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Long term impact.

FY2024 ICD-10-PCS Updates

Natalie Sartori M.Ed., RHIA, CSS

Learning Objectives

- Review Official Guideline changes effective 10/1/2023
- Examine the new ICD-10-PCS codes that will be implemented on 10/1/2023
- Review pertinent clinical information necessary to understand new codes
- Summarize ICD-10 Coordination and Maintenance Committee materials for rationale behind new codes

Update Summary

Change Summary

2023 Total	New Codes	Revised Titles	Deleted Codes	2024 Total
78,530	78	14	5	78,603

Change Detail

Section	FY 2023	FY 2024	Difference
Medical & Surgical	68,038	68,058	+20
Extracorporeal or Systemic Assistance and Performance	51	54	+3
Other Procedures	78	88	+10
New Technology	303	343	+40

FY 2024 ICD-10-PCS Guideline Changes

FY 2024 Guideline Updates – Approach Guidelines

Guideline Revision (underline/highlighted text are ADDITIONS)

B5.2b Percutaneous endoscopic approach with hand-assistance or extension of incision

Procedures performed using the percutaneous endoscopic approach with hand-assistance, or with an incision or extension of an incision to assist in the removal of all or a portion of a body part, or to anastomose a tubular body part with or without the temporary exteriorization of a body structure, are coded to the approach value Percutaneous Endoscopic.

Examples: Hand-assisted laparoscopic sigmoid colon resection with exteriorization of a segment of the colon for removal of specimen with return of colon back into abdominal cavity is coded to the approach value percutaneous endoscopic. Laparoscopic sigmoid colectomy with extension of stapling

FY 2024 Guideline Updates

Note: The previous guideline update seems to contradict advice provided in the 3rd Q 2014 (P.16)

Question:

A patient underwent a complete nephroureteroscopy. The kidney and proximal ureter were removed via “hand assisted” laparoscopy and the distal ureter was removed from the bladder via an incision. What is the appropriate PCS codes assignment for a left nephroureterectomy when two planned approaches are used to completely removed the removed the ureter?

Answer:

The left kidney and proximal ureter were excised using a hand port laparoscopic assisted approach. At surgery an 8 cm (3.12 inches) incision was made to gain access to the distal ureter site. This is consider and open approach. Assign codes:

0TT10ZZ Resection of Left Kidney, Open Approach

0TT70ZZ Resection of Left Ureter, Open Approach

Rationale:

Given guideline revision I would recommend using the following code for the nephrectomy

0TT44ZZ Resection of Left Kidney Pelvis, Percutaneous Endoscopic Approach

FY 2024 Guideline Updates – B6 Devices

Guideline Revision (strikethrough text are DELETIONS)

B6.1a A device is coded only if a device remains after the procedure is completed. If no device remains, the device value No Device is coded. In limited root operations, the classification provides the qualifier values Temporary and Intraoperative, for specific procedures involving clinically significant devices, where the purpose of the device is to be utilized for a brief duration during the procedure or current inpatient stay. If a device that is intended to remain after the procedure is completed requires removal before the end of the operative episode in which it was inserted ~~(for example, the device size is inadequate or an event documented as a complication occurs)~~, both the insertion and removal of the device should be coded.

FY 2024 Guideline Updates – B6 Devices

Code Insertion & Removal When

- The device is inserted and removed and at the end of the operative episode there is no device in place.
- This is supported in the 4th Q 2017 (p.104) when a Watchman is placed in the left atrial appendage then removed prior to the completion of the procedure because the device was found to be inadequate. Another Watchman device placement was not attempted. In this case the insertion and removal were coded.

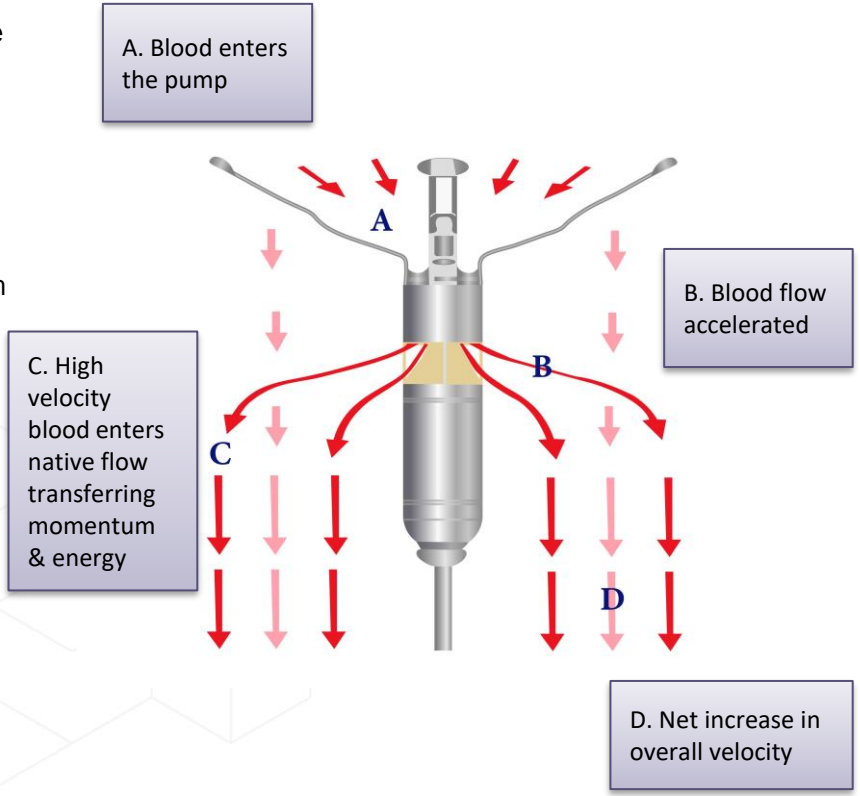
Do Not Code Insertion & Removal When:

- The device is inserted and removed (due to inadequate size, breakage etc.) but a different device is successfully placed before the end of the operative episode then the original intent of the procedure is achieved and the appropriate root operation is assigned.
- This is supported in the 3rd Q 22022 (p.21) when an intervertebral cage device was inserted and removed twice due to breakage on insertion. However, a third titanium interbody body cage was successfully placed without incident. In this case the appropriate fusion code was assigned.

FY 2024 ICD-10-PCS Updates: Medical & Surgical Updates

Insertion of Percutaneous Mechanical Circulatory Support Device into Thoracic Aorta

- For patients with chronic, stable heart failure (HF) there are multiple pharmacologic and device-based treatment options. However, for patients with acute decompensated heart failure (ADHF), many medical therapies have been tested in this patient population without success.
- Aortix™ is a percutaneous mechanical circulatory support (pMCS) device positioned in the thoracic aorta designed to treat acute decompensated heart failure patients who are currently treated with medication and unresponsive to medication alone.
- The Aortix™ percutaneous mechanical circulatory support device is utilized in the inpatient setting and is typically implanted in the cardiac catheterization lab/O.R., is used for up to 7 days, and subsequently removed in the cardiac catheterization lab/O.R.
- The pump body includes the motor, the rotor assembly (impeller) and the struts for localizing and centering the pump in the aorta.
- By boosting blood flow in the aorta and reducing aortic root pressure, the Aortix device could reduce the effective systemic vascular resistance the heart pumps against, in turn allowing the heart to work better (increased ejection fraction and cardiac output) and more efficiently (lower energy and oxygen use).



Medical & Surgical Section

Section	0 Medical and Surgical
Body System	2 Heart and Great Vessels
Operation	H Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	Approach	Device	Qualifier
W Thoracic Aorta, Descending	3 Percutaneous	0 Monitoring Device, Pressure Sensor 2 Monitoring Device 3 Infusion Device D Intraluminal Device R Short-term External Heart Assist System Y Other Device	Z No Qualifier

Medical & Surgical Section

Section	0 Medical and Surgical
Body System	2 Heart and Great Vessels
Operation	P Removal: Taking out or off a device from a body part

Body Part	Approach	Device	Qualifier
W Thoracic Aorta, Descending	3 Percutaneous	R Short-term External Heart Assist System	Z No Qualifier

Medical & Surgical Section

Section	0 Medical and Surgical
Body System	2 Heart and Great Vessels
Operation	W Revision: Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device

Body Part	Approach	Device	Qualifier
W Thoracic Aorta, Descending	3 Percutaneous	R Short-term External Heart Assist System	Z No Qualifier

Medical & Surgical Section

Section	0 Medical and Surgical
Body System	C Mouth and Throat
Operation	S Reposition: Moving to its normal location, or other suitable location, all or a portion of a body part

Body Part	Approach	Device	Qualifier
R Epiglottis S Larynx T Vocal Cord, Right V Vocal Cord, Left	0 Open 7 Via Natural or Artificial Opening 8 Via Natural or Artificial Opening Endoscopic	Z No Device	Z No Qualifier

Body part value S Larynx added to identify procedures such as the repositioning of thyroid cartilage.

Medical & Surgical Section

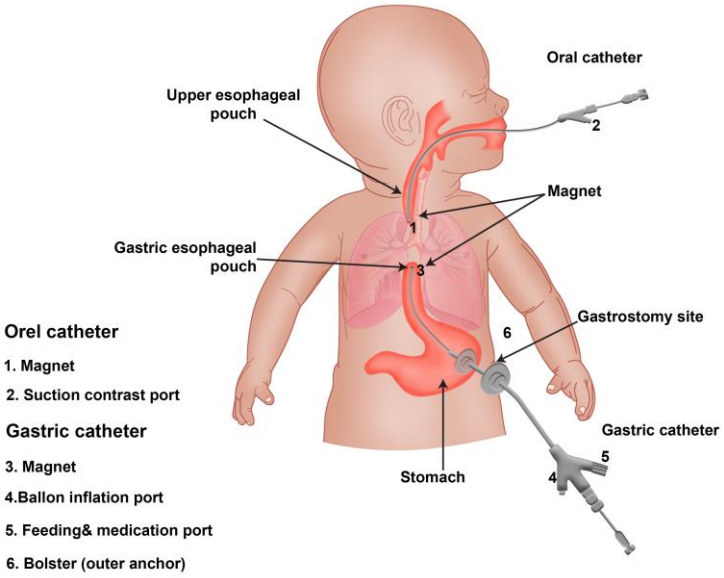
Section	0 Medical and Surgical
Body System	D Gastrointestinal System
Operation	H Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	Approach	Device	Qualifier
1 Esophagus, Upper 2 Esophagus, Middle 3 Esophagus, Lower	7 Via Natural or Artificial Opening	J Magnetic Lengthening Device	Z No Qualifier

- There are currently no unique ICD-10-PCS codes to describe insertion of magnetic devices for non-surgical lengthening of the esophagus.
- Esophageal atresia (EA) is a medical condition in which an infant is born with an upper esophagus that ends in a pouch rather than connecting normally to the stomach, resulting in the inability for food to pass from the mouth to the stomach. The condition can also lead to the accumulation of saliva in the upper pouch. One or more fistulae may occur between the malformed esophagus and the trachea.

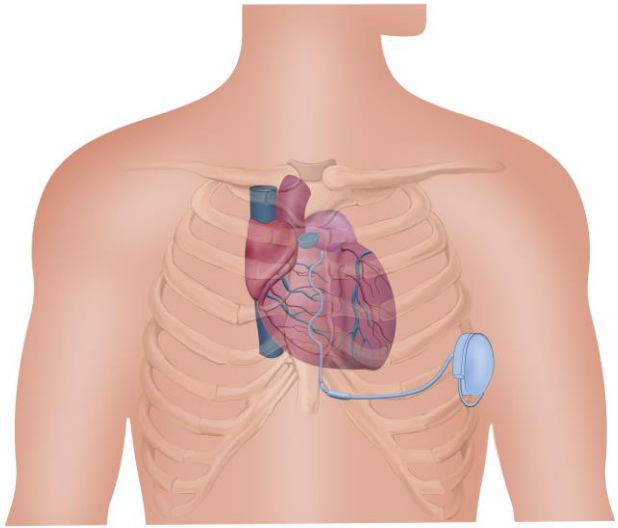
Insertion of Lengthening Device for Esophageal Atresia

- In eligible candidates for the Flourish® device, the distance between the atretic segments is assessed under fluoroscopy using radiopaque flexible catheters and metal probes.
- After identification of the pouches, the oral/esophageal catheter is inserted orally and advanced until the magnet is located at the distal end of the upper pouch. The gastric catheter is inserted over a wire guide, under fluoroscopy through a mature stoma and advanced until the magnet is located at the distal end of the lower pouch.
- Daily biplane chest radiographs are taken to assess the distance between magnets. Once approximated, the surrounding tissues grow together while the tissue between the magnets undergoes necrosis, causing development of an anastomosis, thereby creating a connected passage from mouth to stomach.
- The Flourish® device is used in the inpatient setting only, as patients must be interned throughout the indwelling days. Use of the device will be dictated into the procedure section of the operative notes in the medical record



Extravascular Implantable Defibrillator Leads

- Extravascular implantable defibrillator leads (EV ICD) are an alternative to transvenous leads and subcutaneous leads.
- Rather than being situated in the heart or in subcutaneous tissue to the side of the sternum, EV leads are placed in the anterior mediastinum against the underside of the sternum.
- For this reason, EV leads are also sometimes referred to as substernal leads.



Medical & Surgical Section

Section	0 Medical and Surgical
Body System	W Anatomical Regions, General
Operation	H Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	Approach	Device	Qualifier
C Mediastinum	0 Open 3 Percutaneous 4 Percutaneous Endoscopic	1 Radioactive Element 3 Infusion Device G Defibrillator Lead Y Other Device	Z No Qualifier

Medical & Surgical Section

Section	0 Medical and Surgical
Body System	W Anatomical Regions, General
Operation	P Removal: Taking out or off a device from a body part

Body Part	Approach	Device	Qualifier
C Mediastinum	0 Open 3 Percutaneous 4 Percutaneous Endoscopic X External	0 Drainage Device 1 Radioactive Element 3 Infusion Device 7 Autologous Tissue Substitute G Defibrillator Lead J Synthetic Substitute K Non-autologous Tissue Substitute Y Other Device	Z No Qualifier

Medical & Surgical Section

Section	0 Medical and Surgical
Body System	W Anatomical Regions, General
Operation	W Revision: Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device

Body Part	Approach	Device	Qualifier
C Mediastinum	0 Open 3 Percutaneous 4 Percutaneous Endoscopic X External	0 Drainage Device 1 Radioactive Element 3 Infusion Device 7 Autologous Tissue Substitute G Defibrillator Lead J Synthetic Substitute K Non-autologous Tissue Substitute Y Other Device	Z No Qualifier

FY 2024 ICD-10-PCS Updates: Extracorporeal or Systemic Assistance & Performance Section Updates

Extracorporeal or Systemic Assistance & Performance Section

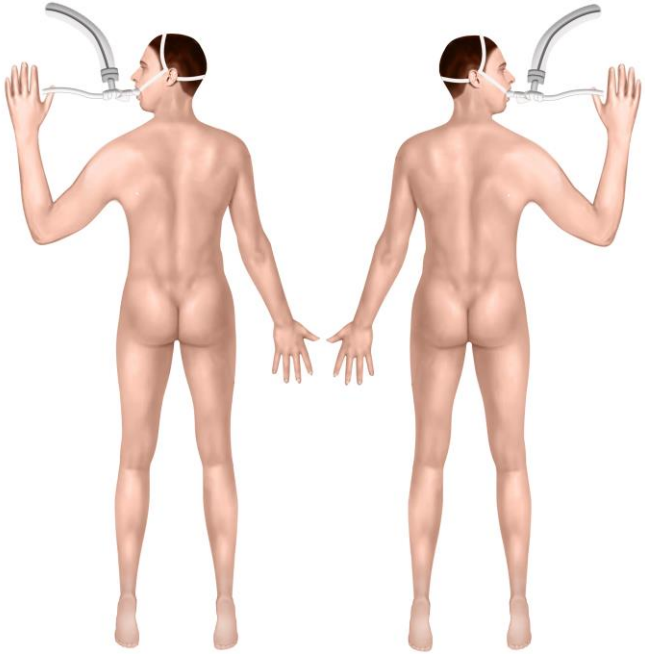
Section	5 Extracorporeal or Systemic Assistance and Performance
Body System	A Physiological Systems Operation 0 Assistance: Taking over
Operation	0 Assistance: Taking over a portion of a physiological function by extracorporeal means

Body System	Duration	Function	Qualifier
9 Respiratory	B Less than 8 Consecutive Hours C 8-24 Consecutive Hours D Greater than 24 Consecutive Hours	5 Ventilation	K Intubated Prone Positioning

Prone positioning has been shown to be beneficial in patients with moderate-to-severe acute respiratory distress syndrome (ARDS), which is a common form of acute respiratory failure in critically ill patients with high mortality.

Prone Position for Intubated Patients

- Prone positioning is the coordinated turning of a patient from lying on the back (supine position) to the chest (prone position) by a team of skilled healthcare providers. Because patients with moderate-to severe ARDS are dependent on a mechanical ventilator and often simultaneously connected to multiple life-sustaining tubes, catheters, and monitors, several preparatory steps are needed to prevent accidental dislodgement of the endotracheal tube, catheters and lines.
- In the proned position, the weight of the heart, abdomen, and chest wall are shifted off the lungs, and the mechanics of the diaphragm and rib cage are altered. As such, lung compression is relieved and alveolar ventilation is distributed more equally across the lung, improving oxygenation.



FY 2024 ICD-10-PCS Updates: Other Procedures Section Updates

Extracorporeal or Systemic Assistance & Performance Section

Section	8 Other Procedures
Body System	E Physiological Systems and Anatomical Regions
Operation	0 Other Procedures: Methodologies which attempt to remediate or cure a disorder or disease

Body Region	Approach	Method	Qualifier
U Female Reproductive System	0 Open 3 Percutaneous 4 Percutaneous Endoscopic 7 Via Natural or Artificial Opening 8 Via Natural or Artificial Opening Endoscopic	E Fluorescence Guided Procedure	N Pafolacianine
W Trunk Region	0 Open 3 Percutaneous 4 Percutaneous Endoscopic 7 Via Natural or Artificial Opening 8 Via Natural or Artificial Opening Endoscopic	E Fluorescence Guided Procedure	N Pafolacianine Z No Qualifier

- Create new qualifier value N Pafolacianine applied to existing body region value W Trunk Region for the lung indication and add new body region value U Female Reproductive System for the ovarian indication, applied to existing method value E Fluorescence Guided Procedure and to all available approach values, to identify the fluorescence guided surgery using pafolacianine.
- CYTALUX® (pafolacianine)illuminates, making cancer visible within the surgical field.
- Facilities would also report the appropriate code(s) for any lesion(s) excised.

FY 2024 ICD-10-PCS Updates: New Technology

New Technology

Section	X New Technology
Body System	0 Nervous System
Operation	5 Destruction: Physical eradication of all or a portion of a body part by the direct use of energy, force, or a destructive agent

Body Part	Approach	Device/Substance/Technology	Qualifier
1 Renal Sympathetic Nerve(s)	3 Percutaneous	2 Ultrasound Ablation	9 New Technology Group

- Renal sympathetic efferent and afferent nerves, which lie adjacent to the wall of the renal artery, are crucial for production of catecholamines which contribute to hypertension.
- The Paradise™ Ultrasound Renal Denervation System is intended to reduce blood pressure by treating the overactive renal sympathetic nerves.
- The Paradise™ Ultrasound Renal Denervation System is an endovascular catheter-based system indicated to reduce blood pressure in adult patients 22 years of age and older with uncontrolled hypertension, who may be inadequately responsive to, or who are intolerant to anti-hypertensive medications. The goal of the procedure is to achieve a reduction in systemic arterial blood pressure by using a minimally invasive procedure to treat overactive renal nerves with ultrasound energy.

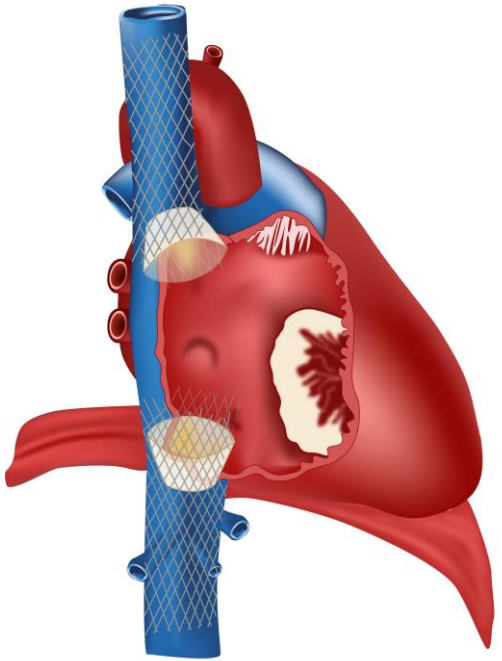
New Technology

Section	X New Technology
Body System	2 Cardiovascular System
Operation	H Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	Approach	Device/Substance/Technology	Qualifier
0 Inferior Vena Cava 1 Superior Vena Cava	3 Percutaneous	R Intraluminal Device, Bioprosthetic Valve	9 New Technology Group
2 Femoral Vein, Right 3 Femoral Vein, Left	0 Open	R Intraluminal Device, Bioprosthetic Valve	9 New Technology Group
6 Atrium, Right K Ventricle, Right	3 Percutaneous	V Intracardiac Pacemaker, Dual-Chamber	9 New Technology Group
L Axillary Artery, Right M Axillary Artery, Left X Thoracic Aorta, Ascending	0 Open	F Conduit to Short-term External Heart Assist System	9 New Technology Group

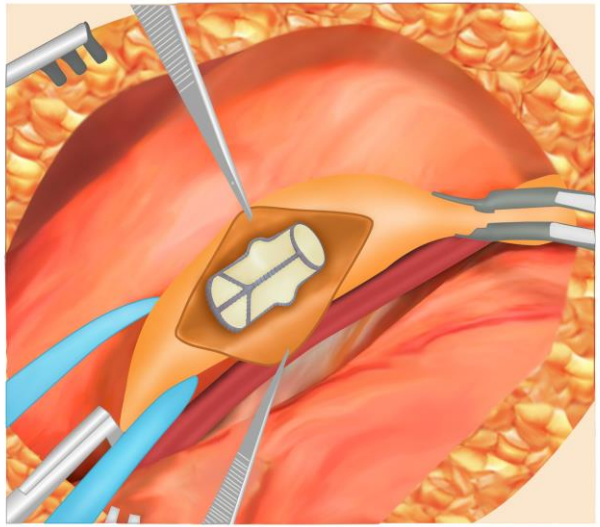
Transcatheter Bicaval Valve System

- The TricValve® Transcatheter Bicaval Valve System is a bicaval transcatheter tricuspid valve implantation system, which includes the TricValve® Transcatheter Bicaval Valve for heterotopic placement of a Superior Vena Cava (SVC) valve and for an Inferior Vena Cava (IVC) valve.
- Tricuspid regurgitation (TR) is a condition that occurs as a consequence of malcoaptation of the tricuspid valve leaflets. This results in retrograde blood flow to the right atrium and subsequent loss of forward flow into the right ventricle.



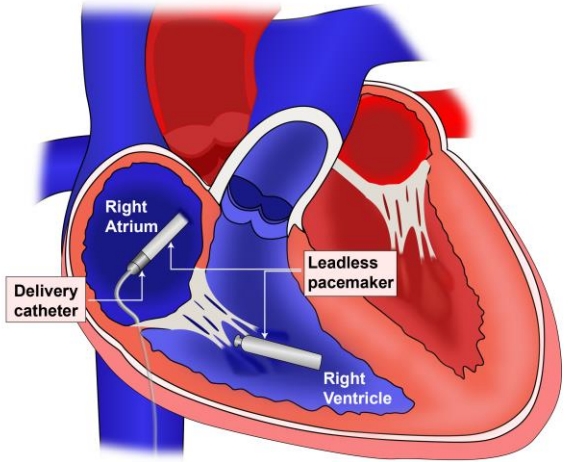
Implantation of Bioprosthetic Femoral Venous Valves

- There are no unique ICD-10-PCS codes to describe the implantation of a bioprosthetic femoral venous valve for chronic venous insufficiency.
- VenoValve® was granted Breakthrough Device Designation on August 3, 2021 as a treatment for chronic venous insufficiency (CVI). VenoValve® is currently under review by the FDA for Premarket Approval
- The veins of your leg do not function properly, causing blood to flow backwards and pool in the lower leg, leading to elevated venous pressure inside the leg veins.
- The purpose of the SAVVE study is to determine whether the VenoValve is a safe and effective treatment for patients with severe, deep venous CVI.
- The VenoValve® is a single use device that is permanently implanted in the femoral vein via an open surgical approach for the treatment of patients with deep venous CVI.



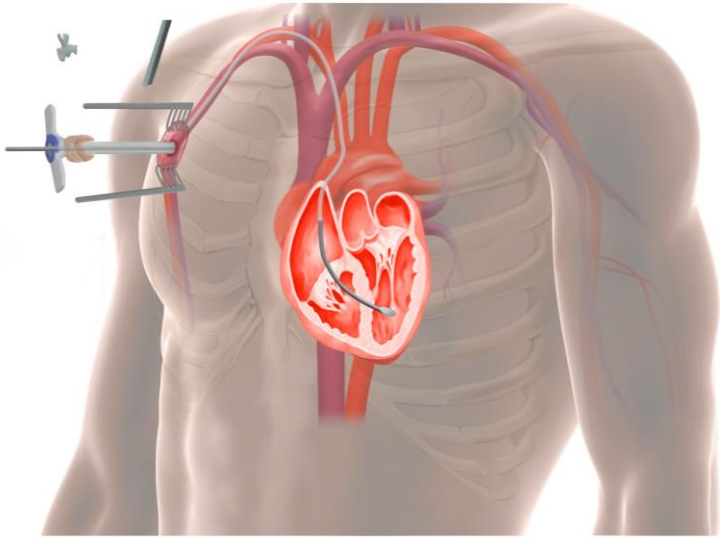
Insertion of a Dual-Chamber Leadless Cardiac Pacemaker

- There are currently no unique ICD-10-PCS codes to describe the percutaneous insertion of a dual-chamber leadless pacemaker or a right atrium leadless pacemaker.
- The atrial and dual-chamber leadless pacemaker systems have received Breakthrough Device Designation from the FDA.
- The Aveir™ leadless system is a modular programmable system that consists of implanted pacemaker devices that are placed within the myocardium and paces the heart without the need for traditional “wired” leads.
- Each leadless pacemaker is delivered to the target heart chamber (right atrial and right ventricular) percutaneously via the femoral vein.



Insertion of a Short-term External heart Assist System with Conduit

- The Impella® 5.5 with SmartAssist® System is a temporary ventricular support device intended for short-term use and is indicated for the treatment of ongoing cardiogenic shock that occurs immediately (< 48 hours) following acute myocardial infarction or following open-heart surgery.
- The Impella® 5.5 with SmartAssist® surgical pump can be inserted either into the ascending aorta through an open chest approach (median sternotomy or anterior thoracotomy) or through an infraclavicular surgical incision into the axillary artery. In the axillary approach, the axillary artery is exposed and isolated from the surrounding structures. A surgical graft conduit is anastomosed to the axillary artery by a surgeon in the operating room. When an axillary artery or ascending thoracic aorta conduit is inserted for the short-term external heart assist device, a separate code is assigned to report the insertion of the external heart assist system.
- While the Impella® 5.5 with SmartAssist® is typically implanted as a standalone procedure, there are some instances when the patient requires right heart support during the same operative procedure; in those cases, a device may be inserted to support the right ventricle. The Impella® 5.5 surgical heart pump is not considered permanent and is removed prior to discharge from the hospital.



New Technology

Section	X New Technology
Body System	2 Cardiovascular System
Operation	U Supplement: Putting in or on biological or synthetic material that physically reinforces and/or augments the function of a portion of a body part

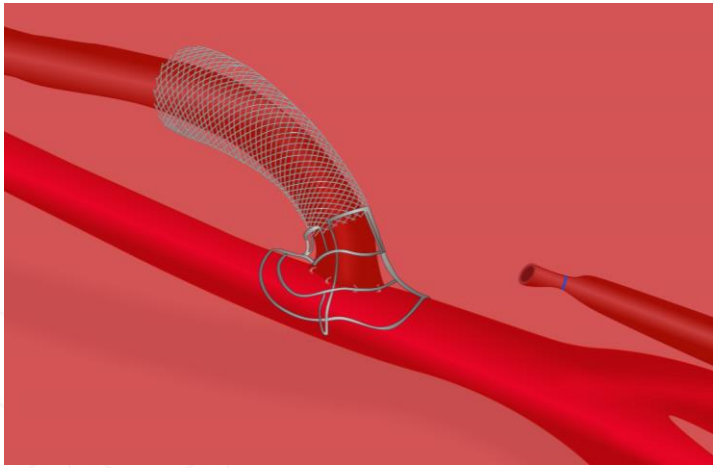
Body Part	Approach	Device/Substance/Technology	Qualifier
4 Coronary Artery/Arteries	0 Open	7 Vein Graft Extraluminal Support Device(s	9 New Technology Group
Q Upper Extremity Vein, Right R Upper Extremity Vein, Left	0 Open	P Synthetic Substitute, Extraluminal Support Device	9 New Technology Group

Extraluminal Vein Graft Support During Coronary Artery Bypass Grafting

- Saphenous vein grafts (SVG) are the most frequently used bypass conduits in CABG surgery. SVG disease, early after CABG, is typically dominated by intimal hyperplasia which predisposes the graft to accelerated atherosclerosis.
- Arterial pressure coupled with abnormal flow patterns generated mainly by luminal irregularities is the main contributor to both focal and diffuse intimal hyperplasia. However, despite major advances in surgical techniques and perioperative care, vein grafts continue to have high failure rates, limiting the long-term outcome of CABG. SVG failure rates range from 35% to 50% 5 to 10 years following CABG surgery.
- VEST™ is a novel, first of its kind, external support device which can be fitted over the saphenous vein bypass conduit in CABG surgery.
- 22% **REDUCTION** IN INTIMAL HYPERPLASIA*
  18% **REDUCTION** IN LUMEN IRREGULARITIES*
  42% **REDUCTION** IN ISCHEMIC DRIVEN REVASCULARIZATION*

Extraluminal Support Device During Arteriovenous Fistula Creation

- VasQ™ External Support, was designed to address the high rate of primary fistula failure and repeat procedures experienced by hemodialysis patients.
- The VasQ device is a subcutaneous arteriovenous conduit for vascular access. It is an external support of conduits for brachiocephalic or radiocephalic AVF only.
- The device has no contact with the blood circulation and no suturing to the blood vessel.



The device addresses the root causes of AVF failure:

- Turbulent flow
- Increased venous wall tension that may lead to stenosis and thrombosis
- It has proved safe and effective in human cases and can reduce medical costs and hospital stays.

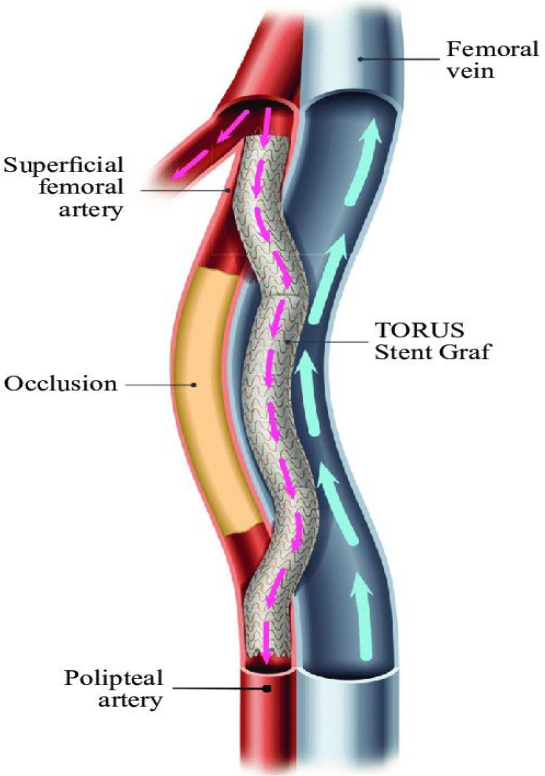
New Technology

Section	X New Technology
Body System	2 Cardiovascular System
Operation	K Bypass: Altering the route of passage of the contents of a tubular body part

Body Part	Approach	Device/Substance/Technology	Qualifier
H Femoral Artery, Right J Femoral Artery, Left	3 Percutaneous	D Conduit through Femoral Vein to Superficial Femoral Artery E Conduit through Femoral Vein to Popliteal Artery	9 New Technology Group

- There are currently no unique ICD-10-PCS codes to describe percutaneous femoral-popliteal artery bypass using a conduit through the femoral vein.
- The ENDOCROSS® Device and the TORUS™ Stent Graft Delivery System are used to create two arteriovenous anastomoses (superficial femoral artery into the femoral vein, and femoral vein into the popliteal artery) by delivering a guidewire from the arterial segment, proximal to the target lesion, through the femoral vein and back into the artery distal to the target lesion

Percutaneous Femoral-Popliteal Artery Bypass with Conduit Through the Femoral Vein



New Technology

Section	X New Technology
Body System	N Bones
Operation	H Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	Approach	Device/Substance/Technology	Qualifier
G Tibia, Right H Tibia, Left	0 Open	F Tibial Extension with Motion Sensors	9 New Technology Group 9

- The Canturio™ tibial extension is implanted to increase the stability of the tibial plate
- Canturio™ embedded highly accurate sensors precisely measure the knee's motion, allowing the surgeon to monitor how a patient's mobility is changing
  - Counts patient steps
  - Measures range of motion and stride length
  - Tracks walking speed
  - Monitors gait quality

New Technology

Section	X New Technology
Body System	N Bones
Operation	R Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part

Body Part	Approach	Device/Substance/Technology	Qualifier
8 Skull	0 Open	D Synthetic Substitute, Ultrasound Penetrable	9 New Technology Group 9
L Tarsal, Right M Tarsal, Left	0 Open	9 Synthetic Substitute, Talar Prosthesis	9 New Technology Group 9

Ultrasound Penetrable Cranioplasty Plates - ClearFit® PMMA cranioplasty implants enable bedside non-invasive, real-time, post-surgical monitoring of neurosurgery patients. ClearFit® Sonolucent Implants enable enhanced diagnostic applications previously limited by cranial bone

Total Talar Prosthesis with Total Ankle Replacement

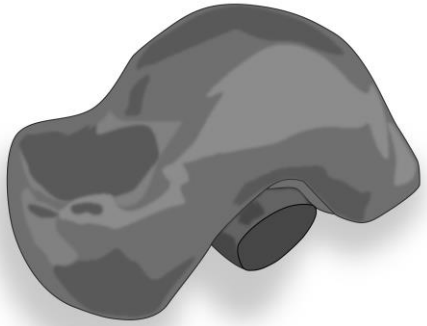
Key Features & Benefits

1. Talar dome mates to ankle replacement

- Allows for implantation with ankle replacement tibial components
- Can be deployed concurrently with ankle replacements or retroactively as part of an ankle replacement revision
- Preserves ankle joint motion

2. Talar body & head mate to native anatomical structures

- Preserves talocalcaneal and talonavicular joint motion
- Volume is patient -matched 4WEB Medical Total Ankle Talar ReplacementTM.



New Technology

Section X New Technology
Body System R Joints
Operation G Fusion: Joining together portions of an articular body part rendering the articular body part immobile

Body Part	Approach	Device/Substance/Technology	Qualifier
A Thoracolumbar Vertebral Joint B Lumbar Vertebral Joint C Lumbar Vertebral Joints, 2 or more D Lumbosacral Joint	0 Open 3 Percutaneous 4 Percutaneous Endoscopic	~~R Interbody Fusion Device, Customizable~~ R Interbody Fusion Device, Custom-Made Anatomically Designed	7 New Technology Group 7
J Ankle Joint, Right K Ankle Joint, Left L Tarsal Joint, Right M Tarsal Joint, Left	0 Open	B Internal Fixation Device, Open-truss Design	9 New Technology Group 9

Revise the device/substance/technology value from Interbody Fusion Device, Customizable to Interbody Fusion Device, Custom-Made Anatomically Designed. This change request is from the manufacturer to help minimize misinterpretation of the term “customizable”.

Implantation of Open-Truss Ankle Fusion Device

- The 4WEB® Ankle Truss System™ (ATS) is a single, permanent device implanted via an open surgical procedure.

<u>Open truss architecture</u>

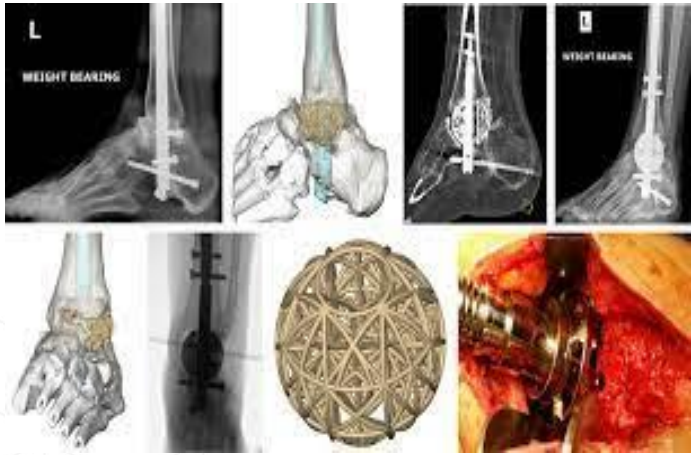
- Allows for osteogenic ingrowth across the defect area
- Preserves limb length

<u>Device geometries</u>

- Flexibility of device shapes (e.g., ArthroSphereTM and ArthroBlockTM) fill various bone defect shapes and sizes
- Volume is scaled for a patient -matched fit

<u>To be used in conjunction with nail fixation</u>

- • Central hole allows use of nail for fixation of the Ankle Truss SystemTM
- • Supports the nail intended use, as an accessory, to address bony defects



New Technology

Section	X New Technology
Body System	V Male Reproductive System
Operation	5 Destruction: Physical eradication of all or a portion of a body part by the direct use of energy, force, or a destructive agent

Body Part	Approach	Device/Substance/Technology	Qualifier
~~0 Prostate~~	~~8 Via Natural or Artificial Opening Endoscopic~~	~~A Robotic Waterjet Ablation~~	~~4 New Technology Group 4~~

This table was deleted.

New Technology

Section	X New Technology
Body System	W Anatomical Regions
Operation	0 Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products

Body Part	Approach	Device/Substance/Technology	Qualifier
0 Skin	X External	~~2 Bromelain-enriched Proteolytic Enzyme~~ 2 Anacaulase-bcdb	7 New Technology Group 7
1 Subcutaneous Tissue	X External	~~2 Bromelain-enriched Proteolytic Enzyme~~ 2 Anacaulase-bcdb	7 New Technology Group 7

Revise the device/substance/technology value from Bromelain-enriched Proteolytic Enzyme to Anacaulase-bcdb. This change request is from the manufacturer and reflects the final generic name of the drug.

New Technology

Section	X New Technology
Body System	W Anatomical Regions
Operation	0 Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products

Body Part	Approach	Device/Substance/Technology	Qualifier
1 Subcutaneous Tissue	3 Percutaneous	L Elranatamab Antineoplastic	9 New Technology Group 9
1 Subcutaneous Tissue	3 Percutaneous	S Epcoritamab Monoclonal Antibody	9 New Technology Group 9
3 Peripheral Vein 4 Central Vein	3 Percutaneous	K Sulbactam-Durlobactam	9 New Technology Group 9
3 Peripheral Vein 4 Central Vein	3 Percutaneous	P Glofitamab Antineoplastic	9 New Technology Group 9
3 Peripheral Vein 4 Central Vein	3 Percutaneous	Q Posoleucel R Rezafungin	9 New Technology Group 9

New Technology

- Elranatamab - Treatment of relapsed and refractory multiple myeloma (RRMM) constitutes a specific unmet medical need. Patients with relapsed and refractory disease are defined as those who, having achieved a minimal response or better, experience disease progression while on therapy, or experience disease progression within 60 days of completion of their last therapy. Elranatamab offers a new mechanism of action for the treatment of RRMM.
- Epcoritamab - pcoritamab-bysp is approved to treat adults with: Diffuse large B-cell lymphoma (DLBCL) or high-grade B-cell lymphoma that has relapsed (come back) or did not get better after at least two other systemic therapies.
- Sulbactam-Durlobactam - Acinetobacter baumannii (A. baumannii) is a Gram-negative bacterial pathogen that has emerged globally as a major cause of hospital-acquired infections. s. Sulbactam is a penicillin derivative and classified as a beta-lactamase inhibitor but also has intrinsic antibacterial activity against Acinetobacter baumannii. Durlobactam effectively restores sulbactam activity against ABC organisms due to its potent inhibition of serine β-lactamases.
- Glofitamab - Diffuse large B-cell lymphoma (DLBCL), the most common form of non-Hodgkin Lymphoma (NHL), involves the malignant proliferation of B lymphocytes or B cells during different stages of development, often resulting in rapidly growing and spreading masses in the lymph nodes. Glofitamab is a novel T-cell engaging bispecific antibody that activates the patient's own immune system to eradicate malignant B cells.
- Posoleucel - Posoleucel is a polyclonal multi virus-specific T cell (VST) product that recognizes and eradicates actively replicating virus-infected cells. These cells are currently being evaluated for the treatment of viral infections in adults and children after allogeneic hematopoietic stem cell transplants (HSCT).
- Rezafungin - Candidemia and invasive candidiasis are rare, serious, and life-threatening infections. Rezafungin is an echinocandin, a class of antifungal drugs that inhibits the synthesis of 1,3-beta-D-glucan, an essential component of fungal cell walls.

Extracorporeal or Systemic Assistance & Performance Section

Section	X New Technology
Body System	W Anatomical Regions
Operation	0 Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products

Body Part	Approach	Device/Substance/Technology	Qualifier
5 Peripheral Artery	3 Percutaneous	T Melphalan Hydrochloride Antineoplastic	9 New Technology Group 9
D Mouth and Pharynx	X External	J Quizartinib Antineoplastic	9 New Technology Group 9
D Mouth and Pharynx	X External	N SER-109	9 New Technology Group 9

- Melphalan Hydrochloride - The HEPZATO™ KIT (melphalan hydrochloride/Hepatic Delivery System) is a drug/device combination intended for the treatment of patients with unresectable primary and metastatic tumors in the liver.
- Quizartinib - AML is a rapidly growing type of blood cancer in which immature bone marrow cells are overproduced and accumulate in bone marrow and other tissues. Quizartinib is a novel kinase inhibitor with a proposed indication in combination with standard cytarabine and anthracycline induction and standard cytarabine consolidation chemotherapy, and as continuation monotherapy following consolidation
- SER-109 - C. diff is the leading cause of hospital-acquired infections (HAIs) in the United States, and is connected with over 20,000 deaths. SER-109, an investigational microbiome therapeutic, is a consortium of purified Firmicutes bacteria spores administered to prevent recurrent C. diff infection. SER-109 prevents recurrent CDI by repairing the microbiome by replenishing Firmicutes bacteria.

Extracorporeal or Systemic Assistance & Performance Section

Section	X New Technology
Body System	W Anatomical Regions
Operation	1 Transfusion: Putting in blood or blood products

Body Part	Approach	Device/Substance/Technology	Qualifier
3 Peripheral Vein	3 Percutaneous	F OTL-103 G OTL-200 ~~J Exagamglogene Autotemcel~~	8 New Technology Group 8
3 Peripheral Vein	3 Percutaneous	H Lovotibeglogene Autotemcel	9 New Technology Group 9
4 Central Vein	3 Percutaneous	F OTL-103 G OTL-200 ~~J Exagamglogene Autotemcel~~	8 New Technology Group 8
4 Central Vein	3 Percutaneous	H Lovotibeglogene Autotemcel	9 New Technology Group 9

Lovotibeglogene autotemcel (lovo-cel) gene therapy is an investigational one-time treatment being studied for sickle cell disease (SCD),

Extracorporeal or Systemic Assistance & Performance Section

Section X New Technology

Body System X Physiological Systems

Operation 2 Monitoring: Determining the level of a physiological or physical function repetitively over a period of time Anatomical Regions

Body Part	Approach	Device/Substance/Technology	Qualifier
0 Central Nervous	X External	8 Brain Electrical Activity, Computer-aided Detection and Notification	9 New Technology Group 9
F Musculoskeletal	3 Percutaneous	W Muscle Compartment Pressure, Micro-Electro-Mechanical System	9 New Technology Group 9

- Brain Electrical Activity, Computer-aided Detection and Notification - The Ceribell® Delirium Monitor is a medical device system consisting of a single-use patient headband, bedside recorder, and proprietary software that utilizes a machine learning model to analyze EEG signals to detect delirium and guide caregiving decisions.
- Muscle Compartment Pressure, Micro-Electro-Mechanical System - The MY01 Continuous Compartmental Pressure Monitor is used for real-time and continuous measurement of muscle compartment pressure

New Technology

Section	X New Technology
Body System	X Physiological Systems
Operation	E Measurement: Determining the level of a physiological or physical function at a point in time

Body Part	Approach	Device/Substance/Technology	Qualifier
2 Cardiac	X External	1 Output, Computer-aided Assessment	9 New Technology Group 9
5 Circulatory	X External	Y Infection, Other Positive Blood/Isolated Colonies Bimodal Phenotypic Susceptibility Technology	9 New Technology Group 9

- **Output, Computer-aided Assessment** - Heart failure affects over 6 million adults in the United States according to the CDC. EchoGo Heart Failure 1.0 is an automated machine learning-based decision support system, indicated as a diagnostic aid for adult patients over 25 years of age undergoing routine functional cardiovascular assessment using echocardiography.
- **Infection, Other Positive Blood/Isolated Colonies Bimodal Phenotypic Susceptibility Technology** - The Selux Rapid AST Platform is a phenotypic antimicrobial susceptibility testing (AST) system, intended to assist medical professionals in the identification of in vitro susceptibility or resistance to specific antimicrobial agents.

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