



DominionTM
SURGICAL

INSTRUCTIONS FOR USE

PATIENT POSITIONING SYSTEM

DOMINION SURGICAL

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SPD QUICK-REFERENCE INSERT

DOMINION® PATIENT POSITIONING SYSTEM

Intended Audience: Sterile Processing Department (SPD) and hospital support staff

Purpose: Fast-reference guide for inspection, assembly, cleaning, and sterilization.

A. PRE-USE INSPECTION (EVERY CYCLE)

Before assembly or sterilization, visually and manually inspect all components.

Verify:

- ✓ No cracks, deformation, or corrosion on metal components
- ✓ Locking handles and knobs rotate smoothly and fully engage
- ✓ Support rods are straight and free of excessive wear
- ✓ Rotation joint moves freely when unlocked and locks securely

Do NOT use if:

- ✗ Any locking mechanism does not hold position
- ✗ Excessive looseness or unintended movement is present
- ✗ Structural damage or irreparable wear is observed

B. FOOT HOLDER ASSEMBLY — SPD SEQUENCE

Refer to IFU Figures 1—8. Images below correspond directly to each assembly step and should be used as visual confirmation during SPD assembly.

STEP 1. IDENTIFY COMPONENTS

Complete Foot Holder Assembly with all components visible: Foot Holder Body, Interface Saddle, Rotation Joint, Locking Handle and Knob, Support Rod, and Foot

Figure A1. Complete Foot Holder Assembly (8 Components)



STEP 2. INSTALL LEG SPAR COUPLER

Shows coupler detached and upright orientation. Ensure coupler is fully seated on distal Leg Spar and locking handle is accessible

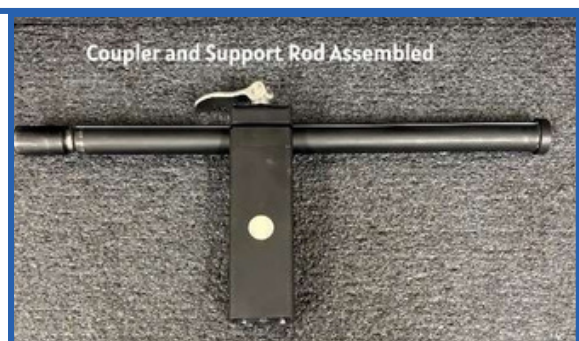
Figure A2. Foot Holder—Leg Spar Coupler with Locking Handle



STEP 3. INSERT SUPPORT ROD

Support Rod inserted through the coupler and centered. Rod should translate

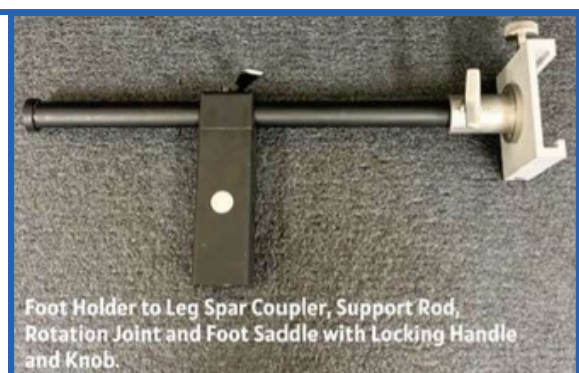
Figure A3. Coupler and Support Rod Assembled



STEP 4. ATTACH INTERFACE SADDLE AND ROTATION JOINT

Interface Saddle installed on Support Rod with Rotation Joint seated. Locking components remain loose for alignment.

Figure A4. Interface Saddle and Rotation Joint



STEP 5. INSTALL FOOT HOLDER BODY

Foot Holder Body mounted onto Interface Saddle. Orientation verified using front, side, and bottom reference views.

Figure A5. Foot Holder Body — Front, Side, and Bottom Views



STEP 6. FINAL TIGHTENING

All locking handles and knobs tightened. Confirm no unintended rotation or translation.

Final SPD Check: All locks secure; assembly rigid; no component movement detected.

Figure A6. Foot Holder—Leg Spar Coupler Assembled and Locked



C. DISASSEMBLY FOR CLEANING

1. Loosen and remove Foot Holder Body
2. Remove Interface Saddle and Rotation Joint
2. Slide out Support Rod
3. Remove Coupler from Leg Spar (if required)

Keep components grouped to ensure correct reassembly.

D. MANUAL CLEANING (VALIDATED PARAMETERS)

1. Pre-soak in enzymatic cleaner (per detergent manufacturer instructions)
2. Rinse with warm tap water
3. Clean using instrument detergent (pH 9.0) and soft, non-metallic brush
4. Rinse thoroughly
5. Apply hospital-approved / EPA-approved germicide
6. Final rinse with warm tap water
7. Dry completely

DO NOT:

- ✗ Use bleach or harsh chemicals
- ✗ Use abrasive pads or cleaners
- ✗ Lubricate components
- ✗ Place in milk bath

E. STEAM STERILIZATION (PRE-VACUUM)

Steam Sterilization (Pre-Vacuum)

(Replace entire current Section E with the text below)

Sterilization Method:

Steam sterilization (autoclave) is the only validated sterilization method for the Dominion Patient Positioning System. All other sterilization methods have not been validated and are not recommended.

Preparation Prior to Sterilization:

- Ensure all components are thoroughly cleaned and dried prior to sterilization.
- Ensure all movable components are placed in an open and unrestricted position before sterilization.
- Do NOT lubricate the system before or after sterilization.
- Do NOT place the system in a milk bath.

Packaging:

Components may be sterilized using one of the following methods, in accordance with facility practice:

- Double wrapping using two disposable sterilization wraps
- Placement in an autoclave-approved generic sterilization pan, case, or tray

When disposable wrap is used, components shall be double wrapped using two disposable wraps with a minimum size of **48 in x 48 in (122 cm x 122 cm)**.

Any generic pan, case, or tray used must be validated for steam sterilization, allow adequate steam penetration and condensate removal, and be configured to prevent component damage or movement during the sterilization cycle.

When using a rigid sterilization container, pan, case, or tray system, follow the container manufacturer's Instructions for Use (IFU).

Recommended Steam Sterilization Parameters

Pre-Vacuum Cycle

Packaging Configuration	Temperature	Exposure Time	Dry Time
Double wrap (no case)	132°C–134°C (270°F–272°F)	4 minutes	20 minutes
Sterilization pan, case, or tray	132°C–134°C (270°F–272°F)	4 minutes	30 minutes

Allow all components to cool completely prior to handling or assembly.

⚠ Caution:

Improper loading, overloading, or restricted steam access due to tray or container configuration may compromise sterilization efficacy. Components must be cool to the touch before handling or clinical use.

Post-Sterilization Handling

- Allow all components to cool completely prior to handling or patient contact.
- Inspect all components after sterilization to confirm:
 - No residual moisture is present
 - Locking mechanisms function correctly
 - No visible damage or deformation has occurred

F. STORAGE

After use and prior to storage, carefully disassemble the Dominion Patient Positioning System components in accordance with Section C. Take care to ensure that all components are accounted for and no parts are misplaced or lost.

- The system is shipped in a box with **pre-cut foam** inserts designed to secure individual components. These inserts may be used as the primary storage vessel to help prevent movement, impact damage, and loss of components.
- If the original shipping box and foam inserts are **not used**, note that individual components may be more vulnerable to damage, wear, or loss with repeated handling and storage cycles.
- Store all components in a **clean, dry, and protected environment**, away from excessive moisture, heat, or impact hazards.
- **Any extra Foot Holder or boot assembly components** that do not fit within the original shipping box should be stored **fully assembled**, where possible, and placed in a secure, dry location to minimize the risk of part separation, damage, or loss.

⚠ Storage Caution: Improper storage or incomplete disassembly may result in component damage, missing parts, or compromised device performance at next use.

⚠ All motorized mechanisms must be returned to their original positions before disconnecting and storing.