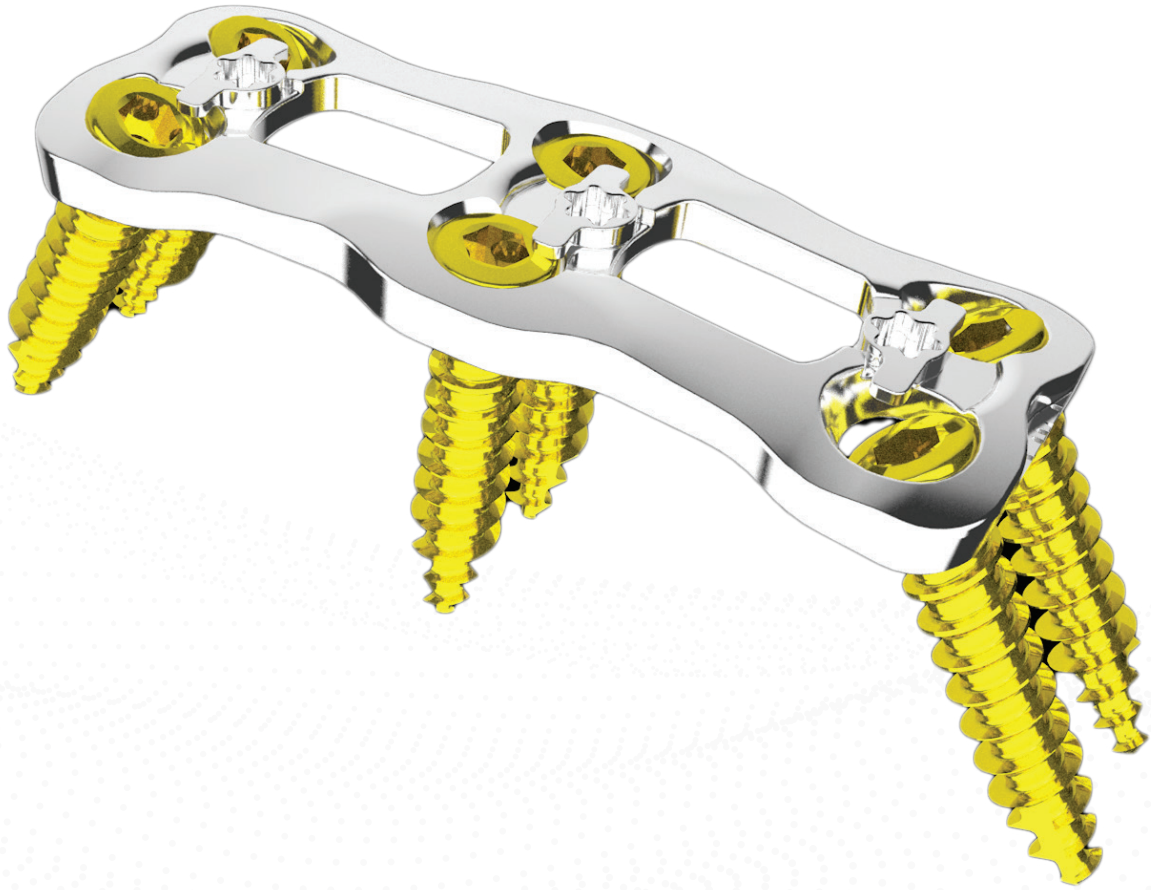
quantum™

ADDITIVE MFG CERVICAL PLATE

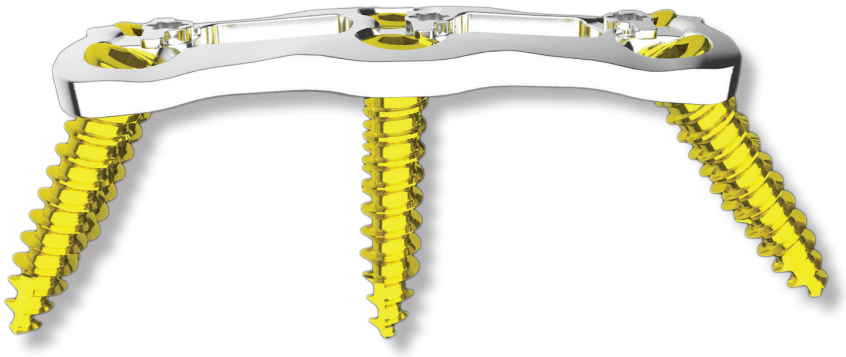
Surgical Technique Guide



NVision™

biomedical technologies

quantum™
ADDITIVE MFG CERVICAL PLATE



Introduction

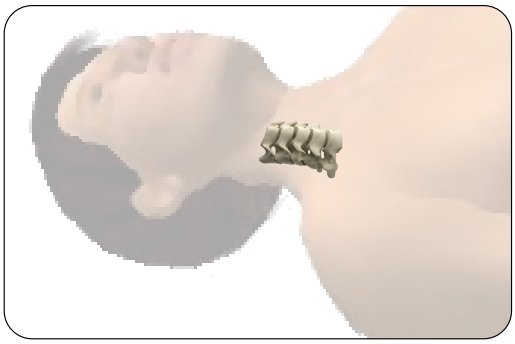
The **Quantum™ Anterior Cervical Plate** is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to T1). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion.

Indications for Use

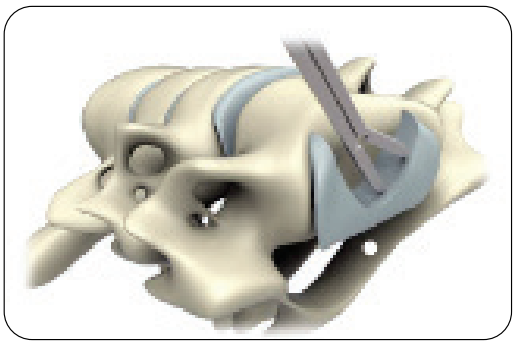
- Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
- Spondylolisthesis
- Trauma (i.e. fractures or dislocations)
- Tumors
- Deformity (defined as kyphosis, lordosis, or scoliosis)
- Pseudarthrosis
- Failed previous fusion
- Spinal stenosis

Step 1 - Site Preparation

The patient is positioned supine on the operative table with a folded towel beneath the intrascapular region to maintain the head in slight extension. The use of a head halter attached to an outrigger for traction may be helpful. If fluoroscopy is used, it can be utilized at this point to confirm positioning and check that the desired vertebral levels can be adequately visualized.

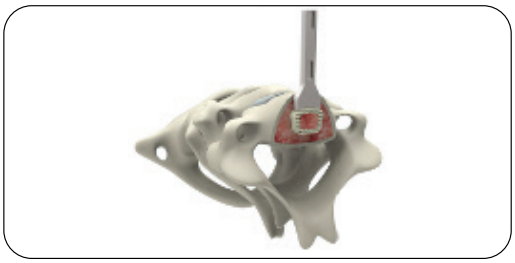


The standard anterior approach to the mid and lower cervical spine is utilized. This can be through one of several incisions with the exposure typically medial to the carotid sheath and lateral to the trachea and esophagus. Adequate fascial plane release is important for optimal exposure. After identification of the disc space through intraoperative confirmation of levels with x-ray, preparation for anterior interbody fusion is begun.



The discectomy and resection of osteophytes is performed. Further preparation of the interbody fusion bed or for corpectomy is performed as indicated.

Interbody grafts or a strut graft is then positioned and impacted into place. Any distraction previously applied can be released at this point to assess graft stability. It is critical to remove anterior osteophytes for proper plate placement. Repeat the procedure at each disc space as necessary.



Step 2 - Plate Positioning

The Quantum plates are available in one, two, three, four, and five level styles and range in length from 8mm to 110mm. Select the desired style and estimated plate length.

Insert and position the plate on the anterior surface of the spine with the Plate Holder. Review landmarks to ensure that the plate is centered appropriately medially/laterally on the spine. Confirm that the superior and inferior screw holes are in correct position on the vertebral bodies. Alignment laser marks on the superior and inferior ends of the plate can aid align the plate with the cervical endplates for

Note: Lordotic curvature can be adjusted if needed using the plate bender included
Note: Temporary Fixation Pins may be inserted in the screw holes to provide fixation while drilling holes and inserting bone screws.

Plate Bender

Step 3 – Drill / Awl

Drill Guide Positioning

Drill Guide options are as follows:

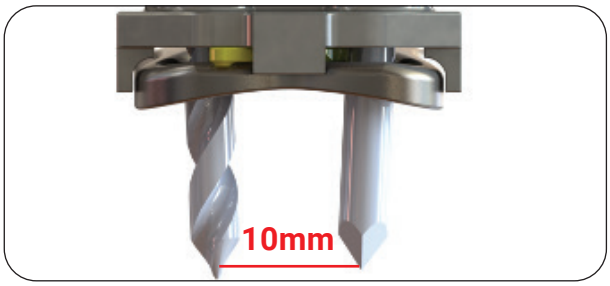
- The Single Fixed Drill Guide presets the screw angle at 5° toward the midline of the plate. The cranial/caudal angle is neutral.
- The Single Variable Angle Drill Guide allows for a 22° cone of angulation for middle screw holes, and up to 30° of terminal angulation and cephalad and caudal screw holes.
- The Double Fixed Drill guide presets the screw angle at 10° toward midline of the plate.
- The Single Fixed and Double Fixed drill guides allow for the screw to be placed through the guides. The Single Variable Drill Guide does not allow the screw to be placed through the guide.

Single, Variable Drill Guide Tip

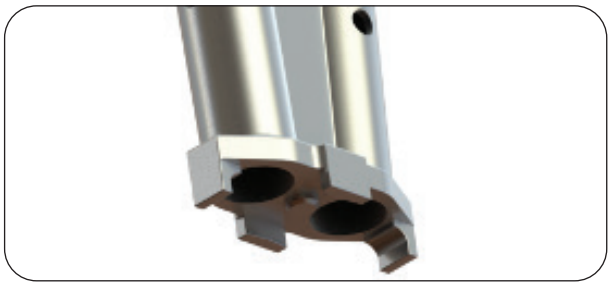
Single, Fixed Drill Guide Tip

For each guide, the drill guide tip should be fully seated into the screw hole of the plate. Once the drill guide is inserted into the bone screw hole instrumentation like the Awl, Drill, Tap, and Screw Inserter with screw can be used.

Drill and Awl are set to stop 10mm from posterior side of plate.



Drill and Awl

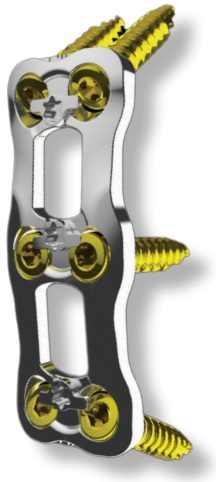


Double, Fixed Guide Tip

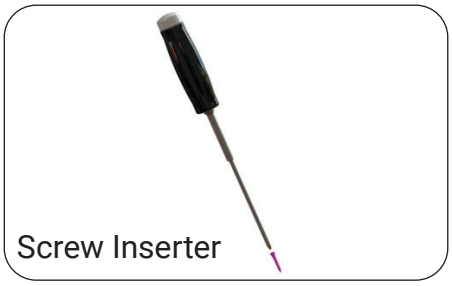
Step 4 - Screw Insertion

Select diameter and length of screw, then insert the appropriate length bone screw through the plate until the screw head fully seats. If using the cannulated inserter (optional) the threaded rod can be used to lock the screw to the inserter. Remove the Screw Inserter from the bone screw. Once opposing screws have been seated into the plate use the inserter to engage the central lock and turn until the arms fully cover screw heads Use of the lock engagement tool (optional) may be used to turn the lock to the final locked position. Repeat with all screw locations and locks.

Screws



- Ø3.75mm screws are self-drilling and self-tapping
- Ø4.25mm screws are self-drilling and self-tapping
- Ø4.75mm variable only, not self-drilling or self-tapping



Screw Inserter

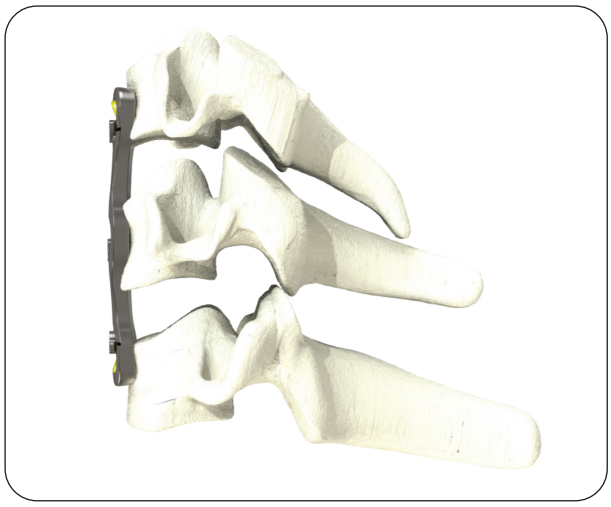
Step 5 - Screw Insertion

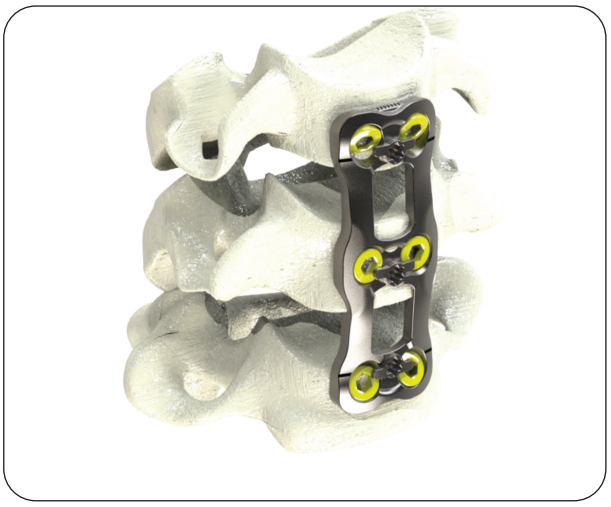
- **Closure**
  After implantation of the Tangis Anterior Cervical Plate System is complete, closure is performed in layers according to standard protocol.

- **Post-Operative Care**
  A soft collar may be used postoperatively for patient comfort. Postoperative radiographs should be taken.

Implant Removal

- Removal of the Tangis Anterior Cervical Plate System is performed by reversing the order of the implant procedure. The screw inserter is used to rotate the lock mechanism back to the open position and then used to remove the screws.





Indications for Use:
The Quantum Anterior Cervical Plate is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to T1). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with:

- degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
- spondylolisthesis,
- trauma (i.e. fractures or dislocations),
- tumors,
- deformity (defined as kyphosis, lordosis, or scoliosis),
- pseudarthrosis,
- failed previous fusion,
- spinal stenosis

Device Description:
The Quantum Anterior Cervical Plate is intended for anterior screw fixation of the plate to the cervical spine. The fixation construct consists of a cervical plate that is attached to the vertebral body of the cervical spine with self-drilling and self-tapping bone screws using an anterior approach. Plates are available in a variety of lengths (08mm – 110mm), addressing multiple levels of fixation (one to five). The plate incorporates graft visualization holes on the longitudinal center line for intraoperative visualization. Bone screws are available in three diameters (3.75 mm, 4.25 mm, and 4.75 mm) and a variety of lengths (10 mm – 20 mm). All components are made from titanium alloy per ASTM F136.

Contraindications:
Contraindications include, but are not limited to:

- Suspected or documented material allergy or intolerance.
- Patients with infection, inflammation, fever, leukocytosis, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcomes.
- Grossly distorted anatomy caused by congenital abnormalities.
- Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
- Any patient not described in the indications.
- Any patient unwilling to follow postoperative instructions.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked shift in the WBC differential count.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Prior fusion at the level(s) to be treated.

Warnings:

1. Implants and instruments are provided non-sterile and must be sterilized prior to use. Sterilization instructions are noted in this insert. Implants should never be reused under any circumstances.
2. This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
3. The implants must be implanted by an experienced spinal surgeon who has reviewed and undergone training in the use of an anterior cervical plate spinal system. Preoperative planning, including knowledge of the surgical technique, proper selection of device size, proper placement of the device is critical for the achievement of successful results. Conditions such as levels of implantation, patient weight, patient activity level and other patient conditions may impact the performance of the system and should be taken into consideration during patient selection.
4. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
5. Care must be taken to protect implant surfaces from being scratched, nicked or damaged during handling and storage of the implant as these could become focal points for failure or breakage of the device.
6. Due to the presence of implants, interference with CT and/or MR imaging may result. The system has not been evaluated for safety and compatibility in the MR environment. The system has not been tested for heating or migration in the MR environment.
7. Some degree of corrosion occurs on all metal and alloy devices. Contact of dissimilar metals, however, may accelerate the corrosion process. Components of this system should not be used in conjunction with components of any other manufacturer's spinal system.
8. Potential Adverse Effects:
9. Possible adverse events or complications include, but are not limited to:
10. Implant migration and/or subsidence
11. Breakage of implant
12. Foreign body (allergic) reaction to the implants
13. Post-operative change in spinal curvature, loss of correction, height, and/ or reduction
14. Infection
15. Loss of neurological function including paralysis (partial or complete), radiculopathy, and/or the development or continuation of pain, numbness, spasms, or sensory loss
16. Non-union (pseudoarthrosis), delayed union, mal-union
17. Inability to perform the activities of daily living
18. Fracture, micro-fracture, resorption, damage or penetration of any spinal bone
19. Loss or increase in spinal mobility or function
20. Pain, discomfort, or abnormal sensations due to the presence of the device
21. Hemorrhage of blood vessels and/or hematomas
22. Herniated nucleus pulposus, disc disruption or degeneration at, above or below the level of surgery
23. Post-operative change in spinal curvature, loss of correction, height and/or reduction
24. Death.

Disclaimers:
This publication details recommended procedures for using Nvision Biomedical Technologies' devices and instruments. It offers guidance but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required. A workshop training is recommended prior to the first surgery. Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling. For additional information please refer to the instructions for use (IFU) delivered with each implant. The surgeon must discuss all relevant risks, including the finite lifetime.
All possible complications listed are not typical of Nvision Biomedical Technologies products but are in principle observed with any implant. Promptly inform Nvision Biomedical Technologies as soon as complications occur in connection with implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality, or mechanical stability is suspected, please provide Nvision Biomedical Technologies with explant(s) in a cleaned, disinfected, and sterile condition. Nvision cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of osseous implant bed in the case of implants, incorrect indication or surgical technique, or with any incorrect patient information and consequent incorrect patient behavior.

Additional Information:
CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician. This brochure describes the surgical technique used by Nvision Biomedical Technologies development surgeons, as the manufacturer of this device, Nvision Biomedical Technologies does not practice medicine and does not recommend this product or any specific surgical technique for use on any individual patient. The surgeon who performs any implant procedure is responsible for determining the appropriate product(s) and utilizing the appropriate technique(s) for said implantation in each individual patient.

ORDERING INFORMATION

quantum™
ADDITIVE MFG CERVICAL PLATE

Implants - Plates

Part Number	Description
PCP-1-10	1 Level 10mm long
PCP-1-12	1 Level 12mm long
PCP-1-14	1 Level 14mm long
PCP-1-16	1 Level 16mm long
PCP-1-18	1 Level 18mm long
PCP-1-20	1 Level 20mm long
PCP-1-22	1 Level 22mm long
PCP-1-24	1 Level 24mm long
PCP-2-25	2 Level 25mm long
PCP-2-26	2 Level 26mm long
PCP-2-29	2 Level 29mm long
PCP-2-32	2 Level 32mm long
PCP-2-35	2 Level 35mm long
PCP-2-38	2 Level 38mm long
PCP-2-41	2 Level 41mm long
PCP-2-44	2 Level 44mm long
PCP-3-38	3 Level 38mm long
PCP-3-39	3 Level 39mm long
PCP-3-40	3 Level 40mm long
PCP-3-41	3 Level 41mm long
PCP-3-43	3 Level 43mm long
PCP-3-46	3 Level 46mm long
PCP-3-49	3 Level 49mm long
PCP-3-52	3 Level 52mm long
PCP-3-55	3 Level 55mm long
PCP-3-58	3 Level 58mm long
PCP-3-61	3 Level 61mm long
PCP-3-64	3 Level 64mm long
PCP-3-67	3 Level 67mm long

Instrumentation

Part Number	Description
ACP-1001T-AWL	Awl
ACP-1001T-PAWL	Punch awl
ACP-1001T-TAP	Tap 3.75mm dia.
ACP-1001T-DRI	Screw Inserter
PCP-1000T-SINF	Single drill guide fixed
PCP-1000T-SINV	Single drill guide variable
PCP-1000T-DOUF	Double drill guide fixed
ACP-1000T-CDRI	Cannulated Screw Inserter
ACP-1000T-LOCK	Lock engagement tool
ACP-DRL-10	Drill 10mm depth
ACP-DRL-12	Drill 12mm depth
ACP-DRL-14	Drill 14mm depth
ACP-DRL-16	Drill 16mm depth
ACP-DRL-18	Drill 18mm depth
ACP-DRL-20	Drill 20mm depth
ACP-1000T-THRD	Fixation Pin Threaded
ACP-1000T-PUSH	Fixation Pin Push
ACP-1001T-BEND	Plate Bender
ACP-1001T-HOLD	Plate Holder
ACP-1000T-500	N-RTCH, Sport Grip 3.7, A-O Pull ADPT W/Spin Cap

Screws - Fixed

Part Number	Description
PCP-375-10F	3.75mm dia. 10mm long fixed screw
PCP-375-12F	3.75mm dia. 12mm long fixed screw
PCP-375-14F	3.75mm dia. 14mm long fixed screw
PCP-375-16F	3.75mm dia. 16mm long fixed screw
PCP-375-18F	3.75mm dia. 18mm long fixed screw
PCP-375-20F	3.75mm dia. 20mm long fixed screw
PCP-425-10F	4.25mm dia. 10mm long fixed screw
PCP-425-12F	4.25mm dia. 12mm long fixed screw
PCP-425-14F	4.25mm dia. 14mm long fixed screw
PCP-425-16F	4.25mm dia. 16mm long fixed screw
PCP-425-18F	4.25mm dia. 18mm long fixed screw
PCP-425-20F	4.25mm dia. 20mm long fixed screw

Screws - Variable

Part Number	Description
PCP-375-10V	3.75mm dia. 10mm long variable screw
PCP-375-12V	3.75mm dia. 12mm long variable screw
PCP-375-14V	3.75mm dia. 14mm long variable screw
PCP-375-16V	3.75mm dia. 16mm long variable screw
PCP-375-18V	3.75mm dia. 18mm long variable screw
PCP-375-20V	3.75mm dia. 20mm long variable screw
PCP-425-10V	4.25mm dia. 10mm long variable screw
PCP-425-12V	4.25mm dia. 12mm long variable screw
PCP-425-14V	4.25mm dia. 14mm long variable screw
PCP-425-16V	4.25mm dia. 16mm long variable screw
PCP-425-18V	4.25mm dia. 18mm long variable screw
PCP-425-20V	4.25mm dia. 20mm long variable screw
PCP-475-10V	4.75mm dia. 10mm long variable screw
PCP-475-12V	4.75mm dia. 12mm long variable screw
PCP-475-14V	4.75mm dia. 14mm long variable screw
PCP-475-16V	4.75mm dia. 16mm long variable screw
PCP-475-18V	4.75mm dia. 18mm long variable screw
PCP-475-20V	4.75mm dia. 20mm long variable screw

Cases

Part Number	Description
PCP-1000C-101	Quantum Base
PCP-1000C-102	Quantum Base Lid
PCP-1000C-103	Quantum Case Insert
PCP-1000C-104	Quantum Plate Caddy
PCP-1000C-105	Quantum Plate Caddy Lid
PCP-1000C-106	Quantum Screw Caddy
PCP-1000C-107	Quantum Screw Caddy Lid
PCP-1000C-108	Quantum 4-5 Level Plate Caddy
PCP-1000C-109	Quantum 4-5 Level Plate Caddy Lid

Nvision™
biomedical technologies

Nvision Biomedical Technologies
4590 Lockhill Selma
San Antonio, TX 78249
210-545-3713 ext. 112
orders@nvisionbiomed.com
www.nvisionbiomed.com

Scan to visit our website.

Scan to view Quantum in augmented reality.