

## Graceful: Galaxy II Retrospective Safety and Effectiveness Follow Up Long-term Study–An Original Article

Angela Spang\*

### Abstract

A new self-retaining retractor was invented to remove loose screw parts, use less plastic, provide superior surgical access and improve patient safety compared to older retractor models. The retractor is designed to be used in a range of specialties from pediatric ENT to inguinal hernia, urology, andrology, orthopedics, and spinal surgery, in any surgery that retracts delicate and/or solid tissue. This study aims to assess the use of this new retractor in the National Health Service (NHS) in the UK for 4 years since introduction, specifically looking at patient safety as recorded in adverse events and infection rates.

**Keywords:** Inguinal hernia; Urology; Orthopaedics; Spinal surgery; Treatment; Solid tissue; Self-retaining retractor; Patient safety; ENT; Hernia; Solid tissue; Surgery; National Health Service; Pediatric specialties; Infection rates.

### Introduction

Surgical self-retaining retractors have been without significant improvements for decades. Old devices with loose screws have dominated, and many surgeons have instead opted to use the manual labor of assistants or student to retract tissue; a costly and sometimes even risky approach.

### Manual retraction

Junior doctors or medical students have traditionally been the source of labor for manual tissue retraction. However, the long hours of physical presence in operating rooms are no longer felt to be appropriate. With changes in methods of surgical education and a reduction in time spent watching and

\*Spang Group, Mosaic Surgical, June Medical, EveryBaby, London Medical Education Academy, United States

\*Corresponding Author: Angela Spang, Spang Group, Mosaic Surgical, June Medical, EveryBaby, London Medical Education Academy, United States.

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learning in surgery a corresponding reduction in hands available to retract tissue in surgery [1] mean hands on assistance in operating theatres is often insufficient.

### How retracting tissue affects operating room nurses

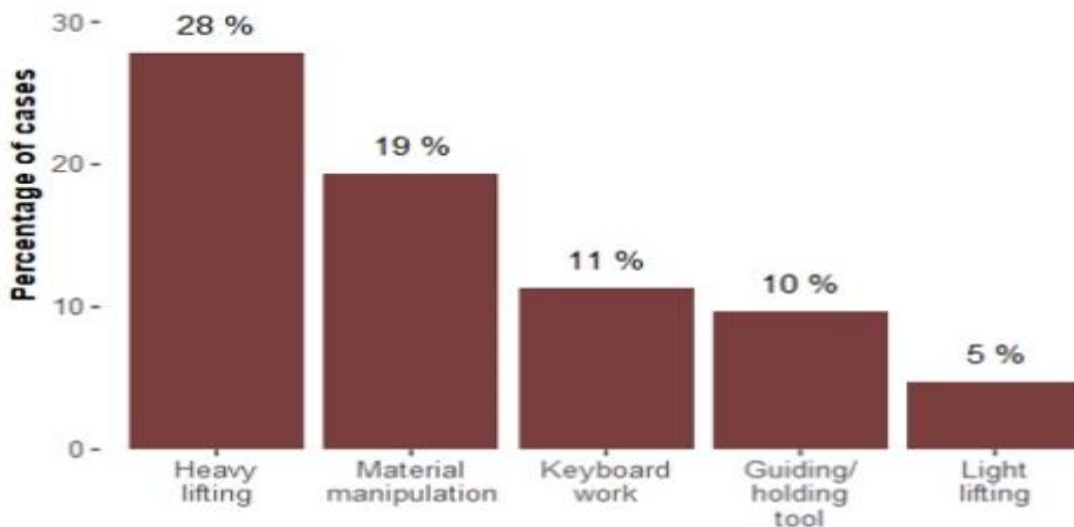
Musculoskeletal disorders (MSDs) are prevalent among workers. These disorders are characterized by injuries and conditions affecting vital areas such as the back, limbs, and joints. They usually result from strenuous manual labor, such as crouching often, repetitive movements, and carrying out a task for an extended period. One health professional does all these movements on a regular basis: the operating room or surgical nurse. As such, they're among the professionals most likely to be MSD patients [2].

### One major task contributing to MSD in the surgical nurse is retracting tissue

The expanded role of a surgical nurse [3] includes assisting in surgeries and taking roles at ambulatory surgery centers. These tasks involve a lot of physical labor, including retracting tissue. This involves holding an incision open with tools so a surgeon can perform a procedure. Surgeries can take a few minutes to hours, so nurses must stay crouched and hold incisions open for prolonged periods of time. Their hands can get strained from holding equipment like retractors at the right angle and pressure to avoid unnecessarily harming the patient. This puts them at a higher risk of developing MSDs and may compromise their ability to deliver quality healthcare consistently.

Manual retraction of tissue involves

- a) Guiding/holding tool (10%).
- b) Material manipulation (19%) and, depending on surgery.
- c) light (5%) or heavy (28%) lifting.

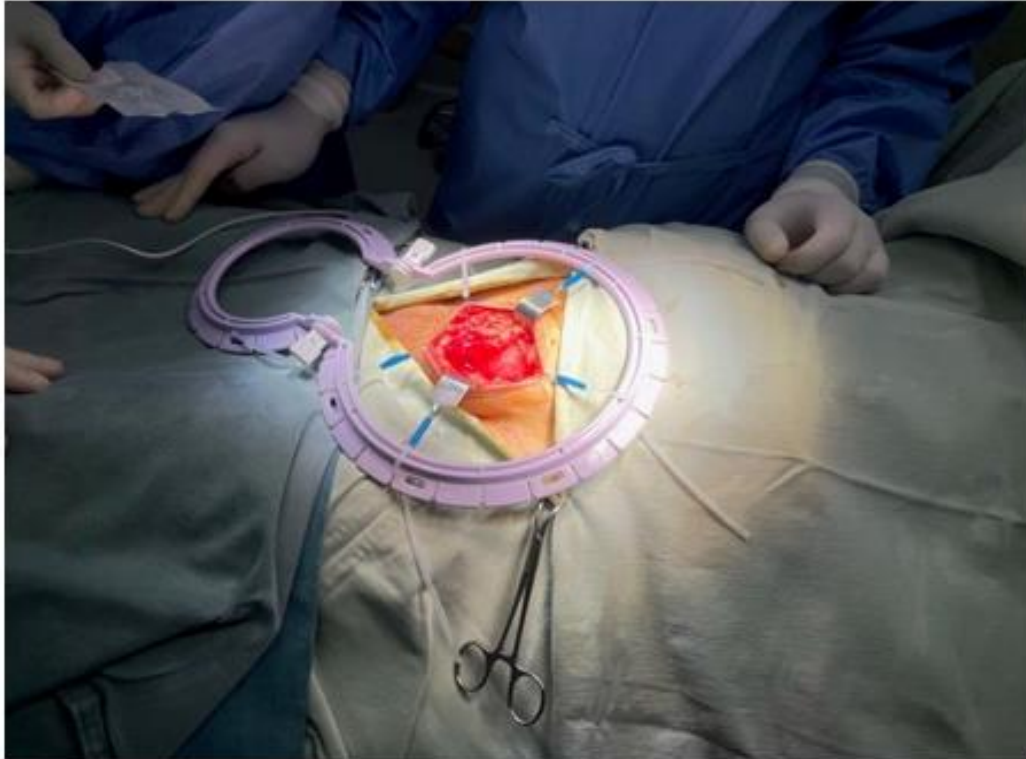


**Figure 1:** Percentage of work-related musculoskeletal disorders reported. Split in work-related musculoskeletal disorders as reported to THOR-GP split by main task, 3 year aggregated between 2013- 2015 in United Kingdom [4].

## Safer retraction

Galaxy II is a modern surgical self-retaining retractor manufactured in the United Kingdom, available for use both in UK and USA and several other countries. Post Market Surveillance [5] has showed an excellent safety and efficacy profile, and a high rate of

customer satisfaction. The self-retaining retractor reduce the need for assistants holding the retractor, reduce clutter at the operative site, improve access to surgery and provides better vision. With light weight yet strong frames and low-profile hooks, the Galaxy II has become the product of choice for leading surgeons [6] all over the world.



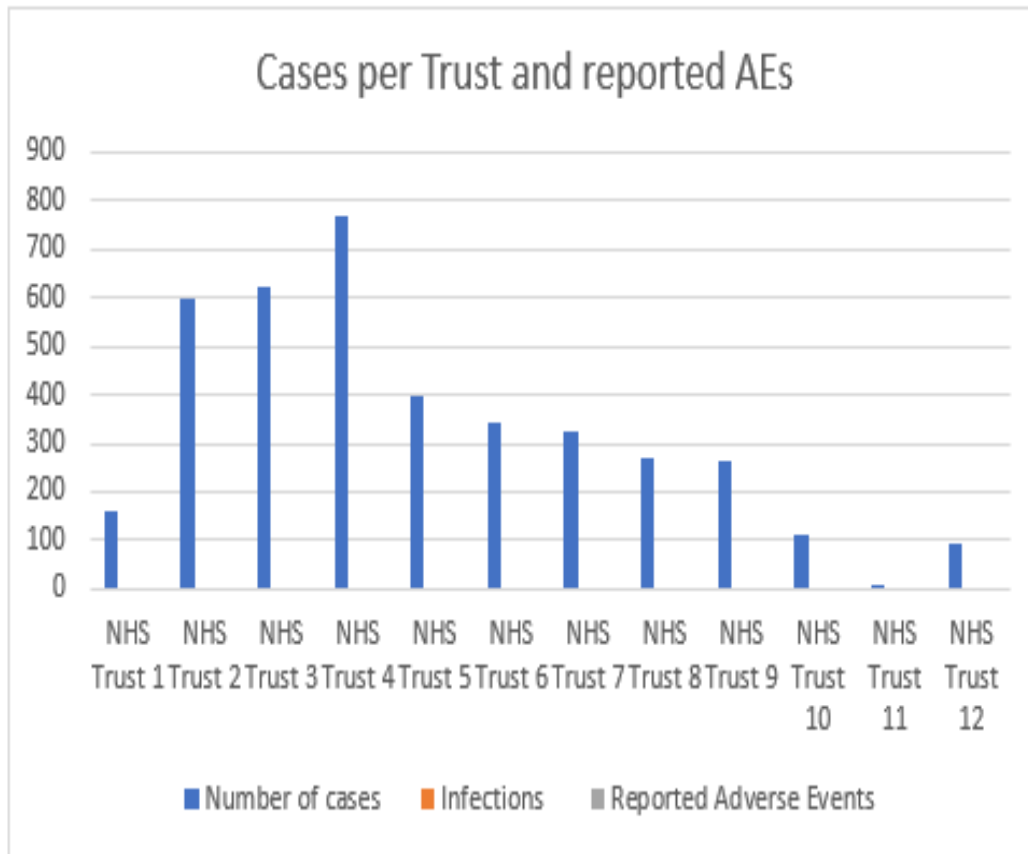
**Figure 2:** Galaxy II used in an Inguinal Hernia: Galaxy II Snowman frame 2 x 12 mm Blunt hooks, 2 x 22mm Claws, 1 x 5mm Sharp low-profile hook. The flexible hook tails give a less rigid hold on surrounding tissue, which anecdotally improve post-operative patient comfort and speed up recovery. Image credit Prof Aye Than.

## Objective

This observational retrospective clinical study is looking to ensure that Galaxy II meets the requirements for safety and efficacy, by retrospectively assessing the surgeries performed using the device in 12 NHS [7] trusts in the UK.

## Study design

12 leading NHS Trusts in the UK performed over 3967 surgeries using Galaxy II. This article collates the quantitative data from use in those procedures as well as qualitative surgeon feedback up until February 2023.



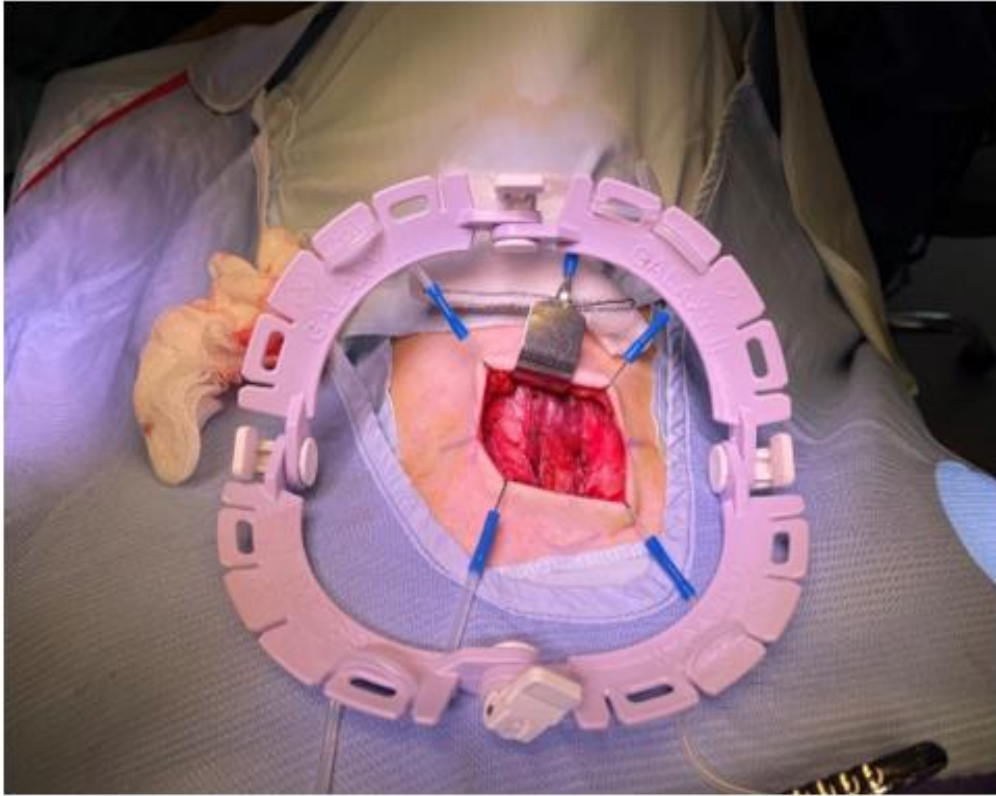
**Figure 3:** Number of cases successfully completed using Galaxy II per UK National Health Service (NHS) Trust, compared to number of recorded devices induced infections (o zero) and number of reported Adverse Events due to device failure (o Zero) 2018-Feb 2023.

### Data gathering

Questionnaires were sent out to lead surgeon in each trust, and responses were recorded in excel [8]. Data was cross-referenced with internal shipping data [9], product complaints log, MAUDE database [10] and MHRA [11]. The majority of cases used a frame and hooks together, but 3 Trusts reported on cases using hooks on their own (clamped to drapes or handheld by assistant). For this publication, an average of 6 hooks were determined to represent one case. 317 cases were recorded using hooks only.

### The following questions were asked

1. Have doctors ever recorded a Galaxy II induced infection?
2. Have doctors ever seen an intra-surgery complication caused by Galaxy II?
3. What is the intra operative performance vs. not using a retractor?
4. Did the Galaxy II retractor retract tissue well?
5. How many surgeries have doctors and surgeons of hospital completed with Galaxy II?



**Figure 4:** Galaxy II Square frame used in Pediatric ENT with 4 × 5mm Blunt low profile hooks and 1 × 22mm claw. The low-profile frame and its 4 points of flexible joints allow for improved access and instruments are not restricted to the frame height. Hooks here are double slotted from under the frame (this surgeon’s personal preference) which further improves access as the hooks hold tissue down and away from the incision.

## Interviews

Surgeon’s feedback was recorded as part of interviews, captured in online systems [12], and is summarized by representative comments in the following section:

“It is a great product that enhances the surgical outcome, as it removes the problem of the assistant’s boredom/hunger/tiredness from the equation, and it is very easy to use.”

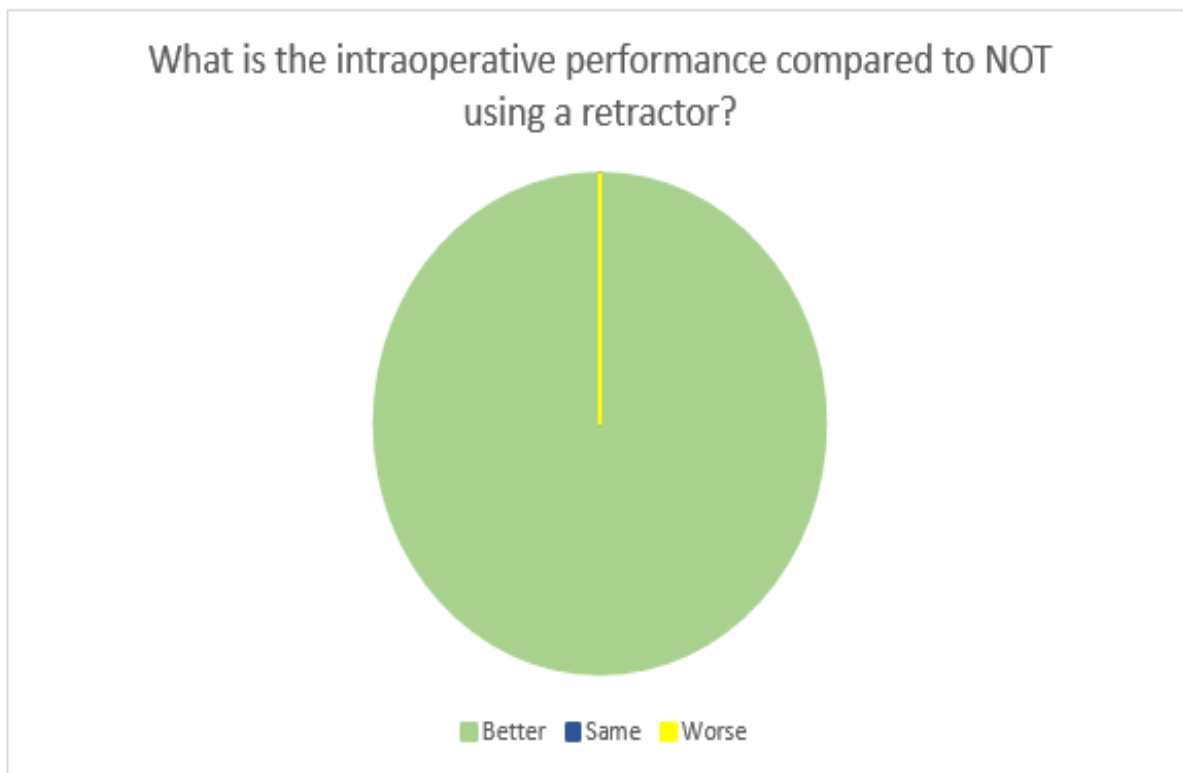
“Self-retaining retractors are very useful, but the Galaxy II indeed took this to the next level. This is better (actually essential now).”

“While it is very similar in shape to the retractor used previously, the Galaxy II is easier to use, with cam locks rather than a screw mechanism to secure it, allowing single-handed operation.”

“The simple, single-handed operation means that it is easier to adjust and readjust the retractor during a surgery. Surgeon can make changes faster and without any assistance, which saves the time and allows the procedure to be completed more quickly and efficiently.” “Surgeon don’t operate without it [sic Galaxy II] now.”

Data	Summary
Device induced infection	0%
Intra-surgery complication caused by the device	0%
Intra operative performance vs. not using a retractor?	100% respond "Better"
Did the device retract tissue well?	100% "Yes"
Number of cases	3967

**Table 1:** Data summary in table form from 3967 cases in the UK recorded during 2018-2023.

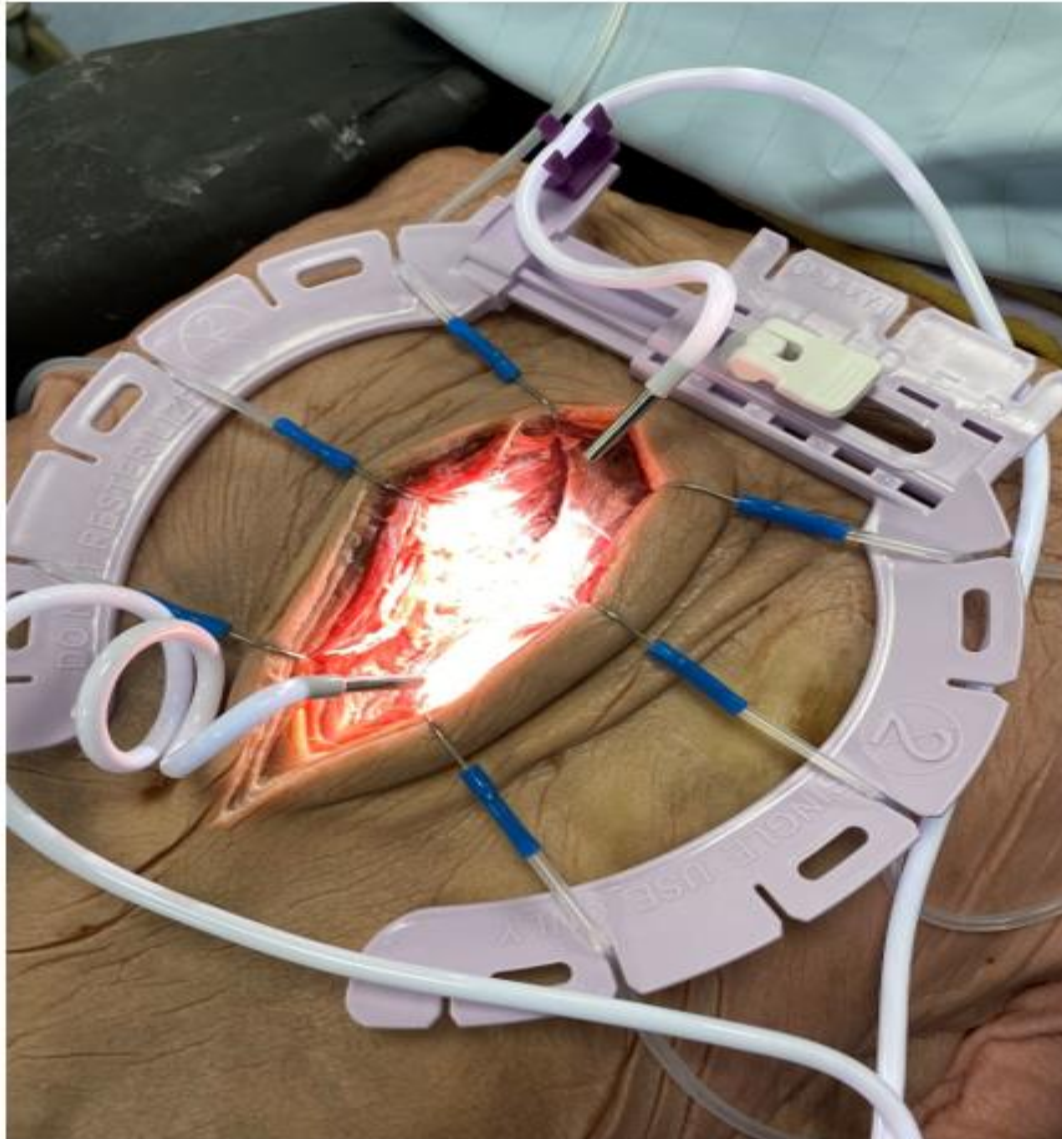


**Figure 5:** 100% of surgeons in 3967 cases reported that using a Galaxy II retractor was "better" than not using a retractor with several surgeons mentioning it being "better than an assistant holding a manual retractor", or "better than older/other retractor models".

### Summary

Out of 3967 patients, 0 (zero) patients had a post op infection [13] caused by Galaxy II, and 0 (zero) intraoperative [14] complications

were recorded. The performance is recorded as "Better" than alternative in 100 % of the cases, and 100% of surgeons agreed that Galaxy II retracted tissue safely and effectively.



**Figure 6:** Galaxy II Slider demonstrated with 6 × 12 mm Blunt hooks and LUX Connect light attachment.

## Discussion

Indicated to assist in a wide range of surgical procedures [15], the Galaxy II is used in any specialty where retraction of tissue is helpful for surgical success. Despite differences in procedures, the retraction of human tissue is similar and requires the same features: stability, reliability, strength and ease of use to optimize control.

Manual retraction, meaning the task performed to separate tissue with intention of providing access to the surgical site, brings with it a high risk for musculoskeletal disorders.

Most commonly, the strain and injuries reported affect the hands, arms, shoulders, neck, and back. Recently, minimally invasive and laparoscopic procedures have led to the

development of instruments that reduce the need for manual retraction, but many surgeries cannot be done endoscopically. The use of self-retaining retractors enables the surgeon to handle tissue and maintain complete control of the surgical site, and use exposure techniques that do not require extended manual retraction. There are guidelines with a specific algorithm for perioperative care providers to determine if and when manual retraction of tissue is safe and when self-retaining retractors should be used instead [16].

The surgeons involved in this study operate in and around the most challenging human anatomy from an infection and sterility

perspective [17] and the results demonstrated shows that Galaxy II is suitable for use all over the human body with safe outcomes. Further studies could look at the actual improvement in health and safety (MSD) for surgical staff and the reduction of risk for assistants.

## Conclusion

Galaxy II had no adverse events, is safe and effective to use in any surgery, is an improvement over older retractors and can reduce the risk of MSD in nurses and assistants. The unique range of low profile and light-weight frames and hooks provide better access and increases visibility thus making surgery safer.

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