



ACCESORIOS DE ORTOPEDIA

INVENTARIO TÉCNICO

Nombre: ACCESORIOS DE ORTOPEDIA

Modelo: S/M

Marca: STERIS

Referencia: BF-720

Cantidad	Rack	Columna	Tramo
14	L	1	1

Manual de instalación:

STERIS®



OPERATOR MANUAL

TenZor™ Carbon Fiber
Traction Unit Assembly

(04/11/07)

P150832-354

A WORD FROM STERIS CORPORATION

Thank you for choosing this fine STERIS product. STERIS is committed to ensuring your continued satisfaction. This manual contains important information on proper use and maintenance of the TenZor™ Carbon Fiber Traction Unit Assembly¹. **All personnel involved in the use and maintenance of this equipment must carefully review and comply with the Safety Precautions and instructions contained in this manual.** These instructions are important to protect the health and safety of personnel operating these extensions and should be retained in a conveniently accessible area for quick reference.

STERIS carries a complete line of surgical table accessories. STERIS representatives will gladly review these with you.

Advisory

A listing of the *SAFETY PRECAUTIONS* to be observed when operating and servicing this equipment is found in *SECTION 1* of this manual. Do not operate or service the equipment until you have become familiar with this information. Failure to comply with the *SAFETY PRECAUTIONS* could result in personal injury and/or equipment damage.

Any alteration of the equipment not performed or authorized by STERIS will void the warranty. Such alterations may also adversely affect product safety and performance.

Indications for Use

This Carbon Fiber Traction Unit Assembly is designed to provide traction during applicable orthopedic surgical procedures. Traction force is achieved from the screw thread mechanism housed within the traction unit assembly. Smooth and precise control of applied traction as well as smooth and precisely controlled release of traction at the appropriate time is achieved with this accessory. Assembly is equipped with a quick connect mechanism enabling the use of various accessories like a traction boot, skeletal traction bow/block and skeletal traction block.

¹ TenZor is a Trademark of Composite Manufacturing Inc., San Clemente, CA.

TABLE OF CONTENTS






Section	Title	Page
1	SAFETY PRECAUTIONS	1-1
2	UNCRATING INSTRUCTIONS	2-1
3	OPERATING INSTRUCTIONS	3-1
3.1	Before Using Carbon Fiber Traction Unit	3-1
3.1.1	General	3-1
3.1.2	Component Data	3-2
3.1.3	Other Features/Benefits	3-3
3.2	Attaching Carbon Fiber Traction Unit Assembly	3-3
3.3	Transferring Patient to Table	3-4
3.4	Using Carbon Fiber Traction Unit and Accessories	3-4
4	ROUTINE MAINTENANCE	4-1
4.1	Cleaning Carbon Fiber Traction Unit	4-1
4.2	Replacement Parts	4-1
5	DISPOSAL HAZARDS	5-1

SAFETY PRECAUTIONS






The following *Safety Precautions* must be observed when operating or servicing the TenZor™ Carbon Fiber Traction Unit Assembly. WARNING indicates the potential for personal injury and equipment damage and CAUTION indicates the potential for damage to equipment. For emphasis, certain *Safety Precautions* are repeated throughout the manual. **It is important to review ALL *Safety Precautions* before operating or servicing the unit.**


WARNING – PERSONAL INJURY AND/OR EQUIPMENT DAMAGE HAZARD:

-  Read and understand all instructions presented in this manual before attaching/removing the Carbon Fiber Traction Unit Assembly. Follow each step in the order presented in these instructions. If you need technical assistance or additional instructions, call STERIS.
-  Attach the TenZor Carbon Fiber Traction Unit Assembly **only** to a Cmax or Amsco 3080/3085 SP Surgical Table or Amsco OrthoVision Orthopedic and Fracture Table. The use of this device with other surgical tables is **not** recommended.
-  Check the table Orthopedic Extension abductor bars, siderails and Carbon Fiber Traction Unit for possible damage or wear prior to each use. Do not use the Carbon Fiber Traction Unit if any damage is apparent, if parts are missing or if it does not operate as expected. Cracked or splintered siderail or abductor bar surfaces may cause injury.
-  Patient must be secured to the table in accordance with recommended positioning practices to prevent unanticipated table movement.
-  Do **NOT** pull Carbon Fiber Traction Unit Assembly circular knob, located just above blue tensiometer, while unit is under tension.



WARNING – TIPPING HAZARD:

-  Do **not** place a patient on the surgical table unless the table floor locks are engaged.
-  Do **not** release the surgical table floor locks while the patient is on the table.
-  Do **not** exceed 400 lb (181 kg) maximum patient weight.

WARNING – INFECTION HAZARD:

-  When cleaning the Carbon Fiber Traction Unit, follow the STERIS supplied instructions, applicable national requirements and the cleaning product manufacturer's instructions and precautions.

CAUTION – POSSIBLE EQUIPMENT DAMAGE:

-  Handle the Carbon Fiber Traction Unit with care. To prevent damage, avoid dropping the equipment. Do not use if damaged.
-  Follow each step in the order presented in these instructions. If any damage (no matter how slight) is discovered, show it to your supervisor.

UNCRATING INSTRUCTIONS

2



CAUTION – POSSIBLE EQUIPMENT DAMAGE:

- Follow each step in the order presented in these instructions. If any damage (no matter how slight) is discovered, show it to your supervisor.
- Handle the Carbon Fiber Traction Unit with care. To prevent damage, avoid dropping the equipment. Do not use if damaged.

Open shipping carton(s) as follows:

1. Inspect cartons and report any damage found.
2. Position cartons to ensure a clear work area on all sides.
3. Open TenZor™ Carbon Fiber Traction Unit Kit carton by carefully removing the shipping tape.
4. Discard foam blocks (Items 3 and 4, Figure 2-1).
5. Carefully remove Carbon Fiber Traction Unit with Foot Support (Item 2, Figure 2-1) and place in Accessory Cart.
6. Remove Traction Boot With Straps (Item 1, Figure 2-1) and place in Accessory Cart.
7. Discard shipping carton (Item 5, Figure 2-1)..

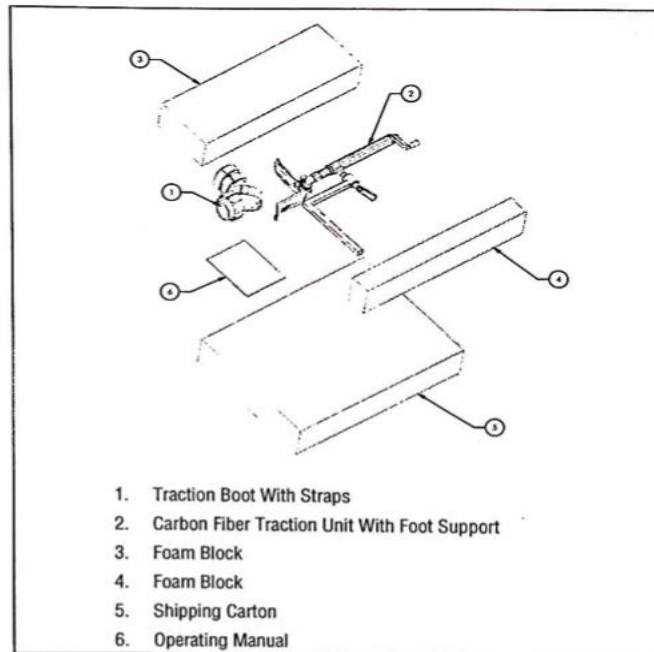


Figure 2-1. Remove Carbon Fiber Traction Unit (Typical)

8. Open Traction Bow carton (if supplied) by carefully removing the shipping tape.
9. Carefully remove Traction Bow (Item 1, Figure 2-2) and place in Accessory Cart.

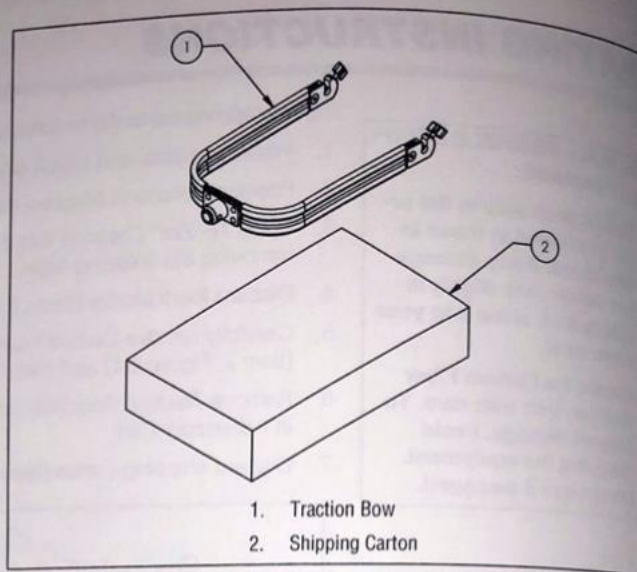


Figure 2-2. Remove Traction Bow (Typical)

10. Discard shipping carton (Item 2, Figure 2-2).
11. Open Skeletal Traction Block carton (if supplied) by carefully removing the shipping tape.
12. Carefully remove Skeletal Traction Block (Item 1, Figure 2-3) and place in Accessory Cart.
13. Discard shipping carton (Item 2, Figure 2-3)

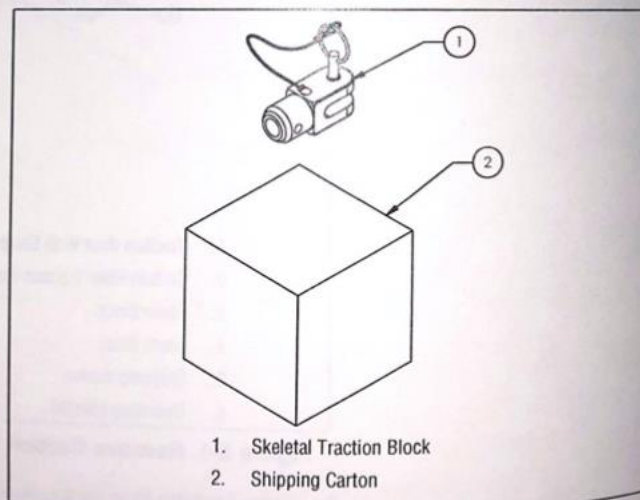


Figure 2-3. Skeletal Traction Block (Typical)

OPERATING INSTRUCTIONS

3

3.1 Before Using Carbon Fiber Traction Unit



WARNING – PERSONAL INJURY AND/OR EQUIPMENT DAMAGE HAZARD:

- Read and understand all instructions presented in this manual before attaching/removing the Carbon Fiber Traction Unit Assembly. Follow each step in the order presented in these instructions. If you need technical assistance or additional instructions, call STERIS.
- Attach the TenZor Carbon Fiber Traction Unit Assembly only to a Cmax or Amsco 3080/3085 SP Surgical Table or Amsco OrthoVision Orthopedic and Fracture Table. The use of this device with other tables is not recommended.

The following instructions and procedures are intended as a guide for using the TenZor™ Carbon Fiber Traction Unit Assembly (see Figure 3-1).

NOTE: Refer to the operator manual for your Amsco® 3080 (P129361-861) or Amsco® 3085 SP (P150830-353) or Cmax™ (P150830-685) Surgical Table or Amsco® OrthoVision® Orthopedic and Fracture Table (P129362-425) for specific instructions and Safety Precautions on operating the table.

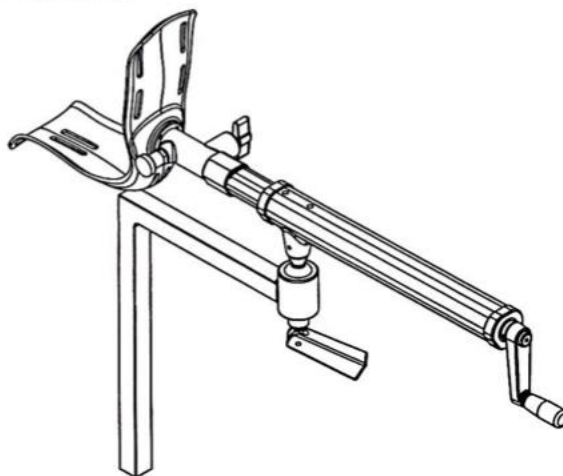


Figure 3-1. Carbon Fiber Traction Unit (With Foot Support)

3.1.1 General

This Carbon Fiber Traction Unit Assembly is designed to provide traction during applicable orthopedic surgical procedures. Traction force is achieved from the screw thread mechanism (tensiometer) housed within the traction unit assembly (see Figure 3-2). Smooth and precise control of applied traction as well as smooth and precisely controlled release of traction at the appropriate time is achieved with this accessory. Assembly is equipped with a quick connect mechanism enabling the use of various accessories like a traction boot, carbon fiber traction bow/block and skeletal traction block.

The tensiometer (through equipped force gauge) gives the user an indication of the amount of traction being applied to the operative limb. The tensiometer has a range of 10 to 60 lbs (5 to 25 kg) of traction (see Figure 3-2).

NOTE: The traction force readings (see Figure 3-2) are for reference only and are not intended to dictate surgical setup and practice. Carbon Fiber Traction Unit Assembly is capable of generating traction force greater than maximum indicator value.

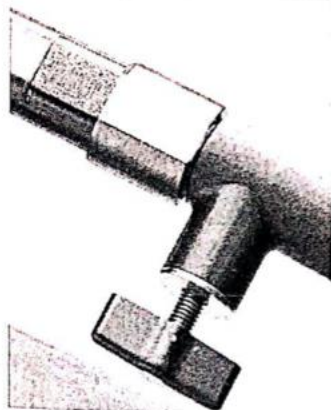


Figure 3-2. Tensiometer and Force Gauge

3.1.2 Component Data

Note the following TenZor Carbon Fiber Traction Unit Assembly component data:

NOTE: Carbon Fiber Traction Unit is rated for use with patients weighing up to 400 lb (181 kg).

1. Weight (Approximate):
 - Traction Unit Assembly: 7 lb (3 kg)
 - Foot Support: 1 lb (0.5 kg)
 - Traction Bow: 1 lb (0.5 kg)
 - Traction Block: 1/2 lb (0.2 kg)
2. Environmental Conditions:
 - Temperature, Operating: 50 to 140°F (10 to 40°C)
 - Temperature, Storage: -40 to 158°F (-40 to 70°C)
 - Humidity Limits, Operating: 30 to 75%
 - Humidity Limits, Storage: 10 to 100% (including condensation)
3. Equipment or Part Numbers:
 - Traction Unit Assembly: BF720
 - Traction Boot, Adult (Pair): BF721
 - Traction Boot, Bariatric Adult (Pair): BF722
 - Traction Boot, Child (Pair): BF723
 - Carbon Fiber Traction Bow/Block: BF724
 - Skeletal Traction Block: BF725
 - Traction Boot Strap Replacement Set: BF726
 - Cmax™/Amsco® 3085 SP/3080 Orthopedic Extension Set-Up Guide (P150832-316)

3.1.3 Other Features/Benefits

3.2 Attaching Carbon Fiber Traction Unit Assembly

⚠ WARNING – PERSONAL INJURY AND/OR EQUIPMENT DAMAGE HAZARD:

- Check the table Orthopedic Extension abductor bars, siderails and Carbon Fiber Traction Unit for possible damage or wear prior to each use. Do not use the Carbon Fiber Traction Unit if any damage is apparent, if parts are missing or if it does not operate as expected. Cracked or splintered siderail or abductor bar surfaces may cause injury.
- Attach the TenZor Carbon Fiber Traction Unit Assembly only to a Cmax or Amsco 3080/3085 SP Surgical Table or Amsco OrthoVision Orthopedic and Fracture Table. The use of this device with other tables is not recommended.

⚠ CAUTION – POSSIBLE EQUIPMENT DAMAGE: Handle the Carbon Fiber Traction Unit with care. To prevent damage, avoid dropping the equipment. Do not use if damaged.

4. Optional Accessories Might Include:

- L-Shaped Traction Extension: BF0003
- Traction Accessory Clamp: BF00020
- Carbon FiberTibia/Lateral Countertraction Support: BF00062
- Clark Socket: BF083
- Universal Leg Holder: BF266
- Straight Traction Extension: BF00268
- Table Accessory Cart: BF700

Note the following other features and benefits:

- **The Carbon Fiber Traction Unit is rated for use with patients weighing up to 400 lb (181 kg).**
- The stainless-steel Accessory Cart provides ample storage room for the Carbon Fiber Traction Unit and a full variety of orthopedic accessories.

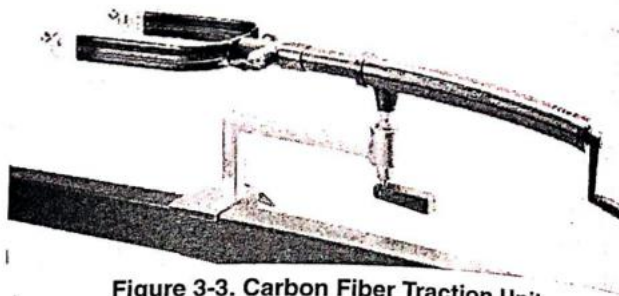
Complete each step in the order presented below and attach the TenZor Carbon Fiber Traction Unit to a surgical table or Orthopedic Extension abductor bars as follows:

NOTE: Refer to Cmax/Amsco 3085 SP/3080 Orthopedic Extension Set-Up Guide (P150832-316) for specific procedures, instructions and illustrations.

1. Determine required orthopedic procedure and use Orthopedic Extension Set-Up Procedure (P150832-316) for positioning recommendations and required accessories. Place required accessories inside accessory cart.
2. Prior to use, inspect Carbon Fiber Traction Unit for any damage or lack of functionality. Do not use unit if not functioning properly or if any damage is apparent.

NOTE: The Carbon Fiber Traction Unit is designed to be used only with STERIS orthopedic product offerings.

3. Before using, ensure traction unit and accessories are clean and disinfected (refer to **SECTION 4.1, CLEANING CARBON FIBER TRACTION UNIT**).
4. Determine approximate desired location for needed Carbon Fiber Traction Unit(s).
5. Install Traction Accessory Clamp(s) on the abductor bar(s) - see Figure 3-3.
6. Insert Carbon Fiber Traction Unit steel support tube into Traction Accessory Clamp (either a straight or L-shaped traction extension). Tighten the locking knob to secure the traction unit at the desired height (see Figure 3-3).



**Figure 3-3. Carbon Fiber Traction Unit
(With Bow and L-Shaped Traction Extension)
Mounted on Orthopedic Extension Abductor Bar**

3.3 Transferring Patient to Table

WARNING – TIPPING HAZARD:

- Do not place a patient on the surgical table unless the table floor locks are engaged.
- Do not release the surgical table floor locks while the patient is on the table.
- Do not exceed 400 lb (181 kg) maximum patient weight.

WARNING – PERSONAL INJURY AND/OR EQUIPMENT DAMAGE HAZARD: Patient must be secured to the table in accordance with recommended positioning practices to prevent unanticipated table movement.

3.4 Using Carbon Fiber Traction Unit and Accessories

CAUTION – POSSIBLE EQUIPMENT DAMAGE: Handle the Carbon Fiber Traction Unit with care. To prevent damage, avoid dropping the equipment. Do not use if damaged.

Transfer patient onto the surgical table as follows:

1. Confirm Carbon Fiber Traction Unit(s) is properly attached and locked to surgical table. See *SECTION 3.2, ATTACHING CARBON FIBER TRACTION UNIT ASSEMBLY*, and review all *Safety Precautions*.

2. Ensure surgical table floor locks are engaged.

NOTE: Refer to your surgical table operator manual for specific instructions on operating the surgical table.

3. Insert patient transfer board, with 4" (102 mm) pad.
4. Transfer patient onto surgical table.

NOTE: Use the patient transfer board to temporarily support the patient's weight while applying and adjusting accessories.

5. Position and secure patient per procedure instructions supplied in Orthopedic Extension Set-Up Guide (P150832-316) and *SECTION 3.4, USING CARBON FIBER TRACTION UNIT AND ACCESSORIES*.

Note the following information when using the TenZor Carbon Fiber Traction Unit and accessories:

1. Before using, ensure accessories are clean and disinfected (refer to *SECTION 4.1, CLEANING CARBON FIBER TRACTION UNIT*).
2. Position accessory cart within reach to easily obtain needed accessories.
3. For foot traction, proceed as follows:
 - a. Apply Traction Boot Assembly (see Figure 3-4) to patient's anatomy and secure with hook and loop fastener system attached to foot support.

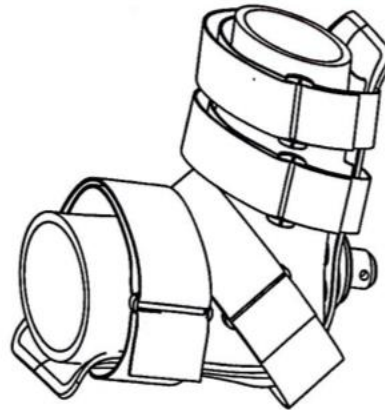


Figure 3-4. Traction Boot Assembly

- b. Insert Traction Boot Assembly Foot Support into Carbon Fiber Traction Unit quick connect receptacle. Rotate foot support slightly until an audible click is heard to ensure support is secure.
- c. Position Carbon Fiber Traction Unit at optimum distance distally PRIOR TO APPLYING TRACTION. Support opposite anatomy and secure (see Figure 3-5).

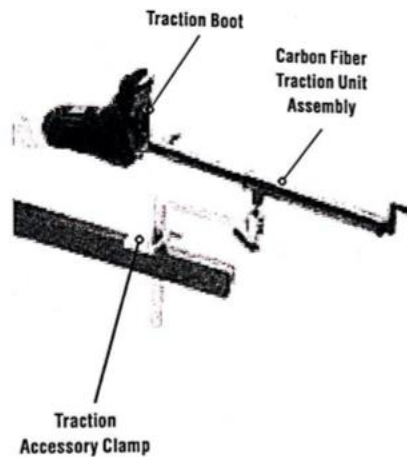


Figure 3-5. Typical Carbon Fiber Traction Unit Setup

- d. Slowly and smoothly rotate traction drive mechanism in indicated **TRACTION** direction (see Figure 3-6) to apply desired level of traction. Refer to traction force indicator contained inside blue housing which displays a traction force reading as traction is applied (see Figure 3-2).

NOTE: The traction force readings (see Figure 3-2) are for reference only and are not intended to dictate surgical setup

and practice. Carbon Fiber Traction Unit Assembly is capable of generating traction force greater than maximum indicator value.

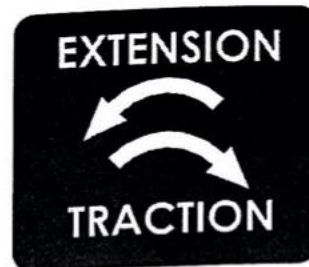


Figure 3-6. Carbon Fiber Traction Unit Operation Label

- e. If adjustment is needed, loosen or tighten lever below ball joint rotation device (located at distal end of metal L-shaped component of traction unit assembly) to reposition and realign boot and patient's lower extremity. This ball joint permits a full range of motion.
4. For other uses and adjustment of Carbon Fiber Traction Unit Assembly (see Figure 3-7):
 - a. Flat lever screw located just above blue tensiometer component allows lateral rotation of traction boot, skeletal traction block (an accessory inserted into Traction Unit assembly to permit use of a Steinman pin and accompanying holder, both not provided by STERIS; see Figure 3-8) or skeletal traction bow/block (an accessory which can be inserted into traction unit assembly when performing procedures in supine or lateral position; see Figure 3-9).

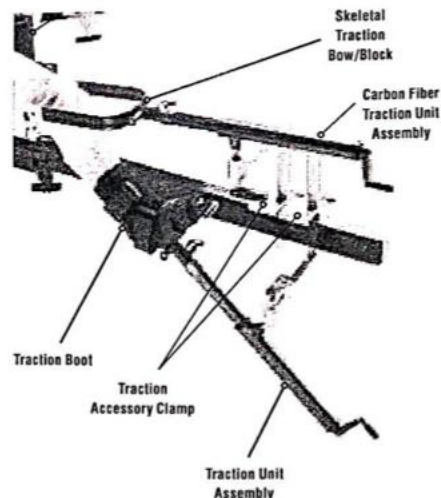


Figure 3-7. Using Skeletal Traction Bow/Block (Typical)

WARNING - PERSONAL INJURY AND/OR EQUIPMENT DAMAGE HAZARD: Do NOT pull Carbon Fiber Traction Unit Assembly circular knob, located just above blue tensiometer, while unit is under tension.



Figure 3-8. Skeletal Traction Block Accessory

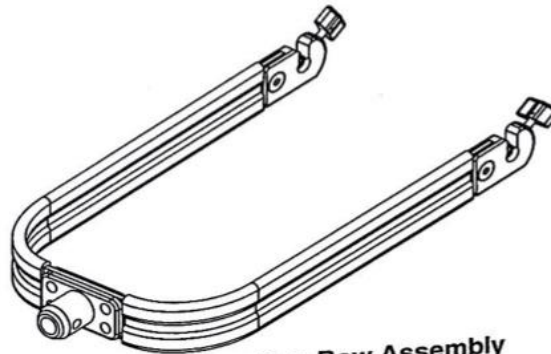


Figure 3-9. Traction Bow Assembly

- b. For quick and easy detachment of traction boot, skeletal traction block or skeletal traction bow/block, pull out circular knob, located just above blue tensiometer. Do NOT pull this knob while unit is under tension.
- c. Check rotation position of quick connect receptacle prior to inserting skeletal traction accessories. If an audible click is not heard, confirming a secure connection, then rotate either receptacle or accessory until an audible click is detected.

ROUTINE MAINTENANCE

4

4.1 Cleaning Carbon Fiber Traction Unit

WARNING – INFECTION HAZARD: When cleaning the Carbon Fiber Traction Unit, follow the STERIS supplied instructions, applicable national requirements and the cleaning product manufacturer's instructions and precautions.

CAUTION – POSSIBLE EQUIPMENT DAMAGE: Handle the Carbon Fiber Traction Unit with care. To prevent damage, avoid dropping the equipment. Do not use if damaged.

NOTE: The user must follow the requirements of the applicable national committee responsible for hygiene and disinfection when cleaning the table accessory.

1. Clean TenZor™ Carbon Fiber Traction Unit Assembly after each use.
2. STERIS recommends Coverage® HB Concentrated Disinfectant Cleaner and Coverage® Spray HB Plus Ready-to-Use One-Step Disinfectant.* See **Table 4-1** for a list of recommended cleaning products.
3. When cleaning, thoroughly read cleaning product's instructions for use and follow all directions and precautions on label. Pay particular attention to areas where fluid migration could occur.

NOTE: The latest space age technology is used to manufacture the carbon fiber matrix material used in the Carbon Fiber Traction Unit parts. These carbon fibers are extremely strong, but are also very brittle. **It is imperative that these parts are not dropped, banged, jarred, damaged or overloaded. Always handle carbon fiber parts with care.**

4. To prevent damage, after cleaning, ensure Carbon Fiber Traction Unit and accessories are completely dry before reinstalling.

Table 4-1. Recommended Cleaning Products*

Product Name	Product Use
Coverage® Spray HB Plus Ready-to-Use One-Step Disinfectant	Hospital-grade quaternary-based disinfectant spray
Coverage® HB Concentrated Disinfectant Cleaner	EPA-registered Hepatitis-B-effective quat
T.B.Q.® Hard Surface Disinfectant	Detergent-based germicide
Germicidal Surface Wipes Disinfecting/Deodorizing/Cleaning Wipes	Surface disinfectant

*Available from STERIS.

4.2 Replacement Parts

Please contact STERIS customer service (1-800-333-8828) for a listing of replacement parts.

DISPOSAL HAZARDS

5

As of the date of this manual, materials (Herculite® Fusion^{®1}, polyurethane foam, carbon fiber, alloy steel, stainless steel, aluminum and adhesives) used in construction of the TenZor™ Carbon Fiber Traction Unit Assembly and accessories are not known to require special disposal methods. When disposal of the Carbon Fiber Traction Unit and/or any accessory becomes necessary, STERIS recommends the customer review applicable federal, state and local regulations in your area to ensure proper disposal.

¹Herculite and Fusion are registered trademarks of Herculite, Inc.

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The best way to prevent costly downtime due to equipment malfunction is with regularly scheduled maintenance performed by qualified technicians trained in the latest technology. STERIS offers annual maintenance agreements to give your capital equipment planned maintenance that will help correct little problems before they become big ones. STERIS Engineering Service combines the precise maintenance program and factory-trained technicians to assure you of maximum productivity.

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ITEMS

