

*No. 1 choice
of hospitals
& mothers*

Calmita: Research-based hospital feeding solution
**Designed to support
neonatal oral feeding development**

“Calmita helps preterm infants to achieve earlier full suck feeds that lead to a shorter length of stay in the hospital. By allowing the infant’s natural feeding behaviour, Calmita increases breastfeeding rates at discharge; thus supporting and protecting breastfeeding.” Prof. Karen Simmer



Calmita Starter

Calmita

Allows similar mechanical action and tongue movement as at the breast.



Calmita Advanced

Breastfeeding is natural



Intrauterine life with placental support is completely different from that outside the womb and requires significant adaptations of both the mother and the neonate. Breastfeeding assists in the transition from intrauterine to extrauterine life by maintaining the infant's connection to its mother. The close body contact during breastfeeding regulates infant respiration, acid-base balance and temperature, helps conserve energy reserves¹ and soothes the infants.^{2, 3}

Suckling of the mammary gland to obtain milk for nourishment and immune protection is a behaviour unique to mammals. Suckling promotes numerous responses in both the mother and infant and these are thought to have evolved to ensure survival of the infant in harsh environmental conditions.⁴ As such, human milk is species-specific and has been carefully tailored over time to meet the nutritional requirements of the human infant.⁵

Human milk, therefore, is the natural food for infants. It is unequalled and is universally recognised as the optimal feeding choice for every infant. As a global public health recommendation of the World Health Organisation, infants should be exclusively breastfed for the first six months of life. This recommendation aims to ensure infants benefit from human milk nutritionally, immunologically and developmentally⁶, in addition to the physical and psychological benefits direct breastfeeding provides to the health of the mother.⁷

For preterm infants, adaptation to extrauterine life occurs far too early, creating a unique and complex set of challenges. Preterm infants are not simply "small" full-term infants. Preterm birth introduces tiny infants into an extrauterine world for which their tissues and organs are not yet developed to completion. These infants have substantially diminished stores of micro- and macronutrients that are ordinarily deposited during the last trimester *in utero* in preparation for the outside world. Nevertheless, they still need to make the same adaptation to life outside the uterus that full-term infants do, but they do so with significant challenges.

The natural act of breastfeeding is a complex physiological process.

The benefits of this process run along two lines:

- I What is fed to the infant – human milk
- I How the infant is fed – the mechanics of breastfeeding

Human milk

In the case of preterm infants, human milk is especially important for the development of the gastrointestinal tract, for neurological development and for conferring immunological protection. Compared to milk of term mothers, preterm milk has higher levels of energy, lipids, protein, nitrogen, fatty acids, some vitamins, and minerals. In addition, the levels of immune factors, including cells, immunoglobulins, and anti-inflammatory elements in preterm milk are higher than in term milk.⁸ The potent benefits of human milk are such that all preterm infants should receive it.⁹

However, preterm human milk still does not meet the micro- and macronutrient requirements of extremely premature infants due to their high nutrient demands, and the restrictions in the volumes these infants can safely ingest. Premature infants would normally be undergoing a period of rapid foetal growth and nutrient accumulation. They need to grow at a faster rate than full-term infants since they missed the intrauterine growth spurt of the last trimester.

Thus, the food for these infants needs to be higher in caloric value, but in smaller, more concentrated, volumes. Many facilities now strive to ensure that mother's own milk, fresh or frozen, should be the primary diet for these infants. For the infant born weighing less than 1.5 kg the American Academy of Pediatrics⁹ recommends that human milk should be fortified with protein, minerals, and vitamins to ensure optimal nutrient intake¹⁰, while deriving benefits from human milk.^{11, 12}

The mechanics of breastfeeding

Research using ultrasound imaging has shown that 'lactiferous sinuses' cannot be observed in the lactating breast.¹³ The low number and size of the ducts, the rapid branching under the areola and the absence of sinuses suggest that ducts transport breastmilk, rather than store it.¹³

Further ultrasound imaging research has demonstrated that, during breastfeeding, the tip of the nipple does not reach the junction of the hard and soft palate and that milk flow from the nipple into the infant's oral cavity coincides with both the lowering of the infant's tongue and with peak vacuum. Therefore, vacuum is likely to play a major role in milk removal from the breast.¹⁴

During a suck cycle¹⁴ (Figure 1), the vacuum begins at the baseline, that is the minimum vacuum required to maintain attachment without milk flow. As the tongue lowers, vacuum increases and milk begins to flow. Vacuum reaches a maximum when the tongue is at the lowest point. The tongue then rises and comes to rest again at the baseline – and the milk stops flowing.

This feeding technique used during breastfeeding is beneficial to the infant. The vacuum-controlled flow allows a safe and coordinated milk removal, commanded by the infant. The process of breastfeeding may also impact upon the normal orofacial development of the infant. It is suggested that this is because the mechanical action of breastfeeding leads to a well-shaped jaw.^{15, 16} In addition, breastfeeding is important for the proper development of the swallowing action of the tongue, proper alignment of the teeth, and the shaping of the hard palate.¹⁶⁻²⁰ The feeding technique used during breastfeeding has also been associated with lower risk of otitis media when compared to feeding with conventional teats.^{21, 22} Some research suggests that breastfeeding contributes to proper oral motor development, leading to clearer speech and improved tonal quality in later childhood.²³⁻²⁵

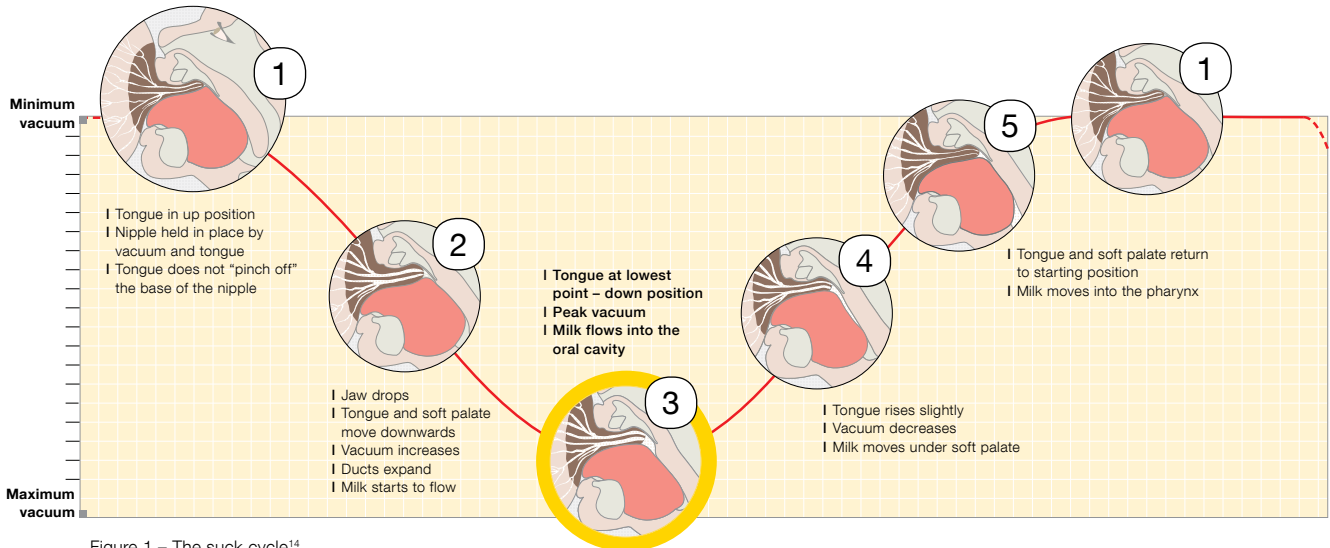
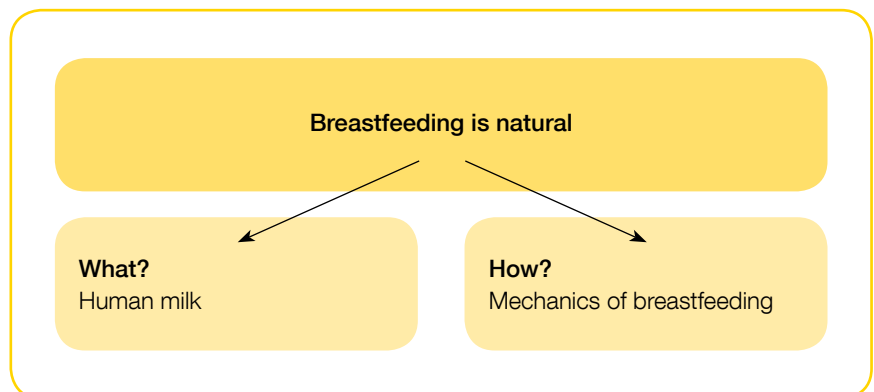


Figure 1 – The suck cycle¹⁴



In the preterm scenario, the challenge to the gold standard of breastfeeding is not only the infant who is born earlier than expected; the mother and her anatomy also need to adapt to this earlier milestone. Mothers need extra support to initiate and maintain their milk supply. For those health situations where infants cannot be fed at the breast, the choice of the best alternative to answer the question **what** to feed the infant – expressed milk from the infant’s own mother, human milk from a milk bank, or formula – depends on individual circumstances. In any case, the answer to the question **how** to feed the infant with this alternative should be feeding the newborn in such a way that the infant is in control of the milk flow, similarly as at the breast; thus avoiding the need to learn an unnatural feeding technique.

Challenges for breastfeeding



Both term and preterm populations can experience infant-related breastfeeding challenges. These are commonly associated with infants being too small, having a weak physical condition and/or other difficulties applying their natural feeding technique.

Breastfeeding in the neonatal intensive care unit (NICU) is uniquely challenging. Due to immaturity plus medical complications, it is difficult for a preterm infant to go directly to its mother's breast after birth and feed naturally. Safe and successful oral feeding requires not only appropriate sucking, swallowing, and breathing, but also the coordination of these three functions in order to prevent adverse episodes of apnoea, bradycardia, oxygen desaturation, and/or aspiration.²⁶ Well infants born after 34 weeks are usually able to coordinate sucking, swallowing, and breathing, and so establish breastfeeding. In less mature infants, oral feeding may not be safe or possible because of neurological immaturity or respiratory compromise.²⁷

Low muscle tone or hypotonia is a significant factor affecting the extremely low-birth-weight infant's ability to feed orally because it decreases endurance and intraoral vacuum needed to control milk flow, leading to increased "work of sucking".²⁸ Hypotonia may prevent infants from achieving an effective latch because they may be unable to open their mouths wide enough or maintain the latch during the sucking pause (baseline vacuum).²⁹

The challenges for breastfeeding do not only come from the infant's side. It is widely acknowledged that mothers of preterm infants, especially extremely low-birth-weight neonates, experience both physiological and emotional challenges that adversely affect breastfeeding rates for this population.³⁰⁻³² Due to maternal-infant separation, inadequate stimulation for milk ejection can take place.³³ Separation thus interferes with the establishment of breastfeeding and increases the likelihood of complications.³⁴

Moreover, once a mother does achieve a milk supply, the milk might require fortification to meet the energy demands of the infant.¹⁰ Therefore, for the feeding process the milk needs to be expressed from the breast, fortified, and then fed to the infant. This adds an extra layer of complexity when discussing mother-infant separation. There are also occasions in which, for medical reasons, mothers of term infants have difficulties breastfeeding. It is important that the principal goal when not feeding at the breast is the creation of an experience similar to breastfeeding, so that the infant can benefit from applying and developing a natural feeding behaviour.

Feeding the preterm infant



Currently several methods can be used to ensure adequate nutrition for premature infants. These depend on infant gestational age, birth weight, condition and health care institution. Depending on the hospital facility, the feeding regime may vary; it can start with parenteral nutrition, moving to tube feeding and finally advancing to oral feeds, with the goal of using a natural feeding technique in order to reach full breastfeeding.

Most premature infants born before 32 weeks of gestation are unable to coordinate sucking, swallowing, and breathing effectively in the beginning. These infants may be fed enterally, that is, through a tube that is inserted into the stomach either through the nose (nasogastric feeding) or the mouth (orogastric feeding).

Preterm infants studied while they were in a transition from being enterally-fed to being fully bottle-fed, exhibited approximately three times as many episodes of desaturation with oral feeding compared to enteral feeding.³⁵ One of the frequent observations noted in neonatal nurseries is the difficulty premature infants have in keeping up with the milk flow when introduced to oral feeding. It has therefore been suggested that a restricted pattern of milk flow be used when oral feeding is initiated in premature infants, especially for those born before 30 weeks of gestation.^{36, 37}

For infants fed orally, there is a greater physiological stability during breastfeeding compared to bottle feeding with a conventional teat. Breastfeeding requires the infant's natural feeding behaviour, therefore presenting fewer physiological challenges to growing preterm infants.^{38, 39} For example, oxygen saturation is higher during breastfeeding than during conventional bottle feeding.⁴⁰⁻⁴² The swallow-induced breath-holding reduces minute ventilation; more rapid milk flow results in more frequent swallowing and more significant ventilatory interruption.^{43, 44} A fast milk flow can lead to aspiration and choking, particularly in premature infants.³⁷ It goes without saying that stress and low oxygen saturation can negatively affect infant development.

The modification of traditional feeding protocols in the healthy premature infant may reduce the number of days to transit from enteral feeding to oral feeding, maintain growth and reduce the length of hospitalisation.⁴⁵ For instance, preterm infants receiving a non-nutritive sucking intervention have been found to have a significant decrease in transition time from tube to bottle feeds, a decrease in length of stay and a better bottle feeding performance.⁴⁶

To feed orally, an infant must be able to sustain awake behaviour, coordinate sucking, swallowing and breathing, and maintain cardiorespiratory stability for the time required to ingest a caloric volume adequate for growth.⁴⁷ Although a healthy term infant has these abilities, a neurologically premature infant (less than 32–34 weeks postmenstrual age) often does not. Therefore, even though breastfeeding is clearly best for infants, it may not always be possible. In such cases, a differentiated teat – the function of which is close to the mechanics of breastfeeding – would be very useful, particularly for preterm infants with bronchopulmonary dysplasia, who exhibit significant desaturation during and immediately after bottle feeding.⁴⁸

Given the high per diem costs of NICUs, it is apparent that the most effective means of reducing costs is to shorten length of stay.⁴⁹ Since hospital discharge is largely dependent on the ability to achieve full oral feeding,⁴⁹ a reduction in length of stay could be achieved with earlier full suck feeds. Clearly, research should attempt to find the most efficient method to assist in the transition to natural oral feeding, so that mother and infant can achieve earlier the goal for all infants: the complete breastfeeding experience.

Meeting the challenge

The need for a feeding device to help premature and weak infants to attain the goal of ever being breastfed was evident. There was a necessity for a feeding device that would combine the most successful strategies for these infants to improve oral feeding skills: vacuum build-up training⁴⁶ and self-paced feeding.³⁷ A feeding device based on the neonate's natural behaviour to remove milk; that means particularly the parallel tongue movement and the application of vacuum including the possibility to maintain a baseline vacuum to suck, swallow and breathe.

Improving oral feeding skills will not only accelerate attainment of independent oral feeding and thus shorten hospitalisation, but, importantly, reduce the risk of iatrogenic infection and other adverse events, lower the financial burden on families and society by reducing hospitalisation care and patient costs, allow earlier family reunification, and facilitate the development of more appropriate mother-infant interaction and bonding.⁵⁰ Potentially, it may also decrease long-term feeding difficulties/disorders.²⁶ In order to fully explore these areas, Medela partnered with King Edward Memorial Hospital and The University of Western Australia, in Perth, Australia to help develop and test Calmita, a new hospital feeding solution designed to meet the specific needs of the preterm infant.

The randomised controlled trial, supervised by neonatologist Professor Karen Simmer, saw the recruitment of 100 preterm infants aged between 25 and 34 weeks post-menstrual age and their randomisation into two groups, intervention and control (Groups A and B, Figure 2). The intervention group used a test feeding device (Calmita prototype developed by Medela) to address the specific needs of the developing preterm infant whilst the control group used a common, conventional preterm feeding device.

Importantly, the design of the study was pragmatic in nature; the only intervention between the two study groups was the use of the feeding device. No changes to hospital policy or practice were made. Indeed, the breast was always the first feeding option for these infants. When a bottle was required, the infants used the teat that they had been originally randomised to.

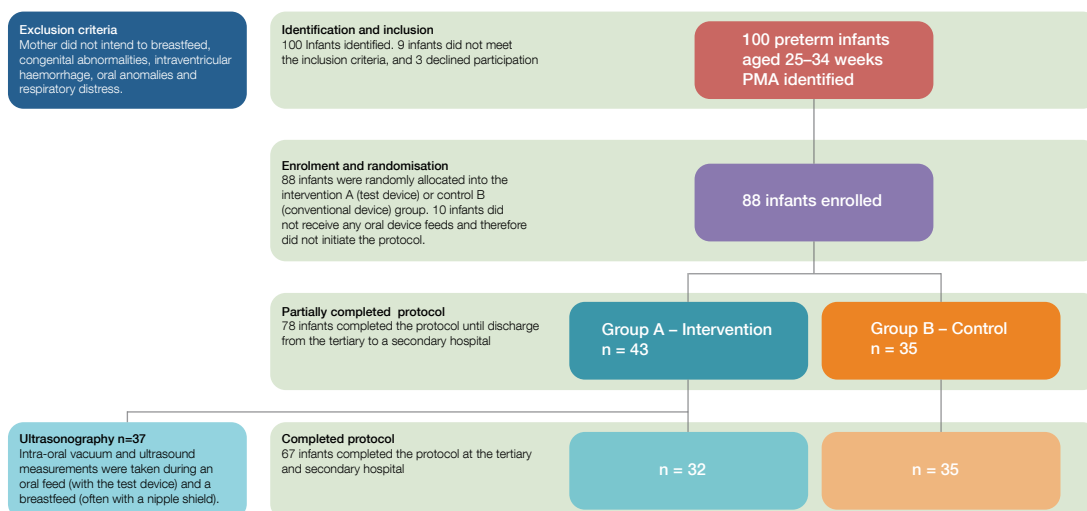


Figure 2 – Study protocol

Outcomes of the randomised controlled trial*

The test feeding device used can positively affect breastfeeding at discharge

Infants who were in the intervention group and who completed the protocol (Fig. 3) were more likely to be doing any breastfeeding at discharge when compared to infants in the control group ($p=0.025$).

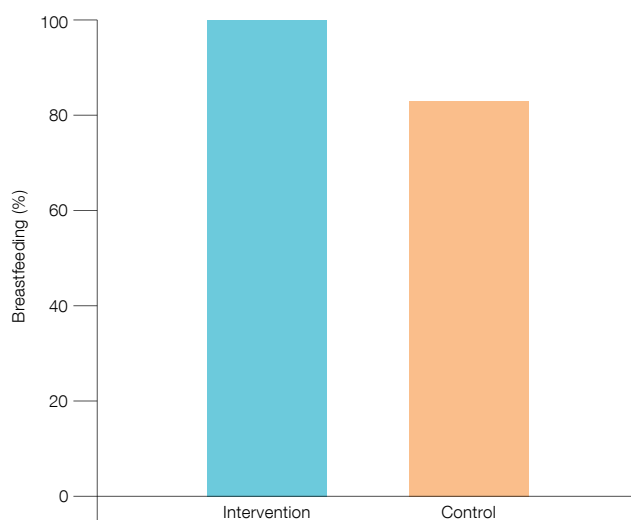


Figure 3 – Rate of any breastfeeding at discharge: More infants using the test device (100%) were performing any breastfeeding at discharge compared to infants in the control group (83%). $p=0.025$.

The reason for the better breastfeeding outcomes may be linked to the mechanical action and tongue movement used by the infants in the intervention group when feeding from the test device.⁵¹

Figure 4 shows that the pattern of tongue movement used during feeding was similar to when breastfeeding. The fact that the infants do not have to learn a different, unnatural feeding behaviour might be positively affecting breastfeeding at discharge.

*Simmer, K., Kok, C., Nancarrow, K., Hepworth, A.R. Improving transition time from tube to sucking feeds in breastfeeding preterm infants – Novel teat study. *Manuscript in preparation.*

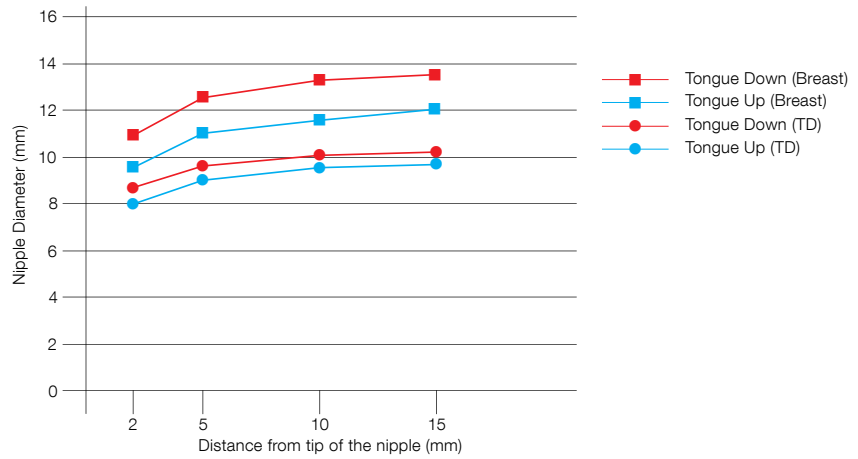


Figure 4 – Similar feeding behaviour (breast vs. test device): The parallel tongue movement observed during breastfeeding was also observed when feeding with the test device (TD). The graph shows the diameter of the nipple and the test device at points along the nipple/teat starting 2 mm back from the tip (0 mm) when the tongue is in the up and down positions.⁵¹

The test feeding device used can lead to a decrease in length of stay

There was a trend for infants feeding with the test device to reach full suck feeds 3 days younger ($p=0.14$). This apparent acceleration in reaching full suck feeds provides an explanation for the significant reduction in infant length of stay in the hospital, since attaining full oral feeds is one of the key hospital discharge criteria.

Infants who used the test device had a corrected gestational age at discharge home of an average 3.5 days younger than those infants in the control group ($p=0.005$). This led to a decreased length of stay of 3 days.

The evidence for Calmita



Calmita is a research-based hospital feeding solution that allows newborns to train and apply their individual and natural sucking behaviour. The integrated vacuum-controlled valve allows the infant to decide when to drink and when to pause. Milk flows when the infant reaches a certain vacuum. The neonate creates its own sucking rhythm, thereby efficiently removing just the right amount of milk at an individually suitable pace. This rhythm, as during breastfeeding, should enable maintaining good oxygen saturation levels and a constant heart rate due to the ability to suck, swallow, pause and breathe whilst feeding. Calmita's vacuum-controlled milk flow ensures stability and a relaxed, calm feeding – even if not at the breast.

Calmita's design, which allows similar mechanical action and tongue movement as at the breast, enables neonates using Calmita to achieve full suck feeds earlier. The transition time from enteral to full oral feeding is accelerated and thus the number of days with a feeding tube in place is reduced. Since reaching full suck feeds is a key discharge criterion in many NICUs, the use of Calmita significantly reduces length of stay in the hospital.

The technology behind Calmita lets neonates apply their natural feeding behaviour, since Calmita allows a comparable mechanical action and parallel tongue movement as at the breast.⁵¹ Infants using Calmita do not have to learn an unnatural feeding technique and in this manner, Calmita supports and protects breastfeeding. Indeed, there is an increased breastfeeding rate at discharge for infants using Calmita.

Since Calmita allows comparable attachment and similar feeding behaviour as at the breast,⁵¹ the resulting involvement of similar muscles should positively influence the infant's orofacial development, by supporting appropriate shaping of the jaw and proper, even spacing of the teeth, as breastfeeding does.¹⁶⁻²⁰ By using the same feeding behaviour as at the breast, the muscles in the soft palate, which help keep the Eustachian tubes open, ought to be exercised in a similar way as in breastfeeding. This could contribute to reducing the risk of otitis media with a discharge when the child is older.²¹

Calmita is available in two versions in which the threshold levels of the vacuum-controlled valve are different. These levels reflect the infant's oral feeding development and offer the possibility of training the feeding behaviour of the neonate in such a way that an incremental build-up of skills can be achieved. Depending on the capacity of the neonate to generate an intraoral vacuum, the suitable Calmita version should be used.



Calmita Starter with 35 ml Colostrum Container

Calmita Starter (white) has a low threshold level of the vacuum-controlled valve and is suitable for preterm infants in transition from enteral to oral feeding, late preterm infants and term infants with a weak suck. Once these infants can create the necessary intraoral vacuum, they can move on to the next step. Calmita Advanced (yellow) has a moderate threshold level of the vacuum-controlled valve. Late preterms and term infants unable to feed at the breast might begin using Calmita Advanced directly.



Calmita Advanced with 80 ml disposable bottle

The dimensions of Calmita (equal for both types) facilitate latching on for small premature infants. The nipple length of Calmita has been defined taking into account the dimensions of the foetal hard palate at 32 weeks.⁵² The shape of Calmita and the radius of its base ought to allow different latch on positions to meet the infant's orofacial development. Infants should attain their individual latch with the tip of the nipple positioned some millimetres away from the hard and soft palate junction, thus allowing the creation of an anterior seal – as during breastfeeding.¹⁴

Calmita is a novel hospital feeding solution that can be used to facilitate oral feeding of infants who demonstrate sucking difficulties, not only from prematurity, but also from poor endurance and/or an uncoordinated suck-swallow-breathe pattern. Whenever direct breastfeeding in the hospital is not possible, Calmita enables infants to apply their natural feeding behaviour, as on the breast, and thus supports and protects breastfeeding.

I Earlier full suck achievement

Calmita allows similar mechanical action and tongue movement as at the breast. This accelerates the transition time from enteral to oral feeding and reduces the number of days with a feeding tube in place.

I Earlier discharge

Using Calmita significantly reduces length of stay by allowing the infant to meet hospital discharge criteria earlier. In many NICUs successful and complete oral feeding is considered as one of the key discharge criteria.

I Natural feeding behaviour

Calmita's vacuum-controlled valve allows a natural feeding behaviour as the neonate itself controls the milk flow. Therefore, the infant is able to pause and breathe while no milk flows. This is expected to reduce oxygen desaturation, bradycardia and apnoea during feeding.

I Increased breastfeeding rate

Calmita increases the chance that the neonate can ever be breastfed. By allowing similar attachment and feeding behaviour as at the breast it supports and protects breastfeeding.

I Reliable, safe and user-friendly

The quality and simplicity of the Calmita design ensure consistency in flow, safe application, easy handling and leak-proof attachments within the Medela product range.

More information about Calmita is available on www.medela-calmita.com

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