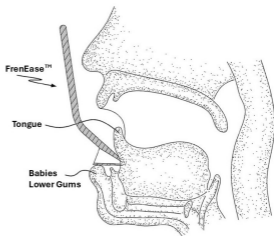


# FrenEase™ Slot Retractor

## Indications for Use:

FrenEase™ for frenotomy, or tongue-tie release in infants, is designed to allow primary care physicians (neonatologists, pediatricians, family physicians, nurse specialist) to perform frenotomy in the nursery or office.



## Note:

Frenectomy may be contraindicated in cases of airway obstruction, coagulopathy, craniofacial anomalies, hypotonia, laryngopharyngeal reflux, micrognathia, nasal obstruction, neuromuscular disorders and retrognathia. These conditions may complicate the procedure or indicate that it is not medically necessary.



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US Patent No. D751, 197S & I0,064,614 B2

REF FE26FN

## Instructions:

1. The tongue-tie release should be performed under a warming station in the nursery or physician's office. The baby *should be separated from the parents* and wrapped securely in a blanket. An assistant should gently restrain the baby's head and shoulders. Analgesia should be administered by oral sucrose shortly before the procedure.
2. The care provider, while holding open the baby's lower jaw with his or her thumb, should insert the plastic FrenEase™ retractor (provided in the kit) under the tongue (See Figure 1).
3. Once the FrenEase™ retractor is in place, with the handle pointed toward the baby's nose, the tongue-tie ligament should be well visualized, isolated, and immobilized. The surrounding tissues will be well protected by the retractor wall shields (See Figure 2).

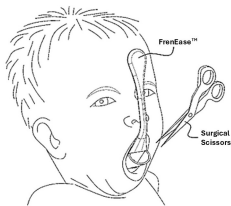


Figure 1

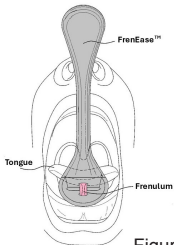


Figure 2

4. The tongue-tie will then be cut completely with blunt-end sterile sissors (not included). A sterile gauze swab (not included) should be used to compress the root of the mouth floor (See Photo #1).





Photo #1

5. The baby will then be returned to the mother to breastfeed (with better latching). The mother should be interviewed one hour after the frenotomy regarding any changes in breastfeeding or nipple soreness and for any persistent bleeding in the baby's mouth. Later, before hospital discharge, the baby's mouth should be re-examined for any postoperative complications (bleeding, swelling, partial division).
6. All contents of the FrenEase™ kit should be disposed of properly after use.

*We identify gaps in patient care.*  
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