

SECURE-C[®]

Cervical Artificial Disc

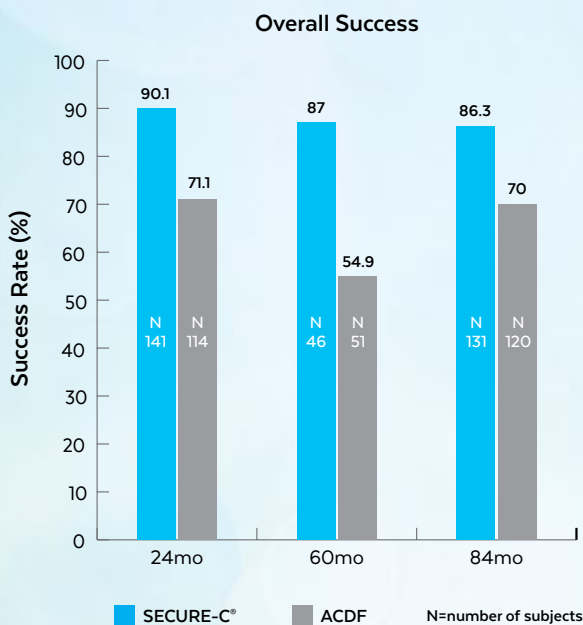


7 YEAR CLINICAL STUDY RESULTS

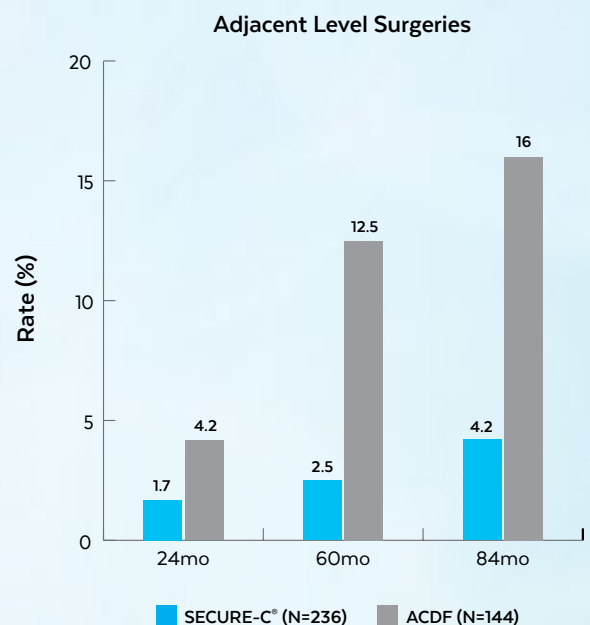
SECURE-C[®] Clinical Trial

A multi-center, prospective, randomized IDE clinical study was conducted to compare the safety and effectiveness of the SECURE-C[®] Cervical Artificial Disc to the control anterior cervical discectomy and fusion (ACDF). A total of 380 patients were enrolled at 18 sites (89 non-randomized SECURE-C[®] patients, 151 randomized SECURE-C[®] patients and 140 randomized ACDF patients), according to inclusion/exclusion criteria defined in the clinical protocol. Clinical data were collected through 84 months (7 years) postoperative. For statistical analysis, the posterior probabilities of non-inferiority and superiority were calculated using Bayesian statistical methods.

SECURE-C[®] is **statistically superior** to ACDF in terms of overall success at 24 and 84 months.



ACDF patients had adjacent level surgery **earlier** and **more often** than SECURE-C[®] patients.



Overall Success Composite Criteria:

Each subject was considered a success if all of the following criteria were met:

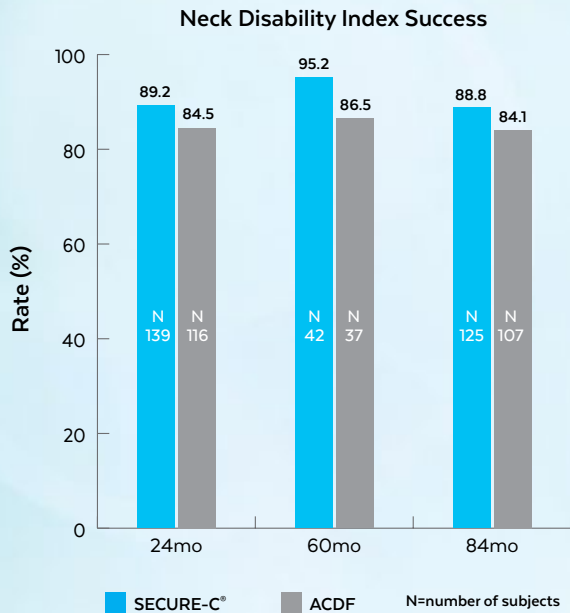
- Pain/disability improvement in NDI of at least 25% compared to baseline
- No device failures requiring revision, removal, reoperation (or supplemental fixation)
- No major complications defined as major vessel injury, neurologic damage, or nerve injury
- For fusion patients only, radiographic fusion, as defined by the presence of bridging trabecular bone, without evidence of pseudoarthrosis

Adjacent Level Surgery

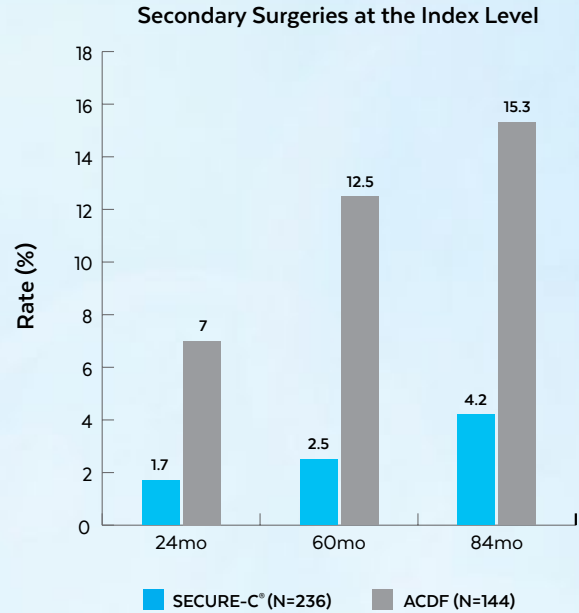
Postoperative symptoms associated with adjacent levels include arm pain, dysesthesia, neck and arm pain, neck pain, and neck pain/myelopathy.

SECURE-C® Cervical Artificial Disc 7 YEAR CLINICAL STUDY RESULTS

SECURE-C® patients had **higher** NDI success rates than ACDF patients at all time points.



Fewer SECURE-C® patients had secondary surgery at the treated level than ACDF patients.



Neck Disability Index (NDI) Success

NDI success is defined as pain/disability improvement in NDI of at least 15 points compared to baseline. SECURE-C® is non-inferior to ACDF with regards to NDI Success.

By 7 years postoperative, the percentage of patients requiring secondary surgery was lower for the SECURE-C® group (4.2%) than the ACDF group (15.3%).

Other Key Highlights From 7 Year Clinical Data

PATIENT SATISFACTION

A greater percentage of SECURE-C® patients (96%) responded that they were definitely satisfied or mostly satisfied with their treatment than ACDF patients (88%).

ADVERSE EVENTS

The number of device-related adverse events as adjudicated by the independent Clinical Events Committee (CEC) was statistically lower for the SECURE-C® group (4.2%) than the ACDF group (15.3%).

Indications For Use

The SECURE-C® Cervical Artificial Disc is indicated in skeletally mature patients for reconstruction of the disc at one level from C3-C7 following single-level discectomy for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to a single-level abnormality localized to the disc space and at least one of the following conditions confirmed by radiographic imaging (CT, MRI, X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels. The SECURE-C® Cervical Artificial Disc is implanted using an anterior approach. Patients should have failed at least 6 weeks of conservative treatment prior to implantation of the SECURE-C® Cervical Artificial Disc.