

System Name:

 $Alloquent^{\mathsf{TM}} Cervical\ Allograft\ System$

<u>Description:</u> The Alloquent[™] Cervical Allograft System consists of precision-machined bone implants and instrumentation. The allograft is supplied in a double peel pouch.

Alloquent Cervical Monolithic Grafts are available in heights of 5 to 10mm, in 1mm increments and Alloquent - S Assembled Cervical Grafts are available in heights of 5 to 12mm, in 1mm increments allowing the surgeon the capability to adjust to individual anatomical conditions.

This instrumentation will allow the surgeon to quickly measure the prepared intervertebral space during an anterior cervical decompression procedure. Trial sizers, corresponding to the graft sizes, will help the surgeon choose the appropriate size of allograft for a precise fit. The inserter has been designed to enable the surgeon to fully place the graft with a single tool, if desired. An impactor is supplied as an additional means to fully seat the graft. The graft holder is used with the corticocancellous allograft.

The cervical allograft instruments are provided non-sterile, and therefore, must be sterilized before each use.

<u>Cleaning:</u> All instruments must first be cleaned using established hospital methods before sterilization and introduction into a sterile field. Additionally, all instruments that have been previously taken into a sterile surgical field must first be cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning can include the use of neutral cleaners followed by a deionized water rinse. All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

<u>Sterilization:</u> The Alloquent[™] Cervical Allograft Instruments are supplied NON-STERILE. Prior to use, all components should be steam sterilized by the hospital using the recommended cycle:

Method: Steam Or: Method: Steam Cycle: Gravity Cycle: Prevac

Temperature: 250°F (121°C)

Exposure Time: 30 Minutes

Temperature: 270°F (132°C)

Exposure Time: 8 Minutes

<u>Product Complaints:</u> Any Healthcare Professional (e.g., customer or user of this system of products), who has any complaints, or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the company.



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| R _{only} | Caution: Federal (USA) law restricts these devices to sale by or on the order of a physician. | | |
|-------------------|---|--|--------------|
| <u></u> | See Instructions for use | | Manufacturer |
| NON STERILE | Provided Non-Sterile | | |

