

numnuts®



# final report

Project code: P.PSH.1008  
Prepared by: Robin Smith  
Senesino Ltd  
Date published: 27 May 2019

PUBLISHED BY  
Meat and Livestock Australia Limited  
Locked Bag 1961  
NORTH SYDNEY NSW 2059

## Numnuts Phase 4: Late Stage R&D - Numnuts Low Pain Marking

This is an MLA Donor Company funded project.

Meat & Livestock Australia acknowledges the matching funds provided by the Australian Government to support the research and development detailed in this publication.

This publication is published by Meat & Livestock Australia Limited ABN 39 081 678 364 (MLA). Care is taken to ensure the accuracy of the information contained in this publication. However MLA cannot accept responsibility for the accuracy or completeness of the information or opinions contained in the publication. You should make your own enquiries before making decisions concerning your interests. Reproduction in whole or in part of this publication is prohibited without prior written consent of MLA.

## Executive summary

### Why the work was done (what was the problem)

Castration and tail docking remain important husbandry procedures for sheep in Australia, but both result in distress to the animals through associated pain.

'Elastrator' constrictor rings, the most widely used methodology for castration and tail docking, cause notable and sustained pain and discomfort to young lambs. A substantial body of scientific evidence suggests that the methodology is ineffective in meeting the modern standards of animal welfare (Mellor and Stafford, 2000).

Thus far, attempts to administer local anaesthetic in a farm environment simultaneously with the application of constrictor rings (two actions), have, in practice, failed. While the administration of an anaesthetic is technically demonstrable under controlled conditions (Coetzee, 2012), it is generally considered too cumbersome to apply in practice.

Consumer pressure focusing on animal welfare is building, demonstrated by the increasing number of campaigns initiated by animated advocacy groups, which have the potential to influence broader consumer behaviour and buying patterns. For example, campaigns concerning eggs and the welfare of dairy cattle, chickens and pigs have led to changed codes of practice and legislation. As a result of these changing expectations, consumer behaviour is increasingly migrating towards products that have some form of explicit animal welfare promise labelling, even if this carries with it a pricing premium. It is possible that developments in government legislation may follow.

### How it was done

This project (Numnuts Phase 4) continued towards a practical solution to incorporate ringing simultaneously with the application of local anaesthetic. A series of increasingly refined working prototype devices were produced and trialled successfully on-farm in both Australia (CSIRO, Armidale, NSW) and the UK (MRI), and in-house on test rigs. Based on these prototypes, the production of injection moulds, via the supply of engineering drawings and specifications by 4c Design to our manufacturing partner, was undertaken. The goal was to make Numnuts viable for commercial release. This has involved building commercial relationships with partners in three key areas: -

- Hardware manufacture (injection moulding)
- Anaesthetic supply
- Anaesthetic Distribution

**What was achieved**

The aim of this project was to ready the Numnuts system for commercial production. Injection mould tools required to make the Ring Only device and the Pain Relief Cartridge & Injector were produced by our manufacturing partner. 'Alpha samples' of the Ring Only device and 'alpha units' of the Numnuts system were assembled and tested to meet performance standards. The drug and package labelling for NumOcaine was also finalised: the packaging, labelling and branding all meet the APVMA regulatory standards for veterinary pharmaceuticals.

**What industry benefit/s will arise from the work**

The outcome is a fully ergonomic device that is practical to use in a field environment which can be produced in high volume. Use of the Numnuts system will permit Australian farmers to anticipate changes in consumer behaviour and potential legislative pressures concerning animal welfare practices and meet changing market demands, as seen in the wool industry in response to mulesing.

## Table of contents

<b>1</b>	<b>Background .....</b>	<b>6</b>
1.1	Lamb Castration and Tail Docking – The Issue .....	6
1.1.1	Scientific Evidence .....	6
1.1.2	Market Potential.....	6
1.1.3	Present Practice .....	6
1.1.4	Practical Challenges .....	6
1.1.5	Local Anaesthetic Administration.....	6
1.1.6	Potential Interest .....	7
1.1.7	Potential Market.....	7
1.2	Previous work – Numnuts Phase 1 .....	7
1.2.1	Phase 1 (previous project) Results and Recommendations .....	7
1.3	Previous work – Numnuts Phase 2 .....	7
1.3.1	Design Development & Refinement .....	7
1.3.2	Efficacy in lambs .....	8
1.3.3	Phase 2 (previous project) Results and Recommendations .....	8
1.4	Previous work – Numnuts Phase 3 .....	8
1.4.1	Design Development & Refinement .....	8
1.4.2	Field Trials on lambs .....	8
1.4.3	Phase 3 (previous project) Results and Recommendations .....	8
<b>2</b>	<b>Project Objectives.....</b>	<b>9</b>
2.1	Design Development, Refinement and Production .....	9
2.2	Drug Labelling, Regulation and Packaging.....	9
<b>3</b>	<b>Methodology.....</b>	<b>10</b>
3.1	Design Development, Refinement and Production .....	10
3.1.1	Ring Only Applicator .....	10
3.1.2	Pain Relief Cartridge & Injector .....	11
3.2	Drug Labelling, Regulation and Packaging.....	11
<b>4</b>	<b>Results .....</b>	<b>13</b>
4.1	Design and Development during Numnuts Phase 4 (this project) .....	13
4.1.1	Ring Only Applicator .....	13
4.1.2	Pain Relief Cartridge & Injector .....	13
4.1.3	Drug Labelling, Regulation and Packaging.....	16

---

<b>5</b>	<b>Discussion .....</b>	<b>19</b>
5.1	Outcomes Against Project Objectives .....	19
5.1.1	Ring Applicator Tool.....	19
5.1.2	Pain Relief Cartridge & Injector .....	19
5.1.3	Validating the Manufacturing Process & Materials in the Field.....	19
<b>6</b>	<b>Conclusions/recommendations .....</b>	<b>21</b>
6.1	Conclusions .....	21
6.2	Further development steps .....	21
6.3	Potential Further R&D .....	21
<b>7</b>	<b>Key messages .....</b>	<b>23</b>
7.1	Value proposition and benefits to the Australian red meat industry .....	23
7.1.1	Farmers .....	23
7.1.2	Veterinary community.....	23
7.1.3	Agricultural supply distributors .....	23
7.1.4	Agricultural Contractors .....	23
7.1.5	Meat processing and packing industry.....	23
7.1.6	Supermarkets.....	23
7.1.7	Legislators .....	24
<b>8</b>	<b>Bibliography.....</b>	<b>25</b>
8.1	Consortium .....	25
8.2	Scientific.....	25
8.3	Government.....	25
8.4	Professional Organisations .....	25
8.5	Market .....	26
8.6	Consumer.....	26
<b>9</b>	<b>Appendix.....</b>	<b>27</b>
9.1	Milestone Design Reports, Documentation & Drawings .....	27

# 1 Background

## 1.1 Lamb Castration and Tail Docking – The Issue

### 1.1.1 Scientific Evidence

A large body of scientific evidence from the UK and Australia indicates that current methods of castration and tail docking of lambs inflict considerable pain (Molony et al, 1995; Molony V et al, 1997; Stafford et al, 2002; Stafford et al, 2005). The UK Farm Animal Welfare Council has stated that if a commercially viable and practical method for providing pain relief could be developed, it should be made mandatory (Farm Animal Welfare Council, 2008).

### 1.1.2 Market Potential

There is a potentially extensive market opportunity within the global agricultural industry for a new technology which can enable improved castration and tail docking of lambs through the reduction of pain during these procedures. This opportunity exists due to global demands from farmers, agricultural groups, veterinary scientists, animal welfare groups, emerging consumer groups and probable developments in government legislation.

### 1.1.3 Present Practice

A substantial body of authoritative scientific work demonstrates that the current technologies of lamb castration and tail docking are ineffective in meeting the modern standards of animal welfare (Mellor and Stafford, 2000). The most progressive mainstream technology for castration and tail docking is that of elastrator constrictor rings, which when applied, cause notable pain and discomfort to young lambs that is particularly acute 1-3 hours after application.

### 1.1.4 Practical Challenges

Market attempts to administer pain relieving drugs at the time of constrictor ring application have not been practical in field conditions until now. While the administration of a local anaesthetic is technically demonstrable under controlled conditions (Coetzee, 2011) it is generally thought to be too cumbersome to apply in practice.

### 1.1.5 Local Anaesthetic Administration

Research conducted by the Edinburgh Veterinary School in conjunction with the Moredun Research Institute overcame the practical problems associated with administering local anaesthetic using conventional hypodermic syringes and needles by introducing the anaesthetic with a needleless device. 4c Design undertook a short feasibility project funded by Genecom in the UK in 2010 to investigate the possibility of developing the needleless injector prototype commercially. It was discovered that the manufacturing costs of the needleless injector would be too expensive to be viable, thus alternative designs and business models were explored. The design, creation and testing of these alternative products is the focus of the present project.

### **1.1.6 Potential Interest**

A new device which castrates/tail docks effectively and can be applied quickly with minimal pain would receive rapid uptake from the first world farming communities. Further, the realisation of such a technology could make management of pain during castration and docking part of regional agricultural law.

### **1.1.7 Potential Market**

The international market for this technology is significant. Combining Australia, New Zealand and the EU represents a potential market for up to 225 million units per annum. Even a small portion of this market retains significant commercial potential.

## **1.2 Previous work – Numnuts Phase 1**

4c Design, Moredun Research Institute (MRI), CSIRO and the MLA began working to improve lamb castration and tail docking technologies in 2013 (4c Design, 2014). A new device was developed and tested to prove the concept that it could castrate/tail dock effectively and could be applied quickly, in addition to reducing animal discomfort. Two castration pilot studies were conducted by CSIRO with small groups of lambs during Phase 1. No systematic investigation of price acceptability to the end user was carried out although the design focus was to produce a minimal cost solution.

### **1.2.1 Phase 1 (previous project) Results and Recommendations**

The Numnuts device that delivered local anaesthetic resulted in significantly fewer pain related behaviours during the first hour after application in comparison to the controls who were castrated using conventional elastrator rings.

The results of Phase 1 generated the proof of concept evidence that the ‘numnuts approach’ should deliver the benefits sought. It was therefore recommended that the project proceed to Phase 2.

## **1.3 Previous work – Numnuts Phase 2**

Numnuts Phase 2 continued towards a practical solution to incorporate ringing simultaneously with the application of local anaesthetic. A series of increasingly refined working prototypes devices were produced around the existing castration ring and trialled successfully in both Australia (CSIRO, Armidale, NSW) and the UK (MRI). In Phase 2, trials were carried out to establish if the device is effective at removing tails and at delivering pain relief and to establishing the impact of anaesthetic volume and needle length on efficacy for both castration and tail docking.

### **1.3.1 Design Development & Refinement**

The devices produced for the Phase 1 trials were early prototypes prepared using rapid prototyping techniques only suitable for less than one hundred devices. To engineer a product that can be produced in very high volumes a large amount of design development and refinement must be carried out so that its function and the use of the materials can be made as efficient as possible. The applicator device was developed to further increase the efficiency when producing >2000 units.

### **1.3.2 Operational advantages and the effectiveness in lambs**

The intention of the project was to develop a tool capable of carrying out tail docking as well as castration, and therefore it was necessary to test the effectiveness of applying local anaesthetic using the prototype for tail docking.

### **1.3.3 Phase 2 (previous project) Results and Recommendations**

The results of Phase 2 demonstrated the benefits of Numnuts for both castration and tail docking. The Numnuts tool was shown to be highly effective in alleviating the pain responses of lambs to the procedure of tail docking and reduce pain related behaviours at the time of castration. Further animal trials indicated that a needle depth of 8-10 mm and a volume of 1.5 mL Lignocaine 2% were most favourable, and these have therefore been incorporated into our development.

The results of Phase 2 demonstrated the operational advantages of the effectiveness of the Numnuts device, and on the basis of this it was recommended that the project proceed to Phase 3.

## **1.4 Previous work – Numnuts Phase 3**

Numnuts Phase 3 continued to simplify and develop the Numnuts design. A series of increasingly refined working prototype devices were produced and trialled successfully in Australia. Investigations were carried out to find whether a single injection was adequate, as well as the optimum needle length and volume of local anaesthetic.

### **1.4.1 Design Development & Refinement**

The injector was integrated into the ring applicator, simplifying the consumable portion of the device. The injector mechanisms also had to be simplified with manufacturing considerations in mind.

The consumable portion consists of four main elements: the needle, fluid control (valves), the bottle and an enclosure or chassis that ties each of the other elements together. At this stage, the consumable was the least resolved element of the project and much of the design effort was focused there to bring it in line with the aspects of the device.

A proof of concept prototype was built, and the redesigned injection mechanism and consumable tested. Moving forward, the development could therefore be split into three main areas; ring applicator, consumable and injector.

### **1.4.2 Field Trials on lambs**

The full v12.1 prototype assembly was used for testing in Australia in March 2017. Reported in MLA 2017 Field study report [B.AWW.0256 Final Report](#)

### **1.4.3 Phase 3 (previous project) Results and Recommendations**

Phase 3 generated the V12 prototype that was used for field testing March 2017. Following the positive impact that came from this study, it was recommended that the project proceed to Phase 4.



## **2 Project Objectives – Phase 4 MDC Project**

### **2.1 Design Development, Refinement and Production**

The production of the applicator moulds was undertaken via the supply of engineering drawings and specifications to our manufacturing partner. The injection mould tools required to make the ring only device was produced successfully, and from these moulds ‘alpha samples’ have been made and completed ‘alpha Ring Applicator Tools’ were produced and tested to 100,000 cycles on a specially constructed test rig. From this foundation the Numnuts applicator including injector and pain relief cartridge were refined, designed for manufacture, tooling designed and constructed, and a first ‘alpha’ batch of Numnuts Ring Applicators complete produced.

### **2.2 Drug Labelling, Regulation and Packaging**

Numnuts® is adding a premium to a longstanding process of tail docking and castration with an elastrator band. Thus simple, good product packaging, labelling and branding, especially for the pain relief cartridge (which is a repeat purchase) improves product understanding and will help drive good adoption. Following extensive negotiations an Australian veterinary pharmaceutical manufacturer was selected. The authorisation for their branded lignocaine was extended to include sheep and approval obtained for the assembly in 100ml bottles complete with the patented Numnuts ‘quick change’ module, all from APVMA within the project timescale.

## 3 Methodology

### 3.1 Design Development, Refinement and Production

#### 3.1.1 Ring Only Applicator

The design engineers at 4c Design carried out design development using best practice engineering techniques; building CAD (Computer-aided design) models, generating rapid prototypes and working through iterative development steps of testing and validating the designs, first on the lab bench then in the workshop (on test rigs), concluding with engineering testing carried out in the field on commercial farms. All prototypes were produced in-house by 4c Design in Glasgow, Scotland.

Before committing to the mould tools of the ring-only applicator, 4c Design refined and built several Ring Only applicator prototypes. The prototypes underwent a commercial trial programme on five farms in New South Wales and western Victoria by both farm owners and with a number of marking contractors who would be classed as ‘professional users’, delivering ten times as many rings as a normal user would in a similar time frame.

In addition to field testing, these Ring Only prototypes have been tested on an accelerated test rig to understand their failure modes. The first round of testing with the test rig completed with over 160,000 cycles applied to the ring applicator in prototype materials. Metal parts were made of machined aluminium while plastic components were of either SLS (3D printed), FDM (also 3D printed) or machined acetal plastic. A further round of high cycle testing was undertaken with investment cast parts replacing the machined aluminium parts.

To move the design to TRL 8 4c Design’s engineers finalised 3D models and created 2D tolerance engineering drawings. This information was uploaded into 4c’s product data management vault to handle revision control and issued files were sent to the toolmaker for production of the inject mould tools. Hardened steel injection tools were then produced. 4c Design selected MCL Components Ltd., a precision moulding and assembly company in Malta, that is 100% renewably powered (solar cells) to carry out production.



The ring only applicator mould tools in manufacture

### 3.1.2 Pain Relief Cartridge & Injector

4c Design's engineers have developed a bespoke Pain Relief Cartridge (PRC) & Injector for the Numnuts® system. The PRC houses and delivers local anaesthetic (LA) through a series of fluid handling components that lock the bottle into the applicator system. The PRC is a key component within the Numnuts business model. For marketing purposes, the PRC name has been changed to Quick Change Cartridge (QCC) as this name expresses the user benefits better.

We first built a PRC & Injector prototype. This required CNC machining of the core elements from billets of the actual material to be used for injection moulding, allowing the production engineers to explore, understand and develop the small features within the mechanism. This PRC & Injector prototype design underwent engineering trials on two Australian farms in June 2018, delivering over 8000 Numnuts procedures.

We then integrated feedback from the manufacturer and supply chain stakeholders and undertook bench tests to prove the design of the PRC & Injector. The final design passed approvals: it is fit for purpose, with reliable broaching and fluid handling valves; and has achieved over 5,000 injections during testing. This concluded the production engineering design of the PRC & Injector through to the completion of the injection mould tools that will produce these parts in high volumes, economically.

To move the design to TRL 8, 4c's engineers finalised 3D models and created 2D tolerance engineering drawings. This information was uploaded into 4c Design's product data management vault to handle revision control and issued files were sent to the toolmaker for production of the inject mould tools.



Hardened steel injection tools were then produced, this image show the PRC & Injector parts as they are being sampled, checked and commissioned.

Over 800 PRCs have been moulded and assembled, and 500 have been tested to destruction as they are a 'single use' tamper proof part.

Early product assembly by MCL in Malta

### 3.2 Drug Labelling, Regulation and Packaging

The graphic design and product labelling and approvals process for NumOcaine™ is an important part of creating brand acceptance and loyalty towards our product. However, the labelling of drugs, is a closely regulated issue. Developing the brand and label for the bottle was challenging due to the tight regulations regarding the formatting and text that can be displayed on veterinary pharmaceuticals.

The design engineers at 4c Design engaged the services of Ruth Davis at Redcap Solutions Pty Ltd as our chosen regulatory affairs advisor. 4c Design's graphic designers then interfaced with Ruth and Mavlab Pty Ltd., our chosen contract pharmaceutical company, to develop drug and package labelling

that met the strict standards laid out by the APVMA The process was iterative, with draft designs, text and layouts going back and forth numerous times before a final label was approved.

Owing to the arduous nature of achieving approval for novel formulations, the strategy deployed by the Numnuts® team has been to use an off-the-shelf, approved local anaesthetic. Mavlab, a good manufacturing practice (GMP) supplier, have an approved lignocaine and we have had the name change of this product from 'Lignomav' to NumOcaine™ approved by the APVMA (see documents in appendix). We have also gained approval for the addition of sheep as a species onto the label claim.

The packaging was also designed with an awareness of our contractual obligations to acknowledge the support provided by MLA on all product packaging. This has been done on the multipack shipper, the item that has the highest sales. We also intend to do this on all packaging that protects the hardware. The APVMA guidelines on the information that can and can't be on bottle label and single carton shipper along with the limited space available means it is not possible to put the MLA credit on these two items. Reference to MLAs contribution is on the website [www.numnuts.store](http://www.numnuts.store) and key documentation such as the 'Vets Guide'.

### 3.3 Results Design and Development during Numnuts Phase 4 (this project)

#### 3.3.1 Ring Only Applicator

The family of mould tools required to make the ring only applicator was completed and ‘alpha samples’ made by MCL in Malta. The samples were sent to 4c Design and underwent reliability testing on the test rigs developed in-house.



The mould tools for the ring only applicator



The image opposite shows five ‘alpha Ring Applicator Tools’. These tools are with 4c Design in Glasgow, with further tools in various locations including with MCL (in Malta) who used them to create the assembly jigs required to be able to assemble these tools in the thousands.

#### 3.3.2 Pain Relief Cartridge & Injector

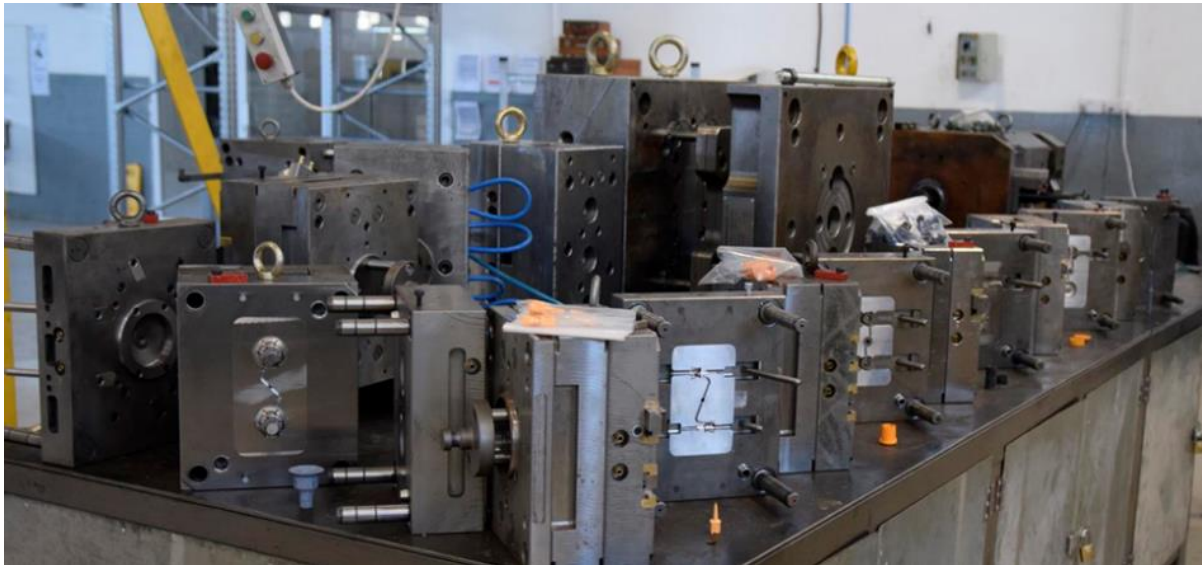
During Milestone 4 we built a PRC & Injector prototype. This required CNC machining of the core elements from billets of the actual material to be used for injection moulding, allowing the production engineers to explore, understand and develop the small features within the mechanism.

During Milestone 5 we integrated feedback from the manufacturer and supply chain stakeholders and undertook bench tests to prove the design of the PRC & Injector. The final design passed approvals: it is fit for purpose, with reliable broaching and fluid handling valves; and has achieved over 5,000 injections during testing.



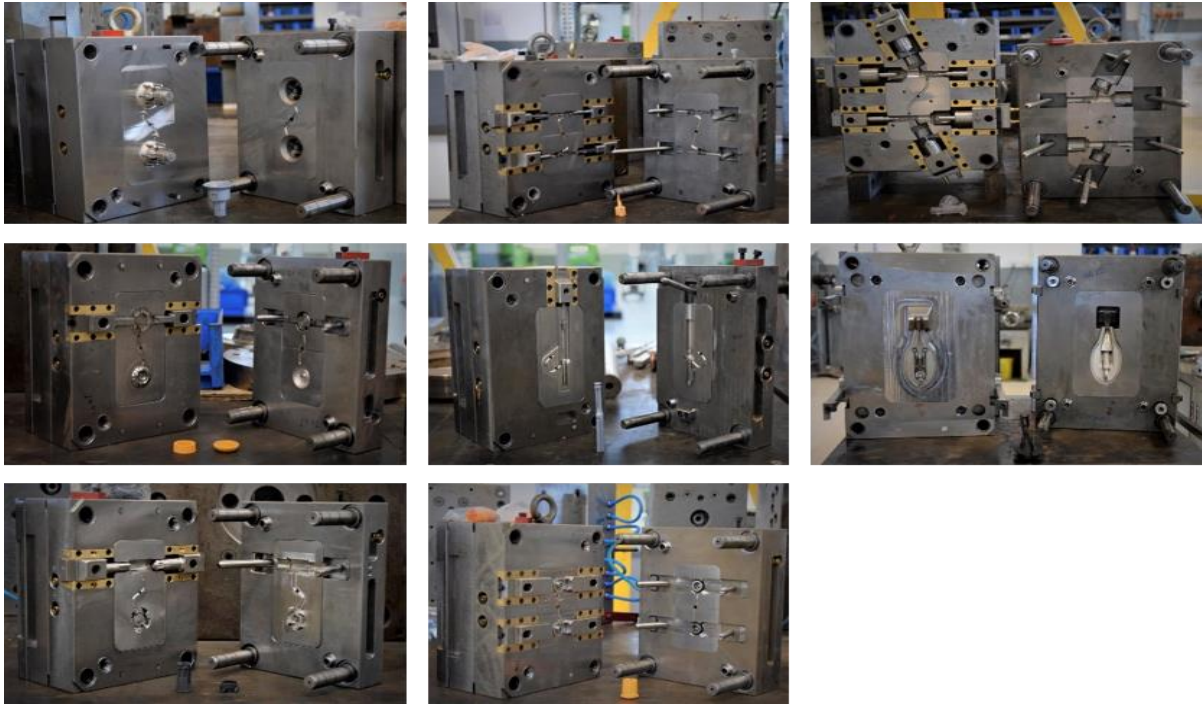
This concluded the production engineering design of the PRC & Injector through to the completion of the injection mould tools that will produce these parts in high volumes, economically.

The family of mould tools required to make the PRC & Injector is now complete and alpha samples have been made.



The fluid handling mould tools on a strong bench. The family weighs more than 1 ton in total.

4c Design engineers have been onsite at the manufacturing facility in Malta on multiple occasions during Q1-2 2019, commissioning these moulds. The PRCs have been undergoing reliability testing on a specialist test rigs produced to test this assembly. Our original plan estimated we may need 12 moulds; however we were able to 'double up' some parts for moulding efficiency. Hence with rationalisation, 8 moulds were produced.



The 8 PRC moulds, some with two pockets.

In the first sample production run 60 Numnuts devices were produced, and 50 of these have been allocated for demonstration purposes at pilot launch events and for issue to key stakeholders. 300 PRCs were allocated for demonstrating the novel QCC system.



Ten fully assembled 'alpha units'



Demo Numnuts units in preparation for launch at the AVA Conference 2019

### 3.3.3 Drug Labelling, Regulation and Packaging

The product packaging has been finalised thus: -

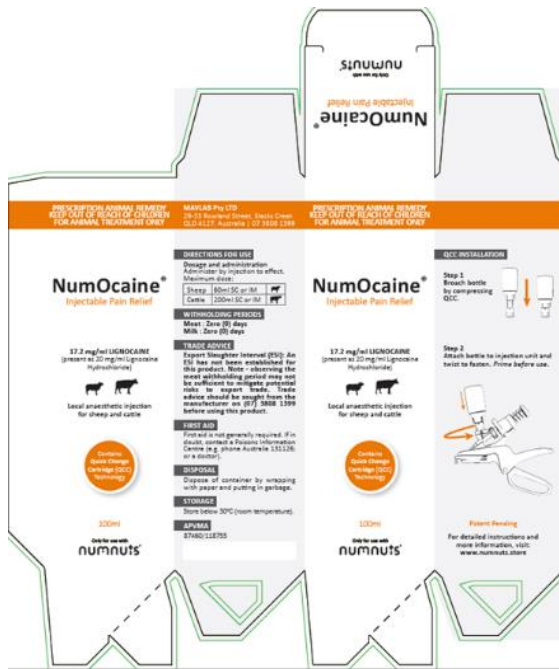


Multipack Shipper graphic design and labelling



The bottle label design & text





Single carton layout

The images below show mock ups of the packaging with labelling that Senesino has developed in collaboration with Mavlab’s packaging supplier: -



Mock-up of single carton packaging and NumOcaine bottle with label and Quick Change Cartridge, and a mock-up of the multipack shipper. Please note: the actual multipack packaging will be in brown card.



Mock-up of single carton packaging, NumOcaine bottle and Multipack shipper.

## 4 Discussion

### 4.1 Outcomes Against Project Objectives

#### 4.1.1 Ring Applicator Tool

Before committing to the final moulds, we refined and build several Ring Only Applicator prototypes which were modified to improve production logistics efficiency of manufacture and ease of maintenance by the farmer. This required the design of a new top cap plate and the production logistics of new parts. We integrated design for manufacture feedback that will improve the downstream production efficiency of the tool and increase its maintainability by the farmer. These prototypes underwent a field test program and were used on an accelerated test rig to understand their failure modes.

#### 4.1.2 Pain Relief Cartridge & Injector

The team have developed and patented a two-stage injector mechanism. The advantage of the dual stage system is that the needle must travel its full stroke (into the animal) before the local anaesthetic can be expelled, reducing the chance of the anaesthetic being deposited on the skin. In December 2016 this mechanism was tested in lambs as part of the v11 prototype, but due to its method of construction, the prototype was somewhat unreliable, and it was deemed too risky to carry this forward to the large market approval field study carried out in March/May 2017.

Our conclusion was that the geometry and design principles were probably fine; the problem was simply that we could not produce by the rapid prototype methodology to the level of precision and material stability that are possible with injection moulding. When this was communicated to our prospective injection moulding engineers, they were confident that the dual stage design can be made to work reliably and cost effectively, by injection moulding.

To test this, we made the core elements of the mechanism by CNC machining them from billets of the actual materials intended for injection moulding, but without some of the complex mount features that would be difficult and costly to machine as a one-off. This allowed the production engineers to explore, understand, and develop the tolerances and strength of the small features contained within the mechanism. These parts were costly to make, but not in the same order of magnitude as mould tools. Once the mechanism was de-bugged using these machined parts, they were trialled with simulative loads as required to create the correct anaesthetic injection pressure. These prototypes met the desired testing outcomes, and the design was then deemed ready to commit to injection mould tooling.

#### 4.1.3 Validating the Manufacturing Process & Materials in the Field

The prototypes developed up to Phase 4 have been made by 3D printing, a technology that has served its purpose well for trials within the research organisation context, but due to the fragility of the materials and the prohibitive cost of this method of manufacture, is not suitable for pilot scale market launch of the technology.

Thus, the engineering work carried out in this project focused on: -

1. Enabling the batch manufacture of pilot quantities of Numnuts devices
2. Ensuring the pilot devices used the final materials required for mass production and were structurally robust enough to be used on farm
3. Ensuring that the pilot devices were 'cost engineered' for economic downstream commercial production

To achieve the above outcomes, moulds were produced to inject the final engineering plastics under high pressure and temperature. From these moulds, 'alpha Ring Applicator Tools' and assembled PRC & Injector 'alpha units' were successfully completed.

## 5 Conclusions/recommendations

### 5.1 Conclusions

Numnuts has developed a unique approach to the simultaneous application of 'Elastrator' rings and local anaesthetic for tail docking and castration of lambs. The present project has taken the prototype device through a series of engineering development, manufacturing development and reliability testing stages, with the goal of making Numnuts viable for commercial release. The Numnuts device is now ready for introduction to the market and has been licensed to Senesino for delivery to the Australian market. Numnuts was officially launched to vets at the AVA Conference in Perth (5-10<sup>th</sup> May 2019) and is currently in use on several Australian farms under normal commercial farming conditions (May 2019).

### 5.2 Further development steps

The device will be officially launched to the Australian farmer and sheep producer community at the 2019 Merino Link Conference & Field Day (19-20<sup>th</sup> June 2019), with widespread distribution to the Australian market from August 2019 onwards.

Further on-farm research will be conducted to test Numnuts under commercial conditions: this research will build on the data collected in previous pen and field trials conducted in Scotland and Australia and will further assess pain response behaviours during lamb marking, in particular the impact at the 'mob' or flock level in terms of economic farm management. It is envisaged that these large-scale commercial field trials will include up to 40 progressive sheep farmers and producers, alongside vets and scientists from MLA, CSIRO and other 3rd party research organisations. The data collected so far have shown the advantages of Numnuts in reducing pain during marking, and these additional trials will enhance the robustness of our data and aim to expand the scope of information gathered, including data relating to other on-farm management techniques, such as a potential reduction in mismothering, and the overall economic benefits of adopting the Numnuts system on-farm. Moving forward, further on-farm trials focusing on robustness will also be undertaken.

Feedback from 'pioneer' users has been positive, and widespread uptake of Numnuts during lamb marking will ultimately enhance animal welfare outcomes.

Looking further ahead, our intentions are to then launch in the UK and New Zealand in 2020, contingent on regulatory approval.

### 5.3 Potential Further R&D

Additional to the planned large-scale farm trials, several other avenues of further R&D could be explored moving forward: -

- Animal trials to investigate if the volume of NumOcaine used alters efficacy of pain relief (i.e. if a lesser volume LA can achieve similar effects to the current recommended volume) – reductions in the amount of anaesthesia used would have an improved value for the red meat industry
- Pursue the development path for the use of Numnuts in cattle and other species and undertake the associated animal trials

- The use of Numnuts to deliver a 2-in-1 drug product, for example anaesthetic combined with an NSAID, or anaesthetic combined with vaccine

## 6 Key messages

### 6.1 Value proposition and benefits to the Australian red meat industry

Stakeholder issues which Numnuts will help to solve: -

#### 6.1.1 Farmers

Numnuts provides a viable solution for farmers to a long-identified animal welfare issue that is leading to consumer resistance to sheep products. It is a one-shot tool and consumables combining LA at critical position with castration/tail docking. Numnuts delivers: -

- Reduced animal discomfort
- Improved animal wellbeing
- No significant operational penalty with traditional marking techniques
- Can be applied quickly within bundle of activities at same time as marking
- Meets incoming consumer/supermarket QA labelling focussing upon improved animal welfare

#### 6.1.2 Veterinary community

Numnuts provides a viable on-farm answer to an animal welfare issue identified many years ago by the veterinary profession. Numnuts also offers the opportunity of increased business income for practicing vets. Numnuts therefore: -

- Fulfils veterinary recommendations
- Potential for additional income margin via increased volume of LA sold through prescription

#### 6.1.3 Agricultural supply distributors

Numnuts provides a fresh, new product line with a significant tail of consumables thus providing better margins at no significant extra cost. Benefits are: -

- New product range
- Increased margins c.f. current tool and rings

#### 6.1.4 Agricultural Contractors

The ergonomic design of the Numnuts tool will reduce operator fatigue over a full shift thereby providing improved operative satisfaction. As industry codes of practice and operational requirements develop Numnuts will provide compliance with new industry norms.

#### 6.1.5 Meat processing and packing industry

Numnuts therefore offers the industry a stake in delivering a higher value, higher margin product demand by consumers.

#### 6.1.6 Supermarkets

Numnuts offers supermarkets the opportunity to differentiate animal-friendly products further through quality-assured labelling: -

- Addresses positively the growth of welfare conscious consumer markets
- Supports the opportunity to raise prices for premium quality-assured products
- Products which are defensible to animal welfare activists claims

#### **6.1.7 Legislators**

The commercial availability of Numnuts as a practical, on-farm solution, permits legislators to respond to professional advice received over many years regarding animal welfare.



## 7 Bibliography

### 7.1 Consortium

4c Design (2014) FINAL REPORT - MLA - NumNuts.  
 CSIRO (2015) Analysis of Numnuts Trial Moredun April 2015.  
 CSIRO (2015) Interim Report: Dose-response for castration.  
 MRI (2014) June 2014 MRI - Tail Results Dose Response Behaviour Analyses.

### 7.2 Scientific

Molony V, Kent JE, and Robertson IS (1995) Assessment of acute and chronic pain after different methods of castration in calves. *Appl Anim Behav Sci* 46, 33-48  
 Stafford KS, Mellor DJ. The welfare significance of the castration of cattle: A review (2005) *New Zeal Vet J* 53, 271-278  
 Stafford KJ, Mellor DJ, Todd SE, Bruce RA, and Ward RN (2002) Effects of local anesthesia plus a nonsteroidal anti-inflammatory drug on the acute response of calves to five different methods of castration. *Res Vet Sci* 73, 61-70  
 Coetzee JF (2011) A review of pain assessment techniques and pharmacological approaches to pain relief after bovine castration: Practical implications for cattle production within the United States. *Appl Anim Behav Sci* 135, 192-213  
 Dinniss AS, Stafford KJ, Mellor DJ, Bruce RA and Ward RN (1999) The behaviour pattern of lambs after castration using a rubber ring and/ or castrating clamp with or without local anaesthetic, *New Zeal Vet J*, 47(6), 198-203  
 Melches S, Mellema SC, Doherr MG, Wechsler B, and Steiner A (2007) Castration of lambs: A welfare comparison of different castration techniques in lambs over 10 weeks of age. *Vet. J.* 173, 554–563  
 Molony V, Kent JE, Hosie BD, and Graham MJ (1997) Reduction in pain suffered by lambs at castration. *Vet. J.* 153(2), 205-213  
 Kent JE, Molony V, and Graham MJ (1998) Comparison of methods for the reduction of acute pain produced by rubber ring castration or tail docking of week-old lambs. *Vet. J.* 155, 39-51

### 7.3 Government

Public views on ethical retail; UK Government Department of Business Innovation and Skills, Research Series No. 177, June 2014

### 7.4 Professional Organisations

Sheep Standards and Guidelines – Tail Docking Discussion Paper, Prepared by the Sheep Standards and Guidelines Writing Group, January 2013  
 Sheep Standards and Guidelines – Castration Discussion Paper, Prepared by the Sheep Standards and Guidelines Writing Group, January 2013  
 Australian Veterinary Association, Members Directory and Policy Compendium 2006, Policies PRT 10 – Sheep and Goat Health and Welfare at:  
<http://avacms.eseries.hengsystems.com.au/AM/Template.cfm?Section=Policies>

FAWC Report on the Implications of Castration and Tail Docking for the Welfare of Lambs, June 2008, Farm Animal Welfare Council, London at: <https://www.gov.uk/government/publications/fawc-report-on-the-implications-of-castration-and-tail-docking-for-the-welfare-of-lambs>

## **7.5 Market**

Sheepmeat Council of Australia, Sheepmeat Industry Strategic Plan, (SISP) 2010-2015 (Revised August 2012)

Australian Meat Processor Corporation (AMPC), AMPC Strategic Plan 2013

Animal Health Australia, Proposed Australian Animal Welfare Standards and Guidelines – Sheep: Decision Regulation Impact Statement, Edition One, Version 1.0, 30 July 2014

Hobbs JE, Fearn A, Spriggs J (2002) Incentive structures for food safety and quality assurance: an international comparison. *Food Control* 13, 77–81

## **7.6 Consumer**

Mintel: The Ethical Food Consumer – UK, June 2015

Prickett RW, Norwood FB and Lusk JL (2010) Consumer preferences for farm animal welfare: results from a telephone survey of US households. *Animal Welfare* 19, 335-347

## **8 Appendix**

### **8.1 Milestone Design Reports, Documentation & Drawings**

Please see the attached appendices for design reports and additional documentation relating to the Numnuts Phase 4 Milestones:

- Milestone 2 - Ring Only applicator prototypes
- Milestone 3 - Test Rig - Ring Only applicator
- Milestone 4 - Injector Development TRL7
- Milestone 5 - Design development Summary
- Milestone 5 - v14 on farm test report
- Milestone 7 - Numocaine - approved E-Label - 12 Dec 18
- Milestone 7 - Numocaine - E-Label - 7 Jan 19 (amended by APVMA 25 Feb 19)
- Milestone 7 - Numocaine - Notice of Registration - 12 Dec 18