VuePASS™ Portal Access Surgical System

SINGLE USE CANNULA AND TUBE KIT - INSTRUCTIONS FOR USE

DESCRIPTION
The VuePASS System Single Use Cannula and Tube Kit is an assortment of oval shaped and circular tubes made from Makrolon® RX2530-1118 for use with the VuePASS Portal Access Surgical System for spine surgery.

The VuePASS Portal Access Surgical System is a retractor system for a minimally invasive approach for posterior spinal surgery. The system includes a series of stainless steel sequential dilators and various sized single use radiolucent oval cannulas and circular tubes. Various instruments are also available as part of the VuePASS System for use by the surgeon to facilitate the placement of the device.

When offered for use to facilitate spinal fixation using the Array® Spinal System or the SpineLink®-II Spinal System, the standard technique for the surgical implant of both spinal systems is not modified for either spinal system beyond the stated limits of system compatibility.

INTENDED USE
The VuePASS Portal Access Surgical System when used with the Array Spinal System or the SpineLink-II Spinal System is indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery.

CONTRAINDICATIONS
The VuePASS Portal Access System is contraindicated in patients with spinal infection or inflammation; morbid obesity; mental illness; alcoholism or drug abuse; pregnancy; metal or foreign body sensitivity; inadequate tissue coverage over the operative site; or open wounds near the operative area.

WARNINGS
The VuePASS System Single Use Cannula and Tube Kit is packaged sterile as a single use device. Do not resterilize for reuse. The safety and effectiveness of retraction devices for spine surgery has been established only for spinal conditions requiring discectomy, nerve decompression, fusion (posterior lateral or inter-body) and fixation with instrumentation. The safety and effectiveness of this device for any other conditions are unknown.

Potential risks identified with the use of this retraction device, which may require additional surgery, include device component fracture, loss of retraction, fracture of the vertebra, neurological injury, and vascular or visceral injury.

LIMITS OF SYSTEM COMPATIBILITY
When used with the Array Spinal System, the use of the VuePASS Portal Access Surgical System is limited to the implantation of a rod length of 50mm or less and excludes the use of system cross connectors or hooks.

When used with the SpineLink-II Spinal System, the use of the VuePASS Portal Access Surgical System is limited to the implantation of link lengths of 36mm or less and excludes the use of system transverse connectors.

STERILIZATION
The VuePASS System Single Use Cannula and Tube Kit is sterilized by exposure to a minimum dose of 25-kGy gamma radiation. For single use only, do not resterilize. Do not use if package has been compromised.
PRECAUTION
The intra-operative assembly of a retraction device for spinal surgery should be performed only by experienced spinal surgeons with specific training in the use of this retraction device system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

CARE AND HANDLING INSTRUCTIONS
Sterile packaged, single use components should be inspected prior to use for any damage or contamination. If components appear damaged, Do Not Use.

CAUTION
Federal Law (USA) restricts this device to sale by or on the order of a physician.

INFORMATION
For further information, please contact the Customer Service Department at:
   Biomet
   100 Interpace Parkway
   Parsippany, New Jersey 07054
   (973) 299-9300
   (800) 526-2579
   www.biometspine.com

Authorized European Representative
Biomet UK Ltd.
Waterton Industrial Estate
Bridgend CF31 3XA
South Wales, U.K.

100 Interpace Parkway
Parsippany, NJ 07054
www.biometspine.com
800-526-2579

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