

ICS 11.020

English Version

## Early care services for babies born with cleft lip and/or palate

Services de prise en charge précoce des bébés nés avec  
une fente labiale et/ou palatine

Fürsorgedienstleistungen für Babies mit Lippen-, Kiefer-  
und Gaumenspalten

This Technical Report was approved by CEN on 7 March 2015. It has been drawn up by the Technical Committee CEN/TC 424.

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EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**

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## Foreword

This document (CEN/TR 16824:2015) has been prepared by Technical Committee CEN/TC 424 "Project Committee – Care services for cleft lip and/or palate", the secretariat of which is held by ASI.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

## Introduction

In Europe around 1 in 700 babies is born with cleft lip and/or palate, the most common congenital anomaly of the head and neck region. The incidence is approximately 1,6 per 1 000 live births, but there is some variance across Europe [1]. Estimates indicate there are over 900 000 individuals (babies, children and adults) with clefts in Europe [2] - a significant figure, especially when one considers that not only the patients but also their families are affected in terms of psychosocial adjustment and having to endure the burden of a long treatment pathway.

In round figures the incidence by type of cleft may be summarized as follows [3]:

**Table 1 — Incidence of Type of Cleft <sup>1)</sup>**

Type of Cleft	Percent of Total
Cleft palate only	50 %
Cleft lip (±alveolus) only	20 %
Cleft lip and palate	20 %
Bilateral cleft lip and palate	10 %

In some cases the cleft may be associated with other problems which need specialist management and these need to be identified early [4]. Accurate diagnosis (antenatal or post natal), the provision of appropriate information and support for the family, and the establishment of a structured care pathway, especially in the early months, will ensure that these infants thrive and develop like all other children. Access to good treatment varies widely throughout Europe, meaning that many children born with clefts are never given the opportunity to realize their full potential. The concept of a comprehensive specialist-team approach to care is not universal. Furthermore babies with clefts are still institutionalized in some countries in Europe [5].

The aim of this report is to provide an informative document which can be used by those countries where national protocols need to be established.

1) For further information on different types of cleft see Annex A.

## 1 Scope

This Technical Report specifies recommendations for the care of babies born with cleft lip and/or cleft palate at time of diagnosis (ante- and/or postnatal) and the year following birth or diagnosis (whichever is later), including referral processes, establishment of feeding, parental support and care pathways.

Recommendations on all aspects of surgery, including timing and the use of pre surgical orthopaedics is excluded.

## 2 Terms and definitions

For the purpose of this document, the following terms and definitions apply.

### 2.1

#### **assisted feeding**

use of a soft, squeezable, bottle and/or adjusted teat and/or sipper spout to allow delivery of milk to the infant who is unable to generate suction to extract fluid independently

Note 1 to entry: It enables the infant to feed, effectively and safely, the required volume within an acceptable time frame.

Note 2 to entry: For further information on types of bottles and teats used for assisted feeding of babies born with clefts see Annex C.

### 2.2

#### **cleft centre**

hospital with a designated cleft team and paediatric facilities

### 2.3

#### **cleft surgeon**

surgeon trained in cleft surgery with a major commitment to cleft care and who practices cleft surgery on a regular and frequent basis

### 2.4

#### **cleft team**

multidisciplinary team which comprises the following members with proven competence in their field of expertise, paediatric experience and a major commitment to cleft care: a care coordinator/manager of the service; a surgeon trained in primary cleft surgery; a surgeon specializing in secondary cleft surgery such as bone grafting and orthognathic surgery; an orthodontist; a speech and language therapist; a nurse specializing in cleft care; a psychologist with recognized clinical training; an audiologist; an ENT surgeon; a geneticist; a restorative dentist; a paediatric dentist; a dental technician

Note 1 to entry: While not all specialities will be required for every patient, access to all these practitioners is available when needed.

Note 2 to entry: If patients receive some aspects of care nearer home (e.g. orthodontics, speech and language therapy) they receive care by trained specialists working in collaboration with the cleft team.

### 2.5

#### **Eurocleft**

Eurocleft Project 1996 – 2000 funded by the European Commission having the aim to improve management and understanding of cleft lip and palate and create a network of European researchers and clinicians to facilitate information exchange