

Stryker PEEK Customized Implant: A Prospective Post Market Follow Up to Evaluate Safety, Performance and Effectiveness

NCT05362370

Status RECRUITING
Sponsor Stryker Craniomaxillofacial
Enrollment 110 participants

Key Eligibility Criteria

Inclusion (6)

- Subject is eligible for a PEEK customized implant as per routine clinical practice.
- Subject is 12 years of age or older (Europe only).
- Subject is 3.5 years of age or older (USA only).
- Adult subjects able to give consent.
- Subjects under the age of 18 will have a legal representative or parents (France - both parents must sign) to provide informed consent.

... and 1 more (see full listing online)

Exclusion (7)

- Subject has an active systemic or local infection.
- Subject has known allergy to plastic or polymers and/or known sensitivity to foreign bodies.
- Comprised bone due to poor blood supply, disease, infection or prior implantation, which would not allow adequate support or fixation of the implant.
- Mental or neuromuscular disorder which could create an unacceptable risk of implant instability or implant fixation failure, or complications in postoperative care.
- Knowingly pregnant or nursing women.

... and 2 more (see full listing online)

Locations (13 total)

University of Louisville 501 E. Broadway, Suite 210, Louisville, Kentucky, United States
Department of Neurological Surgery, New Brunswick, New Jersey, United States
Department of Neurological Surgery, 710 West 168th Street, 4th Floor, New York Presbyterian Hospital, New York, New York, United States

... and 10 more locations