User Manual:

Pediatric Plates and Screws used for Bone Fixation: An Engineering Reference Dataset

Regulatory Science Tool (RST) Reference

RST Reference Number: RST24PD01.1

Date of Publication: 10/23/2024

Recommended Citation: U.S. Food and Drug Administration. (2024). *Pediatric Plates and Screws used for Bone Fixation: An Engineering Reference Dataset* (RST24PD01.1). https://cdrh-rst.fda.gov/pediatric- plates-and-screws-used-bone-fixation-engineering-reference-dataset

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Overview

Engineering characteristics of bone fixation plate and screws (HRS and/or HWC product codes) were collected from premarket notification submissions cleared in FDA's 510(k) database[1]. The search was limited to medical devices with metallic, non-absorbable implants only and at least one pediatric age group[2,3] listed in the cleared indications for use. Spinal, maxillofacial, and cranial devices were excluded. Approximately 250 510(k) submissions met these criteria between 1976 and 2024. From there, submissions with the greatest number of device components were selected to help represent the widest range of pediatric-specific characteristics; this resulted in recording information from 24 submissions cleared between 2000 and 2024. To maintain confidentiality, all information collected from the 510(k) database was aggregated and de-identified with nominal values across multiple submissions presented instead of exact dimensions. After collating the collected data, the device characteristics were compared for consistency against anthropometric data of pediatric anatomy from published literature.[4,5]

The engineering characteristics are applicable to the following types of bones: tibia, fibula, femur, pelvis, metacarpals, carpals, metatarsals, tarsals, humerus, ulna, radius, calcaneus, clavicle, pelvis, olecranon, scapula, acetabulum, phalanges.

Engineering Characteristics of Pediatric Bone Fixation Plates and Screws

Pediatric bone fixation plates and screws were found to have the engineering characteristics outlined in Table 1 and Table 2, respectively. Generic geometric drawings of the plates can be found in Figure 1.

Table 1: Engineering Characteristics of Pediatric Bone Fixation Plates
Plate Material: Titanium alloys, Cobalt Chromium alloys, Stainless Steel[6-12]
Plate Length (L): 16 - 400mm
Plate Shaft Width (W_s): 7.0 - 15.5mm
Plate Head Width (W_h): 7.0 - 38mm
Plate Thickness (T): 1.0 - 5mm
Plate Hole Diameter (D_h, widest point if tapered): 1.5 – 7.5mm
Number of Holes, Long Axis: 2 – 30 with or without hole threading
Plate Blade Angle: 0-50 degrees
Plate Geometries (note: definitions are found in ASTM F382 and ASTM F384[9-10] or are self-explanatory): straight, contour, angled, tubular, letter-shaped (S, T, Y), cloverleaf, cobra head

Table 2: Engineering Characteristics of Pediatric Bone Fixation Screws
Screw Material: Titanium alloys, Cobalt Chromium alloys, Stainless Steel[6-12]
Screw Length: 5 - 150mm
Screw Head Diameter (at widest point if tapered): 1.5 - 7.5mm
Screw Head Depth: 0.8 - 4 mm
Major thread diameter: 1.5 - 7mm
Screw Geometries (note: definitions are found in ASTM F543[11]): cancellous, cortical, non-tapping, partially threaded, self-tapping, types HA/HB/HC/HD, compression (with and without head)

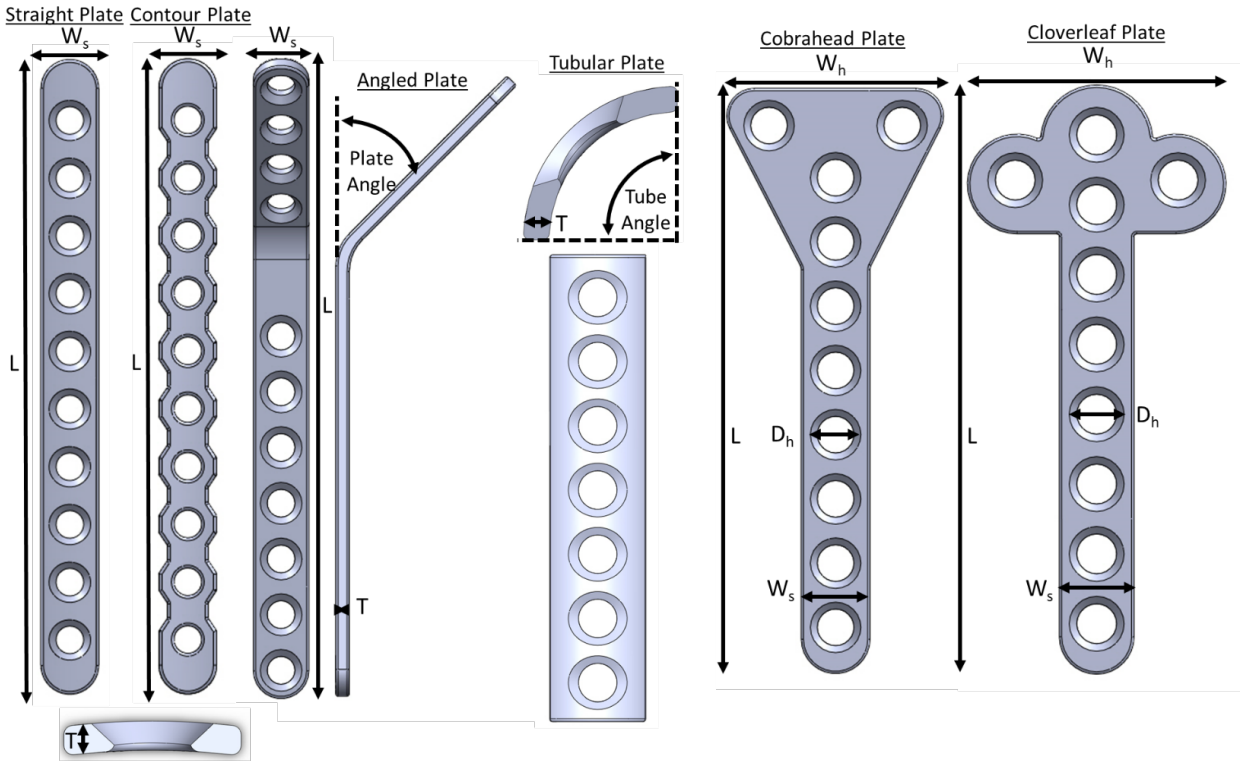

Figure 1. Example plate geometries based on definitions found in ASTM 382-17 and ASTM 384-17[8,9]. Plate Geometries (Left to Right): Straight Plate, Contour Plate, Angled Plate, Tubular Plate, Cobrahead Plate, Cloverleaf Plate. Geometries are labeled with defined dimensions. W_s: Shaft width, W_h: Head width L: Overall Length, T: Thickness, D_h: Hole Diameter

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