

Supporting the feeding of infants who require professional care

# **SUPPORT BOOK**

## **For Infants with Cleft Lip and/or Palate**



# Aiming to provide a way to

## **“Get close to support babies who has feeding difficulties”**

Since its founding, Pigeon has worked with medical and care professionals to support babies who have difficulty nursing and their families.

The care of infants with cleft lip and/or palate who have difficulty nursing\* is one of the areas that Pigeon has long been working on with the mission of solving problems.

Through many years of activities supporting infants with cleft lip and/or palate, we have deepened our understanding of infants with cleft lip and/or palate and have become keenly aware of the importance of support that is timely and well tailored to the baby's condition.

This SUPPORT BOOK was created to provide basic information on cleft lip and/or palate to medical and health care professionals who support infants with cleft lip and/or palate and their families, and to deepen their understanding of nursing care.

We hope that this SUPPORT BOOK will be helpful to all healthcare professionals.

We hope that all babies will be able to establish nursing at their own pace and enjoy healthy growth.



# to support healthy growth for all babies

## How to use this SUPPORT BOOK for Infants with Cleft Lip and/or Palate

The content of this SUPPORT BOOK for infants with Cleft Lip and/or Palate is organized into 3 sections to impart the knowledge and information needed for nursing care.

### Overview of cleft lip and/or palate and treatment/support methods

P04-P09



Overview of cleft lip and/or palate  
Various impacts and treatment roadmap  
Characteristics of nursing and method of feeding support

### Products for infants with cleft lip and/or palate and how to utilize them

P10-P17



Product lineup and use scenarios  
Characteristics of Nursing Bottles for Cleft Lip and/or Palate and voices of users  
Features of Feeder with Long Silicone Nipple and voices of users  
Examples of use in medical practice, introduced through videos

### Pigeon support activities for cleft lip and/or palate

P18-P19



Nursing care initiatives  
Support activities in collaboration with global support groups

\*In this booklet, cleft lip, cleft palate, and cleft lip and palate are collectively referred to as "Cleft Lip and/or Palate (CLP)".

# What is Cleft Lip and/or Palate (CLP)\*?

Cleft lip and/or palate is a congenital orofacial disease in which the infant is born with a cleft in the lips, gingiva, or maxilla. It is the most common facial congenital anomaly, and it occurs in about 1 in 700 people worldwide <sup>1)</sup>. Although it is assumed to be caused by a combination of genetic factors and environmental factors, the details of its etiology are still unknown<sup>2)</sup>.

In addition to the cosmetic features, the disease is characterized by a variety of other features, including feeding difficulties in infancy, susceptibility to otitis media, a need for speech therapy in some cases, and the presence of malalignment or malocclusion.

It is a disease that requires long-term treatment, which in many cases includes multiple surgeries performed according to facial growth stage. However, thanks to the medical development of treatment technologies and care methods, patients can live a healthy life with appropriate surgery and multidisciplinary care.

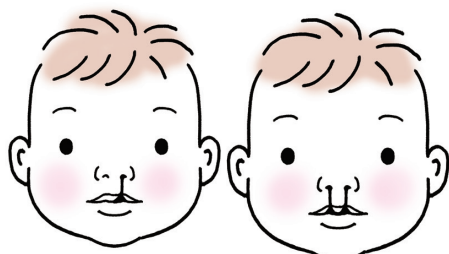
\*In this booklet, cleft lip, cleft palate, and cleft lip and palate are collectively referred to as "Cleft Lip and/or Palate (CLP)".



## Types of cleft lip and/or palate

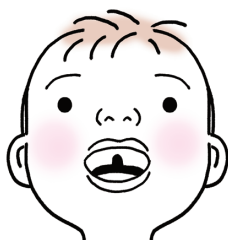
There are many types of cleft lip and/or palate, and numerous disease categories have been reported<sup>3)</sup>. Broadly speaking, based on the cleft site and whether it is cleft lip or cleft palate, it is classified into the following 3 categories.

### ● Cleft lip



Cleft lip refers to an anomaly where the cleft extends only from the lips to the gums. Cleft lip can be further subdivided into a type with cleft nares (complete type) and a type without cleft nares (incomplete type). When accompanied by a gingival cleft, it is classified as cheilognathoschisis or cleft jaw<sup>4)</sup>.

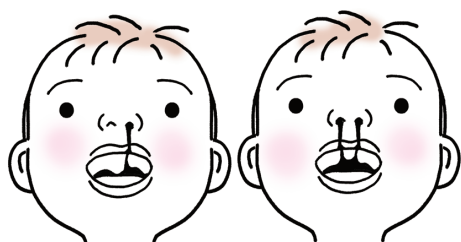
### ● Cleft palate



Cleft palate refers to cases in which there is a cleft in the palate, or roof of the mouth.

Depending on where the cleft is, it is further subdivided into submucous cleft palate, cleft hard palate, cleft soft palate, and cleft hard and soft palate<sup>4)</sup>.

### ● Cleft lip and palate



Cleft lip and palate refers to a case in which both cleft lip and cleft palate are present<sup>4)</sup>.

It has been reported that about 50% of patients have both cleft lip and palate, about 30% have cleft lip alone, and about 20% have cleft palate alone<sup>5)</sup>.

1) P Mossey, et al. Global registry and database on craniofacial anomalies, Report of a WHO Registry Meeting on Craniofacial Anomalies, Bauru, Brazil, 4-6 December 2001. (<https://apps.who.int/iris/bitstream/handle/10665/42840/9241591102.pdf?sequence=1&isAllowed=y>. Last accessed November 1, 2023)

2) Kawai T, Natsume N, ed. Epidemiological study of cleft lip and palate. Higashiyama Shobo, Kyoto, 1998. 7-34.

3) Kobayashi S. Cleft lip and palate, starting from fetal diagnosis — A multidisciplinary approach. Medical View Co., Ltd., Tokyo, 2010, 8-9.

4) The Japanese Cleft Palate Association Board of Directors, eds. Guide to Cleft Lip and Palate. Revised in March 2016, p. 6.

5) JO Boyce, ABM Clinical Protocol #17: Guidelines for Breastfeeding Infants with Cleft Lip, Cleft Palate, or Cleft Lip and Palate—Revised 2019; RA Lawrence, RM Lawrence. Breastfeeding A Guide for the Medical Profession. 9th Edition. ELSEVIER, Amsterdam, 2022.

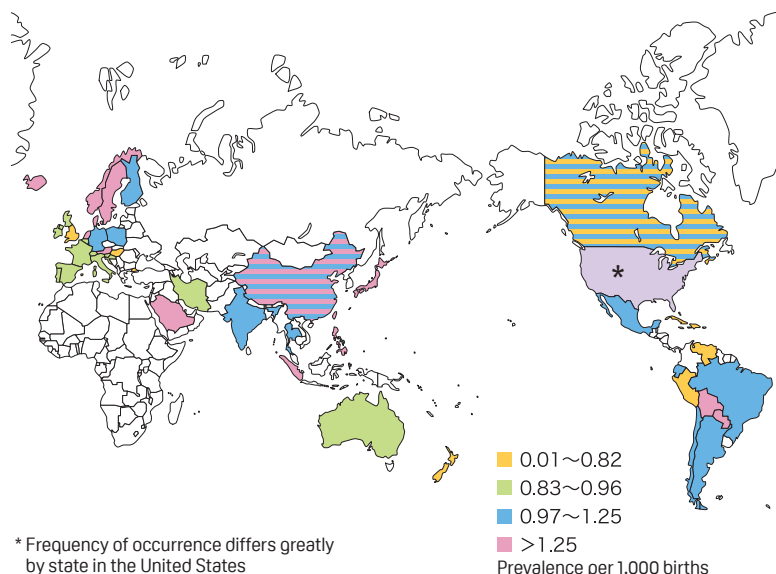


## Worldwide incidence of cleft lip and/or palate

The incidence of cleft lip and/or palate is known to vary greatly depending on geographical area, race, and environment, etc.<sup>5)</sup>.

Racial differences	<ul style="list-style-type: none"> <li>It is most common among Asians and Native Americans, occurring in approximately 1 in 500</li> <li>Among people of European descent, the incidence is 1 in 1,000</li> <li>The incidence is lowest among people of African descent, where it is 1 in 2,500</li> </ul>
Sex differences	<ul style="list-style-type: none"> <li>Cleft lip is more common in males than females at a 2:1 ratio</li> <li>Cleft palate is more common in females than males at a 2:1 ratio</li> </ul>
Left-right difference	<ul style="list-style-type: none"> <li>In patients with unilateral cleft lip, the left side is more commonly affected, at a ratio of 2:1</li> </ul>

### Regional differences in frequency of occurrence



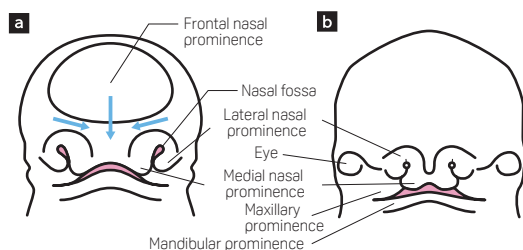
Kobayashi S. Cleft lip and palate, starting from fetal diagnosis — A multidisciplinary approach. Medical View Co., Ltd., Tokyo, 2010.  
Page 33, Figure 1a: Quotation of frequencies of occurrence for cleft lip and/or palate.  
b: Frequency of occurrence for cleft palate omitted.

## Development process of cleft lip and/or palate

The face is formed by the fusion of several prominences that grow toward each other from left and right during the fetal period.

However, if this fusion does not proceed smoothly for some reason, a fissure will remain at the site of the anomaly. A fissure in the lip will result in cleft lip, and a fissure in the oral cavity and nasal cavity will result in cleft palate<sup>6)</sup>.

### Fetal age of 6 to 7 weeks: maxillofacial development process<sup>7)</sup>



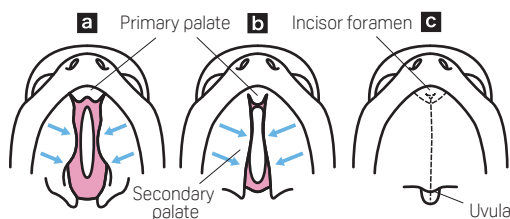
The frontal nasal prominence descends to form the nasal prominences (medial and lateral).

The medial nasal prominence forms the central portion (philtrum) of the lips, which is connected to the maxillary prominences growing toward the middle from the outer sides, forming the upper lip and maxillary alveolus.

**a** : Image of the face at about 6 weeks of gestation

**b** : Image of the face at about 7 weeks of gestation

### Fetal age of 6 to 10 weeks: maxillofacial development process<sup>7)</sup>



A primary palate is formed in the front of the oral cavity.

The palatal processes grow toward one another from left and right and fuse with the nasal septum to form the secondary palate.

The parts of the secondary palate fuse at the median, and the secondary palate also fuses with the primary palate. The junction of the 3 parts then closes, leaving the incisor foramen, and the palate is complete.

**a** : Image of the palate at about 6.5 weeks of gestation

**b** : Image of the palate at about 7.5 weeks of gestation

**c** : Image of the palate at about 10 weeks of gestation

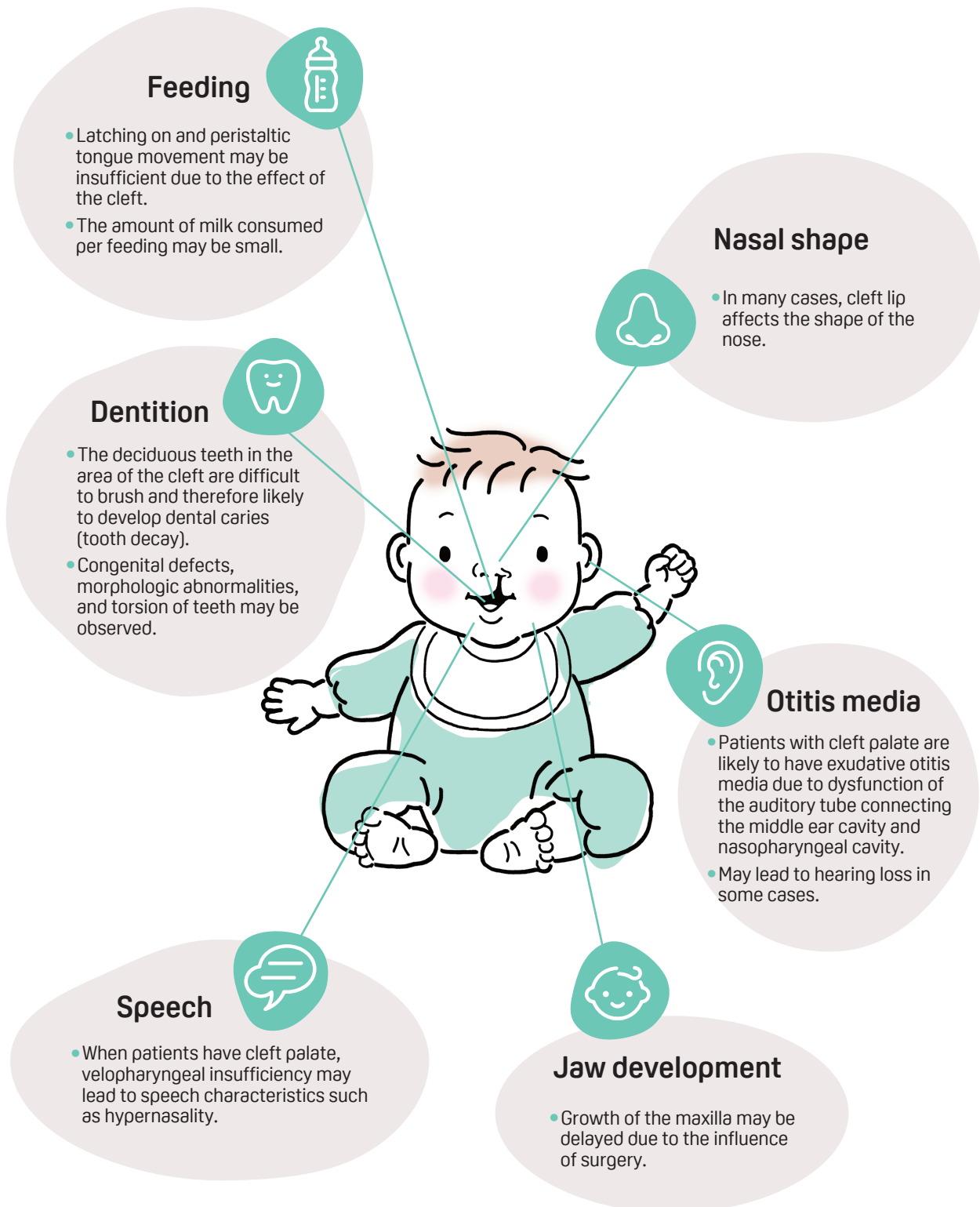
5) JO Boyce, ABM Clinical Protocol #17: Guidelines for Breastfeeding Infants with Cleft Lip, Cleft Palate, or Cleft Lip and Palate—Revised 2019; RA Lawrence, RM Lawrence. Breastfeeding A Guide for the Medical Profession. 9th Edition. ELSEVIER, Amsterdam, 2022.

6) Ohkubo F, comp. Treatment and Care for Children with Cleft Lip and/or Palate. MEDICUS SHUPPAN, Publishers Co., Ltd., Osaka, 2014, p. 9

7) Prepared based on Japan Society for Pediatric ORL, eds. Pediatric Otolaryngology 2nd Edition, Kanehara & Co., Ltd., Tokyo, 2017, pp. 204-205

## Various impacts

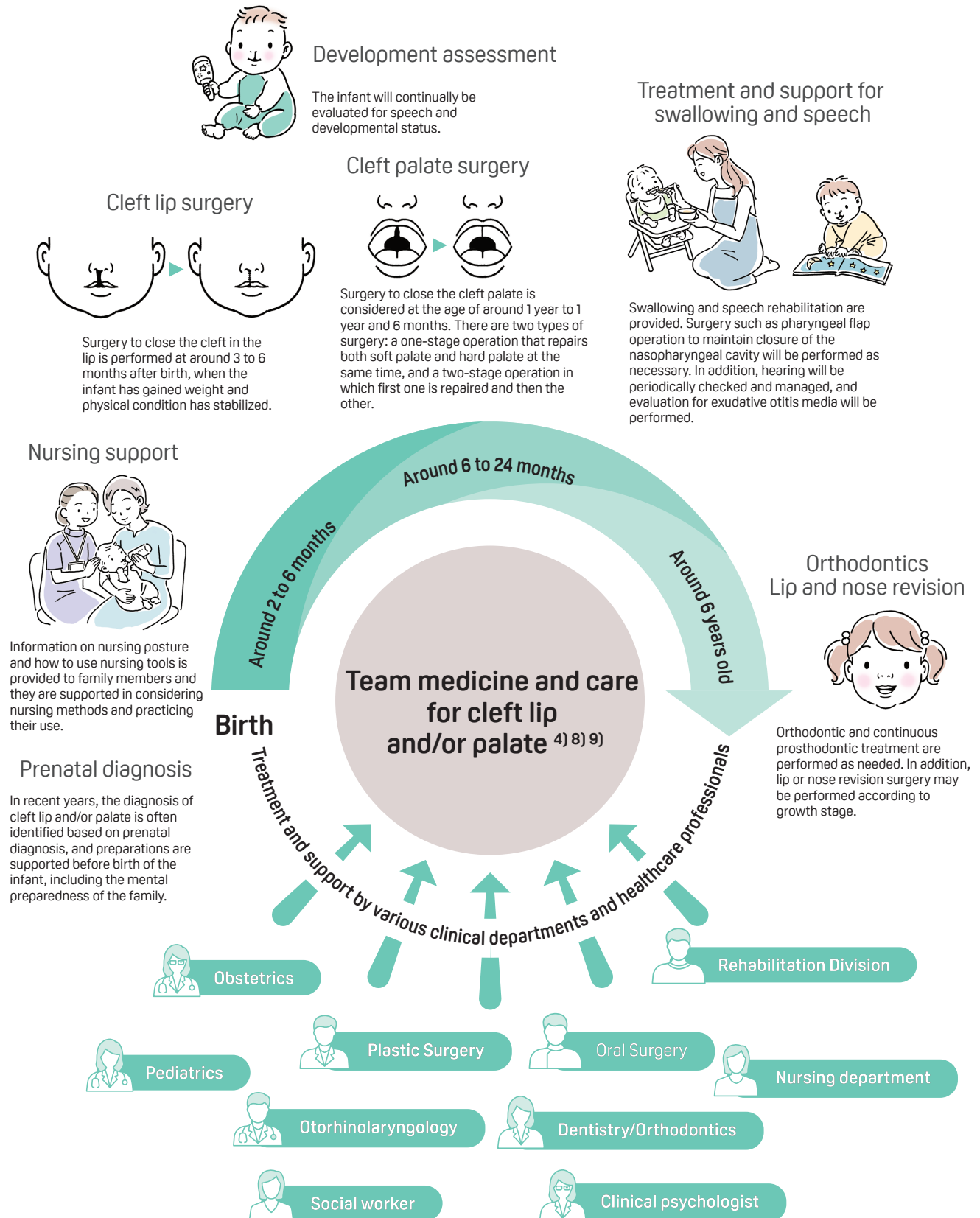
In addition to the morphological characteristics of cleft lip and palate, various other impacts occur as the body grows. Cleft lip and/or palate must be considered on a case-by-case basis because the patient's condition and the treatment method, etc. will determine what sort of impacts occur and when. However, it is important to understand the various symptoms so as to support growth from a long-term perspective.



3) Kobayashi S. Cleft lip and palate, starting from fetal diagnosis — A multidisciplinary approach. Medical View Co., Ltd., Tokyo, 2010.  
4) The Japanese Cleft Palate Association Board of Directors, eds. Guide to Cleft Lip and Palate. Revised in March 2016.  
6) Ohkubo F, ed. Treatment and Care for Children with Cleft Lip and/or Palate. MEDICUS SHUPPAN, Publishers Co., Ltd., Osaka, 2014.

# Treatment roadmap

Team-based medical care is provided with the participation of various specialists in many departments, principal among which are plastic surgery and oral surgery. As the infant grows, long-term treatment will become necessary. The contents and timing of treatment differ depending on the symptoms and the institution.



4) The Japanese Cleft Palate Association Board of Directors, eds. Guide to Cleft Lip and Palate. Revised in March 2016.

8) Tsuchiya S, et al. Neurodevelopmental trajectories in children with cleft lip and palate: A longitudinal study based on the Japan Environment and Children's Study. Eur J Oral Sci. 2022.; 130(2): e12857.

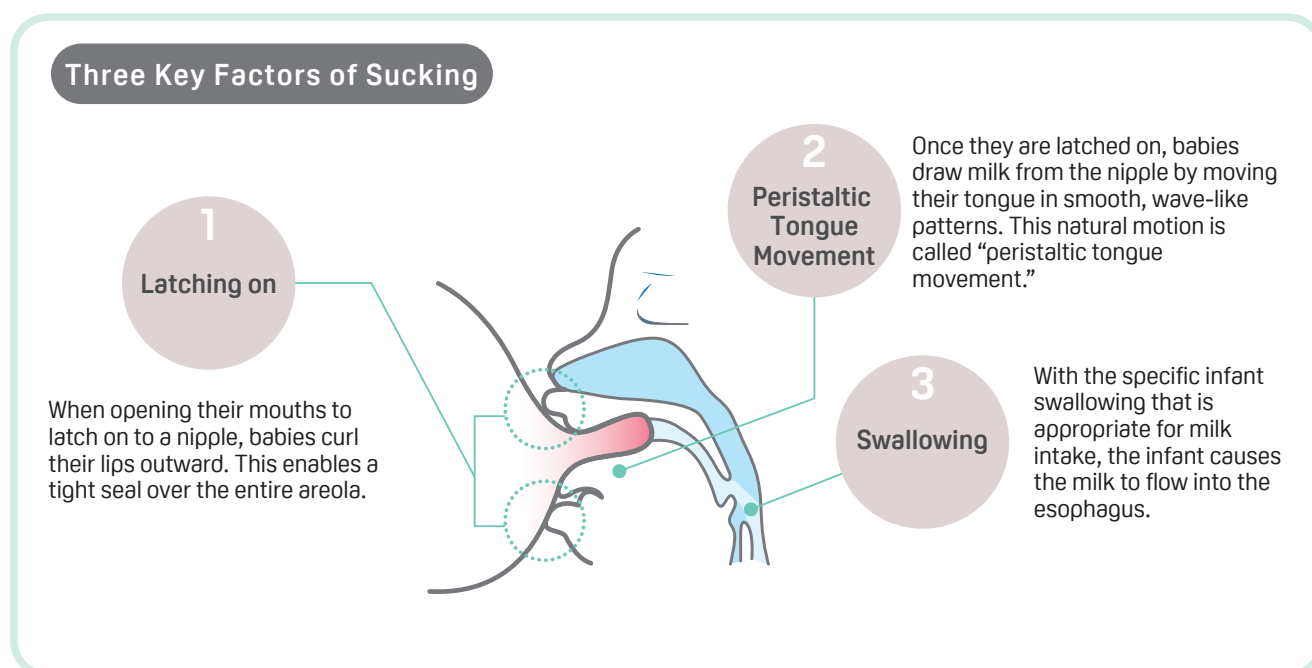
9) NHS Homepage. Treatments for left lip and palate (<http://www.nhs.uk/conditions/cleft-lip-and-palate/> Last accessed February 13, 2023)

## Characteristics of feeding

Pigeon refers to the important factors of nursing movement as the "Three Key Factors of Sucking". Here we investigate the causes of feeding difficulties in infants with cleft lip and/or palate in light of these 3 key factors.

In infants with cleft lip and/or palate, the tongue movement is normal, but the cleft makes it easier for air to enter the oral cavity. In particular, infants with cleft palate often have difficulty in forming the negative pressure that is needed to take milk into their mouth. This may cause them to swallow more air than usual, and because feeding takes a long time, the infant may become tired before feeding is complete <sup>5)</sup>.

Therefore, during breastfeeding, it is necessary to devise ways to make it easier and safer for the infant to drink.



	Ordinary feeding	Feeding with a cleft lip and/or palate
<b>1 Latching on</b>	<ul style="list-style-type: none"> <li>Lips in close contact with the nipple and areola to prevent leakage of milk and swallowing of air.</li> <li>The tip of the tongue is positioned above the lower lip and mandibular gingiva.</li> </ul>	<ul style="list-style-type: none"> <li>Because the cleft makes it difficult to latch on, milk tends to leak from the lips and air tends to be swallowed. <small>*Varies depending on the condition of the cleft.</small></li> <li>There is usually no problem with the position of the tongue.</li> </ul>
<b>2 Peristaltic Tongue Movement</b>	<ul style="list-style-type: none"> <li>Sucking pressure (negative pressure) is formed in the oral cavity by tongue movement.</li> </ul>	<ul style="list-style-type: none"> <li>Ordinarily, tongue movement is normal, but the presence of a cleft in the palate makes it difficult to form negative pressure.</li> </ul>
<b>3 Swallowing</b>	<ul style="list-style-type: none"> <li>If the infant can latch on to the nipple and areola properly, no excess air is swallowed.</li> </ul>	<ul style="list-style-type: none"> <li>Air can easily enter through the cleft, and the infant tends to swallow air.</li> </ul>





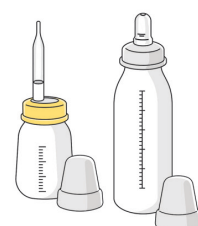

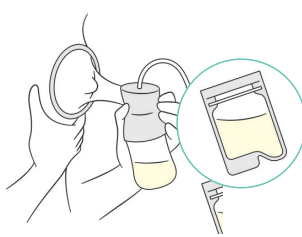

5) JO Boyce, ABM Clinical Protocol #17: Guidelines for Breastfeeding Infants with Cleft Lip, Cleft Palate, or Cleft Lip and Palate—Revised 2019; RA Lawrence, RM Lawrence. Breastfeeding A Guide for the Medical Profession. 9th Edition. ELSEVIER, Amsterdam, 2022.



# Feeding support method

Feeding difficulties in infants with cleft lip and/or palate vary depending on symptoms, the patient's condition, and treatment status, and it is important to consider the appropriate feeding methods for individual infants. If direct breastfeeding is possible, first improve the breastfeeding posture and the position at which the nipple is taken into the mouth. If that is difficult, consider a feeding device that is suitable for the infant's condition.




This booklet will introduce ways of dealing with various conditions in direct breastfeeding and feeding with bottles.

	Cleft lip	Cleft palate	Cleft lip and palate
Direct breast-feeding	<ul style="list-style-type: none"><li>• Hold so that the cleft faces the upper part of the breast.</li><li>• Keep supporting the breast so that the infant can latch on to the breast.</li></ul>  <ul style="list-style-type: none"><li>• Close the cleft with fingers. Support the cheeks to reduce the width of the cleft, enhancing closure. Taping can also be effective.</li></ul> 	<ul style="list-style-type: none"><li>• A semi-upright position is preferred to prevent backflow of milk into the nasal cavity and auditory tube.</li><li>• When the breasts are directed toward the part of the palate where the fissure is smaller, compression becomes easier, and the nipple is prevented from being wedged into the cleft.</li><li>• Since cleft palate patients often have difficulty forming negative pressure in the oral cavity, milk should be squeezed into the infant's mouth.</li><li>• Using a palatal plate such as a Hotz plate to cover the cleft palate is also effective.</li></ul>  	
Bottle feeding	<ul style="list-style-type: none"><li>• Use of a special nipple that makes it possible to extract milk from the nursing bottle without negative pressure is also effective.<ul style="list-style-type: none"><li>* When the infant is at an angle of 45 degrees or more, milk flow into the nasal cavity can be prevented.</li><li>* Take care not to insert the tip of the nipple into the cleft.</li></ul></li><li>• A soft container that adjusts milk flow according to infant's sucking rhythm is also effective.</li></ul>	 	
Common items	<ul style="list-style-type: none"><li>• Because air can easily be swallowed during feeding, it is important to give the infant several breaks and burp the infant during feeding, regardless of the form of feeding (direct breastfeeding or bottle feeding).</li><li>• Even if direct breastfeeding is difficult, the infant can continue to be nurtured on mother's milk collected in a bottle with a breast pump.</li></ul>	 	

\*In this booklet, breast milk and infant formula are collectively referred to as "milk".

# Product lineup and use scenarios

Pigeon provides nursing bottles for infants with cleft lips and/or palate that can be used depending on the stage of treatment and the patient's condition.

	Product Features	Use Scenarios
 <p><b>Nursing Bottles for Cleft Lip and/or Palate</b></p>	Designed to prevent the nipple from wedging deep into the cleft, and to enable feeding even with weak sucking.	<b>Can be used starting immediately after birth</b> <ul style="list-style-type: none"> <li>• Infants who are difficult to breastfeed directly or to feed with an ordinary bottle</li> <li>• Infants who have no problem swallowing but have weak peristaltic tongue movement and cannot continue sucking for long</li> </ul> <p>etc.</p>
 <p><b>Feeder with Long Silicone Nipple</b></p>	The product is designed for infants who cannot open their mouth wide. It makes it possible to feed at the pace that the infant can drink.	<b>Before and after surgery</b> <ul style="list-style-type: none"> <li>• Infants who are difficult to breastfeed directly or to feed with an ordinary bottle</li> <li>• Infants who have trouble opening their mouth, have weak peristaltic tongue movement, and cannot continue sucking for long</li> </ul> <p>etc.</p> <p>* Watch out for aspiration, and use only if there is no problem with swallowing. * It is used not only for cleft lip and/or palate, but also for support in infants who have difficulty feeding for reasons such as micrognathia, epidermolysis bullosa, macroglossia, or autism.</p>
 <p><b>Nursing bottles for general use (SofTouch/Slim-Neck Nursing Bottle, etc.)</b></p>	Nursing bottles based on the 3 principles of sucking. Designed so that infants can nurse with natural feeding movement.	<b>When the baby's condition stabilizes after surgery</b> <ul style="list-style-type: none"> <li>• For infants whose feeding movement has stabilized</li> <li>• In combination with direct breastfeeding</li> </ul> <p>etc.</p>

\*Product names and some specifications are subject to change.

## Use of nursing bottles for cleft lip and/or palate under the guidance of a healthcare professional has been described in the guidelines as an important tool to help improve feeding problems.

Japanese Society of Oral and Maxillofacial Surgeons.  
Clinical Practice Guidelines for Cleft Lip and/or Palate<sup>10)</sup>

### CQ3-3: How do I select a nursing bottle according to the nursing status?

Recommendation (Grade B): Selection of an appropriate nursing bottle for infants with cleft lip and/or palate is useful.

It is important to improve feeding disorders in infants with cleft lip and/or palate. It is also important to provide guidance on the **proper selection and use of a nursing bottle that will make it possible for the infant to nurse efficiently, based on a comprehensive consideration of the condition of the infant's peristaltic tongue movement, the presence or absence of complications, body weight, and cleft type.**

[Explanation] (Omission) It is desirable to select a nipple that has a **backflow prevention valve or has a large hole so that the milk comes out easily.** (Omission) **There is no problem in particular with using any sort of nursing bottle as long as a nipple that is appropriate for the child can be attached, but adjustment is easy with a flexible bottle, because it is possible to push the milk out.** Depending on the condition of the child, priority should first be given to ensuring that the child can drink enough milk. Fine adjustments can then be made, such as attaching a Hotz plate so that the child can switch to a bottle for normal mouth morphology, if possible.

Japan Society of Plastic and Reconstructive Surgery, Japan Society for Surgical Wound Care, and Japan Society of Cranio-Maxillo-Facial Surgery.

"Plastic Surgery Guideline 2021: Cranio-maxillo-facial diseases (congenital/acquired)"<sup>11)</sup>

Recommendation (1C: Strong recommendation, weak evidence) Guidance and assistance with feeding are effective in types of cleft lip and/or palate that are accompanied by cleft palate (cleft palate, cleft lip and palate) because of the difficulty of direct breastfeeding in these cases.

**Rationale and explanation: 2) Method of feeding guidance and assistance:** (Omission) In Japan, **cleft palate nipples are widely used**, and several products are available. Although the structure differs slightly depending on the individual product, **they are made with a backflow prevention valve, etc. so that milk can easily flow out even if negative pressure cannot be formed at the time of peristaltic tongue movement.**

\*The translations of the 2 guidebooks are applicable only within this handbook.

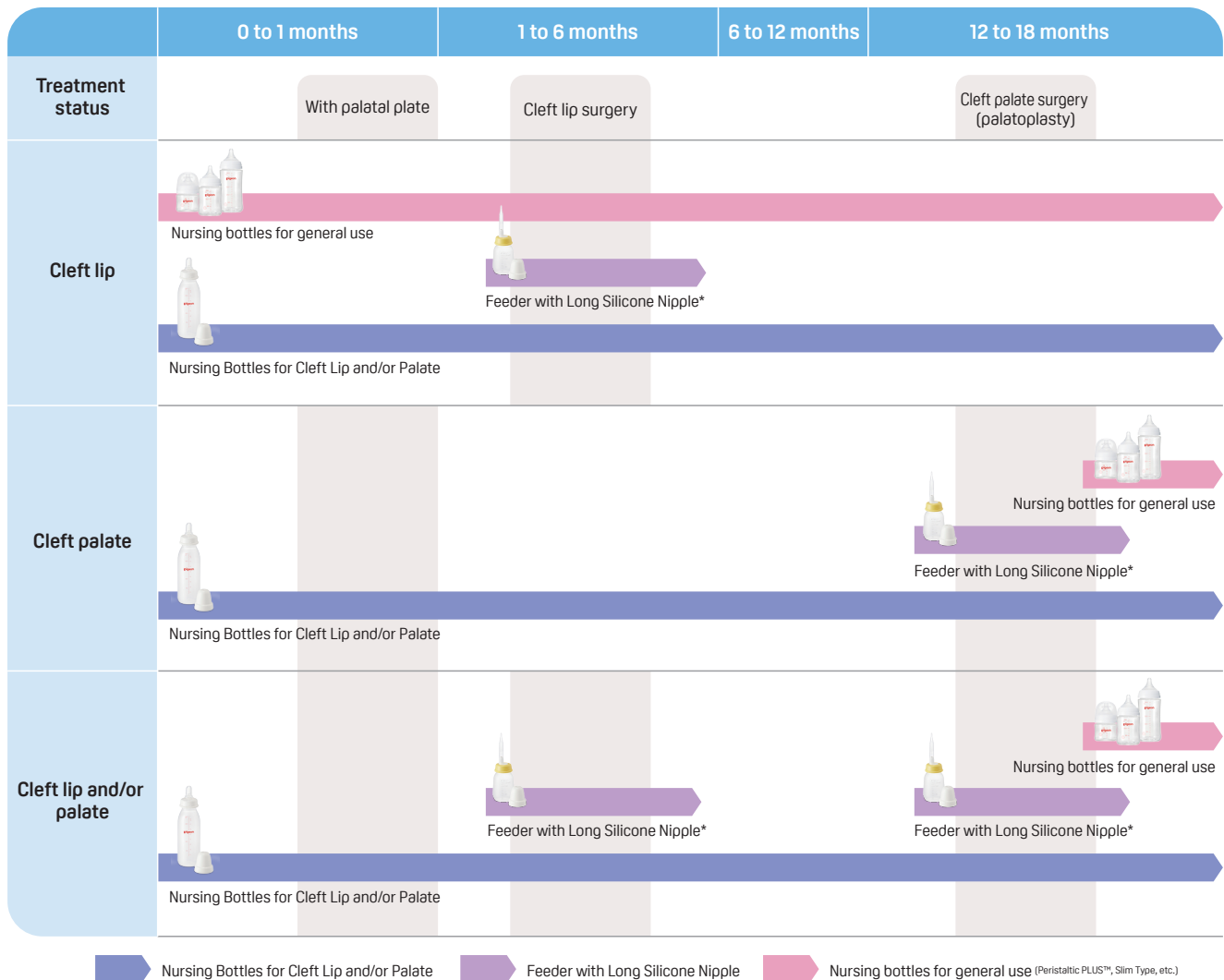
<sup>10)</sup> Japanese Society of Oral and Maxillofacial Surgeons. Quoted/excerpted from "Cleft Lip and/or Palate Management Guideline", pp. 8-9 ([https://www.jsoms.or.jp/pdf/mg\\_cpf20080804.pdf](https://www.jsoms.or.jp/pdf/mg_cpf20080804.pdf), Last accessed November 1, 2023)

<sup>11)</sup> Japan Society of Plastic and Reconstructive Surgery, Japan Society for Surgical Wound Care, and Japan Society of Cranio-Maxillo-Facial Surgery. Quoted/excerpted from "Plastic Surgery Guideline 2021: Cranio-maxillo-facial diseases (congenital/acquired)", Kanehara & Co., Ltd., Tokyo, 2021, pp. 16-99.

## Image of when to use

When using a feeding tool, it is important to select it according to the condition of the infant, such as cleft type and treatment status.

The timing and tools used vary depending on the surgical procedure and facility.



\* Feeder with Long Silicone Nipple are used temporarily when peristaltic tongue movement is difficult, or to avoid impacting the wound after surgery. There may be a preparatory period to enable the infant to acclimate to the method of use and way of drinking before surgery.

## Use of a Slim Neck Feeding Bottle before and after surgery

It takes about 1 month to completely cure the wound after plastic surgery on the lip.

After surgery, the large nipple of an ordinary nursing bottle tends to place a burden on the surgical wound, because the infant's mouth moves during sucking. With a Slim Neck Feeding Bottle, less force is applied to the sutured muscle, there minimizing the impact on the wound.

To continue stable feeding after surgery, it is recommended that the infant be acclimated to the product before surgery.

Before lip plasty



After lip plasty



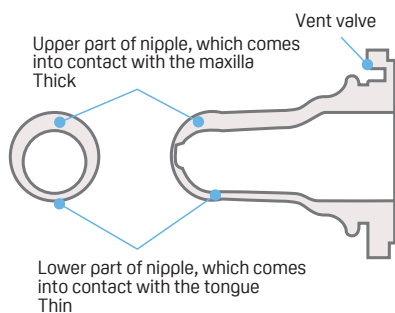
The Slim Neck Feeding Bottle is tall and narrow, has a soft nipple that is easy to put into the mouth, and makes it possible to adjust the milk flow rate while feeding (See pp. 14-17).

# Nursing Bottles for Cleft Lip and/or Palate

\*Product names and some specifications are subject to change.

Designed to prevent the nipple from wedging deep into the cleft, and to enable feeding even with weak sucking power.

## Nipple configuration with attention to thickness



- Prevents nipple from becoming deeply wedged into the maxillary cleft; prevents air leakage and milk leakage.
- Nipple can easily be depressed with the tongue, and milk flows out even with light force

## Y-shaped milk hole



Suction hole that opens when the nipple is pressed with the tongue

- Milk flows out easily, even with light force

## Two sizes of nipples



Regular size



Small size

- Can choose small or regular size, depending on the infant

\*Use small size at times like these:

- Low birth weight infant
- When the volume of the oral cavity has decreased owing to the use of a palatal plate, etc.
- After lip or palate surgery, or when transitioning to ordinary nipple
- When an infant chokes on regular size nipple

## Backflow prevention valve

- Prevents milk from flowing back into bottle so that milk can be released with light force



Set into center of nipple

## Soft elliptical-shaped bottle

- Supports feeding with easy grip and light push

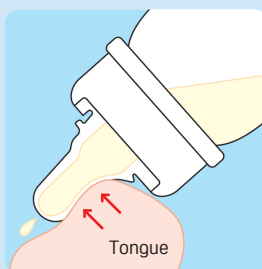


## Designed so that feeding is possible even with weak sucking pressure



### Backflow prevention valve

With a backflow prevention valve, milk does not return to the bottle but accumulates in the nipple, where it can easily come out through the hole even if the nipple is only pressed with weak force from the tongue. Even infants who cannot form negative pressure can nurse with this bottle.



### Lower part of nipple is thin

Because the lower part of the nipple is thin, even weak tongue force can be transmitted directly, making it easier for the milk to flow out even with light force. Can nurse even with weak peristaltic tongue movement.



## Expert voice

Cleft Lip and Palate Center, Aichi Gakuin University Dental Hospital

**Dr. Teruyuki Niimi**



I have been using Pigeon Nursing Bottles for Cleft Lip and/or Palate for many years. In my experience, 90% of infants with cleft lip and/or palate who are unable to drink from regular bottles can drink with this product.

The important points about this product are (a) milk accumulated in the nipple area does not return to the bottle because of the presence of the backflow prevention valve, (b) the upper part of the nipple is thick and thus the nipple does not deform in the mouth and can more easily retain its shape, and (c) the lower part of the nipple is thin, enabling even infants with weak sucking pressure to press it with their tongue so milk comes out more easily. With these innovations, it is possible to comfortably feed infants with cleft lip and/or palate, who often have weak sucking power. There are now 2 types, with a small nipple size (13 mm) added to the regular size (16 mm), so the bottles can even be used by infants who have small bodies or have a smaller oral cavity because of insertion of a palatal plate. A difference of 3 mm is very large for infants, and the fact that you can choose the right nipple size for individual infants is a good point because it makes it possible to cope with various cleft lip and/or palate

conditions.

Infants vary in their condition, but it is very important that they not be limited to tube feeding. All infants need to accumulate experience with drinking by their own ability, and with obtaining nutrition through nursing.

In our hospital, this product is introduced when it is difficult to feed an infant with an ordinary nursing bottle, and we work together with the mothers so that they can learn the proper method of use while using the bottle. No special knowledge or skills are required, and from observing the feedings, I get the impression that it is very simple to feed infants with these bottles.

Even when direct breastfeeding is possible, infants often become fatigued and are unable to drink enough milk. In such a case, mothers can breastfeed the infant directly to the extent that the infant does not tire out, and then switch to using this product while maintaining skin contact with the infant. In this way, it is possible to ensure that the infant can drink enough milk. I feel that this product is a very useful tool that makes it possible to mobilize the infant's own sucking ability, even when it is used in an auxiliary manner.

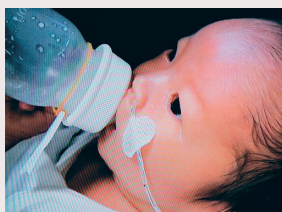
## User's voice

**Mama H**

Right-sided cheilognathopalatoschisis  
Used from immediately after birth to before  
palatoplasty (1 year and 4 months)

My infant was fed with a dropper immediately after birth, but within a few days she developed difficulty drinking, so we started using a Pigeon Nursing Bottle for Cleft Lip and/or Palate. Even though my child has weak sucking power, this product made it possible for her to drink milk by pressing up on the soft part of the nipple with her own tongue. Another good point that makes this bottle very easy to use is that the person giving the feeding can adjust the amount that the infant can drink from pressing on the bottle. I tried other companies' bottles for cleft lip and/or palate, but they were not suitable for my child. I don't know what I would have done had it not been for this product.

By developing products that provide reliable support even for infants who have trouble drinking milk, Pigeon has made it possible for infants like mine to grow and gain physical strength to the point where



The photos are posted with permission.

surgery on the palate can be performed with peace of mind. At a time when we were worried about "How do we take care of our infant from now on?", we were very encouraged to learn that a well-known company had developed products for cleft lip and/or palate and was making them available.

My child is 9 years old now, but we still keep the feeding bottle that helped her grow. To us it is a family treasure. When my child gets bigger, I want to tell her, "This is what helped you grow." Families who welcome an infant with a cleft lip and/or palate are filled with joy at the birth of the infant, but at the same time they have all sorts of anxieties. I want to tell them, "Don't worry. It will be alright." As one user of the product, I hope that it will be available for a long time and help many more families. Thank you for your excellent products.

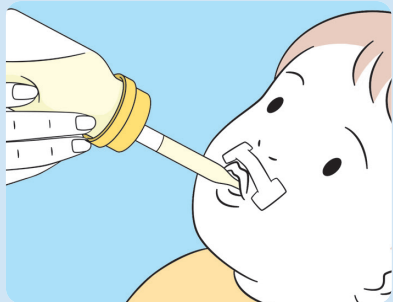
## Feeder with Long Silicone Nipple

\*Product names and some specifications are subject to change.

This product is designed for infants who cannot open their mouth wide. It makes it possible to feed at the pace that the infant can drink.



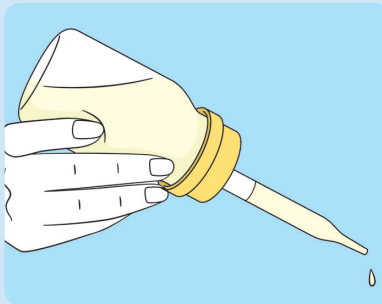
**Designed so that nursing is possible without opening the mouth wide**



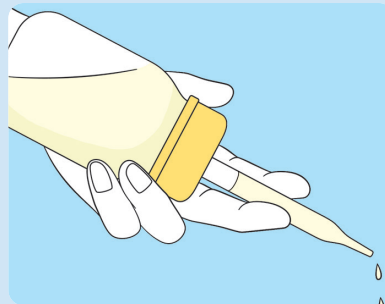
**Long, narrow, soft nipple**

Because the nipple is long and narrow, it is easy to put it into the mouth, and because it is soft, the milk comes out easily even if the infant has weak sucking ability.

**Designed so that infant can nurse at the pace he/she can drink**



**Soft bottle**



**Long, narrow, soft nipple**

The degree to which the nipple and the bottle are advanced forward can be adjusted to optimize milk flow and release timing while harmonizing with the baby's sucking movements, such as peristaltic tongue movement and swallowing, so that the infant will not choke on milk.

## Expert voice

Cleft Lip and Palate Center, Tokyo Medical University Hospital

### Dr. Tomoko Tamura



We use Pigeon Slim Neck Feeding Bottles to protect the affected areas after lip and palate surgery. In addition, I proactively recommend them to mothers who are experiencing stress because their low-birth-weight infant or an infant with a respiratory disorder cannot drink milk smoothly with an ordinary nursing bottle.

Even the ward nurses give this product high marks for the ease with which you can fine-tune the amount of milk at the tip. When I explain use of the bottle to the family, I tell them that you can adjust the flow rate by pressing on the bottle. If it is difficult to feed the infant by holding the bottle, I show them how you can adjust the feeding by holding the nipple between the middle and index fingers. Holding the nipple between the fingers makes it easy to control where the milk drips out from the tip of the nipple. By situating it at the target spot, it is possible to stop the nipple from wobbling, and that makes stable feeding possible.

Another benefit of this product that we should not overlook is the psychological effect upon the mother. Because this product is shaped differently from an ordinary nursing bottle, parents who are worried about

not being able to get their child to drink will respond positively to my recommendation. They think, "With a bottle like this, we might be able to succeed. Let's give it a try!" If feeding does not go well, the baby's body weight will not increase, and tube feeding will become necessary. From the standpoint of the parents' psychology, the sense of mutual touch during feeding is a source of joy, so I would like the parents to be able to feed the infants themselves as much as possible. The structure of this product is such that even infants with weak sucking can drink from it as long as they can swallow. If the nipple is inserted at a position where it is easy to drink, the milk will drip into the mouth, supporting nursing. I have experienced cases in which the parents were very pleased with this product, saying, "We're so glad that we are now able to feed our infant, even if only a little bit."

For this reason, I would like parents to try it as an option, not only after surgery on the lips and palate, but also when they are worried about their child's inability to suck well. For infants who cannot suck well, I recommend the Slim Neck Feeding Bottle.

## User's voice

### Mama T

Bilateral cleft lip and palate

Used the product for 3 weeks, starting on the evening after lip surgery at 3 months



The photos are posted with permission.

We started using the nursing bottles for infants with cleft lip and/or palate following the nasogastric feeding period in the NICU that started immediately after delivery. Then, when my infant underwent lip surgery at the age of 3 months, the attending physician explained that it would be beneficial to switch to Feeder with Long Silicone Nipple, "so that the movement of the infant's lips while sucking on the nipple will not tear the postoperative wound". We then used Pigeon Feeder with Long Silicone Nipple for about 3 weeks.

When we were practicing at home before admission to the operation, I had a hard time getting my infant to drink because we had received no instructions from the hospital on how to use the bottles, but after the operation, we got the knack of it through trial and error, and my infant was able to get used to it in about a day and a half.

I realized that the position that is most stable really depends on the infant. My infant is able to nurse more stably when the nipple is held against the side of his lips rather than inserted from the center.

With this product, it was possible to feed my infant without touching the surgical wound, and because the area where the cleft in his lip had been operated on was well protected, he was able to get through the postoperative course safe and sound. My child is now 4 years old, and his mouth has healed to the point where you would not know it had been operated on. I think that this is owing to the way this product maintained an optimal postoperative condition.

## Examples of use in medical practice, introduced through videos

Osaka University Dental Hospital Osaka Cleft Palate Center

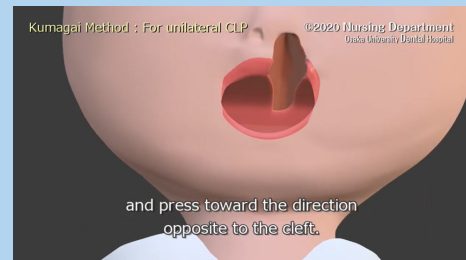
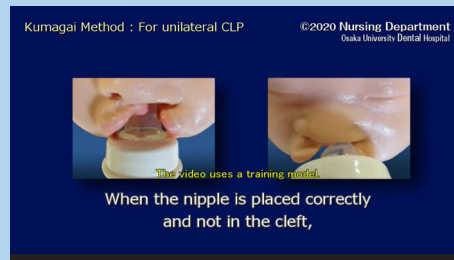
At Osaka University Dental Hospital, the method of providing feeding support for Pigeon's Nursing Bottles for Cleft Lip and/or Palate and Feeder with Long Silicone Nipple is introduced as the Kumagai Method and simply summarized in CG videos.

### Feeding support using Nursing Bottles for Cleft Lip and/or Palate

Explains the key points in the feeding method from immediately after birth to the time the plate is inserted, including the position of insertion for the nipple and the appropriate position at which to hold it steady.

#### ● In the case of unilateral cleft lip and palate

Click here for the video

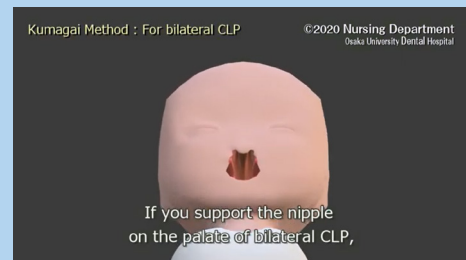
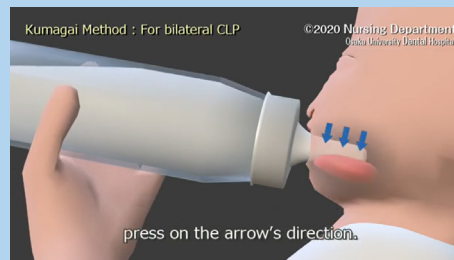


#### Tips for feeding support

Insert the nipple at the center of the tongue and support it so that only half of the nipple comes into contact with the palate.

#### ● In the case of bilateral cleft lip and palate

Click here for the video



#### Tips for feeding support

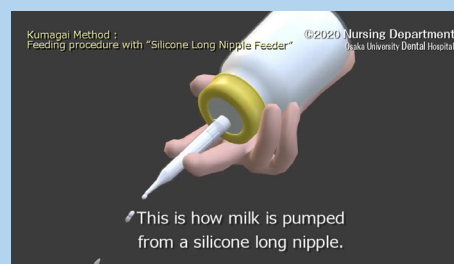
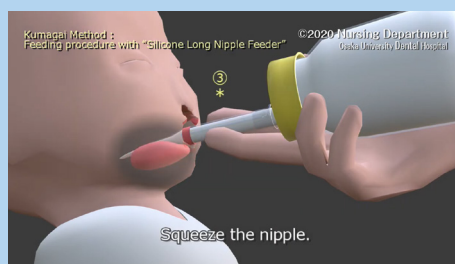
Insert the nipple so that it touches the center of the tongue and then support the nipple while pressing it against the side of the tongue slightly.



## Nursing support using Feeder with Long Silicone Nipple

Explains the key points in the postoperative feeding method using a narrow nipple for cleft lip and/or palate, including adjustment of milk volume, insertion, and holding a fixed position.

Click here for the video



### Tips for feeding support

Insert the tip of the nipple about 3 cm into the mouth. Holding the nipple between 2 fingers, squeeze it to push out the milk. This series of movements takes about 2 seconds.

## My thoughts on the Kumagai Method

Osaka University Dental Hospital Center for Cleft Lip and Palate Treatment  
Nursing Department Director **Yukari Kumagai**



A variety of feeding support tools have been developed for babies with cleft lip and/or palate by manufacturers, etc., and it is known that safe and effective feeding can be achieved by using them skillfully. However, until a palatal plate is inserted, feeding may be difficult, depending on the cleft type<sup>12)</sup>. I hope that parents will refer to this as one method based on my experience thus far<sup>13)</sup>.

The Kumagai Method is something that I arrived at through trial and error after providing feeding guidance for many years and hearing various questions and concerns about daily feeding from families with

infants with cleft lip and/or palate.

One challenge that we face now is that resources for providing appropriate information to the families are limited nationwide.

To help solve this problem, our hospital is committed to providing information on feeding methods for cleft lip and/or palate through its website and various media.

The Kumagai Method uses the characteristics and mechanism of the nipple. We have summarized the key points of successful feeding in a video and released it as an educational tool.

12) Ueki S, Fujita A, Kumagai Y, Hirai Y, Tashiro E, Miyata J. Bottle-feeding techniques for children with cleft lip and palate experiencing feeding difficulties. *Int J Nurs Sci*. 2022;10(1):82-88

13) Yukari Kumagai: Usefulness of a narrow nipple in children with bilateral cleft lip and/or palate who have difficulty feeding. One example of trying a new feeding method (Kumagai Method). *Perinatal Care*. 2021.10; 40 (10): 80-87.

Feeding method for children with cleft lip and/or palate can be learned through the video on the Osaka University Dental Hospital website at [https://hospital.dent.osaka-u.ac.jp/diseases/diseases\\_m\\_000301.html](https://hospital.dent.osaka-u.ac.jp/diseases/diseases_m_000301.html) (Last accessed: November 1, 2023)

## Nursing care initiatives

### Global support for the feeding of infants who require professional care

Since 1977, when Pigeon first launched nursing bottles and feeding accessories for infants who require specialized care, Pigeon has continued to improve its products in collaboration with healthcare professionals, while continuing to study nursing behavior in infants with cleft lip and/or palate. Pigeon Nursing Bottles for Cleft Lip and/or Palate are available in 20 countries and regions, and Feeder with Long Silicone Nipple are available in 13 countries and regions throughout the world. They are widely used for infants that require special care, such as those with cleft lip and/or palate.

Available in  
**20**  
countries/regions



Nursing Bottles for Cleft Lip and/or Palate

● **Countries/regions where available:** Japan, China, Korea, Taiwan, Hong Kong, Indonesia, Malaysia, Singapore, Myanmar, Mongolia, UAE, Finland, Russia, Australia, New Zealand, USA, South Africa, Mexico, Panama, Chile

Available in  
**13**  
countries/regions



Feeder with Long Silicone Nipple

● **Countries/regions where available:** Japan, India, Indonesia, Malaysia, Thailand, Singapore, Hong Kong, Philippines, Russia, Australia, Mexico, Panama, Chile

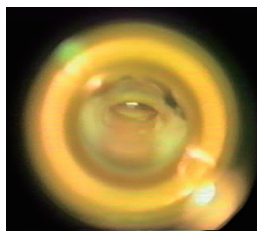
### Getting to the heart of nursing care for cleft lip and/or palate

Through collaboration with healthcare professionals, Pigeon has closely studied many cases of cleft lip and/or palate, and our research on nursing has evolved over the years, along with our products and support methods. Since the pathology and symptoms of cleft lip and/or palate vary from infant to infant and the content of support differs depending on the stage of surgery, it is important to provide nursing support based on the condition of each individual. While deepening our understanding together with healthcare professionals and persons involved in care, we aim to develop products and services that address various conditions in infants.

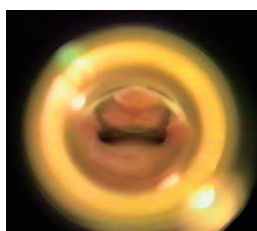
#### ● Contribution of measurement technology to nursing research

We have been working in collaboration with experts to support nursing research for infants with cleft lip and/or palate from the standpoint of observational measurement techniques and tools.

Contributing to intraoral camera-based research



Without palatal plate

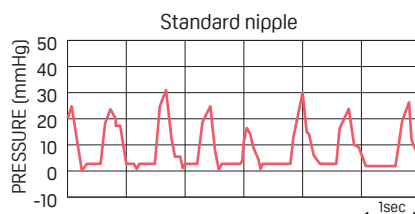
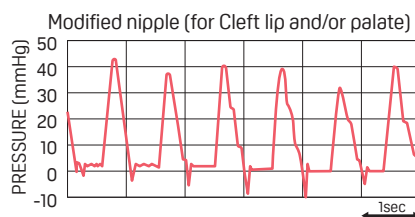


With palatal plate

#### ● Verification of usefulness of development products

We work with healthcare professionals to scientifically verify the usefulness of the products in actual use situations.

Verification of expression pressure of different types of nipples



Mizuno K, Ueda A, Kani K, Kawamura H. Feeding behaviour of infants with cleft lip and palate. Acta Paediatr. 2002;91(11):1227-32.

#### ● Product improvement reflecting voices from the medical field

We have established an interview survey of healthcare professionals and a unique mother-child monitoring system to continuously improve the products, based on how people feel about using the products and their suggestions regarding points that could be improved.



Addition of small size based on opinions of healthcare professionals

# Support activities in collaboration with global support groups

In addition to developing products that support the feeding of infants with cleft lip and/or palate, Pigeon is participating in and cooperating with activities and projects throughout the world that support the medical care and daily lives of infants with cleft lip and/or palate. To make the world more baby-friendly, we will continue our activities in the hope that infants with cleft lip and/or palate can all enjoy healthy growth.

## China

### Collaboration with Operation Smile Support for cleft lip and/or palate surgery

In 2021, in alignment with the activities of Operation Smile®, Pigeon participated in support operations such as providing guidance in laboratories and operating rooms in hospitals in Yunnan Province, when surgery for cleft lip and/or palate is provided to infants free of charge. We are actively working to create a social foundation that supports infants with cleft lip and/or palate and their families.



## Indonesia

### Alignment with Indonesia Cleft Lip & Palate Foundation (YPPCBL) Support for families who have difficulty paying for surgery

From 2016 onward, Pigeon has contributed part of the proceeds of sale of nursing bottles designed with the batik motif of Indonesia's traditional dyed goods to Indonesia Cleft Lip & Palate Foundation (YPPCBL) to support the provision of cleft lip and/or palate surgery to children whose families are unable to pay for the operation.

At the time of the opening of the Indonesian Cleft Craniofacial Center in Jakarta's largest hospital, RSCM, in 2014, we supported the establishment of a collaborative relationship with KK Women's and Children's Hospital, which practices pioneering care for infants with cleft lip and/or palate in Singapore.



## Thailand

### Collaboration with Operation Smile Thailand Support for infants with cleft lip and/or palate

Since 2017, we have been collaborating with Operation Smile Thailand\*1 to provide knowledge and know-how on care for cleft lip and/or palate to families with infants who are affected.

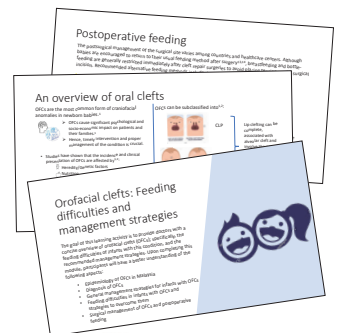


## Malaysia

### Cooperation with Cleft Lip and Palate Association Malaysia Support for activities to increase awareness of nursing bottles for cleft lip and/or palate

Since 2016, in alignment with the activities of Cleft Lip and Palate Association Malaysia (CLAPAM)\*2, Pigeon has been participating in activities to raise awareness of nursing bottles for cleft lip and/or palate among healthcare professionals. In collaboration with projects to provide education on medical treatment and care for cleft lip and/or palate, Pigeon has been participating in events such as the National Symposium of Pediatric Orthopedic Surgeons.

We provide information to healthcare professionals through textbooks that summarize basic information on cleft lip and/or palate, along with knowledge and know-how on nursing care, and they are widely used in workshops at various hospitals, etc.



\*1: Operation Smile is a global non-profit organization working to provide free surgery to people with cleft lip and/or palate.

\*2: CLAPAM is a non-profit, non-governmental organization operated by volunteers. It is formed of parents of children with cleft lip and/or palate, adults with cleft lip and/or palate, and healthcare professionals.



Celebrate babies the way they are