

# Registry of Avance® Nerve Graft's Utilization and Recovery Outcomes Post Peripheral Nerve Reconstruction

**Status:** RECRUITING

## Eligibility Criteria

### Age:

This study is NOT accepting healthy

**Healthy Volunteers:** volunteers

Primary Study Criteria (RANGER Avance):

### Inclusion Criteria:

\* Males and Females who have undergone nerve repair using the Avance® Nerve Graft for the repair of a nerve injury \* Returned for at least one post-operative follow-up visit

### Exclusion Criteria:

\* Subject who in the opinion of the investigator, have not or likely will not complete at least some portion of the investigator's recommended follow-up. Addendum 1 (MATCH) Criteria:

### Inclusion Criteria:

\* Have nerve transection injuries to the upper extremity; \* Have undergone tension free end to end nerve coaptation on both the proximal and distal portion of the nerve gap with nerve autograft or nerve entubulation with nerve tube conduit at a participating ANG-CP-005 registry site after 2004 and; \* Have completed sufficient follow-up assessments at a regeneration rate of 2mm/day to determine the outcomes of the repair or is willing to comply with site specific post-operative care procedures and assessments to determine the outcome of the repair.

### Exclusion Criteria:

\* Direct nerve repairs; \* Nerve gaps greater than 70mm; \* Subjects who, in the opinion of the investigator, were non-compliant to the investigator's post-operative treatment or rehabilitation instructions; \* Any subject who at the discretion of the Investigator is not suitable for inclusion in the study. Addendum 2 (Sensation-NOW) Criteria:

### Inclusion Criteria:

\* Female ≥ 18 years old \* Undergo post mastectomy autologous breast reconstruction with one type of autologous flap (no stacked reconstructions or use of implant with autologous flap) \* Neurotization must be completed using a donor nerve from the flap and a recipient nerve from the chest \* Complete Sensory Assessment Testing with Semmes Weinstein Monofilaments (SWMF) and the following Breast-Q Questionnaires 60

\*120 days post-reconstruction: \* Breast-Q Physical Well Being of the Chest \* Breast-Q Satisfaction with Breast \* Breast-Q Physical Well Being of the Abdomen \* Breast-Q Abnormal Breast Sensations \* Breast-Q Impact of Breast Sensation on Quality of Life \* Breast-Q Return of Breast Sensation \* Able to provide informed consent and are willing to comply with post-operative care procedures and assessments

### Exclusion Criteria:

\* Surgical history of secondary revision surgery for partial or total flap loss \* Bilateral reconstruction with non-uniform treatment (i.e. 1 reconstructed breast is non-neurotized, 1 reconstructed breast is neurotized) \* Currently prescribed medication known to impact nerve regeneration or to cause peripheral neuropathy \* Currently undergoing IV chemotherapy or radiation \* Any subject who at the discretion of the Investigator is not suitable for inclusion in the study or is unlikely to comply with follow-up schedule Additional Eligibility criteria to Modules Module 1: Native Skin Reconstructions with and without neurotization. \* Buried flap reconstructions from nipple sparing mastectomy or skin sparing mastectomy OR a breast reconstruction from a skin sparing mastectomy with exposed flap skin in the peri-areolar region. \* Sensory assessments must be completed on ≥ 8 Zones of Native Skin. \* Center zone measurement may be on either Native Skin or Flap Skin. \* All Inner and Outer zone measurements must be on Native Skin. \* De-identified photo of the breast reconstruction with 9 zones identified.

## Conditions & Interventions

### Interventions:

OTHER: Processed Human Nerve Graft, OTHER: Standard Treatment, Autogenous Nerve Graft, Direct Suture, etc., OTHER: Autogenous Nerve Graft, DEVICE: Nerve Tube Conduit, PROCEDURE: Autologous Breast Reconstruction with Neurotization, PROCEDURE: Autologous Breast Reconstruction without Neurotization

### Conditions:

Peripheral Nerve Injuries

### Keywords:

Sensory Nerve, Mixed Nerve, Motor Nerve, Neurotization, Nerve Injury, Peripheral Nerve Injury

## More Information

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**Phase:**

**IRB**

**Number:**

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