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510 (k) Summary

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Name of Device: Infant Cleft Palate Orthodontic Appliances

Classification Name: Orthodontic appliance and accessories (per 21CFR section 872.5410)

Equivalence Claimed: Standard maxillary dental and palatal expansion screws

Description

Two appliances are the subjects in this description. They are used for improving the alignment of the dental segments in infants with cleft lip and palate. One is for the infant with bilateral clefts of the lip and palate, and the other is for the infant with unilateral cleft of the lip and palate. These will be referred to as follows:

a) Bilateral Cleft Palate Orthodontic Appliance **(ECPR)**
b) Unilateral Cleft Palate Orthodontic Appliance **(DMA)**

Bilateral Cleft Palate Orthodontic Appliance

The appliance performs two alignment functions on the dental segments of the typical condition of bilateral clefts of the lip and palate with protrusion of the premaxillary segment. It may be used to expand the cleft maxillary segments, and at the same time apply a repositioning (or retrusive) force on the protruded premaxillary segment . The major advantage of the expansion component is that the drive screw mechanism is located at the back of the appliance so that in use the anterior palatal area in the midline is clear of appliance parts. The screw mechanism will not obstruct simultaneous repositioning of the premaxillary segment into its correct position in the dental arch.

The Georgiade-Latham expansion appliance is the main component. It is modified by having small rollers mounted on the nasal or upper side of the central drive box, and by having metal hooks or orthodontic buttons mounted one on either side at its front ends. When, in the treatment of the protruding premaxillary segment, a metal pin is placed through the posterior stem of the premaxillary bones, these modifications allow the use of two lengths of orthodontic elastic chain, that are attached to the pin, to be threaded around the rollers then passed forwards to be secured on the hooks or buttons of the expansion appliance.

The expansion appliance is made of 0.030 inch (0.75mm.) thickness sheet stainless steel. It is assembled from two arm pieces and a transverse strut which includes a central drive box. The arm pieces lie on the gum pads over the molar teeth and from their posterior pivot on the transverse strut they have a medial extension to the drive box which act as push levers. Inserted into

the drive box there is a screw (080 thread) with a large head slotted for use with a standard screwdriver. Turning the screw puts a forward push on the expansion lever arms within the drive box as a "T" shaped nut is moved forwards. The part of the screw head that fits into the drive box has four facets, two of these contact the drive box to lock the screw in a fixed position. The spring action of the drive box on the screw permits screw activation in quarter turn amounts.

One advantage of this expansion design is that activation of the appliance is quite easily accomplished by turning a screw by hand with a small screwdriver. The screw has to be turned in the mouth since the appliance is fixed in place on the palate. Parents may be asked to activate the appliance at home as directed.

In order to use the appliance the stainless steel component has to be custom mounted on a plaster cast of an infant's palate with dental acrylic resin. At the setup stage slots are incorporated in the acrylic resin to receive each of the four stainless steel retaining pins. The slots are made by using metal slot formers . These have a guide pin which is inserted into the holes that have been previously drilled in the plaster cast to identify the points of insertion of the retaining pins. The pins are made of orthodontic stainless steel wire of 0.028 inch (0.7mm.) diameter.

Unilateral Cleft Palate Orthodontic Appliance

Previous intraoral appliances used for the infant with a unilateral cleft were limited to use of an expansion screw used in the standard manner for increase of the transverse dimension. The innovation of the present appliance is that the expansion screw is mounted antero-posteriorly . One end acts to push the lesser cleft maxillary segment forwards while the other end pushes backwards on the larger noncleft segment. The latter gives anchorage for the forward push on the cleft maxilla. The backward force also has the effect of rotating the entire noncleft segment so that the anterior part (premaxillary area) is moved backwards. Thus both actions of the screw produce a correction of the positions of each cleft segment to (1) improve the alignment of the dental ridge and (2) reduce the width of the cleft . The efficacy of the appliance depends upon retention to the palatal segments with stainless steel pins in the same way as used for the bilateral appliance.

The appliance components include a metal frame consisting of an arm for each palatal segment and a connecting transverse strut posteriorly and a screw 25mm. long (one inch) with a nut. The frame is made from 0.030 inch (0.75mm.) thickness sheet stainless steel. The screw and nut are of stainless steel (obtained from Small Parts Inc., Miami, U.S.A.). The screw is threaded through a wire loop that is secured in the acrylic resin of the lesser cleft segment. This wire loop acts as a stop for the nut on the screw. The posterior end of the screw rests loosely in a slot in the acrylic resin on the noncleft side of the appliance. Clockwise turns of the screw move the lesser cleft side of the appliance towards the screw head. The range of activation provided on the screw is individually determined for each patient. It is obtained from measurement on the dental cast in the antero-posterior dimension from the alveolar ridge crest on the premaxillary cleft border to a point about 3.0mm. behind the anterior limit of the cleft maxillary gum pad. These are the points to be brought together to produce a correctly aligned dental arch. The screw length ahead of the nut is set to this measurement.

The screw is turned by hand using a small screwdriver. The screw head is conveniently located in the cleft nostril area. The screw is activated by three quarters of a revolution daily by the parents until it tightens and the nut has reached the head of the screw. Screw activation does not usually disturb the infant.

Successful use of the appliance is judged by observing the cleft alveolar segments in good alignment with the alveolar cleft borders touching, or nearly so. If the appliance remains in the mouth for a retention period of three weeks it is advantageous to remove it in the office about three days before surgery. Otherwise it is usual to remove it in the operating room before surgery commences.

There are a number of benefits to the use of the appliance. The apparent forward movement of the cleft maxillary segment brings the alar bases into the same plane and results in more symmetrical alar bases in the reconstructed nose. Reducing the width of the alveolar cleft provides a lip repair with minimal tension. From an orthodontic viewpoint, the aligned and contacting cleft alveolar borders may be surgically reconstructed to provide an intact dental arch at the first surgery. This has the potential to eliminate a bone graft procedure which is usually done at the age of 8-10 years. The intact arch provides opportunities for orthodontic arch perimeter increase later in the interceptive treatment period.

Appliance Insertion

Both appliances are normally inserted in the operating room. For the unilateral appliance only sedation is required and endotracheal intubation is not necessary. The insertion of the bilateral appliance requires general anesthesia with placement of an endotracheal tube. The enclosed instruction sheets give additional details of the insertion procedures.

Pin-retention of Intraoral Appliances

Pin retention of an intraoral appliance was first introduced by Dr. Hagerty of Charleston, S.C., in the nineteen sixties. He used one pin on each side of an appliance to obtain cleft palate expansion. Later Dr. Georgiade, at Duke University, introduced the use of a stainless steel staple to retain each side of the appliance. The present appliances utilize the concept of Georgiade in that two pins of 0.028 inch stainless steel wire are used. The pins are single and the head consists of precisely formed loops to make the pins self-retentive within the slots of the appliance. They are considered to be easier to use. Their location in the appliance and hence within the palate has to be determined precisely by the doctor supervising the appliance fabrication. This entails identifying the location for the pin insertions by inspecting the anatomical detail of the palatal cast and also drilling the four holes in the plaster cast into which slot formers will be placed prior to adding the acrylic resin to the appliance. The pins, at the time of appliance insertion, enter the palatal tissues exactly as predetermined to engage only palatal bone.

Intended Use

Bilateral Cleft Palate Orthodontic Appliance

Infants born with complete bilateral clefts of the lip and palate have an associated protrusion of the premaxillary segment. The amount of protrusion from the molar and cuspids segments (maxillary segments) varies between 8 and 18 mm. Treatment of the protruding premaxillary segment is one of the most difficult problems in orthodontics and plastic surgery. The bilateral cleft palate appliance is indicated for patients with more than about five millimeters of protrusion. It provides the most predictable and rapid method for repositioning the premaxillary segment into the normal dental arch prior to surgical correction of the lip. With the premaxillary segment repositioned it is possible to repair both sides of the lip in one operation. The lip repair can be performed without tension on the lip sutures, thus minimizing scar formation. Surgical repair of the dental alveolar process is also possible and when performed it reduces the incidence of palatal fistulas in the growing child.

Sometimes there is minimal premaxillary protrusion but the maxillary segments are constricted or collapsed. Expansion of the maxillary segments can be accomplished using the bilateral cleft palate appliance.

Unilateral Cleft Palate Orthodontic Appliance

Infants with unilateral complete or incomplete clefts of the lip and palate usually have quite severe nasal asymmetry both laterally and in the antero-posterior dimension. This is related to malformation of the dentoalveolar maxillary segments. The cleft maxilla appears to be retruded and the noncleft premaxillary segment shows a variable degree of protrusion. If the cleft is complete there is usually a wide cleft of the alveolar process in the range of 8 to 24 mm. Surgical correction of the nasal asymmetry is extremely difficult and after the first reconstructive surgical treatment there is frequently residual nasal deformity which may persist until teenage and still be quite difficult to correct.

The unilateral cleft palate appliance is indicated for the newborn infant with a complete lip and palate cleft or one that is nearly complete. It will have the effect of treating the asymmetry of the nasal alar bases so that they are level anteroposteriorly. It will also bring the dentoalveolar segments into alignment. The correction of the dental segments is a very significant benefit because the parts of the cleft lip can be brought together and the lip reconstructed with much less tension on the repaired area. Reconstruction of the nose is very much facilitated when the asymmetry of the nasal alar bases is first eliminated. Treatment with the unilateral appliance usually provides an alignment of the dentoalveolar ridge that permits primary reconstruction of the alveolar process at the first surgical treatment.

Substantial Equivalence Comparision

The present subject devices evolved from standard expansion screws that are used in everyday dentistry for widening the dental arch. Expansion appliances may be used in both removable and fixed appliances. None is designed for cleft lip and palate treatment. The Fan-type expansion screw shown in the catalog page of Dentaurum is particularly useful for expanding collapsed cleft dental segments. Its range of action is less than usually needed in cleft palate treatment. Standard expansion screws have been used for treating infants with cleft palate. These are sold by Dentaurum and Orthodontic/Dental Lab Supply and Equipment.

The subject appliances utilize the screw mechanism for the movement of infant cleft maxillary segments. The bilateral cleft palate appliance provides a similar action to the Fan-type expansion screw, but has a greater range and the screw is located at the back of the palate rather than the front. The unilateral cleft palate appliance introduces a novel vector of force antero-posteriorly within the palate and in this regard is without precedent. However it addresses the specific need for treatment of the unilateral cleft maxillary deformity.

The subject appliances rest on the oral surface of the palate in the mouth. They are readily removed after use, including the pins used for their retention and function. They are custom fabricated by dental specialists including orthodontists, pedodontists and prosthodontists using routine dental laboratory methods, eg. the utilization of cold cure acrylic resin. The appliances described herein identify with the FDA listing for Dental Devices Part 872.5410, Orthodontic Appliances and Accessories, with reference to standard maxillary dental and palatal expansion screws.

Comparison Table for Dental Expansion Screws and Subject Bilateral and Unilateral Appliances.

	Standard Expansion Screws	Bilateral Appliance	Unilateral Appliance
Purpose	widen dental arch	widen dental arch	widen dental arch
	align cleft segments	align cleft segments	align cleft segments
Type of retention	removable or fixed	fixed pin-retained	fixed pin-retained
Removable by patient	if removable yes if fixed no	no	no
Designed for cleft infants	no	yes	yes
Mechanical Safety	good	good	good
Anatomical site	palate	palate	palate
Who adjusts	doctor and/or parent	doctor and/or parent	parent
Adjustment method	by hand with wire key	elastics by doctor, expander by parent with screwdriver	by hand with screwdriver
Material	stainless steel	stainless steel	stainless steel

Safety and Effectivness Information Summary

Infants born with unilateral and bilateral complete clefts are comparatively rare. The bilateral cleft palate appliance has been in use (in principle) for 23 years (since 1973) and the unilateral appliance has been in constant use for 18 years (since 1978). Our records indicate that over the past 14 years the total number of these appliances of both kinds used by Dr. Latham and others is 1,153 appliances. Given the great variation in morphology of the cleft palate deformity we have found that about one in 40 of the unilateral cleft palate appliances fails to treat to the desired clinical result. In the case of very wide clefts, a second appliance may be necessary. In the experience noted above, there has been no report of a safety-related problem.