ottobock.

bebionic.

Reimbursement Guide

2024

Product Information.

"The hand is also one of the most important elements of our self-image, second only to the face. Our hands are a tremendous part of how we present ourselves to others. In addition to interacting with the environment in so many functional ways, our hands are a significant part of our psychological and social selves and are a vital element in our sense of feeling whole." [1]

Multiarticulating/multigrip hands have been shown to provide better function than standard myoelectric hands.[2,3,4,5] Prosthetists should select multiarticulating/ multigrip hands based on the functional needs of their patients.[4,5]

A publication from the University of Örebro, Sweden, on a study with the *bebionic* hand found that patients significantly improved their performance in and satisfaction with ADLs that were important to each patient individually (defined and assessed with the Canadian Occupational Performance Measure [COPM]) at 1, 2, 3, and 6 months after fitting of the *bebionic* Hand. In addition, patients who had reported pain-related disability at baseline experienced a significant reduction in pain-related disability at 3 and 6 months after fitting.[5]

Introduced in 2010, the *bebionic* Hand offers 14 grip patterns that the user can select from, allowing the amputee to participate in activities that non-amputees take for granted.

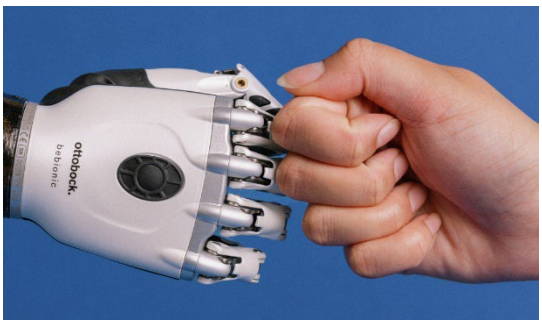
- Tasks related to feeding oneself such as buttering toast, cutting food with a knife, carrying a plate of food, and opening jars.
- Carrying bagged items such as groceries, packages, or a laptop case and still having a hand free to open the door.
- Using a key to open the door.
- Performing household chores such as folding laundry, hanging clothes in the closet, sweeping, putting away dishes, etc.
- Light home maintenance and home renovation.
- Office tasks such as writing with a pen, operating a computer mouse and keyboard, or turning a page in a book.

FDA Status.

Under FDA's regulations, the bebionic Hand is a Class I medical device and exempt from the premarket notification [510(k)] requirements. Given the low risk of Class I medical devices, FDA determined that General Controls are sufficient to provide reasonable assurance of the device's safety and effectiveness; therefore, safety and effectiveness research is not required for this device. The bebionic Hand has met all applicable General Control requirements which include Establishment Registration (21CFR 807), Medical Device Listing (21 CFR part 807), Quality System Regulation (21CFR part820), Labeling (21CFR part 801), and Medical Device Reporting (21 CFR Part 803). The bebionic Hand is listed under External Limb Prosthetic Component; Product Code IQZ; Listing Number A448082.

Health Canada Compliance.

This device meets the requirements of the Medical Device Regulations (SOR/98-282). It has been classified as a class I medical device according to the classification criteria outlined in schedule 1 of the Medical Device Regulations.



Who can provide a bebionic?

The bebionic Hand is prescribed by a physician and may only be provided by a qualified Prosthetist that has received specific product training. Ottobock employs a team of orthotists and prosthetists to educate practitioners on fabricating and fitting our products. This includes in-person and online training, webinars, and technical bulletins. We also provide Cooperative Care Services for the more challenging fittings, which includes on-site assistance with the fitting in conjunction with product qualification training for the practitioner.

Warranty.

A 2-year standard manufacturer warranty is provided for the bebionic Hand. Repair costs are covered except for those associated with damage resulting from improper use. Service inspections (maintenance) are recommended at 24-month intervals, but not mandatory. The 2-year standard warranty can be extended to 3 or 5 years for a fee, and service inspections (maintenance) are included.

Wrist Options.

8E70=* *bebionic* Hand with quick disconnect wrist

8E71=* *bebionic* Hand with short wrist (for Transcarpal amputation or long residual limb)

8E72=* *bebionic* Hand with flexion wrist and quick disconnect

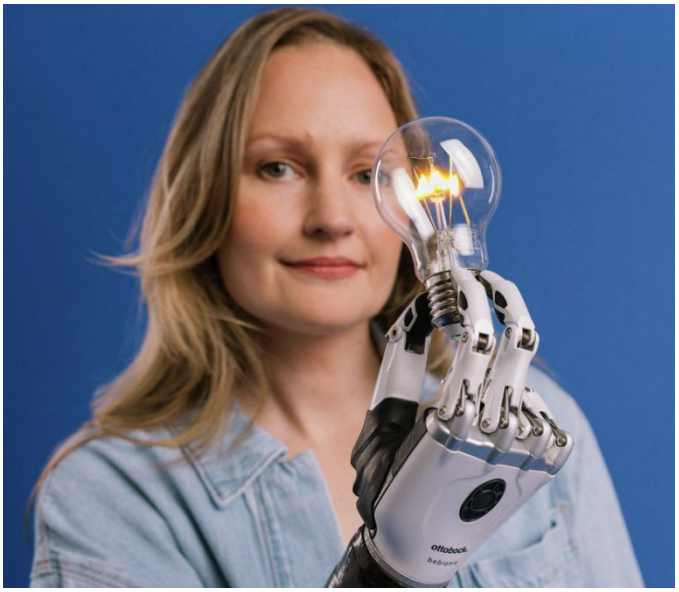
[6] *HCPCS* Coding (U.S. only).

PDAC Verified

The *bebionic* Hand is PDAC verified and following codes apply:

L6880	Myoelectric hand with articulating digits (8E70/8E71/8E72)
L6621	Flexion/extension wrist (8E72)

Additional components that might be included on a claim for prosthesis with *bebionic* Hand.	
L6629	Lamination collar with coupling used for quick disconnect for terminal device interchange (8E70/8E72)
L6050-L6975	External powered base code
L6883-L6885	Replacement socket code
L6680-L6684	Test sockets
L7400-L7405	Socket Material: ultralight/acrylic
Suspension	
L6686	• Suction
L6687-L6690	• Frame
L6691-L6697	• Inserts/Liners
Above Elbow Additions	
L6693	• Forearm counterbalance
L6638	• Electric lock
L7180/L7181	Microprocessor control (sequential/simultaneous)
L7259	Electric wrist rotator
L7009	Additional Terminal Devices: Greifer
L6646	Shoulder Unit
L6672 or L6677 or L6675+L6677	Harness
L6811	Additional Switches or Linear Transducer
L6890	Glove
L7600	Prosthetic Donning Sheath
[6] L7499	Pattern Recognition



References

[1] Smith DG. Introduction to upper-limb prosthetics: Part 1. 2007 March/April:17(2):40-44

[2] Luchetti M, Cutti AG, Verni G, Sacchetti R. Rossi N. Impact of Michelangelo prosthetic hand: Findings from a crossover longitudinal study. J Rehabil Res Dev. 2015;52(5):6054

[3] Proebsting E et al. Ease of activities of daily living with conventional and multigrip myoelectric hands; JPO. 2015;27(2):46-52.

[4] Kannenberg A, Lundstrom R, Hibler KD, Swanson Johnson S. Differences in two multi-articulating myoelectric hands for facilitating activities of daily living in individuals with transradial amputation: A cross-sectional study. J Prosthet Orthot: January 16, 2022; Online first publication, doi: 10.1097/JPO.0000000000000411

[5] Widehammar C, Hiyoshi A, Lidstrom Holmqvist K, Lindner H, Hermansson L. Effect of multi-grip myoelectric prosthetic hands on daily activities. J Rehabil Med 2022; 54: jrm00245, doi: 10.2340/jrm.v53.807

[6] The product/device “Supplier” (defined as an O&P practitioner, O&P patient care facility, or DME supplier) assumes full responsibility for accurate billing of Ottobock products. It is the Supplier’s responsibility to determine medical necessity; ensure coverage criteria is met; and submit appropriate HCPCS codes, modifiers, and charges for services/products delivered. It is also recommended that Supplier’s contact insurance payer(s) for coding and coverage guidance prior to submitting claims. Ottobock Coding Suggestions and Reimbursement Guides do not replace the Supplier’s judgment. These recommendations may be subject to revision based on additional information or alpha-numeric system changes.

[7] It is not recommended to bill L7499 to Medicare for the Myo Plus pattern recognition at this time.

Justification.

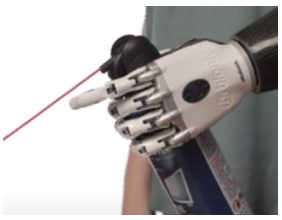
Proportional Control. The *bebionic* Hand's proportional speed and grip force provides precision control when performing delicate tasks, allowing the user to do things like pick up an egg or hold a polystyrene cup.

Automatic Grasp Feature. Its auto grip feature means no more accidents, as *bebionic* automatically senses when a gripped item is slipping and adjusts the grip to secure it. The *bebionic* Hand's multifunctional design and advanced materials makes it strong enough to handle up to 45kg – so the user can confidently use the hand to carry heavy objects, and push up from a seated position. Soft finger pads and a wide thumb profile maximize the surface area and enhances grip.

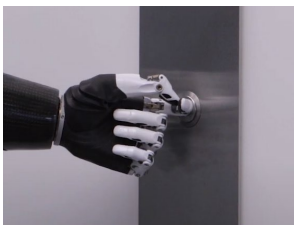
The mobility of multiple fingers is very important to patients, and not just for emotional reasons. The needs and requirements of people who rely on a prosthetic arm have changed; especially in the increasingly digital working world and recreational environment. The *bebionic* Hand is a commercial prosthetic hand designed to enable amputees to perform everyday activities, such as eating, drinking, writing, typing, turning a key in a lock and picking up small objects. *Bebionic* Hand is comfortable, precise and intuitive for patients, transforming the lives and abilities of amputees around the world – from helping them perform simple tasks like tying shoelaces to giving them back their control and their pride.

The *bebionic* Hand includes 14 selectable grip patterns and hand positions which enable the user to perform many everyday activities with ease.

1. Active Index Grip enables the user to effectively operate home and garden appliances with trigger mechanisms, like handheld sprays, hairdryers, and power tools. With active index grip, the user's hand grips the object, while maintaining control over the index finger to operate the trigger. The active index grip is the ideal hand position for using a keyboard. Objects are grasped and held with the thumb, middle, ring and little fingers, and the index finger subsequently bends. The user can then control and position the index finger independently.



2. **Column Grip** allows the user to operate levers and firmly press buttons. The column grip can be used when driving, to use car indicators, at work to operate elevator buttons, or at home to switch on appliances or button a jacket. The user can push objects or operate larger buttons and switches with this grip. We also recommend using it when dressing since the thumb will not get caught in clothing as easily. With the column grip, the thumb is moved from the lateral position towards the palm. The fingers then close over the thumb, making a sort of fist.

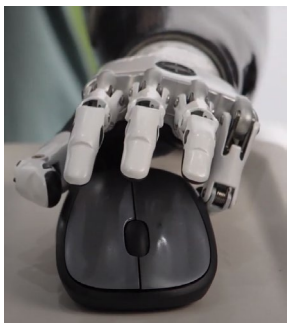


3. **Finger Adduction Grip** is great for picking up and holding thin objects. When eating, the grip can be used to hold cutlery, or it can be used when brushing teeth. Finger abduction can also be used to pick up papers, leaflets, and magazines. The fingers of the bebionic Hand move together naturally as they close. This allows the user to grip thin objects more securely, such as cutlery or magazines, between the fingers for a uniquely confident grasp. Finger adduction performs especially well with the hand closed. It can also be used together with the key grip and pinch grip.

4. **Finger Point Grip** allows the user to perform tasks like pressing small or intricate buttons, such as a doorbell. When using a computer finger point allows the user to operate the keyboard and touch screen. The hand can be moved to the finger point position when the thumb is in the lateral position. The middle, ring and little fingers close against the palm and the thumb moves against the middle finger.

5. **Key Grip** is ideal for reading a magazine, using a spoon or for holding a thin, flat object such as a plate, a credit card, or a key. It provides precise, accurate control, and enables the user to complete intricate tasks such as unlocking a door, folding a towel, or carrying a tray. Fingers close part way when the thumb is in the lateral position. The thumb then closes onto the side of the index finger. The user can then raise and lower the thumb position without moving the other four fingers. This allows for easy release, hold, or reposition of the object being gripped.

6. **Mouse Grip** Whether working in the office, browsing the internet, or playing video games at home, the mouse grip is ideal. The mouse grip lets the user operate a computer mouse. The thumb and little finger close to hold the sides of the mouse, with the middle and ring fingers providing additional stability. The index finger closes on to the mouse button and then backs off to provide the button press. The user can achieve a mouse click with a close signal to the hand and release the mouse with an open signal.



7. **Open Palm Grip** provides an effective way of carrying bowls or plates naturally and safely in the palm of the *bebionic* Hand. The user can fully open the hand to provide a flat palm when the thumb is in the lateral position.

8. **Pinch Grip** allows the thumb and index finger to come together to provide a versatile, useful way to pick up and maneuver a wide range of small objects, including car keys, coins, lids, and pens. The pinch grip is particularly suitable for manipulating objects precisely.

9. **Flexible Power Grip** provides just the right amount of grip to suit any situation, whether shaking someone's hand, throwing a ball, using home and garden utensils, or eating a piece of fruit. This grip pattern enables the user to hold round or cylindrical objects more easily and, above all, more securely.

10. **Precision Closed Grip** provides a quick, reliable method of picking up and moving small objects such as a coin or tissue. With precision closed grip, the index finger grips against the thumb while the rest of the fingers close onto the palm. This grip is similar to the precision open grip but is particularly suitable for situations where extended fingers would get in the way – for instance when working at a desk. The middle, ring and little fingers are bent first and close into the palm; the thumb then moves to the midpoint of its movement range and pauses there. After that, the user has full control of the active index grip.

11. **Relaxed Hand Position** helps to give a natural and lifelike appearance. In the relaxed hand position, the thumb is positioned slightly towards the palm in the lateral position. The other fingers are slightly bent. By applying a further signal, the hand is moved into the hook grip for carrying objects.

12. **Precision Open Grip** offers another useful way to pick up and manipulate small objects quickly and accurately. With precision open grip, the index finger grips against the thumb while the middle, ring and little fingers remain open. With precision open grip, the user can pick up and manipulate small objects with the thumb in opposition. Two activities the user would learn to do with this grip is open a candy bar wrapper and close a zipper. The index finger meets the static thumb in this case. When a close signal is applied, the thumb moves to the midpoint of its range and pauses there. The index finger is then active and under the user's control while the middle, ring and little fingers remain extended.

13. **Tripod Grip** is used to pick up, hold and manipulate a variety of everyday objects including car keys, coins, jar lids and pens. This grip can be used to tie shoelaces and to open/lift a lid. As soon as the thumb is in opposition, the user can close the hand in the Tripod Grip, so the thumb, index and middle fingers meet. The ring and little fingers close.

14. **Hook Grip** provides the perfect solution. Secure and versatile, hook grip enables the user to carry everything from briefcases and handbags to heavy shopping bags.

ottobock.

Upper Limb Clinical Evidence.

1. Amsuss S, Goebel P, Graimann B, Farina D. Simultaneous proportional wrist and hand control for natural dexterous movements of a physical prosthesis by amputees. MyoElectric Controls Symposium, Fredericton, New Brunswick. 2014 (August). download

2. Antfolk C, Cipriani C, Controzzi M, Carrozza MC, Lundborg G, Rosen B, Sebelius F. Using EMG for real-time prediction of joint angles to control a prosthetic hand equipped with a sensory feedback system. J Med Biol Eng. 2010;30 (6): 399-406. download

3. Atkins DJ. Comparison of the "perception of disability" in bilateral prosthetic wearers, bilateral hand transplants and bilateral toe-tohand transfers. MyoElectric Controls Symposium, Fredericton, New Brunswick 2014 (August). download

4. Bayona C. A Subjective View to the Question of Sensation Versus Function; MyoElectric Controls Symposium, Fredericton, New Brunswick 2014 (August). download

5. Bouwsema H, Van Der Sluis CK, Bongers RM. Changes in performance over time while learning to use a myoelectric prosthesis. J Neuroeng Rehabil. 2014;11(1). DOI: 10.1186/1743-0003-11-16. download

6. Bouwsema H, Kyberd PJ, Hill W, van der Sluis CK, Bongers RM. Determining skill level in myoelectric pros thesis use with multiple outcome measures. J Rehabil Res Dev. 2012;49(9):1331-1348. download

7. Brouwers MAH, Roeling IEM, van Wikjk I, Mooibroek-Tieben EPH, Harmer-Bosgoed MW, Plettenburg DH. Development of a test prosthesis: An important tool in the decision making process in providing patients with an upper limb prosthesis. MyoElectric Controls Symposium, Fredericton, New Brunswick, 2014 (August). download

8. Cutti AG, Pareli, Luchetti M et al. Chapter 5: The psychosocial and biomechanical assessment of amputees fitted with commercial multi-grip prosthetic hands. In: Grasping the Future: Advances in Powered Upper Limb Prosthetics. Bentham Science Publisher (2012). download

9. Da Paz Jr. AC, Braga LW. Brain activation in a myoelectric prosthetic hand: The role of the brain in the rehabilitation of amputees. J Pediatr Orthop. 2007;27(8):947-951. download

10. Egermann M, Kasten P, Thomsen M. Myoelectric hand prostheses in very young children. Int Orthop. 2009;33(4)1101-1105. download

11. Esquenazi A. Amputation rehabilitation and prosthetic restoration. From surgery to community reintegration. 2004;26(14-15):831-836. download

12. Esquenazi A; Meier RH. Rehabilitation in limb deficiency. 4: Limb Amputation; Arch Phys Med Rehabil. 1996;77(3);S18-S28. download

13. Geng Y, Zhou P, Li G. Toward attenuating the impact of arm positions on electromyography pattern-recognition based motion classification in transradial amputees. J Neuroeng Rehabil. 2012;9:74. doi:10.1186/1743-0003-9-74. download

14. Kannenberg A, Lundstrom R, Hibler KD, Swanson Johnson S. Differences in two multi-articulating myoelectric hands for facilitating activities of daily living in individuals with transradial amputation: A cross-sectional study. J Prosthet Orthot: January 16, 2022; Online first publication, doi: 10.1097/JPO.0000000000000411 download

15. Kannenberg A, Lundstrom R, Swanson Johnson S, and Morris A. Differences in multigrip myoelectric hands for facilitating activities of daily living. MEC20 Symposium, Jul. 2020. download

16. Kannenberg A, Proebsting E. Difficulty performing activities of daily living with the Michelangelo multigrip hand and traditional myoelectric hands. MyoElectric Controls Symposium, Fredericton, New Brunswick. 2014 (August). download

17. Kuiken TA, Li G, Lock BA et al. Targeted muscle reinnervation for real-time myoelectric control of multifunction artificial arms. JAMA. 2009; 301(6):619-628. download

18. Latour D. Upper Limb Prosthetic Rehabilitation Webinar Series: Introduction, Technology, Evaluation, Management; Occupational Therapy.com. Allied Media, April 2015.

19. Lindner HYN, Eliasson AC, Hermansson LMN. Influence of standardized activities on validity of assess ment of capacity for myoelectric control. J Rehabil Res Dev. 2013;50(10):1391-1400. download

20. Lock BA, Cummins FD. Search engines for the world wide web: simplified approach to myoelectric and electrode placement for success in clinical pattern recognition. MyoElectric Controls Symposium, Fred ericton, New Brunswick, 2014 (August). download

21. Lu TR, Zhang SJ. Functional training and evaluation of myoelectric hand. Chinese Journal of Clinical Re habilitation. 2004;8(32):7320-7322.

22. Luchetti M, Cutti AG, Verni G, Sacchetti R. Rossi N. Impact of Michelangelo prosthetic hand: Findings from a crossover longitudinal study. J Rehabil Res Dev. 2015;52(5):6054 download

23. Lundstrom R, Morris A, Kannenberg A, Swanson-Johnson S. Ease of activities of daily living with multigrip myoelectric hands. Poster presented at: AOPA National Assembly; Sept, 2018; Vancouver, CA

24. Matrone GC, Cipriani C, Carrozza MC, Magenes G. Real-time myoelectric control of a multi-fingered hand prosthesis using principal components analysis. J Neuroeng Rehabil. 2012;9:40. doi:10.1186/1743-0003-9-40. download

25. Meier R, Atkins D. Functional Restoration of Adults and Children with Upper Extremity Amputation. Res Trends for the Twenty-First Century 30: 353–360.

26. Meier R; Weed, RO. Life Care Planning and Case Management Handbook, Second Edition; 2005; 248-273.

27. Miguelez J, Ryan T. Redefining The Norm: Objective funding development in an ever changing payer environment; MyoElectric Controls Symposium, Fredericton, New Brunswick, 2014 (August). download

28. Murray CD. The social meanings of prosthesis use. J Health Psychol 2005;10: 425. download

29. Murray CD. Being like everybody else: the personal meanings of being a prosthesis user. Disabil Rehabil. 2009;31(7):573-581. download

30. Otr OV, Reinders-Messelink HA, Bongers RM, Bouwsema, H, Van Der Sluis CK. The i-LIMB hand and the DMC plus hand compared: A case report. Prosthet Orthot Int. 2010 Jun;34(2):216-20. doi: download

31. Proebsting E et al. Ease of activities of daily living with conventional and multigrip myoelectric hands; JPO. 2015;27(2):46-52. download

32. Pylatiuk C, Schulz S, Doderlein L. Results of an internet survey of myoelectric prosthetic hand users. Prosthet Orthot Int. 2007;31(4):362-370. download

33. Resnik L, Adams L, Borgia M, et al. Development and evaluation of the activities measure for upper limb amputees. Arch Phys Med Rehabil 2013;94(3):488-494. download

34. Segil JL, Huddle S, Weir RF. Functional assessment of transdradial amputees with a myoelectric postural controller and multi-functional prosthetic hand. Myo-Electric Controls Symposium, Fredericton New Brunswick 2014 (August). download

35. Widehammar C, Hiyoshi A, Lidstrom Holmqvist K, Lindner H, Hermansson L. Effect of multi-grip myoelectric prosthetic hands on daily activities. J Rehabil Med 2022; 54: jrm00245, doi: 10.2340/jrm.v53.807 download

36. Whelen L, Farley J. Functional outcomes with externally powered partial hand. Journal of Prosthetics and Orthotics. 2018 April; 30(2):69-73 doi: 10.1097/JPO.0000000000000018. download

37. Whelan L, Wagner N, Farley J. Analysis of factors influencing outcomes of full and partial hand multi-articulating prostheses. MyoElectric Controls Symposium, Fredericton, New Brunswick, 2014 (August). download

38. Wright V. Prosthetic outcome measures for use with upper limb amputees: a systematic review of the peer-reviewed literature, 1970 to 2009. JPO. 2009;21(4S):3-28. download

39. Vilarino M et al. Outcomes and perception of a conventional and alternative myoelectric control strategy: a study of experienced and new multiarticulating hand users. JPO. 2015;27(2)53-62. download

40. Young AJ, Smith LH, Rouse EJ, Hargrove LJ. A comparison of the real-time controllability of pattern rec ognition to conventional myoelectric control for discrete and simultaneous movements. J Neuroeng Rehabil. 2014 Jan 10;11:5. doi: 10.1186/1743-0003-11-5. download

Contact information:
Reimbursement, Ottobock North America
P 800 328 4058 F 800 230 3962
US https://shop.ottobock.us
CA https://shop.ottobock.ca
reimbursement911@ottobock.com