

# DynaCleft®

Dynamic Cleft Approximation

## Instructions for Use

### Introduction

DynaCleft is used to dynamically approximate both unilateral and bilateral clefts in lips. All components and packaging are 100% latex free.

### Indications

DynaCleft is indicated for use in controlling and approximating the soft tissues of a cleft lip. This non-invasive device should be used for as long as possible before cleft lip repair surgery to guide lip segments into place for a lower-tension repair. Typical usage is one strip per day (one pouch per week) for 10-12 weeks. DynaCleft can also be used for 2-3 weeks post-operatively to relieve tension on sutures.

### Contra-indications

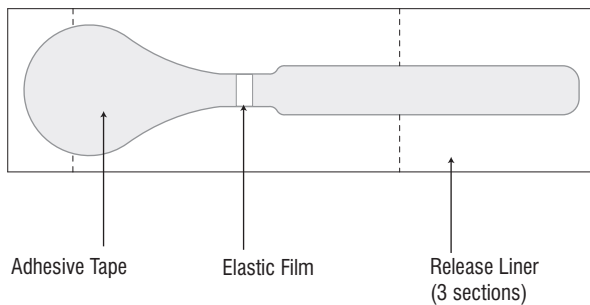
None known.

### Warnings

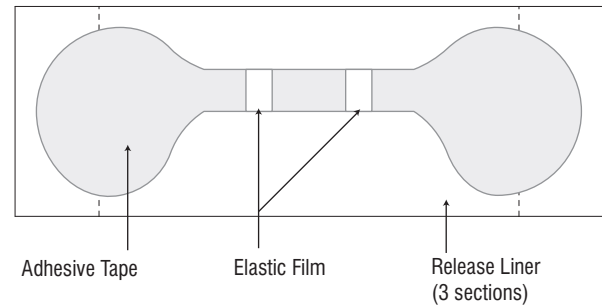
1. If allergic reaction occurs, discontinue use.
2. Exceeding recommended tension may result in skin damage or adhesive failure.
3. When removing DynaCleft from skin, peel outside edges and roll towards middle to prevent damage to skin.
4. Adhesive removing compounds can damage the elastic. If used, ensure all traces of it are washed away from skin before applying DynaCleft.
5. **NO REUSE:** DynaCleft is not intended to be reused. The adhesive tape uses a single-contact adhesive that is not designed to withstand repeated use.
6. Beware that DynaCleft can bring the alveolar segments (or upper ridges of the gum) closer together than is desirable, making palate repair more difficult. Please follow your physician's guidance on how close together the segments should be by the time of surgery (usually no closer than 3 mm).

## Overview of DynaCleft

### Unilateral DynaCleft

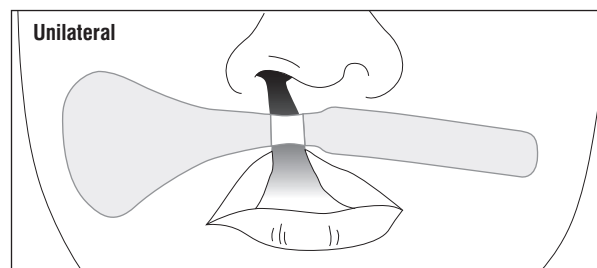


### Bilateral DynaCleft

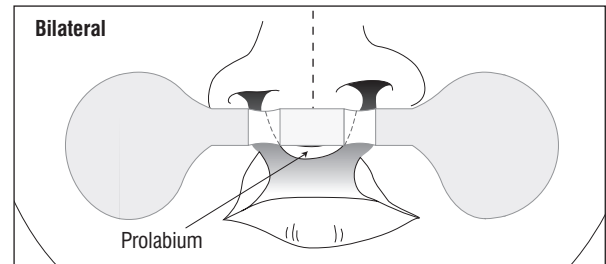


## Instructions

### DynaCleft Layout



The unilateral cleft will be to one side of the midline of the face. The round end of the DynaCleft should be on the side that has the cleft.



The middle section of the adhesive tape should be adhered as low as possible on the prolabium. Once installed, the rounded ends should be on the cheeks on either side being careful to keep the prolabium perfectly centered.

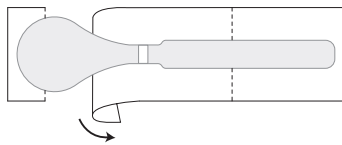
**Note:** Repeated application and removal of any adhesive product can irritate sensitive skin. A skin dressing such as DuoDERM®, Tegaderm™, or OpSite™ can be used as a protective barrier under DynaCleft.

# Application

## UNILATERAL

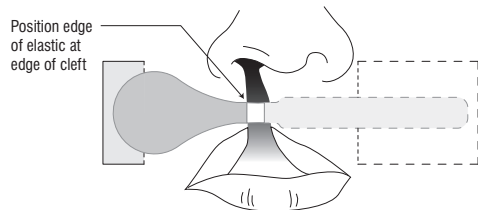
### Peel Center

- 1 Ensure skin is clean and dry prior to installation of DynaCleft. Peel and remove center section of release liner.



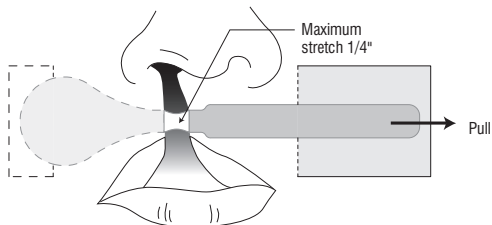
### Position and Press

- 2 Stick the round end of DynaCleft on the skin as shown. Ensure that the edge of the elastic is on the edge of the skin by the cleft.



### Stretch and Apply

- 3 Pull the long end of DynaCleft until elastic is 1/4" long (double the unstretched length). With the DynaCleft still tensioned, gently rub the tape into the skin to ensure a good bond.



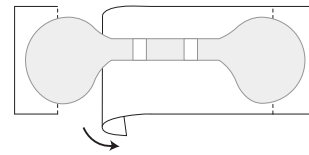
### Peel Ends and Apply

- 4 Peel off outer release liners and complete application to skin. For optimal adhesion, gently rub the tape into the skin. Replace DynaCleft as required to maintain effectiveness.

## BILATERAL

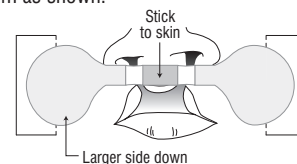
### Peel Center

- 1 Ensure skin is clean and dry prior to installation of DynaCleft. Peel and remove center section of release liner.



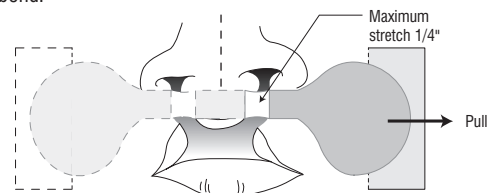
### Position and Press

- 2 Apply the middle section of tape as low as possible on the prolabium as shown.

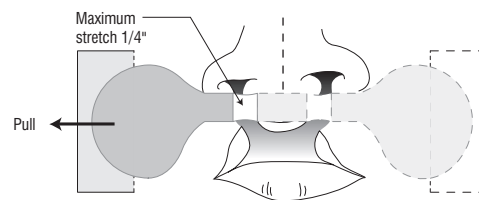


### Stretch and Apply

- 3 Pulling one end at a time, stretch the elastic until it is 1/4" long (double the unstretched length). With the DynaCleft still tensioned, gently rub the tape into the skin to ensure a good bond.



Repeat for the opposite side.



### Peel Ends and Apply

- 4 Peel off outer release liners and complete application to skin. For optimal adhesion, gently rub the tape into the skin. Replace DynaCleft as required to maintain effectiveness.

## Order Information

Description	Part Number
DynaCleft® Unilateral, 1.25" x 4.5" (7 pcs/pouch)	DCX10
DynaCleft® Bilateral, 1.25" x 3.5" (7 pcs/pouch)	DCX20



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