A white line drawing of a spray gun nozzle assembly is centered on a dark teal background. The drawing shows a cylindrical nozzle with a textured, diamond-patterned tip. Below the nozzle is a larger, rectangular body with several screws and a central circular opening. A hose is connected to the side of the body. The overall design is industrial and precise.

# E-400 Elbow

Product Manual

*Fillauer*®



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## Intended Use

The E-400 Series elbows are used with any transhumeral or higher upper extremity prosthesis. These elbows are appropriately sized for larger adults and are the most durable of the Fillauer body-powered elbows. These elbow units feature multiple body-powered locking positions and come in a variety of configurations for color, strength, and weight. All models feature adjustable-friction axial rotation through the proximal turntable and several models can be purchased with or without a [forearm section](#) (see prefabricated forearm table).

## Performance Characteristics

	E-400	E-400HD	E-400XHD	Power Bow
Weight	<b>15 oz. (420 g)</b>	<b>15 oz. (420 g)</b>	<b>17 oz. (480 g)</b>	<b>21 oz. (598 g)</b>
Yoke	<b>Aluminum</b>	<b>Aluminum</b>	<b>Aluminum</b>	<b>Stainless Steel</b>
Locking Positions	<b>11 Single Sector</b>	<b>8 Single Sector</b>	<b>8 Single Sector</b>	<b>8 Double Sector</b>
Saddle	<b>Single Thickness Stainless Steel</b>	<b>Double Thickness Stainless Steel</b>	<b>Double Thickness Stainless Steel</b>	<b>Double Thickness Stainless Steel</b>
Primary Materials	<b>Stainless Steel, Steel, Aluminum</b>			

These devices are intended for single patient use only.

## Storage and Handling

It is recommended that prosthetic elbows be stored in a cool, clean, dry environment away from harsh chemicals (chlorine, acids, acetone, etc.).

## Warnings and Precautions



**NOTICE:** An upper-limb prosthetic device user's ability to drive should be determined on a case-by-case basis by a specialist. Contact your local governing authorities regarding any driving restrictions or limitations.



**WARNING:** Body-powered devices should not rely on cable tension for grasp control if the user has been cleared to drive with the prosthesis. Failure to maintain tension while controlling the steering wheel could cause serious injury or death.



**NOTICE:** To prevent malfunction of the elbow, the instructions below on trimming the lock cable and housing must be followed. Failure to do so will likely result in immediate or premature failure that will not be covered under warranty of the device.



**CAUTION:** Abnormal or improper environmental conditions will lead to malfunctioning and damage of the prosthesis and are not covered under the warranty of the device. This prosthetic component must not be subjected to dust/debris, liquids, abrasives, vibration, activities which would damage the biological limb, or prolonged extreme temperatures (< -5 °C or > 50 °C). Do not allow debris or liquids to remain in the prosthesis and its components during use. Rinse the device with fresh water and dry immediately after exposure.

## Qualified Provider

Attachment, adjustment, alignment, and delivery of this device must be performed by or under the direct supervision of a qualified prosthetist. Unless stated in this manual, any such activities should not be attempted by the user and will potentially void the device warranty.

## Specifications and Preparations Before Use (Risk Management for Installation and Calibration)

### Alignment

Prosthetic elbows should be aligned to match the natural hanging angle of the contralateral elbow and provide the best possible work envelope for a patient's specific goals. Standard alignment begins at 5 degrees of flexion and the adduction angle should match the hanging angle of the contralateral limb while also allowing midline tasks and reaching the mouth as necessary. The height of the elbow axis may match

that of the other arm, but amputees often prefer a slightly shorter prosthetic side for control and weight.

## Installation

- The elbow turntable may be laminated by removing the elbow and cork friction disk from the turntable. They are connected by the  $\frac{3}{16}$ -inch slotted nut on the threaded stud visible in the center of the turntable.
- Place the turntable on the distal end of the humeral section mold (beeswax, foam, plaster or similar). A PVA bag should be used to separate the turntable from the humeral mold if foam or plaster are used. Wax the interior surface and the distal face of the turntable.
- Pack any voids between the turntable and mold with silicone fitting gel or similar to prevent it from filling with laminate.
- Mask the turntable distal to the tie-in groove on the knurled ring surface to keep all laminate clear of the distal end.
- Laminate with the appropriate materials for durability and finish as desired by the patient, being sure to tie each structural layer into the tie-in groove in the lamination ring. Carbon fiber tape is a good choice for reinforcing the connection to the lamination ring and is commonly used for distal to proximal strips tied in with circumferential wraps.
- When reattaching the elbow unit, be sure to install the cork disc between the turntable and elbow, and place both washers under the slotted nut before delivery.
- Tighten the nut to set the proper amount of friction with a  $\frac{3}{16}$  wrench.

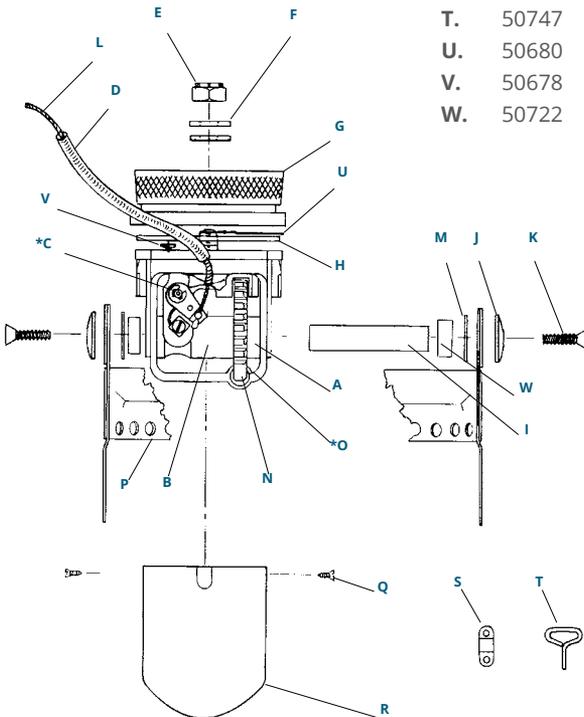
## Shortening the Cable and Housing

The elbow lock cable AND housing should, in most cases, be adjusted in length to allow smooth and consistent cycling of the lock. To shorten the cable housing, the cable must be pulled out distally and the proximal housing ferrule removed. The housing is then cut from the proximal end. NEVER remove the lock cable housing from the elbow to trim it. The housing has been permanently installed on all elbows. If removed, it must be reattached correctly (threadlocker and mechanically altering the thread), or it will thread into the elbow and cause malfunction of the lock.

The lock cable can be replaced. However, it is recommended that only Fillauer-fabricated lock cables (PN 50724) be used. Other cables and/or their attachment methods can and have caused damage to the lock mechanism which will not be covered under warranty.

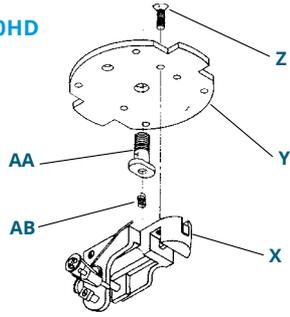
# Elbow Assembly

- A.** 50720 Short Sleeve
- B.** 50721 Long Sleeve
- C.** 57497 Internal Assembly, E-400 and HD
- D.** 50725 Cable Housing Assembly
- E.** 50667 Lock Nut
- F.** 50668 Belleville Washer
- G.** 50658 Turntable, E-400, 400HD  
50659 Turntable, E-400A
- H.** 50665 Cork Washer
- I.** 50719 Shaft
- J.** 50739 Outside Washer
- K.** 50740 Screw
- L.** 50724 Cable Assembly
- M.** 50729 Washer
- N.** 62235 Heavy Duty Gear Sector, E-400 and 400A  
62236 Gear Sector, E-400HD  
62237 Extra Heavy Duty Gear Sector, E-400XD, Powerbow
- O.** 50748 Yoke Assembly, E-400 and E-400HD  
60143 Yoke Assembly, E-400 XHD  
60664 Yoke Assembly, Power Bow
- P.** 50730 Elbow Saddle Assembly, E-400 and 400A  
50738 Elbow Saddle Assembly, E-400HD
- Q.** 50742 Sheet Metal Screw
- R.** Elbow Cap—See Table
- S.** 50427 Anchor
- T.** 50747 Hanger
- U.** 50680 Bolt
- V.** 50678 Screw
- W.** 50722 Bearing



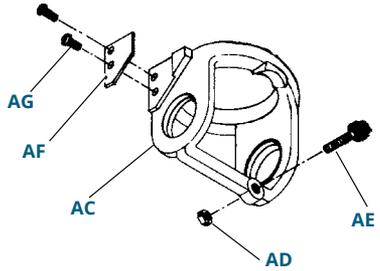
**C. 62243 Internal Assembly, E-400 and E-400HD**

- X. 62242 Internal Cage Assembly, E-400 and E-400HD
- Y. 50677 Base
- Z. 50679 Screw
- AA. 50680 Bolt
- AB. 50715 Locking Bar Spring



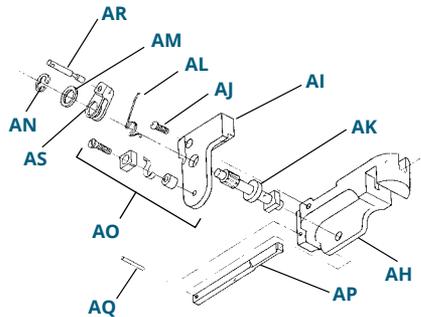
**O. 50748 Yoke Assembly**

- AC. 50671 Yoke
- AD. 50675 Nut
- AE. 50674 Bumper
- AF. 50758 Yoke Cover, Right
- 50773 Yoke Cover, Left
- AG. 50761 Screw



**X. 62242 Internal Cage Assembly, E-400 and E-400HD**

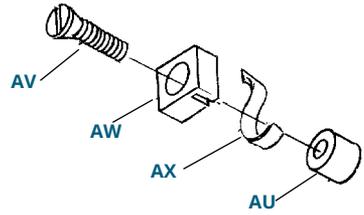
- AH. 62239 Cage
- AI. 50684 Cam Bearing
- AJ. 880108 Screw
- AK. 50687 Cam
- AL. 50689 Spring
- AM. 50701 Washer
- AN. 50160 Retaining Clip
- AO. 50710 Ratchet Assembly
- AP. 50714 Locking Bar
- AQ. 50813 Case Pin
- AR. 50713 Cable Pin
- AS. 55561 Lever Sub Assembly



**60148 Internal Cage Assembly, E-400XHD and Power Bow (SST Double Gear Sector)**

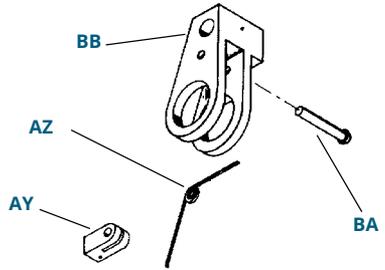
**AO. 50710 Ratchet Assembly**

- AT. 55561 Lever Sub Assembly
- AU. 50711 Spacer
- AV. 50712 Screw
- AW. 50708 Keeper
- AX. 50710 Ratchet



**AT. 55561 Lever Sub Assembly**

- AY. 50630 Pawl
- AZ. 50705 Spring
- BA. 50706 Pin
- BB. 50688 Lever



**Elbow Cap**

Color	Outside Cable	Inside Cable	Friction Elbow
Tan	50645	54437	54436
Light Brown	54435	54405	54433
Medium Brown	54432	54431	54430
Dark Brown	54429	54428	54427
Jet Black	54434	54406	54407

# Compatibility

An Elbow Lift Assist (PN 50752 for left and 50609 for right) may be attached medially (standard) or laterally. For lateral placement, be sure to order the opposite side part number. A Nudge Control (PN 52521 for right and 52522 for left) may be used to lock and unlock the elbow when it is not possible through the harness. Lock Cables may be replaced (PN 50724). **Prefabricated Forearms** (see table below) may be used with all E-400 series elbows. The Northwestern Lift Tab Jig (PN 51040) may be used with E-400 and E-200 Series elbows to properly locate the lift tab assemblies.

## Prefabricated Forearms

	Tan	Light Brown	Dark Brown	Jet Black
Large for 2 in. (50 mm) Wrist	57939	57544	57547	57562
Large for 2 in. (50 mm) Wrist with E-400 Elbow	57542	57503	57506	57567
Large for 2 3/16 in. (55 mm) Wrist	57509	57510	57511	57563
Large for 2 3/16 in. (55 mm) Wrist with E-400 Elbow	57512	57513	57514	57568

# Disposal / Waste Handling

The product must be disposed of in accordance with applicable local laws and regulations. If the product has been exposed to bacteria or other infectious agents, it must be disposed of in accordance with applicable laws and regulations for the handling of contaminated material.

All metal components may be removed and recycled at the appropriate recycling facility.

# Warranty

This product has a 12-month warranty against manufacturer defects

# User Instructions

The providing health care professional must review the following information directly with the user.

## Warnings and Precautions for the User



**NOTICE:** The user should monitor their prosthesis daily and contact their health care professional if they experience changes in device performance or if it begins to make noise.



**CAUTION:** All maintenance should be performed by the qualified health care professional.



**NOTICE:** An upper-limb prosthetic device user's ability to drive should be determined on a case-by-case basis by a specialist. Contact your local governing authorities regarding any driving restrictions or limitations.



**WARNING:** Body-powered devices should not rely on cable tension for grasp control if the user has been cleared to drive with the prosthesis. Failure to maintain tension while controlling the steering wheel could cause serious injury or death.



**CAUTION:** Abnormal or improper environmental conditions will lead to malfunctioning and damage of the prosthesis and are not covered under the warranty of the device. This prosthetic component must not be subjected to dust/debris, liquids, abrasives, vibration, activities which would damage the biological limb, or prolonged extreme temperatures (< -5 °C or > 50 °C). Do not allow debris or liquids to remain in the prosthesis and its components during use. Rinse the device with fresh water and dry immediately after exposure.

## Serious Incidents

In the unlikely event of a serious incident, seek immediate medical help and contact your prosthetist at your earliest possible convenience. Clinicians should contact their local Fillauer representative immediately in the event of any device failure.

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