.<sup>35</sup> An adaptation of the T-Safe Cu380A (T-Cu380S Slimline<sup>®</sup>) has not been shown to alter pregnancy rates.<sup>36</sup>

A 3-year randomised trial compared T-Safe Cu380A with Multiload<sup>®</sup> Cu375 in parous women. Pregnancy rates were low for both devices, but significantly less for the T-Safe Cu380A (1.6 compared to 2.9 per 100 women).<sup>37</sup> A review of four studies comparing Multiload Cu375 with T-Safe Cu380A in parous women also identified lower pregnancy rates for T-Safe Cu380A.<sup>38</sup> Phase III clinical trials of Nova-T<sup>®</sup> 380 identified similar cumulative pregnancy rates of 1.9 per 100 women at 5 years.<sup>39,40</sup>

A Cochrane Review<sup>41</sup> included three trials<sup>42-44</sup> with over 5800 parous women using a T-Safe Cu380A or a frameless device (GyneFix<sup>®</sup>). In a WHO trial<sup>43</sup> the risk of pregnancy was lower with GyneFix between Years 2 and 6 [RR 0.53; 95% CI 0.32-0.91], but pregnancy rates for the whole 6 years were similar.<sup>41</sup> Frameless devices appear to have a lower pregnancy rate in later years, although the absolute difference is small.

T-Safe Cu380A has also been compared with Cu-Safe<sup>®</sup> 300 in 600 women and had a lower pregnancy rate but this was not statistically significant.<sup>45</sup>

Studies have shown a five-fold decrease in pregnancy rates when the copper content increases from 200 to 350 mm<sup>2</sup> (2.2 vs 0.44 per 100 woman-years).<sup>46</sup> With a fall in pregnancy rates, the risk of ectopic pregnancy is also reduced by a factor of five as copper dose increases (0.08 vs 0.015 per 100 woman-years),<sup>46</sup> thus IUDs containing at least 300 mm<sup>2</sup> of copper should be used.