INSTRUCTIONS FOR USE

Important Information — Please Read Prior to Use

Orthofix Inc.
3451 Plano Pkwy
Lewisville, Texas 75056 U.S.A.
214-937-3030

RX Only

System Name:

Alloquent™ PLIF/TLIF Allograft Instrument System

Description: The Alloquent™ PLIF/TLIF Allograft Instrument System allows the surgeon to prepare and measure the intervertebral disc space during a lumbar fusion procedure. Trial sizers, corresponding to the graft sizes, help the surgeon to choose the appropriate size of allograft for a precise fit. Box chisels and rotating cutters are included to allow the surgeon flexibility in endplate preparation. The inserter has been designed to enable the surgeon to fully place the graft with a single tool, if desired. A tamp is supplied as an additional means to fully seat the graft.

The PLIF/TLIF Allograft Instrument System Includes:

- Trial Sizers with Removable Handle
- Lumbar Allograft Inserter
- Box chisels
- Rotating Cutters with T-handles
- Rotating Distractors
- Impactor
- Mallet

The PLIF/TLIF Allograft Instruments are provided non-sterile, and therefore, must be sterilized before each use.

Cleaning: 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 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.

Sterilization: The Alloquent™ PLIF/TLIF Allograft Instruments are supplied NON-STERILE. Prior to use, all components should be steam sterilized by the hospital using the recommended cycle:

Method: Steam Cycle: Gravity Temperature: 250°F (121°C) Exposure Time: 30 minutes	OR:	Method: Steam Cycle: Prevac Temperature: 270°F (132°C) Exposure Time: 8 minutes

Product Complaints: 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, Orthofix Inc., 3451 Plano Pkwy, Lewisville, TX 75056, USA, Telephone: 214-937-3030 or 1-888-298-5700, or via email at complaints@orthofix.com.

RX Only	Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician		
	See Instructions for Use		Manufacturer
	Provided Non-Sterile	LOT	Lot Number
SN	Serial Number	REF	Catalogue Number

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