

SINUSOUTCOMES.ORG

# SWELL BODY RESECTION (AERIN MEDICAL DEVICE) GUIDANCE STATEMENT

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## AUTHORSHIP AND EDITING

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## STATES COVERED BY CASE SUBMISSIONS BY DATE

August 31, 2020: CALIFORNIA, CONNECTICUT, FLORIDA, GEORGIA, INDIANA, MICHIGAN, NEW JERSEY, NEW YORK, SOUTH DAKOTA, TENNESSEE, TEXAS

## CASE DATA REVIEWED BY DATE

August 31, 2020: Total Cases Submitted **2,954** / Total Procedures submitted **3,766**

**114** SWELL BODY RESECTION CASES PERFORMED WITH AN AERIN MEDICAL DEVICE REVIEWED (DATABASE USED: SINUS SURGERY RESPONSES LOCKED 09-6-20-11-05)

## PRIMARY CONSIDERATIONS

- Individual procedures on sinusoutcomes.org are considered for review after approximately 100 cases of the particular procedure have been submitted. Previously reviewed procedures are considered for additional review after every 100 subsequent procedures have been submitted. Each review attempts to determine safety considerations based on data related to the primary outcomes reported.
- Since the onset of the pandemic, the United States has seen different disease characteristics for the virus, state by state, based on multiple factors. Each review of the data will show the size of the data set and the states included in the data set. Results from one set of state specific data or report cannot necessarily be extrapolated to states that have not yet reported data.
- The primary outcomes reported are:
  - Was there any COVID-19 infections reported in the dataset
  - Was there any presumed transmission of COVID-19 to patients
  - Was there any presumed transmission of COVID-19 to surgeons
  - Was there any presumed transmission of COVID-19 to staff

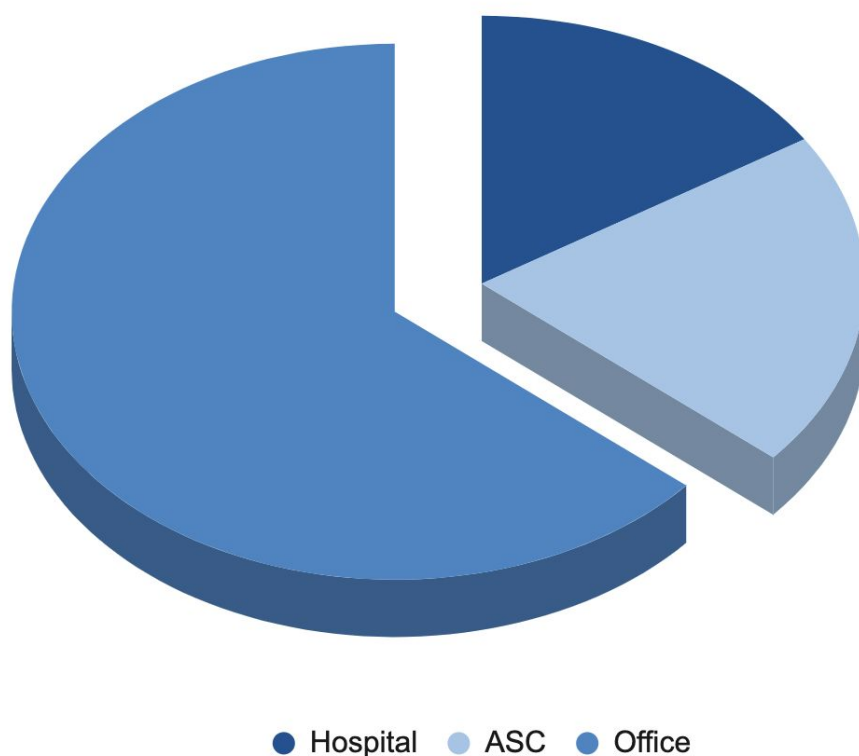
## PRIMARY FINDINGS

Data submitted up to August 31, 2020 Primary Outcomes:

- Swell Body Resection (Aerin) Cases Reviewed: 114 cases
- COVID-19 infections reported in the dataset: none reported
- Presumed transmission of COVID-19 to patients: none reported
- Presumed transmission of COVID-19 to surgeons: none reported
- Presumed transmission of COVID-19 to staff: none reported

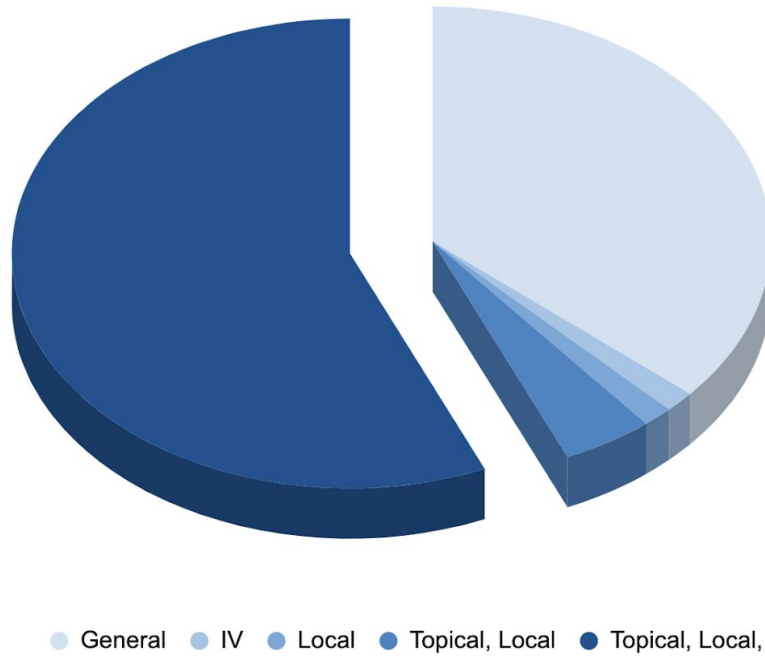
## GUIDANCE ON THE SAFETY OF PERFORMING SWELL BODY RESECTION WITH AN AERIN MEDICAL DEVICE

Data submitted up to August 31, 2020 General Case Data on Site of Service



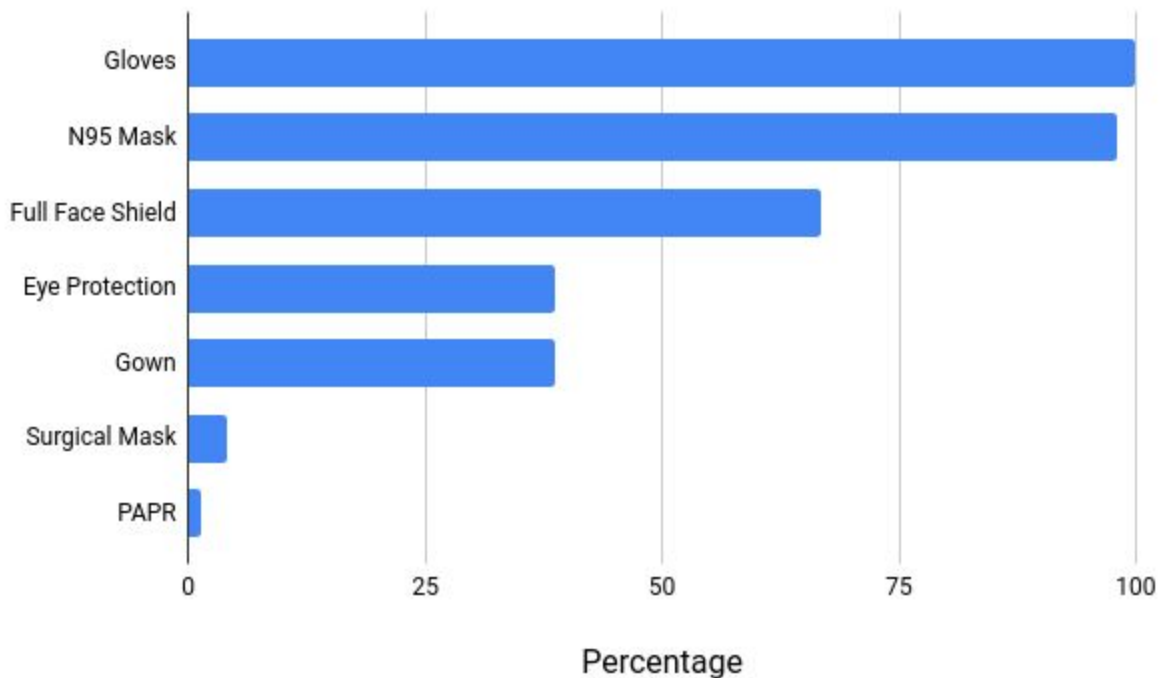
**Discussion:** The data set reviewed showed that the majority of cases were performed as an office procedure with about one-third of cases reported in the ASC or hospital setting. No particular site of service showed any increased risk profile for the covered period.

Data Submitted up to August 31, 2020    General Case Data on Anesthesia Used

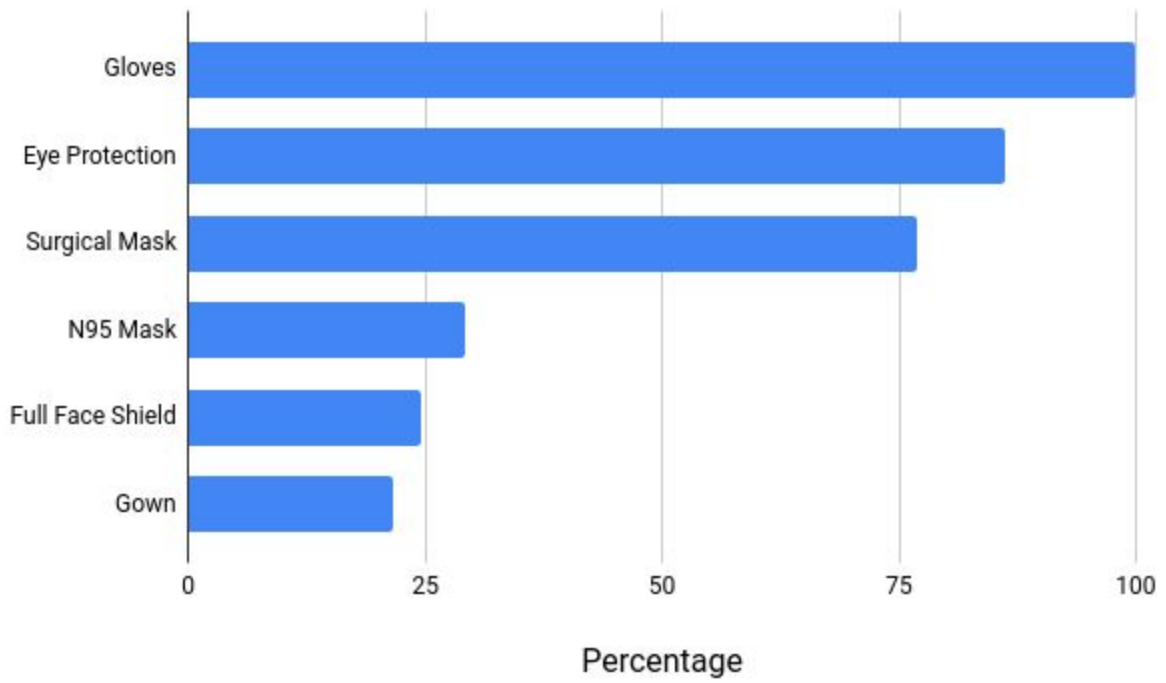


**Discussion:** The data set reviewed showed that the majority of cases were performed in the office setting and used a combination of topical, local, and oral anesthesia. Close to one-third of cases were performed in the operative setting using general anesthesia. No particular type of anesthesia showed any increased risk profile for the covered period.

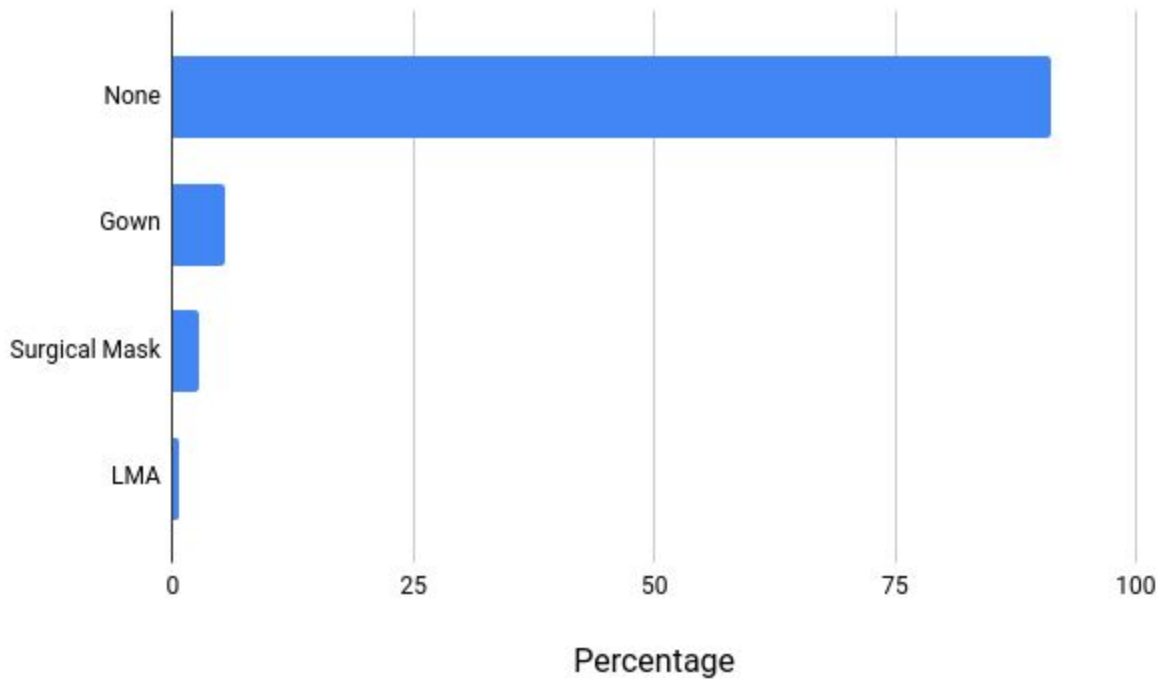
Data submitted up to August 31, 2020    PPE used during the procedure by the Doctor



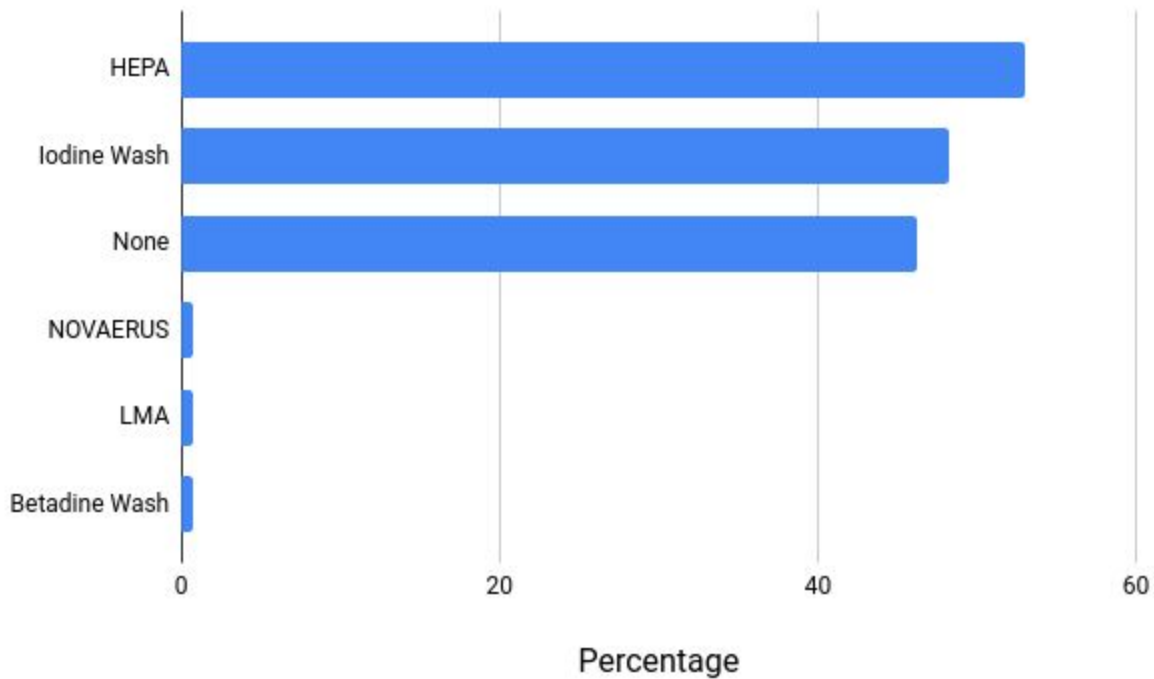
Data submitted up to August 31, 2020 PPE used during the procedure by the Staff



Data submitted up to August 31, 2020 PPE used during the procedure by the Patient



Data submitted up to August 31, 2020 PPE Additional Safety Measures Used



**Discussion:** The majority of cases performed in this data set showed use of N95 surgical masks, gloves, and gowns by both the surgeon and staff. Full face shields or eye protections were also generally used by the surgeon for these procedures. A small percentage, less than 5% of respondents indicated PAPR use by the physician however this did not correlate with a change in risk profile for case transmission.

Surgical Mask use by the patient during the procedure ranked low with less than 5% use. The majority of other respondents did not require the patient to use any PPE for the procedure. About 50% of respondents did not use any additional safety measures for the case. HEPA filtration and Iodine wash ranked first and second in this data set when additional safety measures were studied. Both of these measures were used close to 50% of the time with patients. In this data set, requiring the patient to use PPE during the procedure or using additional safety measures during the procedure does not appear to improve the safety or risk profile of Swell Body Resection using an Aerin Medical Device .

**Safety Opinion:** As of August 31, 2020 Swell Body Resection using an Aerin Medical Device is safe to perform using reasonable precautions in office and operating room settings in the states of CALIFORNIA, CONNECTICUT, FLORIDA, GEORGIA, INDIANA, MICHIGAN, NEW JERSEY, NEW YORK, SOUTH DAKOTA, TENNESSEE, AND TEXAS.

## NEXT REVIEW

WHEN SWELL BODY RESECTION WITH AN AERIN MEDICAL DEVICE ACCUMULATES CASES IN EXCESS OF 200 SUBMISSIONS on SINUSOUTCOMES.ORG