DECLARATION OF MARCUS FILSHIE, DM, FRCOG, MFFP

THE UNITED KINGDOM)
COUNTRY OF ENGLAND)
COUNTY OF NOTTINGHAMSHIRE)

I, Marcus Filshie, am over the age of eighteen and competent to testify to the matters set forth in this declaration and state as follows:

1. I am co-inventor of the Filshie Clip. My co-inventor was Mr Donn Casey—the then Chairman of the Simon Population Trust. The Trust subsidised the research of the clip until it was marketed. At Femcare Ltd my work title was Honorary Medical Director from 1982 to 2001 and then Chairman of Femcare Ltd from 2001 to 2004—Femcare Ltd acquired Nikomed in late 2001 when it became Femcare-Nikomed. In 2004 Femcare Holdings was acquired by Clearwater Corporate Finance PLC in 2004. Utah Medical acquired Femcare Holdings in 2011

2. I qualified in Medicine from King's College Hospital, London in 1966 and obtained my MRCOG in 1972. I worked in Mulago Hospital Uganda in 1972 and was involved in research and clinical practice. I returned to the UK towards the end of the year. I was then appointed Foundation Lecturer in Obstetrics and Gynaecology at the new Medical School incorporated into the University of Nottingham. I rose through the ranks to become Associate Professor before I retired. I have not updated my CV since retirement, but attached hereto is the most recent version up to 2009.

3. I started research on the clip in 1974 using gilts (female virgin pigs)—moving on to humans in 1975. Between 1975 and 1982, over 8000 patients received prototype models including the final one. There were 27 national and international collaborators. Follow up was undertaken and any problems addressed including improvements to the clip and applicators. When the final model was evaluated, all the collaborators agreed that the final model Mark VI was perfectly suitable for marketing as the clip was clinically easy to apply and had a low failure rate. At this point there were very few incidences of clip migration--none of which involved serious morbidity.

4. I have not had any direct involvement in Femcare since retiring in 2004. But I have maintained an academic interest in Filshie Clips since that time and I continue to receive a licensing royalty from their sale due to its use of my name.

5. Over the course of my career, I have been a party to over 140 published medical articles. I have always been thorough in my research and publishing and I am pleased to say that never has one of these articles been questioned as to its data, methodologies, or conclusions. As related to the Filshie Clip, during the time I was directly involved with the product I was meticulous in studying, documentation, and publishing information on clip's side effects, adverse effects, and long-term effectiveness. I believe that this work was critical to ensuring and maintaining the integrity of the product.

6. I believe the Filshie Clip is the best permanent female sterilization device available. This belief is based on the longevity and success of the product—more than 40-years on the market and many millions of clips distributed; on the incredibly low failure rate; and on the fact that both short-term and long-term side effects and adverse events are rare and rarely serious in nature.

7. I am familiar with the article I published in 2001, entitled "Female sterilization: medico legal aspects." That article contains a subsection on clip migration, which reads in full as follows:

> Innocent migration of clips following a normal application are commonplace and it is estimated that the incidence is over 25%. The pathophysiology is related to the speed at which peritoneal-like tissue forms over the clip anchoring it to the fallopian tube. If the peritonealisation is quick, the clip remains *in situ*, if it is slow, the tube may become transected with both ends of the tube healed over to form a cul-de-sac. The clip will have no covering tissue to maintain its position and the clip will fall off and migrate.
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> The clip usually migrates to the omentum but, less commonly, may remain in the pouch of Douglas, paracolic gutters or at any other site. In a prospective study involving over 6000 patients which was presented to the FDA panel hearing in 1996, three clips were noted to have been expelled from the body via the vagina, urethra and rectum but in no case was any morbidity observed on examination. If a pelvic abscess occurs then the clip may be expelled abdominally when the abscess bursts or is incised (Robson and Kerin 1993). Both Filshie clips and Hulka clips have been known to migrate (Gooden et al 1993). Considering that in excess of three million pairs of Filshie clips have been used, only a handful of cases with such problems have been reported in the literature.
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> A review of migration of clips is provided by Amu & Husemayer (1999).
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> If a migrated clip is noted incidentally, eg when x-rays have been taken because of urinary or skeletal problems, reassurance is normally all that is warranted. To inform the patient to use another method of contraception, or to resort to laparoscopy or indeed laparotomy, is not indicated in the overwhelming majority of cases as the morbidity of such procedures is significantly in excess of leaving the clip, whether it be open or closed.

8. I am also familiar with the article I published in 2002 entitled "Long-term experience with the Filshie Clip." That article also contains a subsection on clip migration,

which reads in full as follows:

> Once a Clip has been applied to a fallopian tube, the tissue between the jaws undergoes avascular necrosis. The adjacent tubes heal up with sealed ends. Eventually peritoneal tissue grows over the Clip and the Clip is held in place indefinitely. In some cases, however, peritonealisation of the Clip is slow, and after the tubes have healed the Clip may move away from the tube and migrate. It is estimated that over 25% of patients will experience a migration of one of more Clips. As over three and a half million Clips have been applied, this represents a large number of migrations. The majority of Clips migrate to the omentum, the pouch of Douglas or the paracolic gutters. There has been a small number of cases reported of a Clip being expelled from the body, i.e. from the vagina, the bowel and the urethra. These patients were carefully examined and no harmful sequelae were noted. A full review of migrations of both the Filshie Clip and the Hulka Clip was reported by Amu and Husemeyer. They concluded that 'the remarkable absence of serious sequelae from the migration of each type of Clip is reassuring.'
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> Clips may be dropped from the applicator during the operative procedure. If possible the Clip should be removed after the sterilization procedure has been completed. If the Clip becomes lost, either open or closed, it should be left, as to perform a laparotomy would involve a much greater risk to the patient than leaving the Clip. To date, there has been no report of any serious problem relating to a lost dropped Clip. Naturally the patient should be informed of the lost Clip and reassured.

9. I understand that my estimate of an innocent migration rate of "over 25%" has been cited in medical literature many times since these articles were published, and I also understand it is being relied upon by patients who are making claims against the Filshie Clip.

10. Given that my articles were written over 20 years ago, I do not recall with precision about how I came to this estimate. I believe it was made from either limited anecdotal

experience (such as observations made while performing laparoscopies or hysterectomies on patients who had previously received Filshie Clips) or informal discussions with colleagues. In other words, it was, at best, a guesstimate.

11. The purpose of my providing the estimate in these articles was to emphasize that while migration of Filshie Clips is a known phenomenon given the physiology involved, the instances of migrating clips causing adverse events are incredibly few. This point is borne out by the data from Filshie Clip clinical trials done in the 1990s and by the Amu and Husenmayer study cited in my articles, and it appears to remain true to this day given that millions of Filshie Clips have been applied and that documented adverse events remain rare.

12. Regardless of where my estimate of clip migration originated, it was always simply an estimate. There is no scientific evidence or clinical or statistical data behind it. Given my demonstrated concern for the integrity of my work and my product, I would not want anyone to mistake my estimate for a scientific fact supported by evidence. When I provided the estimate, it was to illustrate a point about the rarity of clip migration causing adverse events. It was not intended to be used as a statistic to inform the decisions of physicians or women as to their choice of contraceptive device.

I DECLARE UNDER PENALTY OF PERJURY UNDER THE LAWS OF THE UNITED STATES OF AMERICA THAT THE FOREGOING IS TRUE AND CORRECT.

EXECUTED ON THE 7th NOVEMBER **, 2023.**

GMH

MARCUS FILSHIE, DM, FRCOG, MFFP