COMMERCIALIZATION WORKSTREAM · MARKETING & FIELD MODEL

Virtual-First Commercial Strategy

Digital outreach, virtual training, remote support, and lifecycle nurture for Endospool — staged across pre-clearance, 1099 overlay, and selective direct. Includes compliance gates, technology stack, budget, and scope of work.

PREPARED
August 2026

ASSUMED ASP
$150–350

REGULATORY POSTURE
Pre-510(k)

BENCHMARK COMPETITOR
Origami Surgical / StitchKit

CONFIDENTIAL
Prepared for Endospool · Not for distribution

ENDOSPOOL

01 The thesis

IN ONE PARAGRAPH

At a **$150–350 ASP on a single-use disposable, the unit economics cannot support a rep standing in the room.** That is arithmetic, not a strategic preference. But the evidence is equally blunt that surgeons buy on rep attributes: in a 201-surgeon study of physician-preference items, **rep follow-up scored 4.39, rep knowledge 4.36, and rep availability 4.16 on a 5-point scale — all above implant cost at 3.21.** So the job is not to eliminate the rep. It is to **replace the rep's responsiveness with a system that answers faster than a rep can**, and to make the product's competence transferable through content rather than through a body.

$125M
BURNED BY AVAIL
Virtual-OR platform shut down Nov 2023 despite a Premier GPO deal

82%
SURGEONS ON WHATSAPP/ZOOM
Already share surgical video on consumer apps — Medtronic, n=1,000

60%
PREFER DIGITAL OVER REPS
IQVIA 2025, 33,000+ HCPs across 38 countries

4.39
REP FOLLOW-UP SCORE
vs 3.21 for cost — service beats price in PPI decisions

$12K
FULL CONFERENCE YEAR
MISWeek booth + SAGES abstract — cheapest surgeon access there is

85%
S&M AS % OF REVENUE
Novel medtech, year 5 post-launch (10-K derived)

Three findings that should shape everything

1. Do not sell "virtual" as the story. Avail Medsystems raised $125M ($100M Series B led by D1 Capital, Oct 2020), placed camera consoles in ORs for free, signed a Premier national GPO agreement, and **shut down overnight in November 2023**. Explorer Surgical was absorbed into GHX. The platform layer for virtual OR presence has not proven out as a business. The winning position is not "we're the rep-less company" — it's **"our product doesn't need a rep in the room,"** which is a product-design and training-content claim, not a platform bet.

2. The repless tailwind is not yours to ride. Hospital pressure to remove reps targets **high-ASP implants where rep commission is a visible line item** — knees, hips, spine, where a $50–100 pedicle screw sells for ~$1,000. Loma Linda eliminated reps for total joints in 2015, reported >50% cost reduction, and **then abandoned the approach**. A $150–350 disposable carries no commission worth hunting. You aren't a target of the movement, and you don't get its momentum either.

3. Meet surgeons where they already are, not where a platform wants them. Medtronic's *State of Surgery US 2024* (n=1,000 US surgeons) found **82% use consumer apps — WhatsApp, Zoom, FaceTime — to share surgical video because no dedicated platform exists.** Any strategy requiring a surgeon to adopt new

software, create an account, or get IT approval will fail. Every touchpoint in this plan is designed to work with **zero login and zero install.**

CORRECTION TO THE SEO AUDIT

The prior audit characterized the pre-clearance posture under 21 CFR 812.7. That was over-cautious. **812.7 applies only to devices under an IDE.** For a 510(k)-pending device with no IDE, **CPG Sec. 300.600 governs — and it expressly permits advertising and display.** The operative language: a firm *"may advertise or display a device that is the subject of a pending 510(k)"* but *"may not take orders, or be prepared to take orders."*

The trip wire is order-taking, not speech. Which means the Shopify cart on endospool.com is still the single most dangerous object on the property — "prepared to take orders" is the exact phrase — while the marketing program described here is substantially more permissible than the audit implied. Section 4 maps it activity by activity.

CONTENTS

02 Audience & segmentation

Four buying roles, three of which most medtech marketing ignores.

ROLE	WHAT THEY DECIDE	WHAT MOVES THEM	REACHABLE HOW
Surgeon champion Robotic/lap general, hernia, bariatric, urogyn	Whether the product enters the hospital at all. Necessary condition; never sufficient.	Peer demonstration, technique video, a device that makes their case cleaner. **Not** ROI decks.	YouTube, LinkedIn, society meetings, peer referral, email
Scrub tech & circulating nurse	Whether it gets used a second time. The most under-marketed audience in surgical disposables.	Back-table setup clarity, count workflow, disposal, not being embarrassed in front of the surgeon.	QR code on packaging, AORN channels, 90-second video, in-service
Value Analysis Committee Supply chain + clinical + finance	Whether it gets a PO. The actual gate. **3–6 month cycle, sometimes 12.**	510(k), peer-reviewed evidence, total cost of ownership, DRG/reimbursement position, implementation plan. Committees meet monthly or quarterly — miss a submission deadline and you lose a quarter.	The champion carries your dossier in. You often get no direct presentation.
OR director / periop leadership	Whether the workflow change is tolerable and whether your reps get in the building.	Turnover time, staff training burden, sharps safety policy alignment, vendor credentialing load.	Society channels, webinars, direct outreach, the champion

TARGETING CONSTRAINT MOST PLANS MISS

Many health systems' vendor policies **prohibit unscheduled or uninvited contact with clinicians** and route all vendor communication through supply chain. Cold LinkedIn or email outreach to an employed surgeon can violate their *employer's* policy even where it violates no law. Employed-physician systems — Kaiser, Geisinger, Intermountain, most academic centers — are the hardest.

Design the targeting around it: ASC and private-practice surgeons are the digitally reachable segment. Academic and large-IDN surgeons come through society meetings, podium, and peer referral — not cold outreach.

BEACHHEAD RECOMMENDATION

Robotic hernia repair and bariatrics, ASC and community hospital, private practice or loosely employed. Rationale: Dr. Munday is a high-volume robotic general surgeon, so founder credibility maps directly; the SEO audit found both procedure clusters are uncontested in search; and Origami's clinical evidence sits in urogyn/sacrocolpopexy, where they have a 422-patient published series and you have nothing. Do not fight them on their turf in year one.

03 The staged field model

Four stages. Each has an entry trigger, a headcount shape, and a defined role for the virtual engine. The virtual engine never goes away — its job changes from *replacing* a field force to *arming* one.

STAGE 0 Virtual-only — build the asset base

Now → clearance (~12–18 mo)

Headcount: 0 reps. One marketing operator (0.75–1.0 FTE) plus fractional regulatory review.

Virtual engine's job: everything. There is no alternative, and no product to sell, so the entire period is audience-building, evidence-building, and content-building — none of which requires clearance.

What you're actually manufacturing in this stage: a named list of 300–800 surgeons who have consumed your content and raised a hand; a library of 8–12 technique and mechanism videos; one original surgeon survey with a quotable statistic you own; one society podium appearance; a complete VAC dossier template; and a credentialed, MLR-governed marketing operation ready to switch on.

Exit trigger: 510(k) clearance granted.

STAGE 1 Virtual + clinical specialist — prove the model

Clearance → ~$1.5M revenue

Headcount: 1–2 clinical specialists (W-2, clinically credentialed, nationally deployed). Zero territory reps.

Virtual engine's job: generate every lead, run every training, cover every case remotely. The specialists fly only for **first-case coverage at a new account** and for VAC presentations that require a body. Everything after case one is virtual.

Why W-2 and not 1099 here: the AKS employee safe harbor (42 CFR 1001.952(i)) broadly protects bona fide employees. A 1099 "clinical advisor" who also sells is a materially riskier structure, and at this stage you cannot absorb a compliance event.

Cost comparison: a virtual case-support function with BAA'd video and one clinical specialist runs an estimated $8K–15K/month fully loaded, against $180K–250K/year for a single W-2 territory rep who covers a fraction of the geography.

Exit trigger: 8–12 reordering accounts, a documented sub-4-hour support SLA being met, and eval-to-reorder conversion above 15%.

STAGE 2 1099 rep-group overlay — buy geography

~$1.5M → $8M revenue

Headcount: 2–4 clinical specialists (now regional) + 8–20 independent rep groups under contract. Virtual team grows by one nurture/ops hire.

Virtual engine's job flips. It stops being the sales force and becomes the **enablement layer for the rep groups**: it generates and qualifies the leads they work, trains their people, and covers their cases so they don't have to be in the room. That is the pitch that gets a bag-carrying rep to actually pick you up.

> **THE 1099 ARITHMETIC — READ BEFORE COMMITTING**
>
> Independent reps take **10–25% of the sale, with disposables at the high end.** At a $250 ASP and 25%, a rep earns $62.50/unit. To make a $150,000 income on your line alone they must move **2,400 units a year in territory.** That is a very large disposable business for an unknown brand.
>
> **Conclusion: no rep group will carry you as a primary line at launch.** They will bag-carry you alongside an existing line. Design accordingly — the product must be sellable in **under 10 minutes of a rep's attention** and require **zero in-case presence**. Your rep-facing asset is not a brochure; it's a 6-minute certification video and a one-page objection sheet.

Exit trigger: two or more metros where reorder volume justifies a dedicated body.

STAGE 3 Selective direct — only where density earns it

$8M+ revenue

Headcount: direct W-2 reps in the 5–8 metros with proven density. 1099 groups retained everywhere else, permanently. Virtual stays the training, support, and nurture backbone for both.

Trigger test per metro: hire a direct rep only when territory revenue exceeds roughly $700K–900K, i.e. the point where a fully loaded $180K–250K rep costs less than the 20–25% commission you'd otherwise pay. Do not hire on optimism; hire on the arithmetic crossing.

Precedent to model: Inspire Medical launched with **fewer than 30 reps**. Nevro and Axonics launched with 100+. At your capital level, Inspire is the relevant precedent — and even then, novel medtech runs S&M at **85% of revenue in year 5**, with the range spanning Shockwave at 45% to Inspire and PulmonX above 100%.

BUDGET THE THING EVERYONE FORGETS

Vendor credentialing. symplr acquired IntelliCentrics (SEC3URE/Reptrax) in 2024 and raised prices effective January 1, 2025; reps covering facilities on both platforms during migration **pay for both**. Per rep, fully loaded across multiple platforms plus immunizations, TB test, background check, drug screen, HIPAA and bloodborne-pathogen training, and $1M/$3M liability proof: **$1,500–$4,000/year**, with **2–6 weeks of lead time** before a new rep can enter an OR.

Two consequences. First, this is the most commonly underestimated line in a medtech launch model and it will delay Stage 1 by a quarter if unbudgeted. Second — **credentialing is facility access, not product promotion, so it is not gated by 510(k) status. Start credentialing your clinical specialists before clearance.**

And critically: **virtual does not bypass credentialing.** Health system policies increasingly scope requirements to access "physically *or virtually*." Do not model a remote video link as a credentialing workaround.

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04 Compliance gates — what you may run, when

This section is the operating constraint on everything downstream. Legend: FINE routinely done and defensible · GUARDRAILS legal with specific conditions · RISKY legal but real exposure · PROHIBITED bright line.

Pre-clearance (510(k) pending, no IDE)

ACTIVITY	VERDICT	CONDITION
Corporate site & product description page	FINE	Conspicuous regulatory-status disclosure; no safety/efficacy claims; never "FDA Approved" or "FDA Cleared"
Email list building, newsletter, gated content	FINE	Not order-taking. CAN-SPAM applies
Nurture emails with clinical/problem education	FINE	Unbranded or device-description only; ad identification + postal address + one-click unsubscribe
Unbranded educational webinars	FINE	Educational framing; status disclosed verbally *and* on slides; no order path, no pricing
LinkedIn organic / founder thought leadership	FINE	Same content rules; every post is intended-use evidence under 21 CFR 801.4
LinkedIn 1:1 targeted outreach	FINE	Targeted, not bulk. Respect employer vendor policies
Conference booth display	FINE	Signage: **"Pending 510(k), not available for sale within the United States."** No POs, no price lists, no volume discounts, no comparative claims
Society podium / abstract / Emerging Technology session	FINE	Scientific exchange. The single best pre-clearance channel available
Press releases, investor and payor communications	FINE	Payor pre-approval communication is expressly protected under FDCA §502(a)(2) / Cures Act §6004
Virtual advisory boards	GUARDRAILS	Written agreement, FMV hourly, documented legitimate need, deliverable required, sales excluded from selection, cap 6–10 participants
Mechanism-of-animation video	GUARDRAILS	Device description and mechanism only. Status disclosure on-screen at open, as a persistent lower-third, *and* in the YouTube description — descriptions are labeling
YouTube performance demo video	RISKY	**This is the Q'Apel fact pattern.** A demo showing device behavior is an implicit effectiveness claim and creates intended-use evidence beyond the pending clearance. Shoot benchtop/cadaver description, not performance

ACTIVITY	VERDICT	CONDITION
Paid HCP media (LinkedIn ads, Doximity, endemic display)	RISKY	CPG 300.600 permits advertising — but most ad platforms' own policies (Doximity, Medscape, Google's medical-device policy) require proof of clearance before serving product ads. A *commercial* blocker even where FDA is silent. Unbranded disease-state and corporate ads are fine
Waitlist / preorder / reservation / deposit	PROHIBITED	The one bright-line CPG 300.600 violation available in a digital funnel. A no-obligation "notify me at launch" list is fine. Anything that queues units, holds allocation, quotes a price, or takes money is order-taking
Publishing pricing or price lists	PROHIBITED	Explicitly "offering for sale"
Distributor / GPO agreements	PROHIBITED	Same
Named comparative claims vs StitchKit	PROHIBITED	Policy bars "comparative descriptions with other devices" pre-clearance. Also invites a Lanham Act suit, which arrives faster and costs more than FDA
Surgeon testimonials on performance	PROHIBITED	Efficacy claim by proxy. A 2016 device warning letter was triggered by an "FDA Approved" claim *inside a testimonial video*
Sending eval / demo units for use in patients	PROHIBITED	Commercial distribution. Unsterilized mock-ups for education are fine and are a good low-risk virtual-training asset

LIVE ENFORCEMENT PRECEDENT WORTH INTERNALIZING

Q'Apel Medical, Feb 5, 2025. FDA cited **promotional videos** showing a nitinol tip compressing and flaring — a design feature not disclosed in the clearance — plus marketing calling the tip "adaptive." Cited §501(f)(1)(B), §502(o), and QMS findings together. **Exer Labs, Feb 10, 2025:** FDA quoted the company's *website copy* verbatim as establishing an intended use for an uncleared device.

Note the pattern: **CDRH has no OPDP equivalent issuing standalone letters for tone.** Device promotion enforcement arrives bundled into an inspection-driven warning letter. The realistic trigger is an inspection or **a competitor complaint through FDA's Allegations of Regulatory Misconduct portal** — which competitors in surgical disposables use routinely. Assume Origami is watching.

What unlocks the day clearance lands

- Commercial distribution, order-taking, pricing, distributor and GPO contracting
- "FDA cleared" / "510(k) cleared" language — **never "FDA approved"**, which is PMA-only and is itself a misbranding claim
- Affirmative safety and effectiveness claims, **strictly within the cleared Indications for Use** and only as substantiated

- Paid HCP media at scale — the ad platforms will now serve you
- Company-conducted training and proctoring programs under AdvaMed Sec. III
- Off-label scientific exchange under the SIUU final guidance (published Jan 7, 2025) — a post-clearance tool only
- Substantiated comparative claims, with legal review
- **And an obligation attaches:** Open Payments reporting begins the program year the device becomes a covered product. See below.

The rules that bind an HCP-payment program

ADVAMED CODE — CURRENT: 2023 TEXT + NOV 1, 2025 DATA-TECHNOLOGIES UPDATE

- **Virtual training is expressly permitted** — "live or virtual training and education programs in settings conducive to the effective transmission of information." Virtual guidance entered in the June 2022 revision.
- **Virtual meals** are permitted for company-run virtual meetings, but you must control ordering and delivery, track attendance so only appropriate participants receive them, and/or **prohibit home delivery**. Cleanest posture: prohibit home delivery entirely.
- **Consulting (Sec. II)** requires all five: legitimate need identified in advance, written agreement, FMV compensation not based on volume or value of business, selection on qualifications with **sales personnel excluded from the decision**, and retained documentation.
- **Third-party conference grants go to the organizer, never to an individual HCP.** You may not pay a surgeon's registration or travel directly, and you may not select who receives grant-funded attendance.
- **Entertainment and recreation: absolute ban.** No exceptions for value, consultant status, or educational secondary purpose.
- **Gifts:** branded promotional items are prohibited even at minimal value. Educational items under

OPEN PAYMENTS — ATTACHES AT CLEARANCE, NOT BEFORE

An "applicable manufacturer" must produce a product for which **Medicare/Medicaid/CHIP payment is available** and which requires FDA premarket notification. A company whose only product has no clearance is generally **not** an applicable manufacturer. **That is a real planning window — use it.**

PY2026 per-payment de minimis	**$13.82**
PY2026 aggregate trigger	**$138.13**
Submission + officer attestation	**March 31** following year
Record retention	**5 years** from publication
Non-knowing failure	$1,000–10,000/payment, $150K cap
Knowing failure	$10,000–100,000/payment, $1M cap

Reportable in a virtual program: speaker honoraria, virtual advisory board fees (as "consulting fee"), virtual/delivered meals identifiable to a named recipient, travel and lodging, and materials for the HCP's own education.

$100 FMV are permitted; textbooks and anatomical models are excluded from the cap.

- **Evaluation product (Sec. XII)** — directly on point: single-use products may be furnished free in "reasonable quantities," not exceeding what is "reasonably necessary for adequate evaluation."
- **Alcohol:** no company-paid alcohol at any HCP program, virtual or live. Free alcohol is an OIG-named suspect characteristic.

Excluded: educational materials that directly benefit patients; product samples not intended to be sold and intended for patient use; **short-term device loans**; buffet food at large-scale conferences where individual attribution is impractical; discounts and rebates.

Eval units: characterize at the time as either a product sample or a short-term loan — both excluded — with documented quantity limits. Open-ended free supply that displaces purchases is neither, and becomes an AKS problem regardless of Open Payments treatment.

Budget ~6 months of lead time to stand up transfer-of-value capture before clearance. You cannot retroactively reconstruct meal attendance.

OIG SPEAKER PROGRAM FRAUD ALERT — NOV 16, 2020 — AND IT APPLIES TO VIRTUAL

OIG is on record as **"skeptical about the educational value of such programs."** It expressly addressed the pandemic shift: *"risks remain whenever payments are offered or made."* Virtual format removes the venue, alcohol, and travel suspect characteristics but **leaves the core ones intact**: little substantive content; repeat attendance at the same topic; attendees without a legitimate business reason; sales influencing speaker selection; above-FMV compensation; and *"a significant period of time with no new medical or scientific information nor a new FDA-cleared indication."*

That last one cuts in your favor — briefly. A genuinely new, just-cleared technology is the strongest possible justification for a training and speaker program. **Front-load these programs into the 12–24 months after clearance while the novelty justification is real, then taper.**

DEFENSIBLE FMV BANDS FOR SURGEON HONORARIA ESTIMATE

TIER	RATE
Community/general surgeon, advisory participation	$300–500/hr
Experienced specialist, regional reputation	$500–800/hr
National KOL — society officer, high volume, published	$800–1,500/hr
Live case proctoring	$2,500–5,000/day
Virtual advisory board, 2 hrs, 6–10 surgeons	$5K–15K honoraria total + $5K–20K facilitation

Commission a formal FMV benchmark before the first payment. Research and Markets publishes per-specialty KOL FMV rate reports; the cost of one is trivial against the cost of defending an above-FMV arrangement.

DIGITAL AND DATA RULES, CONDENSED

- **CAN-SPAM covers B2B — there is no exemption.** Opt-in is not required in the US. Required: accurate headers, non-deceptive subject, ad identification, valid physical postal address, clear opt-out live for 30+ days, opt-outs honored within 10 business days. **Penalty up to ~$53,088 per email.** Also implement RFC 8058 one-click List-Unsubscribe headers — Gmail and Yahoo bulk-sender rules will crush deliverability otherwise.
- **SMS: don't.** TCPA damages are $500 per violation, trebled to $1,500 for willful, **no cap**, with a private right of action. Business cell numbers are fully covered — there is no B2B exemption for texts. A surgeon's mobile is exactly what your CRM will hold. The channel adds little over email and LinkedIn for this audience.
- **HIPAA:** a device manufacturer is *not* a business associate by default — receiving PHI in connection with treatment falls under the treatment exception. You become one if you operate a data platform or service on the hospital's behalf, **or if you sign a BAA**, which hospitals routinely require as a condition of access. Signing is a voluntary assumption of Security Rule and breach-notification obligations. Read before signing.
- **Virtual OR streaming:** operating rule — **never record.** Stream-only, no cloud retention, camera framed on the back table rather than the field or the monitors, patient consent obtained by the provider, BAA/confidentiality agreement in place.
- **Surgeon-submitted case photos and video** are the highest-frequency real risk in medtech marketing. The surgeon needs a HIPAA authorization specifically permitting disclosure to your company for promotional use. De-identification is fragile — full-face images are one of the 18 identifiers, and **DICOM headers and phone EXIF carry patient name, MRN, DOB, and GPS.** Build a metadata scrub into intake.
- **State laws that actually reach device manufacturers: Vermont** (substantive gift ban, $765 registration, April 1 disclosure — the strictest), **Massachusetts** (105 CMR 970: $2,000 registration, mandatory code of conduct and compliance officer, disclosure of any benefit ≥$50, quarterly meal reports, up to $5,000 per violation), and **Connecticut** (APRN transfers, July 1). California's §119402 and DC's AccessRx are pharma-only; Nevada expressly excludes device reps; Minnesota's gift cap is drug-focused. **Build one transfer-of-value data model carrying state, recipient type, purpose, and amount, and you satisfy all four regimes from one dataset.**
- **CCPA has no B2B carve-out anymore** — the exemption sunset January 1, 2023. California surgeons in your CRM have access, deletion, and opt-out-of-sharing rights, and your ad pixels count as "sharing."
- **EU:** geofence it out of paid media and suppress EU domains from email until CE marking is on the roadmap. Germany, Austria, Italy, Spain and Norway require opt-in even for B2B.

THE MLR PROCESS — AND ONE THING THAT DOES NOT APPLY

FDA Form 2253 does not apply to devices. It is a CDER/OPDP drug requirement under 21 CFR 314.81(b)(3)(i). CDRH has no analogous routine submission. Two consequences: you file nothing, and you also get **no advisory-comment channel and no "we submitted it and FDA didn't object" defense. Your MLR file is the only record you will ever have.**

A workable process for a sub-10-person company:

- **Claim substantiation register** — one row per claim: text as it will appear, claim type, evidence source with page cite, on-label check, approver, date, re-review date. No claim ships without a row. Pre-clearance the register's job is to enforce that there *are* no effectiveness claims.
- **Reviewers:** Regulatory (signature authority; a fractional RA consultant at $175–300/hr is sufficient), Clinical for any performance claim, Legal for anything comparative or naming a competitor, Compliance for anything involving HCP payment. Quorum: Regulatory + one other for standard pieces; all four for launch materials and comparative claims.
- **Three tiers** so the team doesn't drown: full MLR for new claims and launch assets; regulatory-only for derivatives reusing approved copy verbatim; a pre-approved copy-block library with expiry dates that marketing may assemble freely.
- **Rep social media:** pre-clearance, prohibit product posting entirely. Post-clearance, restrict to resharing corporate posts with no added commentary. Written policy, annual training, spot audits.
- **Retention: set one 10-year policy** for promotional and HCP-payment records. QMS says 2 years minimum, Open Payments says 5 from publication, and the False Claims Act statute runs 6 to 10. Ten is simpler and it's the number that matters when a qui tam relator surfaces.
- **Do not use email-thread approvals or unversioned Google Docs.** Use a system with an audit trail, unique user IDs, and timestamped e-signatures. Controlled SharePoint or Egnyte + a workflow tool + DocuSign runs $5K–20K/yr and is defensible; Veeva PromoMats and Vodori are $50K–250K/yr and are not for you.
- **One QMS hook people miss:** under the QMSR (compliance date Feb 2, 2026), surgeon comments, DMs, and emails complaining about product performance are **complaints** that must enter the complaint-handling system. Your community manager needs a documented escalation path into QA. Exer Labs' warning letter cited 820.198(a) alongside the promotional claims.

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05 Engine 1 — Outreach

ENGINE 1 **Outreach** — Goal: 800 named surgeons who know the problem by name

CHANNEL PRIORITY, RANKED BY YIELD PER DOLLAR AT THIS STAGE

#	CHANNEL	COST	WHY IT RANKS HERE
1	**Society meetings — abstract first, booth second**	$500 attendee list · $3,500–4,400 booth	SAGES Emerging Technology abstract and the SLS MISWeek Innovation award are *submissions, not purchases*. MISWeek booth is $3,500 early. A ~$12K conference year buys the most concentrated access to your exact surgeon population that exists anywhere in this analysis
2	**YouTube technique library**	$15–30K flagship, $3–8K each after	Peer-reviewed studies consistently find surgical YouTube content is high-volume and **low-quality** — one *Surgical Endoscopy* paper is literally titled "Attending guidance advised." The quality bar is low, distribution is free, and surgeons demonstrably use it for case preparation. YouTube is also the **#1 most-cited domain in Google AI Overviews**
3	**Founder-led LinkedIn**	~$0 + time	Munday is a practicing robotic general surgeon; Senagore is a past ASCRS president and former Director of the American Board of Surgery. That is a credibility asset most pre-clearance startups do not have, and it is currently generating nothing
4	**Original surgeon survey**	$8–20K	See below — this is the highest-strategic-value item in the entire plan
5	**Targeted 1:1 outreach** (LinkedIn + email)	~$1,800/yr tooling	Healthcare cold email runs 33–38% opens and 4–6% replies but only **0.5–1.5% meetings booked**. See the finite-list warning below

#	CHANNEL	COST	WHY IT RANKS HERE
6	**Sermo Engagement Manager**	Free account, self-serve	Launched Oct 2025. The only endemic HCP ad platform with a low enough floor to test at your capital level. 1M+ triple-verified HCPs. Worth a small unbranded test
7	LinkedIn paid	$5.48 CPC · $33.95 CPM · $129 CPL (healthcare)	Right channel, wrong stage. Your addressable audience is ~5,000–25,000 people; at $34 CPM you can reach all of them ten times for under $10K. **Budget for frequency against a tiny list, not reach.** Turn on at clearance
—	~~Doximity~~	Est. $50–150K+ program floor	**Skip.** Their own headline KPI is "customers with TTM revenue >$500,000." Architected for pharma budgets, and they won't serve product ads pre-clearance anyway
—	~~Programmatic HCP DSP~~	$10K/mo minimum	**Skip.** $120K/yr for one channel against a 15,000-person audience is indefensible
—	~~Custom VR training module~~	$75–300K build	**Skip.** 6–12 month build cycle. Revisit at Stage 3 if at all

THE SINGLE HIGHEST-VALUE ASSET IN THIS PLAN

Commission and publish an original surgeon survey. 30–50 surgeons on needle-loss frequency, time-to-retrieval, count-discrepancy workflow, and — the number nobody has published — **OR minutes lost per dropped needle.**

Why this beats everything else you could spend $15K on:

- The Princeton GEO study (KDD 2024) found that **adding statistics and citations produced up to 40% lift in AI-engine citation** — the strongest causal evidence in generative-engine optimization. Original data is the most citable asset type that exists.
- It makes **zero claims about Endospool**, so it is fully compliant pre-clearance and needs no efficacy substantiation.
- It creates a statistic *other people cite*, which is how you enter the citation graph rather than shouting into it.
- **Origami's numbers — 91% of surgeons report 1–5 lost-sharps incidents annually, >80% of losses occur at trocar retrieval — are currently the only stats in the category, and they are Origami's.** Every VAC deck in this space cites their footnotes. That should change.
- It is the missing input to your own ROI model later.

OUTBOUND IS A FINITE RESOURCE HERE — PLAN FOR EXHAUSTION

At a ~1% meeting-booked rate and 200 emails per week per person, you generate 2 meetings a week. To have 100 real surgeon conversations you need roughly **10,000 touches.** Against a total addressable list of ~15,000, **you will exhaust the entire market in about a year.**

Two implications: sequence quality matters vastly more than volume, and you get roughly **one good first impression per surgeon, ever.** Do not burn the list on a generic sequence before the content library exists to make the follow-up worth reading.

THE 1:1 SEQUENCE STRUCTURE

Five touches over 21 days, alternating channels. Every touch leads with the clinical problem, never the product. Pre-clearance, no touch contains a performance claim.

```
Day 0   LinkedIn connect, no pitch, one line referencing their published
        work or a case type they post about
Day 3   Email 1 — the problem. Cite Chen et al. 2026 (J Robotic Surgery,
        33 studies, 37 lost-needle events, the "Trocar Trap" hypothesis).
        Ask one question. No attachment, no link to the product.
Day 8   LinkedIn message — share the technique video. No ask.
Day 14  Email 2 — invite to the unbranded webinar or share the survey
        findings. First and only soft CTA.
Day 21  Email 3 — breakup. "Closing the loop; here's the library if it's
        ever useful." Leave the door open.
Every email: ad identification, physical postal address, one-click
unsubscribe, RFC 8058 List-Unsubscribe header.
Regulatory status disclosure in the signature block.
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06 Engine 2 — Training

ENGINE 2 **Training**

Goal: competence without a body in the room

This engine exists because of one number: **surgeons rate rep *knowledge* at 4.36 out of 5 in device selection.** If nobody from your company is in the room, the knowledge has to arrive some other way — and it has to arrive for the scrub tech and the circulator, not just the surgeon.

Three audiences, three formats, three lengths

AUDIENCE	FORMAT	LENGTH	DELIVERY	SUCCESS TEST
Scrub tech / circulator	Setup and handling video	**90 seconds**	**QR code printed on the package.** No login, no app, no account	A tech who has never seen the device sets it up correctly on first attempt without calling anyone
Surgeon	Technique video, LAP-VEGaS compliant	6–10 min	YouTube + site embed + direct link a peer can text	A surgeon watches it once and can articulate the workflow to their own team
Whole OR team	Live virtual in-service	20 min	Zoom/Teams link, scheduled around the OR board, recorded for the ones who miss it	Booked and attended by ≥3 staff; recording watched by ≥2 more
1099 rep Stage 2+	Certification module + objection sheet	**6 min** + 1 page	Self-serve, on-demand, completion tracked	Rep can position the product in under 10 minutes and never needs to be in a case

THE HIGHEST-ADOPTION MECHANISM FOUND IN THE ENTIRE RESEARCH SET

A QR code printed on the package linking to a 90-second setup video with no login and no app. It costs essentially nothing per unit, works on any phone in any OR, requires zero IT approval, zero credentialing, and zero scheduling — and it delivers the training at the exact moment of need, to the exact person who needs it, which no rep visit can do.

This one design decision does more to replace the in-room rep than any platform in this report.

What the evidence says about virtual training working

- **Erridge et al., *Surgical Innovation* 2019** — systematic review of 66 telementoring studies. Of 12 comparative studies, **7 showed no difference vs on-site mentoring, and no study found telementoring produced poorer postoperative outcomes.** Main barrier cited: connectivity.
- ***World Journal of Urology* 2025** — 11 tele-proctoring studies from 2,510 screened; five live-surgery studies found **no meaningful difference in operative time, narcotic use, hospital stay, or recovery.** Latency: 1.4 ms wired, 7.4 ms wireless.

Honest read: the literature supports remote proctoring as non-inferior for *procedural guidance*. It does not support remote support as a substitute for the rep's *logistical* role — kit availability, back-table setup, troubleshooting. For a $150–350 disposable that logistical role is small, which is genuinely in your favor. Don't overclaim it.

Production plan and where to shoot

Shoot cadaver and benchtop, not live OR — especially pre-clearance. No patient consent, no IRB, no HIPAA exposure, no hospital approval, and you can do it before clearance. Live OR footage is a post-clearance asset.

ASSET	COST	WHEN
Flagship technique video — 1 shoot day + post	$15,000–30,000	Stage 0
Additional procedure videos, reusing the template	$3,000–8,000 each	Stage 0–1
3D mechanism-of-action animation	$15,000–40,000	Stage 0 — this is the safest pre-clearance video asset, since it describes mechanism rather than demonstrating performance
90-second setup video	$2,000–4,000	Stage 0, re-shot at clearance with final packaging
Captions and transcripts	$0.25/min AI + human review	Every asset. ASR mangles anatomical and device nomenclature — always human-review

Industry benchmark: medical device video runs $1,000–10,000 per finished minute; editing ratio is a minimum of 3 days post per 1 day of filming.

Platform posture

Do not buy an OR hardware platform. Avail is dead. Explorer Surgical was absorbed into GHX. Proximie has raised nothing publicly since June 2022. Immertec's operating status could not be verified. Anything requiring a network drop, a VLAN, or wall-mounted hardware triggers a biomed and IT security review that runs 3–9 months and is fatal for a small vendor.

Use what's already in the room: a BAA'd Zoom or Google Meet seat at $20–30/user/month, joined from the circulator's phone or a hospital tablet. If you later need a hands-free option, **Rods&Cones** is the lowest-IT-friction vendor found — smart glasses, plug-and-play, no fixed cabling, ISO 27001 certified — but treat it as a Stage 2 experiment, not a foundation.

07 Engine 3 — Support

ENGINE 3 Support — Goal: answer faster than a rep could have

Surgeons rate rep **follow-up at 4.39** and **availability at 4.16**. This engine is the direct substitute for both, and it is the one place where a small company can genuinely beat a large one — because a named human who answers in twenty minutes is better service than a rep who is in someone else's case.

The published SLA — make it a marketing claim

CHANNEL	HOURS	TARGET RESPONSE	HARD SLA
Phone / text to the support line	OR hours, 6am–7pm local, all US zones	**<10 min**	20 min
Email	Business hours	<2 hrs	4 hrs
Scheduled pre-case call	Booked via a public scheduling link	Same/next day availability	48 hrs
Live in-case link	Pre-arranged only, never cold	Standing by at scheduled time	—

Publish the SLA on the site and print the number on the package. A competitor with five reps cannot make that promise nationally. You can, with one person, because your call volume is low and your product is simple.

The case-support workflow

```
T-7 to T-3   PRE-CASE
  1. Case identified by surgeon or OR scheduler. Confirm SKU and case type.
  2. 15-min video call: surgeon + primary scrub + circulator.
     Screen-share the setup sequence, load order, sharps handling, disposal.
  3. Ship with QR code on the package -> 90-second setup video.
  4. Confirm the hospital's remote-vendor policy IN WRITING.
     Get credentialing / IT clearance if a live link is planned.
T-0          IN-CASE
  5. Audio-only or low-friction video from the circulator's phone
     or a hospital tablet.
  6. CAMERA POINTS AT THE BACK TABLE, NOT THE FIELD.
     Materially reduces PHI exposure and hospital resistance — and the
     back table is where a disposable actually needs support.
  7. Support person standing by, muted. Escalation only. Never narrating.
  8. NEVER RECORD. Stream-only, no cloud retention.
T+1          POST-CASE
  9. 10-minute debrief. Structured capture: units used, wastage,
     time-to-setup, staff friction points, surgeon verbatim.
 10. Log to CRM. Feed directly into the VAC dossier for that account.
```

TWO NON-OBVIOUS RULES IN THAT WORKFLOW

The camera points at the back table. This is the difference between a five-minute conversation with the circulator and a three-month conversation with hospital privacy counsel. It also happens to be where a suture-management disposable is actually used.

Step 10 is the commercially important one. Every debrief is a data point in the value-analysis dossier for that account. Most companies treat post-case as a courtesy call. Treat it as evidence collection, and by the time the VAC meets, the champion is carrying a dossier built from their own OR's data rather than your marketing deck.

Cost

MODEL	ANNUAL COST	COVERAGE
Virtual case support — 1 clinical specialist + BAA'd video + scheduling	$96,000–180,000	National, unlimited cases, 10-minute response
Single W-2 territory rep, fully loaded	$180,000–250,000	One metro, one case at a time
Vendor credentialing, per rep	$1,500–4,000	Plus 2–6 weeks lead time. Applies to virtual access too

08 Engine 4 — Nurture

ENGINE 4 Nurture — Goal: survive a 3–6 month VAC cycle without a weekly human touch

The nurture engine exists because of one operational fact: **the VAC cycle runs 3–6 months and sometimes 12, committees meet monthly or quarterly, and missing a submission deadline costs a full cycle.** Nobody on a sub-10-person team can manually keep 200 accounts warm across that span. The nurture system is what does it.

Five tracks, each with a different job

TRACK	TRIGGER	CADENCE	CONTENT	EXIT
A. Cold educate	Any new contact — content download, webinar reg, conference scan	Bi-weekly, 8 emails over 16 weeks	Pure problem education. RSI epidemiology, the Trocar Trap, count-discrepancy protocols, AORN guidance summaries. **Zero product content pre-clearance**	Two content engagements in 30 days → Track B
B. Warm / engaged	Repeat engagement, or replied to outreach	Weekly, 6 emails	Technique video series, survey findings, founder POV, invitation to the virtual roundtable	Requests a demo or eval → Track C
C. Active evaluation	Eval units shipped, or first case scheduled	Event-driven, not calendar-driven	Pre-case checklist, setup video, post-case debrief scheduler, "how did case 1 go," case-2 prep	Reorder → Track E. Stalled 30 days → Track D
D. VAC pipeline THE DIFFERENTIATOR	Champion confirms VAC submission is in motion	Monthly, aligned to *their* committee calendar	Everything the champion needs to defend you in a room you're not in — see below	Approved → Track C or E. Denied → Track B with a 6-month re-approach
E. Customer / expansion	Second PO	Monthly	New procedure applications, additional surgeons at the same site, peer-referral ask, case-study invitation, reorder reminders keyed to usage rate	—

TRACK D IS WHERE THIS PROGRAM WINS OR LOSES

Almost no small medtech company runs a nurture track aimed at the VAC cycle, because it's invisible work — the champion is inside a building you can't enter, defending you to a committee you'll never present to, using materials you gave them three months ago. **Arm them properly and you win deals your competitor loses on paperwork.**

The VAC dossier the champion carries in:

- 510(k) clearance letter and IFU
- Peer-reviewed evidence — yours and the category literature
- **Your own original survey data** (which by then is a citable third-party-quotable statistic, not a marketing claim)
- **Total cost of ownership model with THEIR numbers filled in**, sourced from the post-case debriefs at their own institution — not a generic ROI calculator
- Reimbursement position: the honest one. A surgical disposable is **bundled into the DRG/APC, not separately reimbursed**. Say so plainly. The value argument is cost-avoidance and throughput, and a VAC that catches you overstating reimbursement stops reading
- Implementation and training plan — the 90-second video, the in-service, the SLA
- Sharps-safety policy alignment mapped to AORN and ACS guidance
- A one-page objection sheet the champion can read in the elevator

And a calendar reminder set to their committee's actual meeting schedule, so the champion gets the right asset the week before they need it. That single operational detail is worth more than any ad spend in this document.

DO NOT BUILD ORIGAMI'S ROI CALCULATOR

Their value-analysis tool outputs a default **3,200% ROI and a 0.4-month payback**, stacks a 10% "throughput opportunity" on top of the same time savings it already counted, and assigns $95,000 of "liability protection" per prevented near-miss with no cited basis. The 30-minute time-savings input driving all of it comes from a non-peer-reviewed two-surgeon white paper co-authored by their own founder/CMO/shareholder.

A competent VAC finds that in one search. **Build a conservative model with cited inputs and a visible sensitivity range instead.** Being the credible one in a two-horse category is a durable position — and it is available.

Benchmarks to plan against

METRIC	BENCHMARK	YOUR TARGET
Email open rate — medical equipment	23.4%	28%+ (tiny, highly targeted list)
Click-to-open rate	12–18%	15%+
Unsubscribe	<0.5%	<0.2%
Webinar registration→attendance	**44–50%** (plan against this, not ON24's self-selected 60%)	45%
Webinar on-demand share of total views	42%	**Build the on-demand library from day one — half your value is the replay**
Content download → engaged	5–10%	8%
Email → webinar registration	8–15%	10%
Email → sample/eval request	1–3%	2%

The eval program — mechanics that keep you clean

Copy the mechanic BiPAD Surgical uses: an online request form capturing facility details, a **nominal $12 shipping-and-handling charge**, tracked dispatch, literature included. The $12 is not revenue — **it filters tire-kickers and creates a billing record documenting that the unit is not an inducement.**

EVAL TYPE	UNITS	DURATION	YOUR COGS EXPOSURE
Single surgeon	5–10	2–4 weeks	$200–800
Multi-surgeon department	25–60	30–90 days	$1,000–5,000
Full VAC-driven system trial	100–300	90–180 days	$4,000–24,000

Conversion to plan against ESTIMATE — NO PUBLISHED RATE EXISTS: surgeon eval → adoption where a champion requested it, 30–50%; adoption → VAC approval, 40–60%; VAC approval → sustained reorder, ~70%. **Net eval-to-revenue roughly 10–20%.** Budget eval COGS as marketing spend, not cost of sales, and cap quantities per AdvaMed Sec. XII.

09 Content system

Twelve assets carry the entire program. Everything else is a derivative. Build in this order.

#	ASSET	SERVES	STAGE	COST
1	**90-second setup video** + QR code on packaging	Training, Support	0	$2–4K
2	**3D mechanism-of-action animation**	Outreach, Training	0	$15–40K
3	**Original surgeon survey** + published findings	Outreach, Nurture, VAC	0	$8–20K
4	Flagship technique video (cadaver/benchtop)	Outreach, Training	0	$15–30K
5	Problem-education hub — 5 articles, ~1,500 words each, cited, question-form H2s, direct-answer opening paragraphs	Outreach, Nurture, AI citation	0	$6–10K
6	Unbranded webinar series — quarterly, on-demand library	Outreach, Nurture	0	$2–4K/ea
7	Specifications page — dimensions, materials, trocar compatibility	Outreach, VAC	0	$1K
8	Regulatory-status page	Trust, partners	0	$1K
9	23 patent pages	Entity, credibility, long-tail	0	$4–8K
10	**VAC dossier template** + conservative TCO model	Nurture Track D	0→1	$8–15K
11	Rep certification module + objection sheet	Stage 2 enablement	1→2	$5–10K
12	Procedure-specific technique videos — hernia, bariatric	Outreach, Training	1	$3–8K/ea

FORMAT RULES — NON-NEGOTIABLE ACROSS EVERY ASSET

- **Direct-answer paragraph in the first 80–120 words** under a question-form heading. This is the format AI engines cite and the format a busy surgeon reads.
- **Dense with attributed statistics.** The Princeton GEO study found citations and statistics were the interventions that produced the visibility lift — not fluency, not keywords.
- **References section on every substantive piece.** Minimum 8 citations.
- **Named, credentialed author byline.** Munday or Senagore. This is the E-E-A-T asset you're not using.
- **Comparison tables** where the content permits — high citation propensity, high scan value.
- **Regulatory status disclosure** in the same visual field as any product reference; for video, on-screen at the open, as a persistent lower-third, *and* in the description field.

10 Tech stack & cost

Stage 0 — pre-clearance

TOOL	CONFIG	ANNUAL	WHY THIS ONE
HubSpot Starter Customer Platform	5 seats	~$1,200	CRM + basic email + forms. Do not buy Marketing Pro until you have volume to justify it
Apollo.io Basic	3 seats	$1,764	Highest-leverage single buy — prospect database, sequencing, and dialer in one, replacing ~$2K/mo of separate tools
Livestorm Pro *or* Demio Premium	—	~$1,200–2,400	Must support custom registration fields (NPI, specialty, institution) and CRM sync. Livestorm is pay-per-attendee, which suits a lumpy webinar cadence
Wistia Business	3 seats	$948	Gated video with lead capture. YouTube for reach, Wistia for conversion
Zoom / Google Meet with BAA	3 seats	~$900	Case support and virtual in-services. **Paid healthcare plan only — the consumer tier has no BAA**
Rev captions/transcripts	~200 min	~$400	AI at $0.25/min then human review — ASR destroys anatomical terminology
MLR: Egnyte/SharePoint + workflow + DocuSign	—	$5,000–8,000	Audit trail, unique IDs, timestamped e-signatures. Do not use email approvals
Transfer-of-value tracking	Structured sheet + expense tags	$0	Defensible in year one under ~$25M revenue. Dedicated tools start at $15–50K/yr — not yet
Slack, Notion, Canva, domain, email infra	—	~$3,000	—
Stage 0 stack total		**~$15,000–19,000**	

Stage 1–2 additions, at clearance

CHANGE	ANNUAL
HubSpot Marketing Pro ($800/mo + $3,000 mandatory onboarding)	$12,600 year one
Wistia Business + Lead Gen	$3,948
Vendor credentialing, 2 clinical specialists	$3,000–8,000
Open Payments capture — dedicated tool if volume warrants	$15,000–50,000
State registrations — VT $765, MA $2,000, CT	~$3,000

EXPLICITLY NOT BUYING, AND WHY

Veeva — $100–150K/yr for ~20 seats on Vault CRM Essentials. Revisit at 25+ reps, not before. **Salesforce + Pardot** — Pardot Growth+ alone is $15K/yr, more than all of HubSpot Pro, and you won't have the ops headcount to run it. **ON24** — median ACV $39,350 across 96 verified transactions. **Movemedical / Implantbase / TikaMobile** — built for 50+ rep orthopedic orgs with $10M+ consignment; run eval tracking in the CRM until ~$5M revenue. **Veeva PromoMats / Vodori** — $50–250K/yr for MLR.

Three corrections to commonly circulated names: **"Movalis" is a brand of meloxicam**, not medtech software. **"Medtrix" is an Indian medical communications agency**, not a CRM. And the real medtech field tools are Movemedical, Implantbase, TikaMobile, and Repfabric — all quote-only, all wrong-sized for you today.

THE BINDING CONSTRAINT IS NOT BUDGET

Every figure above sits comfortably inside a $7M raise. **The constraint is headcount.** HubSpot Pro, a webinar program, and a LinkedIn effort are roughly **0.75 FTE of marketing-ops load on their own** — before anyone writes a word of content or answers a support call. Staff the operator before you buy the stack, or the stack sits idle and you've bought shelfware.

11 Budget by stage

CATEGORY	STAGE 0 PRE-CLEARANCE, 12–18 MO	STAGE 1 LAUNCH YEAR	STAGE 2 SCALE YEAR
Tech stack	$15–19K	$35–45K	$60–80K
Content production	$55–95K	$50–80K	$60–100K
Original surgeon survey	$8–20K	—	$15K (wave 2)
Conferences	$12–18K	$30–45K	$60–90K
Paid media	$5–10K (unbranded test only)	$40–70K	$100–150K
KOL / advisory boards	$15–30K	$40–70K	$60–100K
Vendor credentialing	$3–8K (start early)	$5–12K	$15–40K
Eval program COGS	—	$20–40K	$60–120K
Regulatory/legal MLR support	$15–25K	$25–40K	$35–55K
Compliance — Open Payments, state filings	$3–5K	$20–55K	$25–60K
Program subtotal	**$131–230K**	**$265–457K**	**$490–810K**
Headcount (loaded)	$120–160K 1 marketing op	$400–560K +2 clinical specialists	$800K–1.1M +2 specialists, +1 ops
All-in	**$251–390K**	**$665K–1.02M**	**$1.29–1.91M**

SET EXPECTATIONS WITH THE BOARD NOW

Novel medtech runs **S&M at ~85% of revenue in year 5 post-launch**, with the observed range spanning Shockwave at 45% to Inspire and PulmonX above 100%. Cumulative SG&A over the first five years averages **>$570M** across the companies in that dataset, with total commercial investment of $200M–800M+.

Those are the companies that *succeeded*. **A $7M raise does not fund a commercial launch. It funds clearance plus an evidence-and-audience beachhead** — which is exactly what Stage 0 is designed to produce, and exactly the asset that makes the next round raisable or the acquisition conversation credible.

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12 Metrics & funnel model

Stage 0 — you cannot measure revenue, so measure asset accumulation

METRIC	DAY 90	DAY 180	DAY 365
Named surgeons in CRM with an engagement event	120	350	**800**
Video assets published	3	7	12
Total video watch-hours	150	800	3,000
Email list, opted in	200	500	1,200
Webinar attendees, cumulative	40	150	400
Original survey published	Fielded	**Published**	Cited ≥3×
Society podium / abstract accepted	Submitted	—	**1 presented**
Surgeons who have handled the device	10	35	90
Named champions committed to first case at clearance	2	8	**20**

That last row is the one that matters. Twenty surgeons who have handled the device and committed to a first case is a launch. Everything else in Stage 0 exists to produce it.

Stage 1+ funnel, with real conversion rates

```
Reached          15,000  addressable US surgeons (realistic TAM)
   |  8%
Engaged           1,200  content engagement or webinar attendance
   |  12%
Hand-raised         145  demo request, eval inquiry, meeting booked
   |  45%
Eval shipped         65  5–10 units, $12 S&H, documented as sample/loan
   |  40%          [surgeon eval -> adoption, where champion requested]
Adopted              26  surgeon wants to keep using it
   |  50%          [adoption -> VAC approval]
VAC approved         13  3–6 month cycle, sometimes 12
   |  70%          [approval -> sustained reorder]
Reordering            9  the actual customers
Net eval -> revenue: ~14%.  Reached -> customer: ~0.06%.
```

Read the bottom line honestly: nine reordering accounts from an entire national market touched once. That is what a low-ASP disposable in a narrow niche looks like, and it is why the expansion track (Track E — more surgeons at existing sites, more procedures per surgeon) matters more than net-new logo acquisition after year two.

What to review, and when

- **Weekly:** support SLA attainment (the one metric that *is* the product promise), pipeline movement, content published.
- **Monthly:** funnel conversion by stage, eval-to-adoption, cost per engaged surgeon, VAC calendar — *which committees meet next month and is the champion armed.*
- **Quarterly:** channel ROI, content performance, competitive movement (Origami's clearances, publications, GPO wins), compliance audit of the ToV register.

13 Risks and how they kill you

RISK	SEVERITY	MITIGATION
A YouTube performance demo pre-clearance	CRITICAL	The exact Q'Apel fact pattern. A demo *is* an effectiveness claim and creates intended-use evidence. Ship mechanism animation and device description only until clearance
The Shopify cart / "Shop now" path	CRITICAL	"Prepared to take orders" is the CPG 300.600 bright line. Disable the cart, the collections URLs, and the agent-commerce endpoints this week
A waitlist that behaves like a preorder	CRITICAL	Keep it a mailing list. Never allocate units, quote a price, or take money
Virtual advisory board as disguised awareness channel	HIGH	20+ surgeons, honoraria, no deliverable — that is the OIG speaker alert with a Zoom link. Cap at 6–10, require written deliverables, FMV hourly, sales excluded from selection
Surgeon-submitted case media with intact metadata	HIGH	The likeliest breach event, and it will come from an enthusiastic rep, not from marketing. Standing intake SOP: signed HIPAA authorization uploaded with the asset, metadata scrub, segregated storage, deletion schedule
Vendor credentialing unbudgeted	HIGH	$1,500–4,000/rep and 2–6 weeks lead time delays Stage 1 by a quarter. Start credentialing before clearance — it is not gated by 510(k) status
Exhausting the outbound list before the content exists	HIGH	~15,000 addressable surgeons; you get one first impression each. Do not run outbound until the video library and survey are live
Origami files a competitor complaint	MEDIUM	FDA's Allegations of Regulatory Misconduct portal is used routinely in surgical disposables. Your MLR file is the only defense you will have. Assume they are watching
Platform dependency	MEDIUM	Avail dead, Explorer absorbed, Proximie no public raise since 2022, Immertec unverifiable. Build on Zoom/Meet and YouTube — infrastructure that outlives vendors
1099 reps won't carry the line	MEDIUM	At $62.50/unit commission they need 2,400 units for a $150K income. Design for bag-carry: 6-minute certification, one-page objection sheet, zero in-case presence required
Buying the stack before the operator	MEDIUM	0.75 FTE of ops load before any content is made. Hire first

14 Scope of work & fees

Proposed structure. Fees are indicative and assume a US-only scope; final pricing on confirmation of headcount, asset count, and whether the client retains regulatory counsel separately.

What we own vs. what the client owns

WORKSTREAM	US	CLIENT
Strategy, positioning, messaging architecture	**Own**	Approve
Website rebuild, SEO/GEO remediation, schema, entity fixes	**Own**	Approve
Content production — video, written, VAC dossier, animation	**Own** (manage vendors)	Approve, provide SME time
Original surgeon survey — design, fielding, analysis, publication	**Own**	Fund panel, provide clinical review
Nurture architecture, sequences, CRM build, automation	**Own**	Approve
Outbound sequencing and list build	**Own**	Approve targeting
Webinar program — production, promotion, follow-up	**Own**	Present
Conference strategy, booth, abstract support	**Own**	Staff, present, fund
MLR SOP design, substantiation register build	**Own**	Staff the reviewer roles
Regulatory sign-off on claims	Facilitate	**Own — RA consultant or counsel, signature authority**
Legal review of comparative claims and contracts	Flag	**Own**
Clinical case support delivery	Design the workflow	**Own — must be a clinically credentialed employee**
HCP payments, Open Payments filing, state registrations	Design the capture system	**Own — officer attestation required**
Vendor credentialing	Budget and schedule it	**Own**

Phased engagement

PHASE A — Foundation

Days 1–90 · fixed fee

Deliverables: compliance remediation of the live site (cart, claims, disclosures); full SEO/GEO rebuild per the August audit — 16 title/meta rewrites, alt text, 9 schema types, entity fixes, Wikidata, directory profiles, Bing Webmaster registration; positioning and messaging architecture; MLR SOP and claim substantiation register; CRM and nurture build with Tracks A and B live; surgeon survey designed and fielded; content roadmap with the 12 core assets specced.

Fee: $52,000 fixed, billed 40/30/30 at kickoff, day 45, and acceptance.

PHASE B — Build & audience

Months 4–15 · retainer

Scope: content production management (2–3 assets/month); webinar program (quarterly); outbound sequencing; nurture Tracks A–B operating and Tracks C–E built; conference support (2 meetings); survey published and promoted; monthly reporting; quarterly strategy review.

Fee: $14,500/month retainer. Production pass-throughs billed at cost + 12% (video, animation, panel, booth, media).

PHASE C — Launch sprint

Clearance −30 to +60 days · fixed fee

Scope: claims migration to cleared IFU language across every asset; "FDA cleared" messaging rollout; paid media switched on and optimized; PR and trade-press outreach (MassDevice, MD+O, MPO, MedTech Dive); VAC dossier finalized and distributed to all named champions; rep certification module; training program launched; Open Payments capture live; VT/MA/CT registrations filed.

Fee: $68,000 fixed.

PHASE D — Scale & enablement

Post-launch · retainer + performance

Scope: full four-engine operation; 1099 rep-group enablement; expansion marketing; ongoing content; quarterly competitive intelligence.

Fee: $18,500/month + optional performance component: $1,500 per VAC approval attributable to marketing-sourced pipeline, capped at $15,000/quarter.

The performance component is structured as a marketing-services fee on committee approvals, not on units or revenue — deliberately, so nothing in our compensation is tied to the volume or value of business generated with any individual HCP.

ENGAGEMENT ECONOMICS SUMMARY

PHASE	DURATION	FEE	CUMULATIVE
A — Foundation	90 days	$52,000	$52,000
B — Build & audience	12 months	$174,000	$226,000
C — Launch sprint	90 days	$68,000	$294,000
D — Scale	12 months	$222,000 + performance	$516,000+

Excludes production pass-throughs (video, animation, survey panel, booths, media spend), which are budgeted separately in §11 and billed at cost + 12%.

> **THE ARGUMENT FOR THIS ENGAGEMENT, IN ONE LINE**
>
> Origami is ahead on **credibility surfaces** — seven FDA clearances, a PubMed-indexed series, a SAGES listing, a Premier GPO agreement, six trade-press placements. They are **not ahead on content, digital, or entity presence, because neither company is doing any.** Endospool cannot close the credibility gap with marketing; that gap closes with clearance and publication. What it *can* do in the 12–18 months before clearance is **take the entire content, audience, and training layer uncontested** — so that on clearance day there are 20 named champions, a full asset library, a citable statistic nobody else owns, and a commercial engine that runs at a fraction of a field force's cost.

Method & caveats

- Compiled August 2026 from primary sources: FDA CPGs, warning letters and guidance; eCFR; CMS Open Payments; OIG fraud alerts; the AdvaMed Code (2023 text + Nov 2025 update); peer-reviewed literature; SEC filings and 10-K-derived benchmarks; and published vendor pricing.
- **This is a research summary, not legal or regulatory advice.** Every claim-bearing asset and every HCP payment structure must be reviewed by qualified regulatory and healthcare counsel before use. The permitted/prohibited table in §4 is a planning tool, not an opinion.
- Figures labeled **ESTIMATE** are derived, not cited. Doximity, Proximie, Rods&Cones, Osso VR, GIBLIB, Medscape, Sermo and most medtech field tools **publish no pricing at all** — every figure for them is an estimate.
- No published eval-to-purchase conversion rate exists for surgical disposables. The funnel in §12 is constructed from adjacent benchmarks and should be replaced with actuals after two quarters.
- Fees in §14 are indicative and subject to scope confirmation.

Key sources

FDA CPG Sec. 300.600 · 21 CFR 812.7 · 21 CFR 801.4 · Q'Apel Medical WL, Feb 2025 · Exer Labs WL, Feb 2025 · AdvaMed Code of Ethics · OIG Speaker Program Fraud Alert (2020) · CMS Open Payments · FTC CAN-SPAM Guide · Physician preference items study (n=201) · Medtronic State of Surgery US 2024 · IQVIA ChannelDynamics 2025 · Bain — MedTech sales go virtual · MassDevice — Avail shutdown · Erridge — Telementoring systematic review · World J Urol 2025 — teleproctoring ·

Aggarwal et al. — GEO (KDD 2024) · Health Advances — medtech commercialization benchmarks · VAC process & timelines · symplr / IntelliCentrics transition · SLS MISWeek 2026 prospectus · SAGES Emerging Technology · LinkedIn Ads benchmarks 2026 · Webinar benchmarks (1M+ registrants) · Vermont AG disclosures · 105 CMR 970.00 (Massachusetts)