



**Plié® 3 MPC Knee
CMS Numerical Coding
Recommendations and Justifications**



Freedom Innovations

Plié 3 MPC Knee– Coding Recommendations and Justifications

Product Overview

The enhanced Plié MPC Knee is a single axis prosthetic knee joint system that provides hydraulic control of both the swing and the stance phase of gait. The swing and stance phase control is assisted by sophisticated in-frame load cells and a position sensor that provides data for the microprocessor, which determines when to send a message to enable a modification to fluid management system resulting in an appropriate torque about the knee center necessary for both swing and stance phase of gait. Previously, the knee did not incorporate a position sensor and could only utilize data sent to the microprocessor during stance phase. Advanced software has been developed and incorporated to allow adjustment for each user's walking style and personal preferences. Both the swing flexion and stance extension adjustments are independently optimized. The hydraulic cylinder is also capable of providing stance flexion for level ground walking as well as stair and ramp descent. Stance extension has been engineered into the hydraulic cylinders capabilities as well. An extension assist is also incorporated into the design to compliment the amputee's hip extension movement and reduce effort to extend the shank. Finally, a removable Lithium Ion battery is utilized as the power source for the knee and each knee will come complete with two batteries and a charger.

When properly aligned and programmed the system will enable above knee lower limb amputees to ambulate more confidently and over a wider array of surfaces, including ramps and stairs. The Plié MPC Knee is recommended for a broad spectrum of lower limb amputees including transfemoral, knee disarticulation, hip disarticulation and bilateral amputees. The knee is recommended for lower limb amputees weighing less than 125 kg [275 lb].



Recommended CMS Numerical Coding & Descriptors for the Plié MPC Knee

<u>L Code</u>	<u>Description</u>
L5828	Endoskeletal knee shin system, single axis, fluid swing and stance phase control.
L5845	Endoskeletal knee shin hydraulic stance flexion feature, adjustable.
L5848	Endoskeletal knee shin hydraulic stance extension, dampening feature with or without adjustability.
L5856	Endoskeletal knee shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type



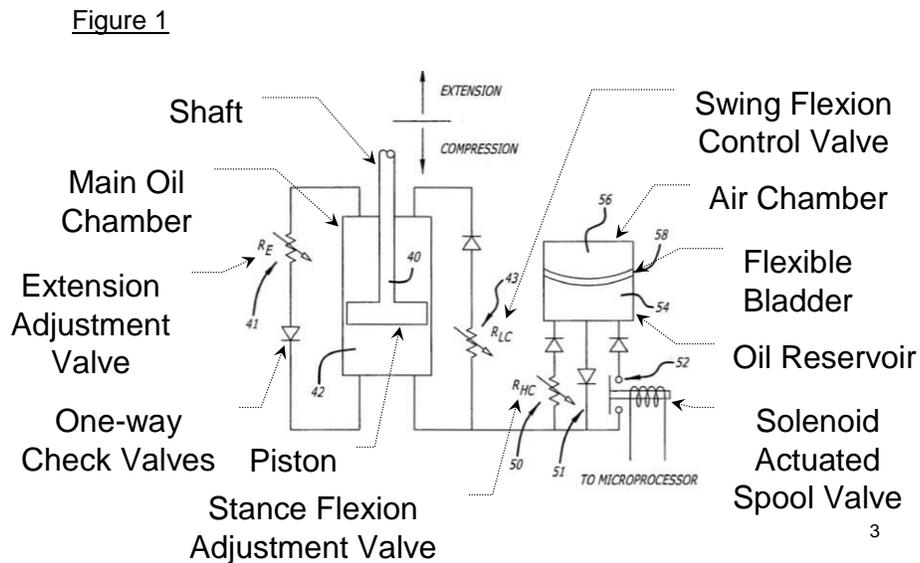
Individual CMS Recommended Codes, Explanation and Rationale

Code

L5828 Endoskeletal knee shin system, single axis, fluid swing and stance phase control.

Explanation & Rationale

Figure 1 is the schematic diagram of the hydraulic cylinder taken from our patent application. It is the easiest way to see how all of the parts of the hydraulic cylinder work together to achieve the desired performance. For reference, the cylinder is compressed when the knee is flexed and is extended when the knee is extended. The cylinder has a main oil chamber where the piston is located. As the shaft moves into the main oil chamber during compression of the cylinder, it displaces oil. Since the oil is an incompressible fluid, the oil displaced by the shaft must have somewhere to go. That's why the cylinder has an oil reservoir adjacent to the main oil chamber. The majority of the flow during compression goes through the swing flexion control valve. The stance flexion adjustment valve meters the flow of oil from the main oil chamber to the reservoir. During extension, all of the flow goes through the extension adjustment valve. The little triangle symbols represent one-way check valves. These valves allow flow in the direction the triangle is pointing and prevent flow in the opposite direction.



Code

L5845 Endoskeletal knee shin hydraulic stance flexion feature, adjustable.

Explanation & Rationale

When the microprocessor has identified that the wearer is still in stance and flexing the knee the majority of the flow during compression goes through the swing flexion control valve (Figure 2). The stance flexion valve is adjusted during ambulation to identify the appropriate amount of resistance for stance flexion during level ground walking and ramp descent. Figure 3 is representative of an individual utilizing the stance flexion capabilities of the product.

Figure 2

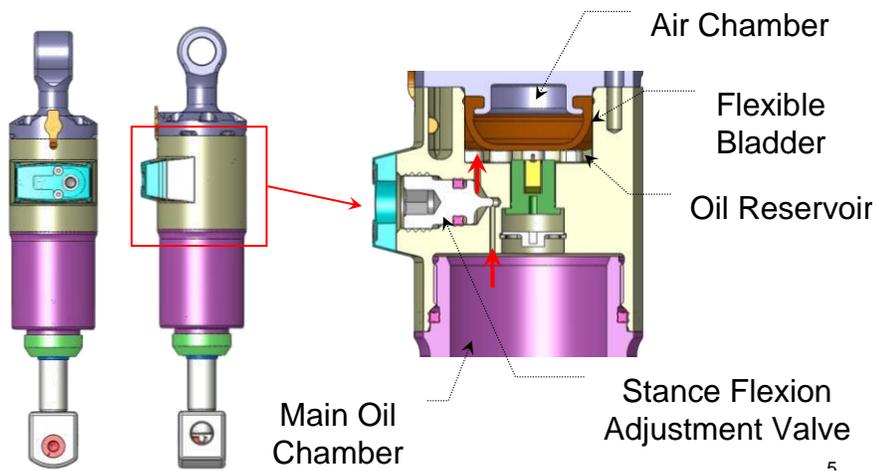
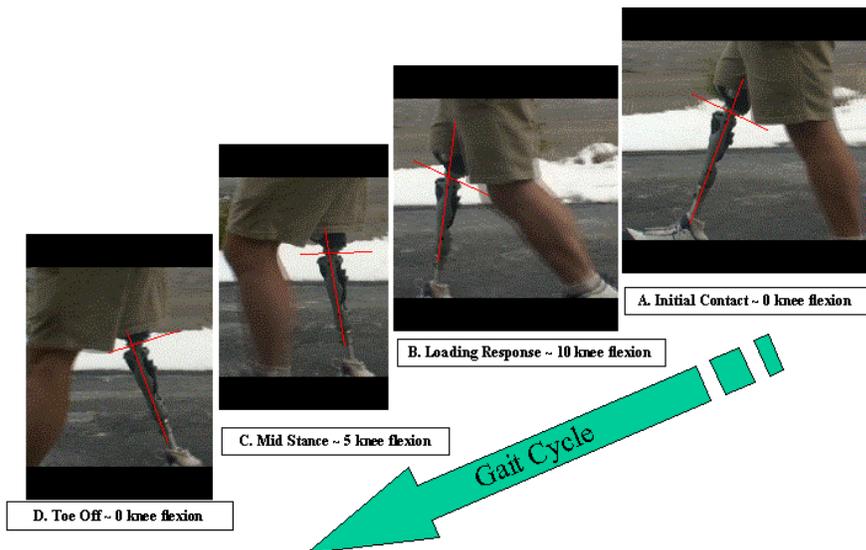


Figure 3



Stance Phase with the Plié MPC Knee

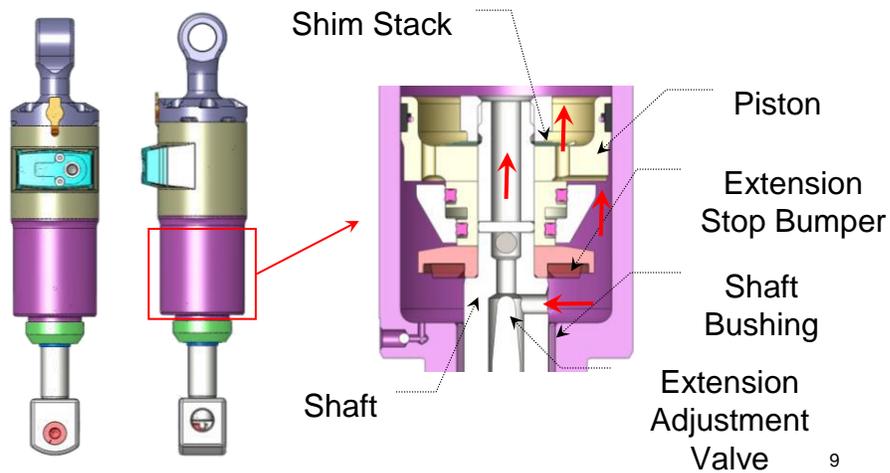
Code

L5848 Endoskeletal knee shin hydraulic stance extension, dampening feature with or without adjustability.

Explanation and Rationale

During extension of the cylinder the oil flows through two paths. Most of the oil flows through a hole in the side of the shaft and up the middle of the shaft through the extension adjustment valve necessary to manage extension during swing phase. At the same time, some of the oil flows up through ports in the piston that are covered by a shim stack that bends upward as the oil flows through these ports (Figure 4). In the last 15 degrees of extension, the hole in the side of the shaft is gradually covered up by the shaft bushing. This redirection of fluid flow forces an increased amount of oil through the ports covered by the shim stack. Because the oil has to bend the shim stack to flow through these ports, the resistance of this flow path is relatively high. In this design, the cylinder generates a large amount of resistance right before the cylinder and knee reach full extension. This large increase in resistance exists right before full extension and hence manages the forces created in stance extension.

Figure 4



Code

L5856 Endoskeletal knee shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type

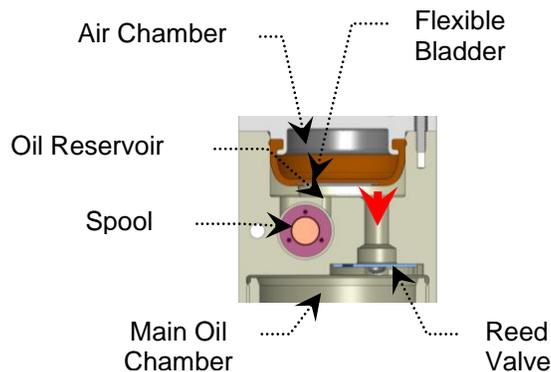
Explanation and Rationale

The Plié microprocessor controlled knee measures input parameters 1000 times a second. The new sensor suite measures total load, bending moment at the bottom of the knee, knee joint angle, knee joint angle rate and time throughout the entire gait cycle (both stance and swing.) The microprocessor control logic is always active and determines transitions from stance into swing and from swing into stance (Figure 7). An extensive stumble recovery and stability system has been implemented in this configuration.

Once the microprocessor control logic decides to enter swing, return to stance is blocked for 20ms (this time is variable in the control system and may change within small limits.) After this delay, the stumble recovery system can command return to stance at any time and the transition occurs in less than 10ms. The stumble recovery logic monitors terminal stance and the entire swing cycle for appropriate changes in the measured parameters. Any deviation from allowable bands or progression timing triggers return to stance.

The new control system will display knee angle, knee angle rate, moment and load (see first paragraph) throughout the gait cycle to aid the practitioner in establishing optimum gait and alignment.

Figure 7



In the enhanced design, the transition from swing flexion mode back to stance flexion mode is now controlled by the microprocessor. The spool valve is now held open during swing flexion by a message sent from the microprocessor. Using data from the new position sensor, the microprocessor determines when swing flexion ends and swing extension begins. At that instant in time, the microprocessor sends a message to the solenoid allowing the spool valve to close which puts the cylinder back in stance flexion as the leg comes forward. In addition, because the spool valve is held open by the solenoid and not a mechanical latch, the microprocessor can now switch the cylinder from swing flexion mode to stance flexion mode any time the microprocessor deems that this is necessary.