Medical Coverage Policy

Effective Date.....9/15/2023
Next Review Date.....9/15/2024
Coverage Policy Number..... 0407

Distraction Osteogenesis (DO) for Craniofacial Deformities

Table of Contents

Related Coverage Resources

Fetal Surgery
Surgical Treatments for Obstructive Sleep Apnea
Orthognathic Surgery
Rhinoplasty, Vestibular Stenosis Repair and Septoplasty

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy

will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses distraction osteogenesis for craniofacial deformities.

Coverage Policy

Coverage for corrective and reconstructive surgery including distraction osteogenesis for craniofacial deformities varies across plans. Refer to the customer's benefit plan document for coverage details.

Distraction osteogenesis is considered medically necessary for the correction of a congenital or acquired craniofacial deformity when BOTH of the following are met:

- **ONE of the following craniofacial deformities is present:**
  - micrognathia in infants and children that is accompanied by airway obstruction (e.g., Pierre Robin sequence, Treacher Collins or Stickler syndromes)
  - mandibular deficiency that requires lengthening of more than 10 mm
  - lengthening a short mandibular ramus (stretching of the pterygomasseteric sling)
  - hemifacial microsomia in children with sufficient bone length to anchor an internal or external distraction device (e.g., Pruzansky Grade I and IIa type mandibular deformity)
  - syndromic craniosynostosis (e.g., Apert, Crouzon, or Pfeiffer syndromes)
  - maxillary hypoplasia due to nonsyndromic cleft lip and palate (CLP)

- **ONE of the following functional impairments is present:**
  - persistent difficulties with mastication and swallowing after causes such as neurological or metabolic diseases have been excluded
  - malnutrition, significant weight loss, or failure-to-thrive secondary to facial skeletal deformity
  - speech dysfunction directly related to a jaw deformity as determined by a speech and language pathologist
  - airway obstruction, such as obstructive sleep apnea, documented by polysomnogram where conservative treatment such as continuous passive airway pressure (CPAP) or an oral appliance has been attempted and failed despite patient compliance

Distraction osteogenesis is considered NOT medically necessary:

- in preparation for dental implants or orthodontic care
- for the sole purpose of improving individual appearance and profile

General Background

According to the American Association of Oral and Maxillofacial Surgeons (AAOMS), distraction osteogenesis (DO) is a surgical technique in which new bone formation is induced by gradual separation of bony segments by means of an appliance in conjunction with an osteotomy. The steps and the basic technique of distraction osteogenesis are:

- Osteotomy phase. An osteotomy or corticotomy with placement of a device either internally or externally across the bony segment.
- Latency phase. This is a period of time in which the healing process is initiated and callus formation begins. In most applications, the latency phase is five to seven days – although there are some maxillofacial situations in which distraction is begun immediately.
- Distraction phase. At this time, the device is activated to create tension across the surgical site. As the segments are distracted, bone formations begin within the callus. The attendant tissues tend to adapt well to change, and there is an increase in size of the soft-tissue envelope. This process is termed distraction histogenesis.
- Consolidation phase. This is the period in which the segments are stabilized in order to allow for complete maturation of the regenerate bone. There is no activation during this phase.
- Remodeling phase. This phase has been recently described in the literature and, as more long-term results have been studied, it is apparent that the soft tissues and bone undergo continuing change over time (AAOMS, 2017).

Craniofacial syndromes encompass a wide range of anomalies of the face and head that can result from abnormal growth patterns, genetics, disease or trauma. Whether congenital or acquired, abnormal growth of the jaw bones can lead to severe functional impairments such as airway obstruction, obstructive sleep apnea, malnutrition, failure to thrive, persistent inability to adequately masticate or persistent speech dysfunction. The severity of functional impairments correlates to the degree of upper and lower jaw deformity. Treatment of these conditions has been managed with such interventions as endotracheal airway support, nasopharyngeal intubation, tracheostomy, appliances that support the soft palate, uvulopalatopharyngoplasty (UPPP), and temporary tongue/lip adhesions.

The most common application site of DO in the craniofacial skeleton is the mandible. It is also used for maxillary advancement and in the upper face and cranial vault. The primary indications for mandibular DO include severe bone deficiency, including those with associated malocclusion, masticatory dysfunction, temporomandibular ankylosis, failed costochondral grafts for reconstruction of the mandibular ramus, obstructive apnea, and apertognathia. Congenital syndromes and recognized anomalies associated with these problems can include Craniofacial microsomia (CFM), Treacher Collins syndrome (TCS), Pierre Robin sequence or syndrome, Nager syndrome (Nager acrofacial), Binder syndrome (maxillonasal dysplasia), Velocardiofacial syndrome (VCFS) (Shprintzen syndrome), Stickler (hereditary arthroophthalmopathy) and Marshall syndromes, Van der Woude syndrome.

Standard treatment for maxillary and mandibular deficiencies includes craniofacial surgery, orthognathic surgery, dental extraction and orthodontic correction. During craniofacial surgery, osteotomies of the mandible, maxilla, and/or craniofacial bones are performed, and the bones are realigned and maintained in place using plates, screws, and wires. Orthognathic surgery involves only the mandible and maxilla.

The advantages of craniofacial DO are numerous. It allows for skeletal lengthening and advancement in three dimensions. The process is gradual, allowing the skin-soft tissue envelope to adapt to and accommodate the skeletal movement. DO is operatively less involved and requires less operative time (generating less blood loss) than the techniques it is replacing. As a result, it can be done in young children and infants.

Complications specific to the distraction process include: device failure; injuries to various branches of the facial nerve; pin-site infection with external or semi-buried devices; nonunion and premature fusion; complications specific to the osteotomy (e.g., neurovascular or dental injuries); and psychosocial issues related to the recovery (length of treatment time and patient's physical

appearance). DO is more involved postoperatively than standard surgery. The role that the patient or parent assumes with the treatment includes having the distraction devices activated two or more times a day for one or more weeks and frequent office visits to ensure compliance and to allow for equipment adjustments. Initial post distraction outcomes are generally good, however some individuals, such as syndromic patients, respond unpredictably. Relapse, compromised adaptation and defective post-distraction growth cannot always be prevented.

Few absolute contraindications to the use of this technique exist; however, caution is advised in patients who, for one reason or another, will not comply with the distraction regime. DO is contraindicated in post-radiation bone. From a surgical standpoint, an adequate bone stock is necessary to accept the distraction appliances and to provide suitable opposing surfaces capable of generating a healing callus.

U.S. Food and Drug Administration (FDA)
The U.S. Food and Drug Administration (FDA) approved several Class II distraction devices for use as early as the 1990s. Some of these include the KLS-Martin™ intraoral distractor (manufactured by Karl Leibinger GMBH, Muhleim, Germany), the TRAK™ intraoral mandibular distraction device (manufactured by Medicon, E.G., Tuttlingen, Germany), the Logic™ and the Spectrum™ mid-face distractor (manufactured by Osteomed L.P., Addison, TX), ACE™ alveolar distractor (manufactured by ACE Surgical Supply Co., Inc., Brockton, MA), and the KLS-Martin IPS® Distraction System (manufactured by KLS Martin L.P., Jacksonville, FL).

Literature Review
There is evidence in the published peer-reviewed literature supporting the clinical effectiveness of distraction osteogenesis (DO) as an early alternative to conventional medical and surgical interventions for the treatment of severe craniofacial deformities. DO has been used for patients with a variety of functional impairments. The procedure can be performed alone or in combination with other standard techniques to address these conditions.

Evidence consists of case reports, both prospective and retrospective case series and published reviews. Much of the evidence focuses on repair of congenital deformities rather than acquired. In a majority of clinical studies the populations were small with short-term follow-up; diagnosis among study groups varied, but generally included microsomia, micrognathia, syndromal craniosynostosis, maxillary hypoplasia due to nonsyndromic cleft lip and palate, facial bone fractures and other maxillofacial mandibular defects. Follow-up times vary but range from the immediate postoperative period to five years post-surgery; few studies have reported outcomes extending beyond five years. When used early for the correction of hemifacial microsomia in particular, additional distraction procedures may be required.

Depending on individual age and condition, distraction rate, length of treatment and degree of correction vary. Nonetheless, DO has proved useful for correction of severe bone deficiencies and deformities of the mandible. Reported clinical outcomes include prevention of tracheostomies, relieved symptoms of sleep apnea, improvement in mandibular occlusion, improvement in facial asymmetry and retrognathia and improved upper airway status. Many children are likely to require staged procedures, with secondary distraction and/or conventional orthognathic surgery, to be able to control the symmetry in multiple planes. In many cases, simultaneous maxillary-mandibular distraction, in which mandibular distraction device drives the maxillary distraction, can be beneficial.

Professional Societies/Organizations
American Association of Oral and Maxillofacial Surgeons (AAOMS): The AAOMS published a Clinical Condition Statement on Distraction Osteogenesis (2017) and addressed indications for distraction of facial bones stating that the obvious indication for distraction osteogenesis is a

situation in which this technique would be more efficient or effective than other available treatment modalities. From that perspective, distraction would be indicated when:

- A degree of improvement unavailable with other techniques would be produced (i.e., a superior result).
- It would produce a similar result in a more cost-effective way. Cost should be considered in a very broad sense, including burden of treatment for the patient and economic factors.

The AAOMS goes on to note that the indications for distraction involving the jaws are limited to conditions in which this technique may be uniquely able to produce significant improvement over more traditional therapy. Examples of these situations are:

- Severe deficiency of either jaw with early correction indicated (e.g., an infant with Pierre Robin with mandibular deficiency so severe that tracheostomy is required and advancement of the mandible is the only way to correct an obstructive situation).
- Severe mandibular deficiency requiring lengthening of the mandible of greater than 10 mm. Growth modification via orthodontics generally produces no more than 5 mm differential growth, and conventional orthognathic procedures become more difficult and less predictable when greater than 8 to 10 mm advancement is needed.
- Need for lengthening of a short mandibular ramus. The nature of distraction osteogenesis is well-suited for stretching of the pterygomasseteric sling, which is not easily overcome by conventional procedures.
- Widening of the maxilla in an adult. Surgically assisted palatal expansion, which is analogous to distraction osteogenesis, has been utilized to overcome this problem for decades with very desirable and stable results.
- Narrow mandible that must be widened. There has been little success in widening the mandible with conventional surgery prior to the advent of distraction. Distraction techniques offer a better way to address this problem.
- Alveolar deficiency. The literature describes grafting techniques for augmenting the alveolar ridge. This is becoming especially popular as an adjunct to implant reconstruction. However, vertical augmentation is often difficult and distraction osteogenesis techniques may offer a means for augmentation of the bony ridge with an increase in soft tissue volume as well.

American Academy of Pediatric Dentistry (AAPD): The AAPD notes it endorses the current statements of the American Cleft Palate-Craniofacial Association (ACPA). The AAPD states that "For patients with craniofacial anomalies, orthodontic treatment may be needed in conjunction with surgical correction (and/or distraction osteogenesis) of the facial deformity" (revised 2019).

Use Outside of the US: No relevant information.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD		No Coverage Determination found.	
LCD		No Coverage Determination found.	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive.

2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
20690	Application of a uniplane (pins or wires in 1 plane), unilateral, external fixation system
20692	Application of multiplane (pins or wires in more than 1 plane), unilateral, external fixation system (eg, Ilizarov, Monticelli type)
20693	Adjustment or revision of external fixation system requiring anesthesia (eg, new pin[s] or wire[s] and/or new ring[s] or bar[s])
20694	Removal, under anesthesia, of external fixation system
20696	Application of multiplane (pins or wires in more than 1 plane), unilateral, external fixation with stereotactic computer-assisted adjustment (eg, spatial frame), including imaging; initial and subsequent alignment(s), assessment(s), and computation(s) of adjustment schedule(s)
21100	Application of halo type appliance for maxillofacial fixation, includes removal (separate procedure)
21110	Application of interdental fixation device for conditions other than fracture or dislocation, includes removal
21195	Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation

References

1. Abdelwahab M, Yoon A, Okland T, Poomkonsarn S, Gouveia C, Liu SY. Impact of Distraction Osteogenesis Maxillary Expansion on the Internal Nasal Valve in Obstructive Sleep Apnea. Otolaryngol Head Neck Surg. 2019;161(2):362-367

2. Abdullatif J, Certal V, Zaghi S, et al. Maxillary expansion and maxillomandibular expansion for adult OSA: A systematic review and meta-analysis. J Craniomaxillofac Surg. 2016;44(5):574-578

3. Alford J, Derderian CA, Smartt JM Jr. Surgical Treatment of Nonsyndromic Unicoronal Craniosynostosis. J Craniofac Surg. 2018 Jul;29(5):1199-1207.

4. Al-Moraissi EA, Ellis E 3rd. Bilateral Sagittal Split Ramus Osteotomy Versus Distraction Osteogenesis for Advancement of the Retrognathic Mandible. J Oral Maxillofac Surg. 2015;73(8):1564-1574

5. Al-Namnam NMN, Hariri F, Rahman ZAA. Distraction osteogenesis in the surgical management of syndromic craniosynostosis: a comprehensive review of published papers. Br J Oral Maxillofac Surg. 2018 Jun;56(5):353-366.

6. American Academy of Pediatric Dentistry. Policy on the Management of Patients with Cleft Lip/Palate and Other Craniofacial Anomalies. Latest revision 2019. Accessed July 2023. Available at URL address https://www.aapd.org/research/oral-health-policies--recommendations/ https://www.aapd.org/research/oral-health-policies--recommendations/the-management-of-patients-with-cleft-lippalate-and-other-craniofacial-anomalies/

7. American Association of Oral and Maxillofacial Surgeons (AAOMS). Clinical Resources. Clinical Condition Statements. Distraction Osteogenesis. 2017. Accessed July 2023. Available at URL address: https://www.aaoms.org/practice-resources/aaoms-advocacy-and-position-statements/clinical-resources

8. American Association of Oral and Maxillofacial Surgeons (AAOMS). Advocacy papers. White Paper. Craniofacial Anomalies. Reaffirmed January 2021. Accessed July 2023. Available at URL address: https://www.aaoms.org/advocacy-and-government-affairs/advocacy-resources/advocacy-white-papers

9. American Association of Oral and Maxillofacial Surgeons (AAOMS). Advocacy & Government Affairs, Craniofacial Anomalies. Accessed July 2023. Available at URL address: https://www.aaoms.org/advocacy-and-government-affairs/advocacy-resources/issue-letters/craniofacial-anomalies

10. American Society of Craniofacial Surgeons. Accessed July 2023. Available at URL address: https://ascfs.org/Professionals/About/Craniofacial-Surgery.cgi (no guidelines)

11. Baas EM, Bierenbroodspot F, de Lange J. Bilateral sagittal split osteotomy versus distraction osteogenesis of the mandible: a randomized clinical trial. Int J Oral Maxillofac Surg. 2015;44(2):180-188.

12. Baas EM, Bierenbroodspot F, de Lange J. Skeletal stability after bilateral sagittal split osteotomy or distraction osteogenesis of the mandible: a randomized clinical trial. Int J Oral Maxillofac Surg. 2015;44(5):615-620.

13. Buchanan EP, Hollier LH. Syndromes with craniofacial abnormalities. In: UpToDate, Weisman LE, Firth HV (Ed), UpToDate, Waltham, MA. Literature review current through June 2022. Topic last updated November 30, 2022.

14. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determinations (LCDs) alphabetical index. Accessed 07/26/2023. Available at URL address: https://www.cms.gov/medicare-coverage-database/reports/local-coverage-proposed-lcds-alphabetical-report.aspx?proposedStatus=A&sortBy=title

15. Centers for Medicare and Medicaid Services (CMS). National Coverage Determinations (NCDs) alphabetical index. Accessed 07/26/2023. Available at URL address: https://www.cms.gov/medicare-coverage-database/reports/national-coverage-ncd-report.aspx?chapter=all&sortBy=title

16. Chen X, Yang X, Gu S, et al. Early hemi-mandibular lengthening by distraction osteogenesis contributes to compensatory maxillary growth. J Craniomaxillofac Surg. 2020;48(4):357-364.

17. Cheung LK, Chua HDP, Hägg MB. Cleft maxillary distraction versus orthognathic surgery: clinical morbidities and surgical relapse. Plast Reconstr Surg. 2006 Sep 15;118(4):996-1008

18. Chua HD, Cheung LK. Soft tissue changes from maxillary distraction osteogenesis versus orthognathic surgery in patients with cleft lip and palate--a randomized controlled clinical trial. J Oral Maxillofac Surg. 2012;70(7):1648-1658.

19. Chua HD, Whitehill TL, Samman N, Cheung LK. Maxillary distraction versus orthognathic surgery in cleft lip and palate patients: effects on speech and velopharyngeal function. Int J Oral Maxillofac Surg. 2010 Jul;39(7):633-40.

20. Han T, Ji Y, Cui J, Kong L, Shi L, Chen J, Shen W. Treated Pierre Robin Sequence Using Placed Allogenic Acellular Bone Matrix and Mandibular Distraction Osteogenesis in the Neonate. Front Pediatr. 2022 May 23;10:890156.

21. Hirjak D, Reyneke JP, Janec J, Beno M, Kupcova I. Long-term results of maxillary distraction osteogenesis in nongrowing cleft: 5-years experience using internal device. Bratisl Lek Listy. 2016;117(12):685-690.

22. Humphries LS, Zapatero ZD, Vu GH, Hoppe I, Swanson JW, Bartlett SP, Taylor JA. Ten Years of Posterior Cranial Vault Expansion by Means of Distraction Osteogenesis: An Update and Critical Evaluation. Plast Reconstr Surg. 2022 Aug 1;150(2):379-391.

23. Imola MJ. Craniofacial Distraction Osteogenesis. Updated Feb 20, 2020. Accessed July 2023. Available at URL address: https://emedicine.medscape.com/article/844659-overview

24. Jiang L, Zheng Y, Li N, et al. Relapse rate after surgical treatment of maxillary hypoplasia in non-growing cleft patients: a systematic review and meta-analysis. Int J Oral Maxillofac Surg. 2020;49(4):421-431

25. Kloukos D, Fudalej P, Sequeira-Byron P, Katsaros C. Maxillary distraction osteogenesis versus orthognathic surgery for cleft lip and palate patients. Cochrane Database Syst Rev. 2018;8(8):CD010403. Published 2018 Aug 10.

26. Leung YY, Lai KKY. Management of obstructive sleep apnoea: an update on the role of distraction osteogenesis. Curr Opin Otolaryngol Head Neck Surg. 2018 Aug;26(4):214-220.

27. Lin X, Zhou N, Huang X, Song S, Li H. Anterior Maxillary Segmental Distraction Osteogenesis for Treatment of Maxillary Hypoplasia in Patients With Repaired Cleft Palate. J Craniofac Surg. 2018 Jul;29(5):e480-e484.

28. Liu K, Zhou N. Long-Term Skeletal Changes After Maxillary Distraction Osteogenesis in Growing Children With Cleft Lip/Palate. J Craniofac Surg. 2018;29(4):e349-e352.

29. Massenburg BB, Susarla SM, Kapadia HP, Hopper RA. Subcranial Midface Advancement in Patients with Syndromic Craniosynostosis. Oral Maxillofac Surg Clin North Am. 2022 Aug;34(3):467-475.

30. Mittal N, Goyal M, Sardana D, Dua JS. Outcomes of surgical management of TMJ ankylosis: A systematic review and meta-analysis. J Craniomaxillofac Surg. 2019;47(7):1120-1133.

31. Mundinger GS, Rehim SA, Johnson O 3rd, Zhou J, Tong A, Wallner C, et al. Distraction Osteogenesis for Surgical Treatment of Craniosynostosis: A Systematic Review. Plast Reconstr Surg. 2016 Sep;138(3):657-69.

32. Murage KP, Tholpady SS, Friel M, Havlik RJ, Flores RL. Outcomes analysis of mandibular distraction osteogenesis for the treatment of Pierre Robin sequence. Plast Reconstr Surg. 2013 Aug;132(2):419-21.

33. Noller MW, Guilleminault C, Gouveia CJ, et al. Mandibular advancement for pediatric obstructive sleep apnea: A systematic review and meta-analysis. J Craniomaxillofac Surg. 2018;46(8):1296-1302.

34. Peacock ZS, Salcines A, Troulis MJ, Kaban LB. Long-Term Effects of Distraction Osteogenesis of the Mandible. J Oral Maxillofac Surg. 2018 Jul;76(7):1512-1523.

35. Ren XC, Gao ZW, Li YF, Liu Y, Ye B, et al. The effects of clinical factors on airway outcomes of mandibular distraction osteogenesis in children with Pierre Robin sequence. Int J Oral Maxillofac Surg. 2017 Jul;46(7):805-810.

36. Tahiri Y, Viezel-Mathieu A, Aldekhayel S, Lee J, Gilardino M. The effectiveness of mandibular distraction in improving airway obstruction in the pediatric population. Plast Reconstr Surg. 2014 Mar;133(3):352e-359e.

37. Taylor BA, Brace M, Hong P. Upper airway outcomes following midface distraction osteogenesis: a systematic review. J Plast Reconstr Aesthet Surg. 2014 Jul;67(7):891-9.

38. Tsui WK, Yang Y, Mcgrath C, Leung YY. Mandibular distraction osteogenesis versus sagittal split ramus osteotomy in managing obstructive sleep apnea: A randomized clinical trial. J Craniomaxillofac Surg. 2019;47(5):750-757.

39. Urban IA, Montero E, Monje A, Sanz-Sánchez I. Effectiveness of vertical ridge augmentation interventions: A systematic review and meta-analysis. J Clin Periodontol. 2019;46 Suppl 21:319-339.

40. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). 510(k) Premarket Notification (and Summary). Nov 1998. ACE Alveolar distractor. K981526. November 1998. Accessed Aug 2023. Available at URL address: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K981526 https://www.accessdata.fda.gov/cdrh_docs/pdf/K981526.pdf

41. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). 510(k) Premarket Notification. March 1997. Intraoral mandibular distraction device (Medicon, E.G.). K970256. Accessed Aug 2023. Available at URL address: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K970256

42. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). 510k Summary. Nov 1997. KLS Martin intraoral distractor. K973275. Accessed Aug 2023. Available at URL address: https://www.accessdata.fda.gov/cdrh_docs/pdf/K973275.pdf

43. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). 510k Summary. March 1999. Osteomed intraoral distractors, various. K990944.

Accessed Aug 2023. Available at URL address: http://www.accessdata.fda.gov/cdrh_docs/pdf/k990944.pdf

44. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). 510k Summary. August 2022. KLS Martin IPS Distraction. K220050. Accessed Aug 2023. Available at URL address: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K220050

45. van de Lande LS, Pluijmers BI, Caron CJJM, Wolvius EB, Dunaway DJ, et al. Surgical correction of the midface in craniofacial microsomia. Part 1: A systematic review. J Craniomaxillofac Surg. 2018 Sep;46(9):1427-1435.

46. Winters R, Tatum SA. Craniofacial distraction osteogenesis. Facial Plast Surg Clin North Am. 2014 Nov;22(4):653-64.

47. Yöndem C, Acar YB, Şener BC, Erverdi AN. Treatment outcomes of archwise distraction osteogenesis in mandibular dentoalveolar retrognathia cases. Int J Oral Maxillofac Surg. 2017 Aug;46(8):1007-1016.

48. Zhang RS, Hoppe IC, Taylor JA, Bartlett SP. Surgical Management and Outcomes of Pierre Robin Sequence: A Comparison of Mandibular Distraction Osteogenesis and Tongue-Lip Adhesion. Plast Reconstr Surg. 2018;142(2):480-509.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	• Updated to new template and formatting standards. • No changes to criteria	9/15/2023