

# Clinical evaluation

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## 1 Introduction

### 1.1 Purpose

The purpose of this evaluation of clinical data is to verify the clinical benefit of the device and ensure that it performs as intended and is safe to use. This report shows that the intended purpose and the claims we make are related to the safety and performance achieved under normal conditions and the intended use of the product.

The clinical evaluation is intended to be objective and evaluates both favorable and non-favorable data.

The design of the clinical evaluation has been made on the basis of: i MEDDEV 2.7.1 Rev 4 *Clinical Evaluation: A Guide For Manufacturers And Notified Bodies* “published in June 2016.

This report should contain sufficient information to be read as a stand-alone document of an independent party (e.g. authority, notified body).

### 1.2 Participant

The following people have participated in the work of identifying clinical data as well as performing the analysis of clinical data.

Participant	Competence and experience
<i>Marina Donner</i>	<i>Doctor, resident physician general medicine. Experience from working at a skin cancer clinic in Katoomba, Australia. Holds Advanced Certificate of Skin Cancer Medicine. Also theoretical education from Sweden in dermatology and dermatoscopy</i>

## 2 Definitions

Concept	Definition
<i>TagMole</i>	<i>medical device that can be used to remove benign skin changes such as skin flaps (in English skin tags), small seborrheic keratoses, benign fibromas and similar harmless skin growths</i>
<i>Skintags</i>	<i>benign small skin tags, commonly found in adulthood, most often on the trunk, in armpits, around the neck.</i>
<i>Small seborrheic keratoses and benign fibromas</i>	<i>Small seborrheic keratoses (sitting on a stalk) are harmless skin growths, more common in adulthood. Benign fibromas are drop-shaped raised skin changes that can also resemble raised birthmarks, both of which are harmless. (1)</i>

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### 3 Summary

#### 3.1 Conclusion

Based on this clinical evaluation, we believe that the product is an effective support in emergency care / skin care and that it does not pose any unacceptable clinical risks due to its design. The benefits of using the product are higher than the risks.

### 4 Detailed description of the product

*TagMole is a medical device that should be used to remove a skin flap, small seborrheic keratoses on a stalk or benign fibromas. This is accomplished by applying a loop around the base of the skin change and tightening so that the blood supply is throttled. The loop is then released from the tightener in TagMole Remove and allowed to remain on the skin change until it eventually turns black and falls off (which usually occurs within 1-3 weeks). By using this non-invasive method, one reduces potential risks that may arise from surgical removal of the aforementioned skin changes such as infection risk and risk of excessive scarring. You can also perform the procedure in your own home, do not have to pay expensive fees for doctor's visits and are well suited for people who are afraid of the hospital environment.*

#### 4.1 Technical description

*The product contains A) a user manual, B) a "tightener"/ tool, C) washcloths with disinfectant and D) 4 pieces of cords, here called "wire cartridges", with a stop knot and must be mounted to the "tightener". The puller/ tool includes a hollow cylindrical handle with a piston inside the handle. A thumb grip is attached to the piston to allow tightening of the wire cartridge. To the piston is connected wire cartridgeone. A wire snare is located at one end of the wire cartridge which must be placed around the skin flap. The noose of the wire cartridge tightens around the skin flap when the cartridge is pulled backwards and stops nutrient supply to it. The wire cartridge is left at the skin flap and falls nest when the skin flap eventually falls off, however, so that the recommendation entails cutting off the thread so that only a short part of the thread remains around the skin flap.*

#### 4.2 Intended use

*TagMole is a medical device intended to be used to cut off blood supply to skin flaps or similar harmless skin growths with the aim of preventing or relieving irritation, abrasions or the like and if you wish to remove the above-mentioned skin changes for cosmetic reasons. From the time strangulation has occurred, it takes 1-3 veccows before the lack of blood supply means that the skin flap / drop-shaped birthmark dried out and fell off. The product can be used several times and with the product comes a total of 5 wire cartridges. A wire cartridge is used to strangle one (1) skin flap/ dropp-shaped birthmark.*

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*Skin flaps look in a very typical way and are benign in their basis. The same applies to small benign fibromas as well as small seborrheic keratoses on a stalk. However, we believe that you should check your skin changes with a doctor at a health center or skin clinic to know with certainty that the skin changes you have is harmless before you start removing these.*

### 5 Scope of analysis

#### 5.1 Development history

*The product has been developed together with Prodelox (2), which is a product development company based in Linköping. When Prodelox was involved, the business idea was clear along with the fact that the strangulation should be done with a string with a stop knot. In addition, there were ideas about what the handheld product that should work as a tightener should look like. Through the last number of iterations, various alternatives were evaluated and rejected until we found a good solution: Moderately large, intuitive design and can be operated with one hand. Several simpler prototypes were manufactured and tested on the way to the goal. Danderyd Hospital's Innovation Centre has also been involved in the development process and contributed ideas and knowledge to the development. Danderyd Hospital's dermatology clinic recommends the product for use at home or at a reception on the above-described indications.*

#### 5.2 Related Products

*The NHS (National Health Service) (3) recommends the use of dental floss to remove skin flaps, by tying the thread around the base, after which it will self-destruct due to a lack of blood supply.*

*TagBand (4) is a British product that uses the flossing principle to remove skin tabs. Tag bands accomplish this by putting an elastic band around the root of the skin flap.*

#### 5.3 Questions from the checklist of essential requirements

The issues that we choose to include in the clinical evaluation that arise from the essential requirements of LVFS 2003: 11 are about patient safety, usability and how well the system performs as intended.

Requirement 1: The risk of devices endangering the clinical condition or safety of patients (or users) due to misuse caused by the ergonomic characteristics of the device and the intended user environment is reduced as far as possible.

Requirement 2: The devices shall achieve the performances specified by the manufacturer and suitable for their intended use.

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## 5.4 Issues from risk management

No unacceptable risks have been identified for this version of TagMole.

## 6 Claim

- Claims: *TagMole can be used to remove skin flaps and similar benign skin growths (such as small seborrheic keratoses on a stalk or small benign fibromas) in a safe and non-invasive manner.*

## 7 Clinical data – summary and evaluation

In order to substantiate thean's language made in chapter 6, a literature search has been carried out. Each search has selected the literature that is deemed independent and relates to these claims, i.e. that either substantiates or disputes the claim. Literature search protocols can be found in Chapter 9. Featured articles are listed in the reference list.

## 8 Analysis

### 8.1 What does the literature say?

*Claims: TagMole can be used to remove skin flaps and similar harmless skin growths in a safe and non-invasive manner.*

*Ref [1] shows that a consultant in dermatology at Karolinska Hospital (Jan Lapins) recommends the use of bear wire to take nestrt skin flaps. The principle behind TagMole Remove is precisely a thread that you tie around the base of the skin flap and thus make it self-destruct and fall off.*

*Ref (3) from the NHS (National Health Service in the UK) shows that you can remove skin flaps in several different ways, for example by applying apple cider vinegar, cutting with scissors, freezing or flossing (the latter is the mechanism of action behind TagMole Remove).*

*Ref (5) from the world-famous and comprehensive skin database DermNetNZ shows that ligation with thread for the purpose of strangling the skin flap from the blood supply is one of the recommended methods for treating skin flaps*

*Ref (6) shows that it is common for people to use bear wire to remove skin flaps and seem to be satisfied with the result.*

## 9 Literature search protocol

Literature search has been performed according to the following method.

1. Broad search, review the first 30 hits and identify relevant articles
2. Narrower search criteria based on relevant articles and questions, go through the first 20 hits and identify relevant articles

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The articles have been selected according to the following criteria:

1. The title of the article contains the keyword or nearby begrepp
2. The age of the article is a maximum of 10 years (articles that are older than can be selected if they are of particular interest for the analysis).
3. The content of the article shall make a meaningful contribution to the clinical evaluation by providing additional data or a new point of view in the analysis.

Search has been done in the following sources of information:

- Google - <http://www.google.se> or <http://google.com>
- Pubmed - <http://www.ncbi.nlm.nih.gov/pubmed>
- DermNetNZ - <https://dermnetnz.org/topics/skin-tag/>

The following search terms have been used:

*For google search:*

- *"skin flap" "remove" "at home"; "skin flap" "remove" "thread"; in English "skin tag" "removal"; "skin tag" "ligation"*

*For pubmed search:*

- *"skin tag" "removal"; "skin tag" "ligation"*

Apart from the search results obtained from the data sources listed above, reference lists identified in the literature have been used as an additional source of information.

### Referenslista

- [1] <https://www.netdoktor.se/hud-har/eksem-torr-hud/fraga-doktorn/konstiga-hudflikar/>
- [2] <https://prodelox.se>
- [3] <https://www.nhs.uk/conditions/skin-tags/>
- [4] <https://tagband.co.uk>
- [5] <https://dermnetnz.org/topics/skin-tag/>
- [6] <https://www.familjeliv.se/forum/thread/59291391-nagon-som-strypt-en-leverflackfodelsemarke>