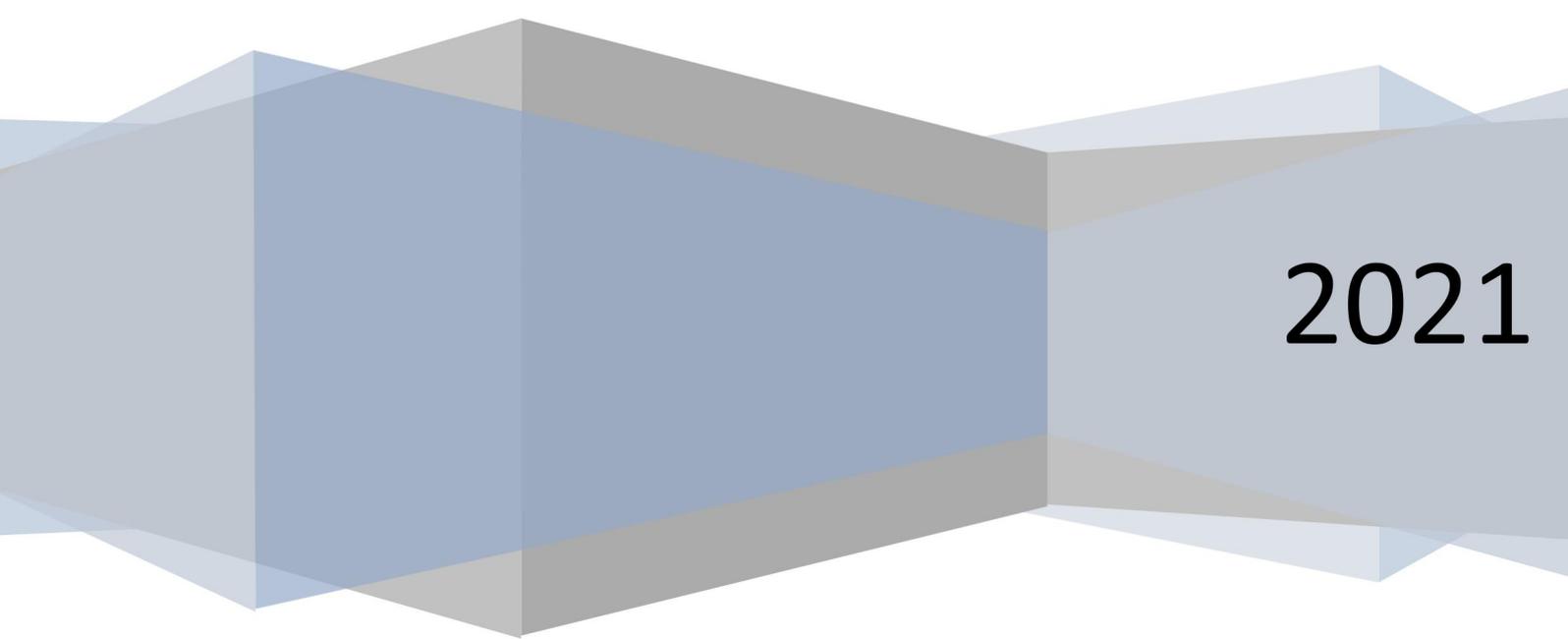




Smart-Clip Series

Background information

Christel Jacobson

A decorative graphic at the bottom of the page, composed of several overlapping, semi-transparent geometric shapes in shades of blue and grey, creating a layered, 3D effect.

2021

Disclaimer

To the best of our knowledge, the information contained herein is accurate and reliable as of the date stated; however, we do not assume any liability whatsoever for the accuracy and completeness of the included information. Jacobson Innovations and its affiliates make no warranties of merchantability or fitness for a particular use or market. It is the responsibility of the potential licensee to inspect and to test our products in order to satisfy themselves as to the suitability of the products to their particular purpose. This document contains approximate numbers only and it is the sole responsibility of the potential licensee to investigate the potential market thoroughly. Any and all numbers are pre-COVID standard years.

This document contains the basics of the Smart-Clip Series, the product applications and a short market analysis. The products are design patented in the United States, European Union, United Kingdom, Norway and Switzerland.

1. Background

Most of the catheters, drains and tubes used in modern hospital settings are part of life-sustaining treatment - accidental dislodgement can be catastrophic. The Smart-Clip Series eliminates the risk of such adverse events; securing ventilator circuits, central lines, all catheters, monitoring equipment - keeping vulnerable ICU patients safe.

2. Currently available products

Typically gauze, hemostasis clamps or tape is used because there is no good option on the market. For ventilator circuits there are adjustable arms and circuit trees. The arm type is hard to maneuver and is only accessible while the patient is in a bed. The circuit tree is only supported by the weight of a mattress and offers very little security. The risk of accidental extubation is immense with both types.

To adhere tubes and lines directly to the patient's body the market is full of tape products, some more complicated than others. Most are made only to suit a particular catheter, filling supply rooms with what will be wet soggy messes that are likely to cause pressure ulcers and catheter dislodgement.

3. Areas of use

Proper securement of medical equipment is essential at all times, even more so when the patient is mobilized. Recent research points out the importance of mobilization, physical therapy and regular shifting of body position, even for the most critically ill comatose patients (1). New products for mobilization are constantly launched, yet there is still an apparent lack of proper securing devices for the most vital equipment. Current research and clinical experience also pushes for keeping critically ill only lightly sedated, which inevitably increases their inclination to accidentally move and remove tubes and lines themselves (2,3). When caring for the critically ill, in-hospital transportation is inevitable – patients need to be taken to OR's, CAT-scans and other procedures. In-hospital transportation is notoriously dangerous, mainly due to the risk of dislodgement of vital tubes, lines and cords.

In addition to the critically ill in advanced health care settings there is a large number of chronically ill in advanced home care, senior homes and hospices that are in need of a permanent urinary catheter. A vital and active patient with a urinary catheter is dependent on a good fixation device to decrease discomfort from pulling. Smart-Clip Skin will firmly fixate urinary catheters and other invasive catheters, tubes and drains to the patient's body without the unhygienic adhesives. In fact, the three devices in the Smart-Clip series will fixate tubes, lines, cords and catheters to the patient's body, bed frame, wheel chair or clothing, thus increasing patient comfort, decreasing risk of dislodgement and facilitating the daily work of health care personnel.

4. The new products

The Smart-Clip series is the solution for all the risks described above, and most importantly - they work. The three different devices have been evaluated by experienced critical care nurses and doctors in the ICU's of the major hospitals of Stockholm, Sweden. In simulation they assessed the user-friendliness and time saving effect as well as perceived safety of patients. The Smart-Clip devices scored an average of nine out of ten points possible and 100% favored Smart-Clip over the currently available products. The diversity and multifunctionality of the three devices was much appreciated, as was the ease of application and the quick release. Furthermore, the fact that the clips are made entirely of non-magnetic material was frequently indicated as an important attribute, significantly facilitating in-hospital transportation specifically to the radiology department.

5. Utilization and Market Potential

The average ICU patient has at least 2.7 invasive tubes, lines or catheters that warrant the use of a Smart-Clip. 11.2 million patients were treated in ICU every year in pre-COVID Europe and US. 11.2 million patients needing 2.7 Smart-Clips each.

5.1. Utilization

Out of all the patients that were treated in a Swedish ICU in the year of 2015, 64.7% received ventilator support, invasive (i.e. traditional ventilator) or non-invasive (e.g. high-flow oxygen therapy or CPAP-mask etc.)¹, whether they are single-line circuits or double line circuits they should be accompanied by a Smart-Clip Multi. Any critical care patient who receive dialysis²,

¹ Includes invasive and non-invasive ventilator treatment, CPAP and high-flow oxygen therapy

² Dialysis includes CRRT, hemodialysis, liver dialysis, peritoneal dialysis and plasmapheresis

has a chest drain or miscellaneous invasive catheters³ would benefit from the use of a Smart-Clip Mini. These groups add up to a total of 32.5 % of critical care patients needing a Smart-Clip Mini. Note that this only includes chest drains that have been applied in the ICU, not ones applied in the OR, ER or step-down unit, neither does it include abdominal surgical drains et cetera.

In addition to this most patients treated in an ICU have a urinary catheter, as do many of the other patients admitted to a hospital, approximately 15-25 % of all patients. There is also a large group of senior citizens and chronically ill with a permanent urinary catheter; >5% of the population of US nursing homes (4). Every person with a urinary catheter could use a Smart-Clip Skin to avoid discomfort and urethral damage, especially when physically active. In addition to anyone with a urinary catheter, patients with invasive tubes, drains and central IV lines could use a Smart-Clip Skin. More than 68.7% of the patients in an ICU would need two Smart-Clip Skin, one for the urinary catheter and one for other lines.

5.2. Yearly Potential, non-COVID years

The potential annual sales volume of Smart-Clip adds up to approximately 70 million units (34.4 million in Europe and 34.7 million on the slightly larger American market).

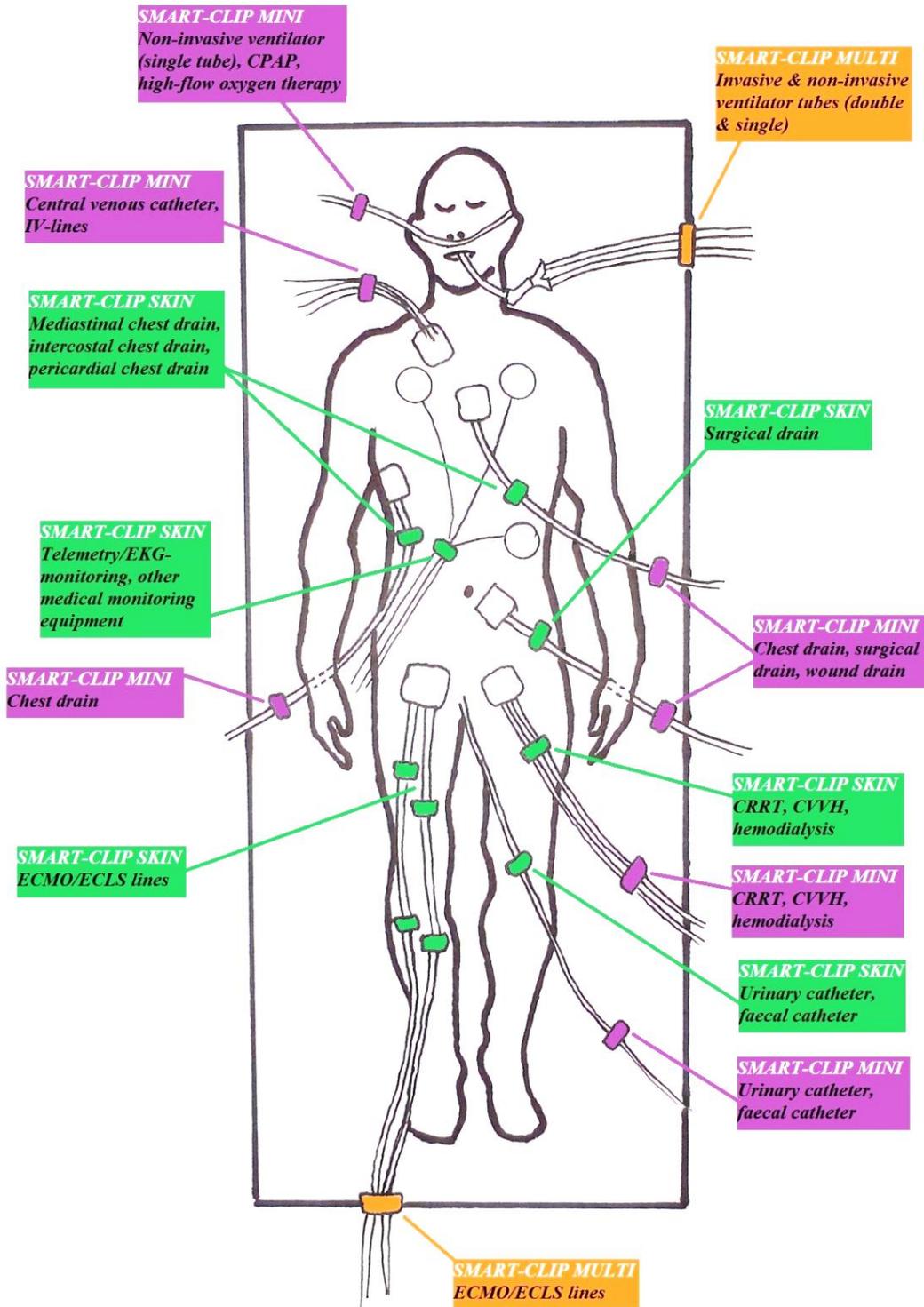
In Sweden alone there are 46,000 patients treated in an intensive care unit every year and more than half of these patients spent less than 24 hours in the ward (5). In the US the number of adult patients treated in intensive care units per year is 5.7 million, spread out over 77,000 ICU hospital beds (6). The corresponding number in Europe is 74,000 critical care beds (7) which should equal approximately 5.5 million patients per year, giving a total of 11.2 million patients per year treated in intensive care units in Europe and the US.

When these statistics are applied to the 11.2 million ICU patients, a yearly potential for Smart-Clip products adds up to 30 million units for ICU patients only. This would include 3.6 million Smart-Clip Multi, providing it is sold as a single-patient use product. Smart-Clip Mini has a yearly potential of up to 7.3 million units. As for Smart-Clip Skin, the critical care patients alone could use 18.9 million units including fixating the urinary catheters.

The approximate number of Foley catheters sold annually is 25 million units in Europe and 25 million in the US (4). Each urinary catheter should be accompanied by a Smart-Clip Skin.

³ Includes intracranial monitoring catheters, epidural catheters and hemodynamic monitoring catheters excluding basic arterial lines

Below is an example of a critical care patient with different applications for Smart-Clip represented



6. Cost of production & Retail price

Retail price of disposable fixation devices vary greatly, ranging between USD 1.4 per piece in bulk to \$36 and more, averaging around \$10 per product. The fixation devices available for larger tubes and lines cost around \$100, these are generally non-disposable. The production cost of Smart-Clip Skin, Mini and Multi should be no more than \$0.85, \$1.35 and \$1.69 respectively. In contrast; the average cost of intensive care in Sweden is \$4000 per 24 hour period (5) and \$13400 in the US (6).

7. Additional information & Business opportunities

The IP is available for license or acquisition to an external party in the European Union, UK, Norway, Switzerland and the United States of America.

Request additional information and detailed descriptions of the products by contacting us directly or through our website www.jacobsoninnovations.com. A demonstration of physical prototypes can be arranged upon request.

We look forward to telling you more about the Smart-Clip series and discussing the future of these inventions.

Sources:

1. Webb, S. A. (2014). Expert consensus and recommendations on safety criteria for active mobilization of mechanically ventilated critically ill adults. *Critical Care*, 18(6), 658. <http://doi.org/10.1186/s13054-014-0658-y>
2. Birkett, KM., Southerland, KA., Leslie, GD. (2005). Reporting unplanned extubation. *Intensive Critical Care Nursing*, 21(2); 65-75.
3. Hodgson, C. L., Stiller, K., Needham, D. M., Tipping, C. J., Harrold, M., Baldwin, C. E., Bradley, S., Berney, S., Caruana, L.R., Elliott, D., reen, M., Haines, K., Higgins, A.M., Kaukonen, K-M., Leditschke, I.A., Nickels, M.R., Paratz, J., Patman, S., Skinner, E.H., Young, P.J., Zanni, J.M., Denehy, L., Webb, S.A., (2014). Expert consensus and recommendations on safety criteria for active mobilization of mechanically ventilated critically ill adults. *Critical Care*, 18(658). DOI: 10.1186/s13054-014-0658-y
4. Enox Biopharma, n.y. www.enoxbiopharma.com/urinarycatheters
5. Swedish Intensive Care Registry [SIR]. www.icuregsw.org
6. Society of Critical Care Medicine [SCCM], n.y. Retrieved from www.sccm.org
7. Rhodes, A., Ferdinande, P., Flaateh, H., Guidet, B., Metnitz., P.G., Morein, R.P., (2012). The variability of critical care bed numbers in Europe. *Intensive Care Medicine*, 38; 1647-16537.