



# Evaluating The Beata Clasp: A Value-Based Framework

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## OVERVIEW

As healthcare organizations strive to improve clinical outcomes, reduce preventable harm, and optimize resource utilization, a standardized and evidence-based approach to product evaluation has become essential. The Beata Clasp medical line organizer—designed to enhance bedside safety, reduce tubing entanglement, and improve workflow efficiency—should be evaluated through a structured process aligned with the principles set forth by the Association of Healthcare Value Analysis Professionals (AHVAP). This includes a three-tiered framework that emphasizes clinical relevance, operational impact, and financial sustainability. By applying human factors principles and involving key stakeholders across nursing, infection prevention, supply chain, and biomedical engineering, healthcare facilities can ensure that The Beata Clasp is reviewed objectively, efficiently, and with the patient at the center of every decision.

This document serves as the foundation for a step-by-step guide, outlining how to evaluate the product using established best practices, with supporting tools and references provided in the following pages.

# Product Overview

## The Beata Clasp Medical Line Organizer

The Beata Clasp is a soft, flexible foam medical line organizer designed to attach securely to any hospital bedrail. Its bank of circular grooves holds tubing, drains, and medical lines in place, preventing impingement, dislodgement, and entanglement. By keeping lines cleanly separated and elevated off the floor, the Beata Clasp reduces the risk of contamination, enhances patient and caregiver safety, and minimizes fall and infection hazards. This simple, non-invasive solution supports safe, efficient line management without requiring adhesives, in-service training, or FDA approval. Its intuitive design empowers nurses, engages patients, and promotes a more organized, patient-centered care environment.



### Key Features:

- No FDA approval required
- No staff in-service needed
- Reusable after sanitization or available as single-patient use
- Prevents tangling, dislodgement, and line confusion
- Keeps medical lines off the floor to reduce contamination risks
- Enhances patient and caregiver safety
- Supports patient involvement in their own care
- Increases nurse efficiency and satisfaction
- Fits securely on any standard hospital bedrail
- Adhesive-free attachment for easy repositioning
- Durable, cost-effective, and environmentally conscious



### How The Beata Clasp Improves Patient Outcomes:

- Reduces infection and contamination risk by keeping lines off the floor
- Engages patients in their care, which is proven to improve outcomes
- Enhances patient satisfaction with improved organization and safety
- Involves families in line awareness and bedside safety
- Decreases supply waste by preventing tubing from needing replacement
- Eliminates unprofessional workarounds with a dependable solution
- Improves nurse efficiency by making line tracing and management easier
- Supports nurse-led education on safe line handling
- Maintains organization during transfers, improving safety across settings
- Provides continuity post-discharge by preventing at-home line tangling



### Quick Assessment for Clinical Fit

As a low-complexity, non-invasive line management accessory, the Beata Clasp presents minimal operational or financial burden and does not require a formal trial or extended multidisciplinary review. Evaluation can be completed through a brief sample review by frontline clinicians to confirm usability and clinical fit.

# The Beata Clasp - Request

## Tier 1: Medical Line Organizer

Based on the AHVAP Position Statement on the Standardized Product Review Process, the Beata Clasp medical line organizer is best categorized as a 'Tier 1: Low Complexity Product Request' within the three-tier evaluation framework. As a low-complexity, non-invasive line management accessory, the Beata Clasp presents minimal operational or financial burden and does not require a formal trial or extended multidisciplinary review. Evaluation can be completed through a brief sample review by frontline clinicians to confirm usability and clinical fit.

To help move the Beata Clasp through a Tier 1 Evaluation Process, please refer to the original AHVAP Process and our helpful outline below, which is specific to our product. Begin with a Request Submission, and rest assured that we are available to support your team after implementation and purchasing with training, education, and any additional resources needed.

### Evaluation Process for Tier 1 Product - The Beata Clasp:

#### 1. Request Submission:

Submit through your institution's value analysis portal or process, including our product details, supporting documentation, and pricing. You can find us listed in GHX (formerly Lumere), Sympplr Value Analysis (formerly Sympplr Spend), and VendorProof. We're also available for virtual presentations with nurse councils, practice committees, or shared governance teams. Additionally, we are registered with SAM and authorized to sell to government hospitals.

#### 2. Preliminary Review:

Initial screening should be completed by the healthcare value analysis team and relevant clinical representatives to ensure the submission is complete. The value analysis team will then review the materials to confirm that a Tier 1 classification is appropriate. To assist in this process, please refer to the table below, which outlines how the Beata Clasp aligns with Tier 1 criteria and supports a streamlined evaluation.

AHVAP Tier 1 Criteria	Beata Clasp Alignment
Minimal patient care impact	The Beata Clasp is a <b>non-invasive accessory</b> that aids line organization but does not directly interface with the patient's physiology.
Considered a commodity / low complexity	The device is <b>mechanically simple</b> , requires <b>no electricity, software, or IT integration</b> , and is similar in scope to items like <b>oxygen/suction tubing</b> or <b>incise drapes</b> .
Quick evaluation recommended (≤30 days)	A sample review and brief clinician feedback is often sufficient for hospitals to approve its use. It doesn't require formal trial periods.
No formal trial needed	Clinical staff can assess usability, safety, and functional value by <b>handling a sample</b> — no live-patient testing required.
Reviewed for functional equivalence and acceptability	Staff review would focus on benefits such as <b>line visibility, safety (fall/trip prevention), and organization</b> , without the need for procedural testing.
No major financial or operational impact	The product is <b>low-cost, reusable</b> , and <b>integrates seamlessly</b> with existing workflows. It does not require policy changes, infrastructure, or special training.

# The Beata Clasp - Request

## Tier 1: Medical Line Organizer

### 3. Vendor and Data Comparison:

When reviewing vendor history, usage data, and existing contracts for The Beata Clasp, please note that your facility has flexible options. You can either set us up directly as a vendor or order through one of our established partners, including ALCO Sales. For facilities outside the U.S., we also work with a growing network of international distributors to support global access and fulfillment. We're happy to provide usage data and references upon request.

### 4. Rapid Clinical Review:

For the Rapid Clinical Review of The Beata Clasp, the key stakeholder is the bedside nurse, whether in medical-surgical, ICU, labor and delivery, or pediatric units—essentially, any department where line management and patient safety are a priority. We offer a free product sample for hands-on evaluation, and because The Beata Clasp qualifies as a Tier 1 low-complexity item, we kindly request a response or completed evaluation within 30 days, in alignment with AHVAP guidelines.

### 5. Operational and Financial Impact Assessment:

To ensure The Beata Clasp aligns with current workflows and budgets, it offers flexible use options—it can be assigned to a single patient as part of a welcome kit, supporting patient engagement and satisfaction, or it can be cleaned and reused between patients using bleach, soap and water, or Sani-Wipes per your hospital's hard-surface disinfection protocol. The product integrates seamlessly into daily care routines across units—from med-surg to ICU to pediatrics—by keeping lines organized, reducing tripping hazards, and preventing tubing contamination. Research supports that taking any proactive step in line management is better than none, and The Beata Clasp helps meet global line safety goals set by organizations like the World Patient Safety Foundation, while also supporting OSHA compliance and reducing the risk of workplace injuries to staff, patients, and visitors.

### 6. Decision and Communication:

For The Beata Clasp, we kindly ask that hospitals complete the evaluation within 30 days and communicate the outcome to all relevant stakeholders, including your clinical, supply chain, and purchasing teams. While the bedside nurse plays a key role in clinical feedback, we also consider ourselves a stakeholder in supporting a smooth and successful adoption. If your facility chooses to purchase directly from us as a vendor and completes the evaluation within the 30-day timeframe, we're pleased to offer a 10% discount on your first order.

#### Category Definition

Tier 1 - Low complexity

#### Review Time Frame

No more than 30 days

#### Review Process

Product sample or demo

# The Beata Clasp

## Value Analysis Reference - Human Factors Engineering & IFU Alignment

### I. Classification Context (FDA HFE Priority List)

The Beata Clasp is not listed on the FDA's Human Factors Priority Device List, meaning formal FDA human factors testing is not required. However, it is important to follow the Instructions for Use (IFU) carefully—such as not permanently affixing the product to equipment and using it only for passive, restrictive movement of lines and cords.

### II. Human Factors Engineering (HFE) Evaluation Summary

Based on the AHVAP Human Factors Engineering Evaluation Checklist, the Beata Clasp aligns with best practices in the following areas:

#### 1. User Interface & Usability Design

- Color-coded: Yellow color helps enhance quick visual identification of high alert lines.
- Intuitive use: Designed for nurses at the bedside to organize lines with minimal effort.
- Minimal training required: Can be adopted rapidly due to its simple, low-tech design.

#### 2. Instructions for Use (IFU) & Labeling

- Clarity: The Beata Clasp IFUs use step-by-step visual diagrams with straightforward language.
- Visibility: Colors allow for ease of visibility.
- Workflow alignment: Use case scenarios in the IFU mimic typical bedside conditions.
- Label comprehension study: Not required.

#### 3. Training & Learnability

- Minimal training required: Easily demonstrated at in-services or shift huddles.
- Job aids available: Posters and cards are available to reinforce correct usage.
- Refresher materials: Can be included in onboarding or annual competencies.

#### 4. Clinical Workflow Integration

- Enhances line visibility and organization: Reduces entanglement, tripping, and line confusion.
- Supports team handoffs: Lines remain organized between units and during transport.
- Speeds workflow: Nurses can quickly identify and trace lines at a glance.

#### 5. Use-Related Risk & Safety

- Mitigates trip/fall hazards: Secures cords off the floor.
- Prevents misconnection risk: Separation allows for ease of line tracing.
- Reduces pressure ulcers and line pulls: Helps keep lines off the patient's body.
- Formal FMEA or MAUDE report history: Not applicable or not available due to class type.

#### 6. Environmental & Physical Considerations

- Bedside compatibility: Works in med/surg, ICU, ER, pediatric, and OB settings.
- No special infrastructure needed: Lightweight, reusable, adhesive free, and manually applied.
- Safe for mobility: Can be clipped to IV poles, beds, or transport equipment.

# Beata Clasp

## Value Analysis Reference - Human Factors Engineering & IFU Alignment

### 7. Human Factors Validation & Regulatory Review

- Formal FDA HFE validation: Not applicable (non-regulated accessory).
- Usability studies via pilot sites: Positive feedback received during trials.
- Design informed by frontline clinicians.

### 8. Post-Market Feedback

- Continuous improvement: Product enhancements based on bedside nurse feedback.
- No known misuse incidents reported.
- Nursing champions report improved workflow and reduced patient risk.
- Integrates well with facility wide Line Management Awareness Programs.

### III. Final Recommendation if Aligned with Human Factors Standards

Approved – The evaluation concludes with a recommendation to adopt the product, supported by clear evidence of its value, safety, and effectiveness within the healthcare setting.

### IV. Additional Notes

- Classified as an organizational accessory; not a regulated medical device under FDA's human factors priority pathway, but highly relevant to patient safety.
- Integration into educational programs (e.g., line management awareness) reinforces human factors alignment and standardization goals.

# 01

#### Safety Simplified

The Beata Clasp enhances product safety and user compatibility through intuitive, one-handed use, adhesive-free design, and simple integration into bedside equipment. Its use of colors to indicate high-risk lines supports clinical awareness and safer, more efficient care delivery.

# 02

#### Risk Reduction

The Beata Clasp reduces risks of human error and miscommunication by clearly separating and securing lines without adhesives, minimizing tangles and dislodgements. Its streamlined design supports efficient implementation and monitoring, improving workflow and bedside safety.

# 03

#### Collaborative Safety

The Beata Clasp reflects human-centered design through collaboration with clinicians, supply chain, and infection prevention teams to support safety goals and reduce costs. Its reusable, adhesive-free design improves system reliability while helping eliminate preventable harm at the bedside.



# Instructions for Use (IFU)

## The Beata Clasp™ – Medical Line Organizer

### Purpose:

To secure and organize medical lines, tubing, and drains at the bedside, reducing tangles, falls, and infection risks.

### Product Description:

The Beata Clasp is a soft, flexible foam device that attaches to hospital bedrails. It features circular grooves designed to hold and separate medical tubing, keeping lines elevated, secure, and organized without the need for adhesives.

### Indications for Use:

Use The Beata Clasp to:

- Prevent tubing from falling to the floor
- Reduce line tangling, dislodgement, and trip hazards
- Improve visibility and access to medical lines
- Promote safer transitions during patient movement (bed to gurney, IV pole, wheelchair, etc.)
- Support patient and family involvement in care
- Improve patient outcomes through safer line management and reduced line-related complications



### Resource Library

Watch how The Beata Clasp easily attaches to the bedrail, how lines are securely placed into the device, and how it can be seamlessly implemented hospital-wide to support safer, more organized line management.

### How to Use

#### Step 1: Placement

- Identify the desired location (e.g., hospital bedrail, walker, gurney rail, or IV pole).
- Gently open the clasp and clip it securely onto the selected rail.
- Ensure the clasp is stable and secure before use. If additional stability is needed, optional fasteners may be used to reinforce attachment.
- Explain the product's purpose to the patient or primary caregiver at the bedside to promote awareness and engagement.
- **Do not permanently affix to equipment**

#### Step 2: Line Insertion

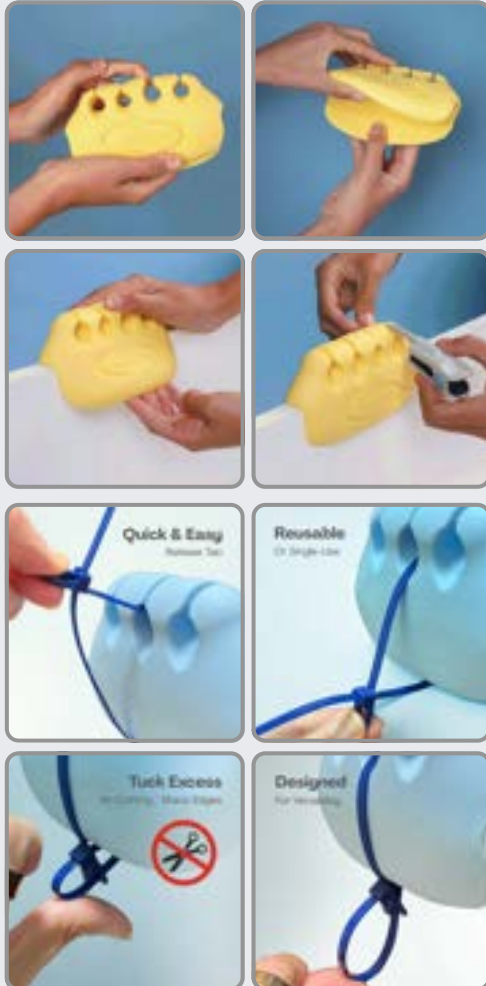
- Place each line or drain into a separate groove in the clasp.
- Do not overfill—use one line per groove for best results.
- Leave slight slack for patient comfort and movement.
- Recommended to place call light in The Beata Clasp to support universal safety protocols.
- **Use nursing discernment and follow physician orders regarding manipulation of sensitive lines (e.g., central lines, arterial lines) that are at high risk.**

#### Step 3: Monitor & Adjust

- Check line placement during each shift change or transfer.
- Reposition the clasp if necessary for patient safety or comfort.
- If more grooves are needed for additional lines, you may add an additional Beata Clasp to accommodate the setup.
- The device may remain in place during transport to maintain line organization and patient safety.

# Instructions for Use (IFU)

## TheBeataClasp™ –MedicalLineOrganizer



### Support & Integration

For additional FAQs, visit our website. We offer sample policies, procedures, and guidelines to support product use. The Beata Clasp integrates seamlessly with World Med Solutions' Line Management Awareness Program, promoting hospital-wide awareness of line safety among all support staff.

### Cleaning and Reuse:

- The Beata Clasp is suitable for single-patient use or can be sanitized and reused per facility policy.
- Wipe down with an EPA-approved disinfectant, bleach solution, or soap and water, following hospital protocols for cleaning hard surfaces.
- It is safe to disinfect with UV light. Always follow facility protocols when determining whether to clean, reuse, or discard the device.

### Safety Precautions:

- Do not overload grooves.
- Ensure lines are not pinched or crimped.
- Always verify secure connections after adjusting lines.
- Not intended for sterile fields.
- Use clinical discernment for patients who are confused or combative to ensure safety and proper use.

### Disposal:

- Dispose of according to your facility's protocol for single-patient-use medical devices if not reusing.
- If reusing between patients, inspect carefully and discard the device if it shows any signs of visible damage or wear.

### Product Highlights:

- Adhesive-free attachment
- Fits most hospital bedrails and mobility devices
- Helps prevent infection and line-related complications
- Encourages patient and caregiver engagement
- Cost-effective and environmentally conscious option
- Requires no power source, adhesive, or permanent fixture
- Ready for immediate use upon arrival
- Designed by clinicians for frontline practicality
- Integrates seamlessly with line management awareness programs
- Support clinical safety initiatives and standardized workflows



# Why Line Management Matters

## TheBeataClasp™ –MedicalLineOrganizer

### Every line tells a story—of safety, teamwork, and care.

Prevent falls, reduce infection, and protect patients by managing cords and tubing with intention, every shift, every room, every time. Top Reasons to Adopt a Line Management Awareness Program:

1. Prevent Fatal Errors and Misconnections
2. Align with National and Global Safety Standards
3. Improve Patient Outcomes and Experience
4. Reduce Sentinel Events and Legal Risk
5. Promote Systems Thinking and Just Culture
6. Empower and Educate Nurses
7. Strengthen Organizational Safety Culture
8. Support Regulatory and Accreditation Compliance
9. High-Impact, Low-Cost Implementation
10. Scalable Across All Units and Facilities



#### Bundle & Boost

Pair our medical line organizer with a Line Management Awareness program to jumpstart safer line management and staff readiness—right out of the box.

