



UNIVERSITY OF
LIMERICK
OLLSCOIL LUIMNIGH

EP4005 New Enterprise Creation

Assignment 3

Business Plan



Group 31

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Concept Description: Breast feeding attachment for mothers of babies with Cleft lip

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Signed Plagiarism Declaration Form and Group Contribution Form



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Service

Love by latch is a service that aims to improve the breastfeeding experience for mothers of children born with a cleft lip. Breastfeeding a baby with a cleft lip is very taxing both physically and mentally. At love by latch we have created a solution to bridge this gap.

This entails a customised nipple attachment that is designed to fill the cleft gap when the baby is breastfeeding. This allows for a better latch and a smoother suction for the baby. This attachment includes a rotating base allowing for various breastfeeding positions. It has adjustable straps that can be easily altered to the mother's preference. The service can be provided through hospitals so that the custom attachment can be created soon after the baby is born. A scan will be taken of the baby's mouth which will be imported into SolidWorks software which will then be prepared for 3D Resin printing.

The purpose of this design for babies born with a cleft lip is to make breastfeeding possible in a way where skin-to-skin contact is not compromised and neither is the breastfeeding experience.

Love by latch is a unique product not found in the market. The only comparisons are feeding bottles with special tips to pour the milk directly into the baby's mouth. This involves formula or breast pumping milk poured into the bottle, which eliminates the option for skin-to-skin contact and adds an extra step to the process. Love by latch offers mothers a choice to breastfeed their children through providing hospitals with a solution that is non-invasive for children with this condition.



Future plans

After the successful creation and implementation of this service in a hospital, Love by latch plans to expand its service to other hospitals in Ireland and throughout Europe. With this expansion, Love by latch hope to expand its service by incorporating staff training and seminars to educate them about the product.

This product is a simple configuration in its mechanical element but is a massive advancement to the medical field in the area of cleft lip. Technology exists but isn't utilised in this context, although it is used in the field of medicine.

With the support of funding from organisations such as the cleft lip foundation and the smile clinic as well as support from hospital staff, taking this project to this next step would require the support of volunteers and staff. To further develop the next product: cleft pallet care, we would need research and product development, but the technology would still be the same (allegedly).

Market

To confirm the viability of this service, both primary and secondary research was conducted.

For primary market research we did semi structured interviews with a mother who has breastfed two babies with a cleft lip, a mother whose child was born with a cleft palate and a person with a cleft lip for closer understanding of the user needs and wants. Findings confirmed the problem at hand. It was clear that this mother was totally unsatisfied with her breastfeeding experience and longed for an intervention. The person with a cleft lip shared her story and her knowledge on the condition.

For secondary research, both national and international data sources were analysed. As reported by Lynch (2014) at Temple Street Children's University Ireland 1 in 700 babies are born with a cleft lip every year. Based on Central Statistics Office (CSO) (2024) birth statistics, this equates to approximately 77 babies born with a cleft lip and/or palate annually in Ireland. Similarly, using European (2023) birth statistics this corresponds to approximately 5,242 babies across Europe each year. Mothers who could start exclusive breastfeeding performed it only for a short period of time. Complications arose quickly for different reasons, leading them to decide to abandon breastfeeding altogether.

Love by latch aims to partner with hospitals to deliver this service, making hospitals the main client market. According to HSE (2025) there are 19 maternity hospitals in Ireland. Love by latch plans to reach these hospitals ensuring this service is available to all mothers. With approximately 77 babies requiring support every year in Ireland, the first year's production has been catered for this figure.

Customers

The primary customers are hospitals with maternity, neonatal, and paediatric services, cleft/craniofacial centres that provide multidisciplinary care and children's hospitals with specialised feeding or lactation teams. Hospitals will require a safe, clinically proven approach that will effectively support breastfeeding babies with a cleft lip. They require a new solution that allows skin-to-skin contact and safe feeding in the early postnatal period. The service must run smoothly and align with hospital protocols and safety standards. To further satisfy hospital needs, they will want easy to use technology that's reliable and highly functional.

The beneficiaries of this service include mothers of babies born with cleft lip and/or palate who need breastfeeding and feeding support. Mothers need an effective solution that makes breastfeeding an option. An option that is effective and comfortable. Mothers will need a product that's easy clean and maintain.

Unique selling point

Hospitals have allocated budgets and so must favour proven clinical solutions. Love by latch offers an innovative upgrade compared to existing feeding options. Hospitals already invest in existing feeding options as support is mandatory for babies born with a cleft lip and so investment in this service is likely. Purchases would be inevitably recurring with the steady birth of babies born with a cleft lip. Love by latch solves an ongoing problem as mothers continue to report feeding challenges showing strong user need.

Market Trends or Issues

Increase in infant feeding specialists

According to HSE there is almost fourfold increase in the number of dedicated infants feeding specialists within hospitals across Ireland. This significant expansion in the relevant workforce reflects both the importance and growing demand for infant feeding support that exists. Hospitals are prioritising and investing in this area. More specialists mean more clinical partners to refer and implement Love by latch.

Strong EU medical device market exists

As reported the EU medical device market is the second largest in the world. This creates huge exporting opportunities for love by latch. This market promotes innovation and widens the scope for funding opportunities. The existence of this market supports the long-term success of this business.

Ireland underscoring in breastfeeding supports.

Ireland has achieved a score of 56/100 when it comes to the support and protection of breastfeeding. This is a relatively average to low score for Ireland. It highlights the need for overall feeding support and an environment that will favour this service. Love by latch is entering an Irish market that is clearly underperforming in this area and needs new solutions.

Competitors

Competitor	Strengths	Weaknesses
Medela Hauberman Cleft Feeding Bottle	Has adjustable flow rate lines: there are markings on the nipple to select different flow rates (short, medium, long lines)	Cleaning and maintenance are more involved: multiple parts (nipple, valve membrane, disc, collar) Eliminates Skin-to-skin Contact
Pigeon Cleft Nursing Baby Feeding Bottle	It has two size options and includes a one-way valve, so milk is easier to inject into babies' mouth	Flow rate may be too fast or too slow: needs careful monitoring. Eliminates Skin-to-skin Contact
Mead Johnson Cleft Nurser	Squeezable bottle, easy to adapt flow of feeding	It does not have a one-way valve system built in. Milk flow is not consistent.

Medela Hauberman Cleft feeding Bottle



Pigeon cleft nursing baby Feeding bottle



Mead Johnson Cleft Nurser



Marketing

Promotional Method	How	When	Cost
MedTech Rising 2025 (Ireland) Medtech start-up conferences.	Through demos, clinical evidence, conference presentations, expert partnerships, and training sessions targeting hospital teams.	Once the product is developed enough to demonstrate safely, during late development and after launch.	For a startup-friendly medical or health-tech conference between €1,000 and €3,000
Partnerships with lactation consultants, midwives, SLTs, and paediatricians who influence hospital purchasing.	In-hospital training sessions to demonstrate ease of use and clinical benefits. Distribution of sample kits to hospital units to encourage trial and adoption.	During late development and continuing after launch, once the product is clinically tested.	Ongoing advisor engagement between €2,000 and €10,000 annually.
Digital marketing and educational content. SEO	Creating a website, creating clear online content, sharing demonstrations, targeting key communities on social media.	During late development and continue after product launch. Ongoing updates.	€6,800 between website development and promotional materials
Partnership with trusted cleft non-profits	Partnering with cleft charities to spread information directly to hospitals and families	Once product can be safely demonstrated and launched.	Depending on the level of engagement in the non-profit, donation of €500 - €2000
			Approx. €15,800

Place/channels of distribution

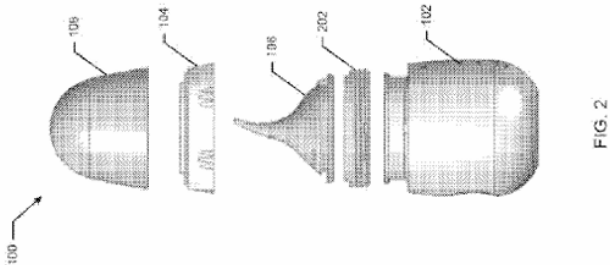
Love by latch will sell directly to hospitals, where the service will be offered and the product will be stored too. All materials can be stored in the hospital facility due to the relatively small size of the materials. Hospitals will take the scans of the infant's mouth which will be sent to the product developer to create the attachment. SolidWorks software will work in conjunction with the 3D Resin printer to develop the main part of the attachment. A liquid silicone injection molding machine will be used to create the rotating base and then the adjustable straps will be applied manually.

Real international business opportunity?

Over 140,000 babies are born with cleft lip/palate every year worldwide. More than 100,000 of these infants require specialised feeding support. It's clear that the struggle of breastfeeding a newborn with a cleft lip is not limited to one country, this is a problem worldwide. This ensures an inevitable demand for this service internationally and therefore the potential for major growth. There are over 80,000 hospitals worldwide that could offer this service, showing strong capacity and possibility for international expansion. No competitors such as Medela, Pigeon and Mead Johnson offer a product that allows safe and comfortable breastfeeding with skin-to-skin contact. Love by latch fills a global gap, as existing products only support bottle-feeding.

Intellectual property

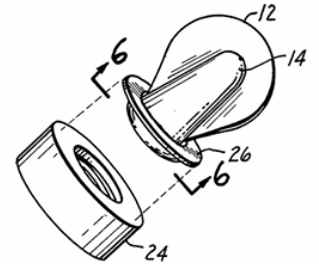
FEEDER FOR INFANTS WITH FEEDING DIFFICULTIES WO 2019/092626 A1



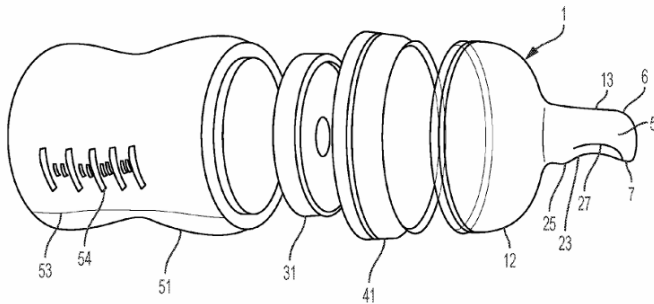
This 2019 patent describes a feeder that uses a bottle with a shaped nipple and side openings to control milk flow for infants with cleft conditions. Our product is not impacted because this invention is strictly a bottle-feeding system, while our solution supports direct breastfeeding, making it fundamentally different.

NURSING DEVICE FOR INFANT WITH CLEFT LIP OR CLEFT PALATE 4,856,663

This 1989 EU-published patent describes a duckbill-shaped shield with a nipple attached underneath that seals the cleft and prevents the nipple from collapsing, allowing a baby to suck from a bottle. Our product, Love by Latch, is not compromised by this patent because it's long expired and uses a completely different mechanism, without a rigid duckbill shield, and focuses on skin to skin, innovative breastfeeding support that makes it clearly distinct.



FEEDING NIPPLE SYSTEMS FOR CLEFT PALATE OR LIP US 2018 / 0110682 A1



Similarly, this 2018 patent describes a specialised bottle-feeding nipple designed for babies with cleft palate, featuring a harder palate section, a softer tongue section with a slit for milk flow, and optional parts to support tongue movement and control feeding speed. While it is a well-designed bottle system, it does not affect our product because our solution focuses on direct breastfeeding support, uses a completely different mechanism, and is not a bottle.

After thorough research concluded that our product, Love by Latch, is vastly different to other products or patents in the market hence corresponding intellectual property does not exist. Every patent that was found was focused on bottle feeding or attachment for said product, but dismisses the possibility of skin to skin contact between the mother and the baby. Going forward this product requires the correct legal patent, so that it is viable for production and can protect the business's exclusive right in order to pursue this endeavour.

Operating hours:

The business will operate in line with standard European business hours, which are Monday to Saturday from 9.00am to 6:00 p.m. Administration and production will be carried out within these hours. Staff training and client liaisons will be scheduled during hospital hours.

Seasonality:

Love by latch expects demand and production to remain relatively steady throughout the year. Promotional activity will increase during specific periods such as World Breastfeeding Week in August and National Cleft and Craniofacial Awareness and Prevention Month in July.

Facilities and resources:

The business will operate within the hospital. Within this facility will be an administrative space with a desktop computer, 3D Resin printing space, and an area for quality testing.

Technology:

3D Resin printer and solid works software on a computer to create the attachment. Liquid silicone injection molding machine.

Human Resources:

The operations team will include a quality assurance officer, a product designer, and a healthcare partnership manager.

Finance

Capital cost

Capital items (owned)	Value €	Capital items (required)	Value€
ICT	0	ICT	599
Resin 3D printer	0	Resin 3D printer	3,176.25
Liquid Silicone injection molding machine	0	Liquid Silicone injection molding machine	3,000
Office stationery	0	Office stationery	50
Office Furniture	0	Office Furniture	310.04
Label Printer	0	Label Printer	77.21
Hand tools	0	Hand tools	135.39
Website setup	0	Website setup	176.16
Sterile Packaging	0	Packaging	5.10
Total	0	Total	7,529.15

Deferred Capital costs	€
SolidWorks Software (year 2)	997
SolidWorks Software (year3)	1662.5
Total	2659.5

Variable costs	Unit cost (€)	Quantity per unit	Cost per unit (€)	Cost per annum (77 units) (€)
Medical grade resin	391.27 per L	.02 L	7.83	602.91
Soft silicone	48.87 per kg	.04 kg	1.95	150.15
Elastic straps	1.50 per m	2.5 m	3.75	288.75
Electricity	.30 per kWh	0.1 kWh (30min print)	0.03	2.31
Sterile packaging	5.10 per 200	1	0.03	2.31
Labour (Product designer)	22 per hr	1.5hrs	34	2618
Quality testing	16.35 per hr	0.5hr	8.25	635.25
Total			55.84	4299.68

Fixed costs

Fixed costs	€ per annum
Hospital facility fees	12048
Manager/admin	43,962
SolidWorks (year 2)	997
Network	369
Advertisement brochures	69.72
Accountancy	1200
Insurance	2000
Legal	900
Bank account fees	18
Drawings	0
Total	61563.72

Pricing

Total unit cost is €55.84. Total variable cost per annum amounts to €4299.68. With a markup of 36.6% to cover any overheads such as insurance, hospital facility fees, equipment maintenance or regulatory compliance. this will also ensure the business will break even. This would result in a final selling price of €76.30.

Sales

Month	1	2	3	4	5	6	
Sales €	228.48	304.60	380.75	456.90	456.90	533.05	
Month	7	8	9	10	11	12	Total
Sales €	533.05	533.05	609.20	609.20	609.20	609.20	5,864

Sales assumptions

Sales assumptions are based on the production capacity of 77 units in the first year. With a selling price of 76.30 sales are estimated total to €228.48 in month 1 assuming 3 units are sold. With increased advertisement and satisfied customers sales are predicted to increase steadily. Selling 4 units in month 2 and 5 units in month 3. By month 4 relationships with hospital staff and consultants will be more developed and sales are predicted to increase €456.90 and then €609.20 by month 8. Demand is expected to remain steady throughout final end of the year and into the following year due to the number of babies born with a cleft lip yearly.

Exports

Initially, no export sales are accounted for, but the potential for future growth is very promising. After, Love by Latch becomes more established in Ireland and builds a strong reputation with Irish client's expansion will be necessary to reach a wider market and increase revenue.

The product must be compliant with regulatory EU requirements allowing for more accessibility. CE marking would allow this service to be offered freely across Europe. Most European countries have similar birth rates and clinical needs proposing a similar demand for the service. Expansion may begin with targeting closer EU countries with larger populations such as France, Spain and Germany. Future growth will be key to the long-term success of Love by Latch.

Funding

Project Costs	€	Sources of Funding
ICT and website set up	775.16	Grants such as Research, Innovation and Development Fund (from 35% grant rate)
Equipment	6,176.25	Funding from organisations such as Operation Smile
Packaging and tools	140.49	Possible donations in partnership with organisations such as Cleft Lip and Palate Association Ireland
Furniture	310.04	Venture Capitalists such as Act Venture Capital

What are the 3 key priority steps in progressing the business?

1.	Establish hospital partnership and begin setting up operations. Meet and establish agreements with hospitals. Secure production space ensuring all is in line with hospital procedures and safety standards.
2.	Finalise quality testing and product safety. Complete the required safety testing of the attachment, confirm the material suitability and safety.
3.	Launch production and marketing. Begin the advertisement of the service through website setup and brochures. Complete set up of equipment and begin production.

Appendices

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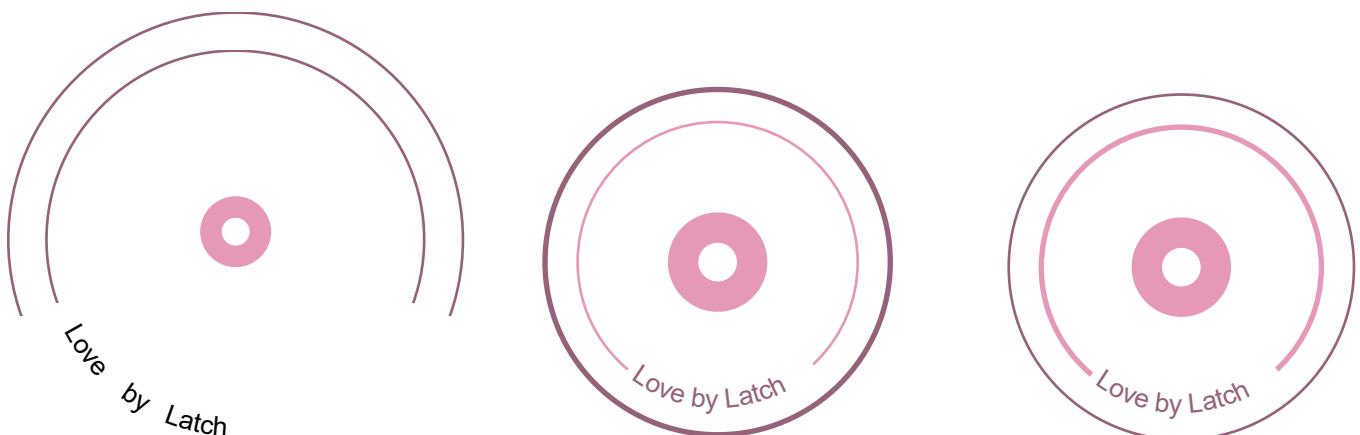
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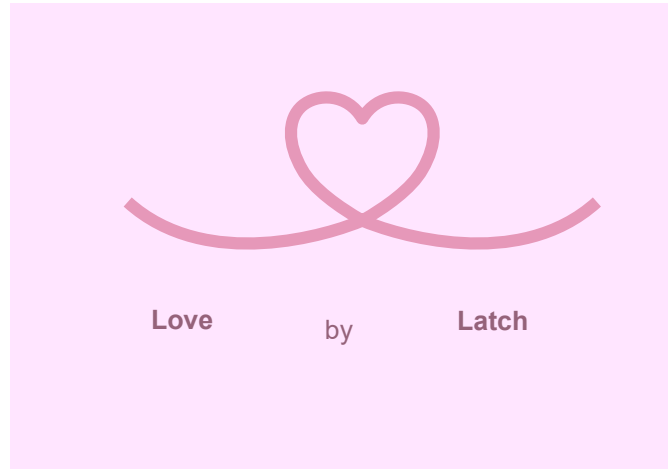
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Love by Latch



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