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Precision Tracheal Access

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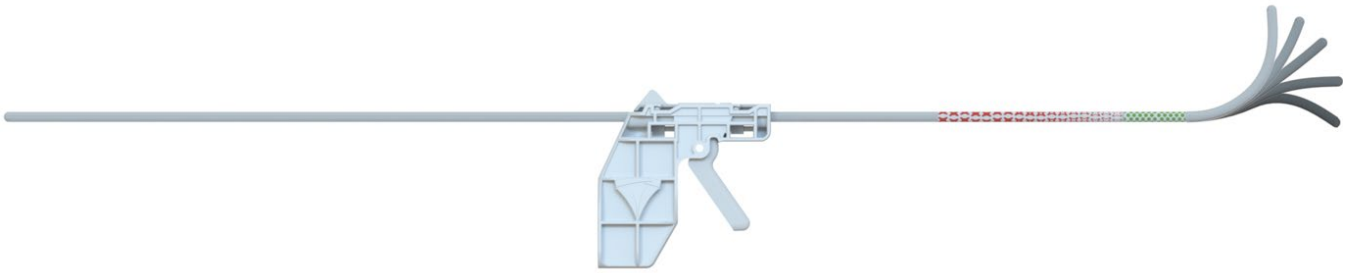
Precision tracheal intubation.

Executive Summary

Runnels Steerable Introducer™ (RuSI™) Tracheal Intubation Use-Case Protocol

US / FDA-governed territories · For healthcare professional use · Harmonized to IFU 001042.D (February 2026)

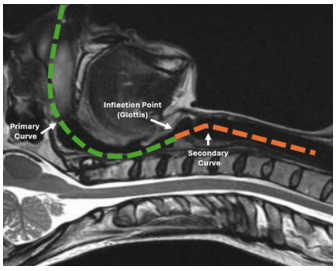


Purpose and scope

This protocol supports clinician education in the use of the RuSI™ dynamic introducer for tracheal access while intubating with a laryngoscope across nine evidence-defined use cases. It is grounded in current difficult-airway guidelines. 1)The Practice Guidelines for Difficult Airway Management published by the American Society of Anesthesiologists (ASA) (2022) and 2) the Guidelines for Management of Unanticipated Difficult Tracheal Intubation in Adults published by the Difficult Airway Society (DAS) (2025); and in peer-reviewed published literature concerning dynamic tracheal access equipment combined with video laryngoscopy. It does not constitute clinical advice, does not supersede the Instructions for Use (IFU), and does not replace clinical judgment.

The clinical problem of the VL era

Video laryngoscopy (VL) reliably improves glottic visualization. However, the dominant failure mode of VL is not visualization; it is failure of **tracheal access with adequate visualization**: the operator can see the glottis but cannot deliver the ETT through the natural serpentine airway geometry described by Greenland et al. (2010). Prekker et al. (N Engl J Med 2023) and Kriege et al. (Anaesthesia 2023) both demonstrated that tracheal access failure is the predominant mode of VL failure. This is in contrast visualization failure as the predominant mode of failure when direct laryngoscopy (DL) is used.



Dynamic tracheal access equipment

The RuSI™ is a purpose-built, single-handed, fully dynamic steerable introducer designed for use with a VL. Its articulating tip and flexible shaft allow the operator to navigate all three elements of serpentine geometry: the primary curve above the glottis; the inflection point at the glottis; and the secondary curve below the glottis, under direct or indirect vision with VL or DL. A color-coded depth-indicator zone (green at the cords with the tip at mid-trachea; red indicates excessive tracheal depth) provides a tracheal depth recognition aid. The RuSI™ is indicated for oral and nasal endotracheal intubation with a VL or DL using single-lumen tubes in adult and pediatric patients and double-lumen tubes (DLT) in adults.

Limit intubation attempts: a key guideline recommendation.

ASA Difficult intubation Guidelines (2022) states: "Limit the number of attempts at tracheal intubation or supraglottic airway placement to avoid potential injury and complications" and notes: "A reasonable approach may be to limit attempts with any technique class to three, with one additional attempt by a clinician with higher skills." The principle of 3 + 1 attempts.

DAS Unanticipated Difficult Intubation Guidelines (2025) maintains the principle of 3+1 attempts (maximum three attempts; a fourth only by a more experienced colleague) and states: "A suboptimal attempt is a wasted attempt. Each subsequent attempt should involve a change to increase the likelihood of success."

Read together, these recommendations provide a guideline-consistent rationale for moving to a technique which combines VL and a dynamic introducer early in anticipated or unanticipated difficult tracheal intubation as either a rescue technique or a primary approach to intubation, rather than repeating attempts with VL and a static-introducer or rigid-stylet. The change to a dynamic tracheal access device constitutes the kind of deliberate, informed change both guidelines recommend. Evidence supporting this rationale is summarized below and detailed in the full protocol.

Field takeaway

An early switch to a dynamic steerable introducer is a rational and deliberate 'technique change' both ASA (2022) and DAS (2025) call for after a failed attempt with VL; a guideline-consistent reason to reach for a dynamic introducer early rather than repeat attempts with VL and static tracheal access equipment.

Evidence overview (with limitations)

Source	Key finding (study type; limitations)
Mazzinari et al. Anesth Analg 2019	RCT, single center, n=158 anticipated difficult airways: VL + dynamic introducer achieved 91% vs. 67% first-attempt tracheal intubation success (P=.001) and ~tenfold lower airway-injury rate (1% vs. 11%, P=.035) vs. VL + rigid stylet. Dynamic device was an FIS used without internal optics;
Shah et al. Open Anesthesiol J 2023	Retrospective, single-center, n=138,387 cases reviewed: in anticipated difficult intubations, combined technique achieved 88.7% first-pass rate vs. 74.2% awake FOB (P<0.001); failure to intubate 1.8% combined group.
Shah et al. A&A Practice 2021	Retrospective case series using VL and dynamic introducer: 100% rescue where both VL and DL had failed. Small n; single-center; hypothesis-generating.
Ganom et al. WAMM Poster 2025	6-year retrospective review, 27,841 intubation notes, single-center: FPS/overall success — anticipated difficult (88.9%/95.8%), novice operator (93.2%/98.1%), unstable c-spine (94.4%/94.4%), nasal (80%/100%), awake (100%/100%), DLT (66.7%/100%). Conference poster; not peer-reviewed.
Lenhardt et al. Anesth Analg 2014	RCT, n=140 anticipated difficult airways, combined technique with VL and FIS as dynamic introducer: no overall difference in success or time; 4 cervical spine patients rescued with dynamic device after 3 failed static-stylet attempts; cervical spine finding is a subgroup observation, not a powered outcome.
Ottoveggio et al. Curr Probl Surg 2025	Prospective observational, n=30 head/neck ENT patients: combined technique with VL and FIS for dynamic access; 96.7% (29/30) first-attempt success; mean intubation 9.56±4.07 s; no complications. No control group; two experienced operators; single-center.
Stein et al. Anaesthesia 2023	Pediatric registry analysis: combined technique VL with FIS as dynamic access. FPS 70% vs. 63% FOB alone (OR 1.4, P=0.1, not significant); eventual success 90% vs. 89%. Retrospective.
Dallyn et al. Anaesthesia 2025	Manikin study (C-MAC® D-blade), five introducers, standard and difficult airways. First-pass success — difficult airway, ranked: **C-MAC stylet 93%; Runnels TCI (RuSI™) 87%; USB 73%; STIG 60%; Portex static bougie 33%.** Standard airway (same order): 100% / 90% / 93% / 80% / 57%. Overall, both scenarios: 97% / 88% / 83% / 70% / 45%. **First-pass success — statistics:** the C-MAC stylet, USB and TCI **(RuSI™)** were statistically indistinguishable from one another and each significantly better than the Portex static bougie. The TCI **(RuSI™)** showed the smallest fall from standard to difficult (−3 points), the most robust of the five. **Time to intubation and ease of intubation:** the C-MAC stylet, USB and TCI **(RuSI™)** were each significantly better than the STIG and the Portex bougie (exact values not labelled on the poster charts).

Source	Key finding (study type; limitations)
	Note: Manikins are force-insensitive, which advantages a rigid stylet; the force-sparing hypothesis is offered to explain why patient data may diverge from the manikin ranking (a hypothesis, not a proven outcome). Values read from the study poster; verify against the full article (Anaesthesia 2025;80:1074–82). “Runnels Total Control Introducer (TCI)” is the study’s name for the device now marketed as RuSI™.
Prekker et al. N Engl J Med 2023 Kriege et al. Anaesthesia 2023	Prekker et al.: VL group ;tracheal access failure (46.7%) approximately twice as common as visualization failure (24.8%) when intubation failed; DL Group; visualization failure (59%) approximately twice as common as tracheal access failure (24%)DL intubation failed. FPS (ED/ICU): DL 70.8%, VL 85.1%. Kriege et al.: VL tracheal access failure 86% vs. visualization failure 14%; FPS routine intubation: DL 82%, VL 94%.

The nine use cases and supporting literature

Use case 1: VL with an adequate view, but difficult tracheal access ("can see, cannot intubate") — *DAS 2025 tracheal tube delivery; Mazzinari et al. 2019 RCT; Ottoveggio et al. 2025*

Use case 2: Optimizing the first (best) attempt with hyperangulated VL — *ASA/DAS attempt-limitation; Shah et al. 2023; Ganom et al. 2025 (anticipated difficult)*

Use case 3: Rescue after failed DL or VL attempt with static tracheal access equipment — *DAS 2025 technique change mandate; Marinari et.al 2018; Lenhardt et al. 2014; Shah et al. 2021*

Use case 4: Cervical spine pathology / restricted neck mobility — *Lenhardt et al. 2014 (c-spine subgroup); Ganom et al. 2025 (unstable c-spine)*

Use case 5: Single-operator combined technique — *ASA 2022 combined-technique framework; Ganom et al. 2025 (novice / single-op)*

Use case 6: Awake intubation for the anticipated difficult airway — *ASA 2022 awake-intubation strategy; Ganom et al. 2025 (awake subgroup)*

Use case 7: Pediatric single-lumen intubation (≥2 years) — *IFU indication; Stein et al. 2023 (Pediatric Difficult Intubation Registry)*

Use case 8: Nasotracheal intubation (NTI) — *IFU indication; Kumar et al. 2020 (case report); Ganom et al. 2025 (nasal subgroup)*

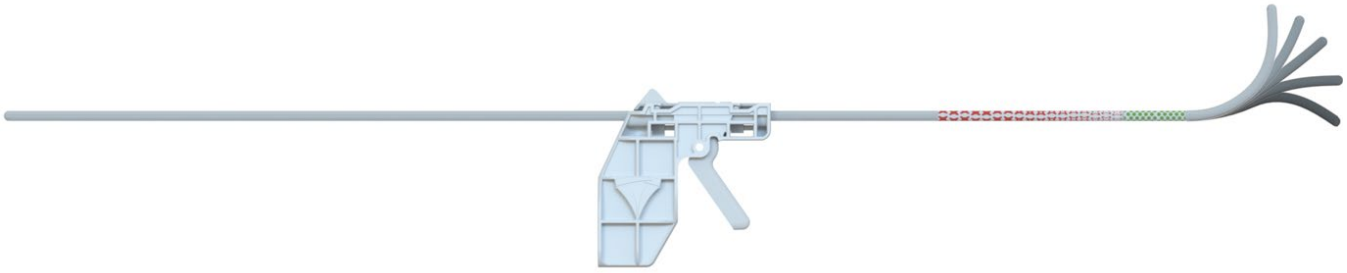
Use case 9: Double-lumen tube (DLT) placement / lung isolation (adults) — *IFU indication; Pollard et al. 2021 (case report); Ganom et al. 2025 (DLT subgroup)*

Language note: tracheal access

This protocol uses 'tracheal access' as the umbrella term for delivering the endotracheal tube through the airway to the trachea — the preferred term per the founder's model. Where a cited guideline or study uses its own wording — 'tracheal tube delivery,' 'tube advancement,' 'tube placement,' 'tube insertion,' or 'first-pass/first-attempt success' — that wording is preserved and glossed with '(tracheal access)' on first appearance in each section. 'First-pass success' and 'first-attempt tracheal intubation success' are outcomes of achieving tracheal access on the first attempt.

RuSI™ Tracheal Intubation Use-Case Protocol

Full protocol — US / FDA-governed territories · For healthcare professional use · Harmonized to IFU 001042.D (February 2026)



Intended use (per current Instructions for Use)

The RuSI™ is intended to facilitate endotracheal intubation — oral or nasal — with a VL or a DL. The product family includes subtypes and sizes for single-lumen tubes in **adult and pediatric** patients (aged ≥2 years) and double-lumen tubes (DLT) in **adults** only. The operator selects the subtype and size appropriate to the patient and the ETT.

Guideline foundation

- **American Society of Anesthesiologists (ASA) Practice Guidelines for Difficult Airway Management (2022).** Recommend immediate availability of equipment for combination ('combined') techniques, defined as VL for visualization paired with a dynamic introducer for tracheal access.
- **Difficult Airway Society (DAS) Guidelines for Management of Unanticipated Difficult Tracheal Intubation in Adults (2025).** Recommend VL as the first-line device; state that tracheal tube introducers (static stylets and bougies or dynamic introducers) may be used routinely and to facilitate intubation when difficulty is encountered.

Attempt limitation and the rationale for early use of a dynamic introducer

Both guidelines press the operator to make the first attempt the best attempt, and to make each subsequent attempt the best possible attempt, while limiting the total number of attempts. Specific recommendations:

- **ASA (2022):** "Be aware of the passage of time, the number of attempts, and oxygen saturation" (strongly agree: 91% anticipated / 88% emergency).
- **ASA (2022): 3+1 attempt principle:** "Limit the number of attempts at tracheal intubation or supraglottic airway placement to avoid potential injury and complications" (strongly agree: 77% anticipated / 83% emergency). A supporting footnote reads: "A reasonable approach may be to limit attempts with any technique class to three, with one additional attempt by a clinician with higher skills."
- **ASA (2022):** "If difficulty is encountered with individual techniques, combination techniques may be performed" (strongly agree: 66%). ASA (2022) defines the combined technique as VL for visualization plus a dynamic introducer for tracheal access.
- **DAS (2025) — 3+1 attempt principle:** "A maximum of three attempts at intubation, with a fourth and final attempt only being undertaken by a more experienced colleague. Each subsequent attempt should involve a change to increase the likelihood of success. *A suboptimal attempt is a wasted attempt*."

Read together: because attempts must be limited and each repeat must be a deliberate, informed change, if using a VL and visualization is adequate, switching from a rigid stylet or static bougie to a fully dynamic steerable introducer is precisely the kind of change both guidelines recommend. Lenhardt et al. (2014) demonstrated rescue with a dynamic device after rigid-stylet failure in patients with limited cervical spine mobility; Shah et al. (2021) reported 100% rescue

where VL and DL had both failed; Ganom et al. (WAMM 2025) demonstrated high success across multiple indication subgroups in a six-year review. All are cited with their limitations below.

Field takeaway

The switch to a dynamic steerable introducer is a rational and deliberate 'change' that both ASA (2022) and DAS (2025) call for on a subsequent attempt — a guideline-consistent reason to reach for it early rather than repeat a static-introducer attempt.

The nine use cases

Use case 1 · VL with adequate view, but difficult tracheal access ("can see, cannot intubate")

Use a dynamic introducer to address tracheal access difficulty on your next attempt

"Make your next attempt your best attempt"

CLINICAL SCENARIO

With a hyperangulated VL the operator has an adequate glottic view, but the styleted ETT or a static introducer cannot be placed into the trachea without the use of excessive force, or tracheal access is impossible.

Primary issue: problematic tracheal access

Example Video of Rescue with RuSI™

GUIDELINE AND PUBLISHED LITERATURE SUPPORT

DAS (2025) identifies tracheal tube delivery (tracheal access) — not visualization — as the distinct failure mode when VL is used, and supports stylets, static introducers, and dynamic introducers to facilitate ETT delivery. Mazzinari et al. (RCT, Anesth Analg 2019) reported higher first-attempt tracheal intubation success (91% vs. 67%, P=.001) and roughly a tenfold lower airway-injury rate (1% vs. 11%, P=.035) with dynamic tracheal access equipment versus a rigid stylet in anticipated difficult airways. Ottoveggio et al. (prospective, Curr Probl Surg 2025) reported 96.7% (29/30) first-attempt success with a combined technique in head and neck surgery patients with difficult airways (no control group; ENT setting; two experienced operators). Ganom et al. (WAMM poster 2025) reported 88.9% first-attempt success (FPS) and 95.8% overall success for anticipated difficult intubation in a six-year retrospective review (n=358; conference poster).

HOW THE OPERATOR USES THE RuSI™

The operator steers the articulating tip anteriorly through the glottis — navigating the primary curve and the inflection point — then posteriorly into the trachea (secondary curve). Once the color-zone depth indicator reads green at the cords (tip at mid-trachea), the operator passes the ETT over the shaft under indirect visualization.

CAUTION

Do not force tracheal access if resistance is encountered. Use only when the tracheal entrance can be visualized.

Use case 2 · Optimizing the first (best) attempt with hyperangulated VL

Tracheal access failure is the main cause of intubation failure when VL is used.

"Make your first attempt your best attempt"

CLINICAL SCENARIO

A known difficult intubation, anticipated difficult intubation, or routine intubation in which the clinical plan is to maximize first-attempt tracheal intubation success and avoid wasted attempts.

Example Video of Primary Approach with RuSI™ in a Patient with an Airway Tumor

GUIDELINE AND PUBLISHED LITERATURE SUPPORT

DAS (2025) 3+1 principle: "the first attempt the best attempt; a suboptimal attempt is a wasted attempt." ASA (2022) attempt-limitation recommendations (above). When using a hyperangulated blade, DAS (2025) states that a stylet, bougie, or flexible bronchoscope should be used, shaped appropriately for the blade geometry. Shah et al. (retrospective, Open Anesthesiol J 2023) reported that VL plus a dynamic introducer in anticipated difficult intubations achieved 88.7% first-pass rate — successful tracheal access on the first attempt. Ganom et al. (WAMM poster 2025) reported 88.9% FPS for anticipated difficult intubation and 93.2% FPS for novice operators in a six-year review (conference poster).

HOW THE OPERATOR USES THE RuSI™

Use case 2 · Optimizing the first (best) attempt with hyperangulated VL

Tracheal access failure is the main cause of intubation failure when VL is used.
"Make your first attempt your best attempt"

The operator uses the RuSI™ as the introducer on the first attempt, steering through serpentine airway geometry under continuous VL visualization and using the color-zone depth indicator to confirm mid-tracheal tip placement.

CAUTION

A suboptimal attempt is a wasted attempt; any repeat attempt should incorporate a deliberate change. Do not force tracheal access if resistance is encountered.

Use case 3 · Rescue after failed DL or VL attempt with static tracheal access equipment

CLINICAL SCENARIO

First-attempt tracheal intubation with a static stylet or static bougie (with DL or VL) has failed; the operator is planning a changed, higher-yield subsequent attempt.

GUIDELINE AND PUBLISHED LITERATURE SUPPORT

DAS (2025): each subsequent attempt should involve a change to increase the likelihood of success — switching from a static to a dynamic steerable introducer is such a change. ASA (2022): limit attempts and perform combination techniques when difficulty is encountered. Lenhardt et al. (RCT, Anesth Analg 2014) reported that four patients with cervical spine pathology could only be successfully intubated with VL and a dynamic device after three failed attempts with VL and a rigid stylet. Shah et al. (A&A Practice 2021) reported 100% rescue in cases where both VL and DL had failed. Ganom et al. (WAMM poster 2025) demonstrated high overall success across a range of rescue-relevant indications (conference poster).

HOW THE OPERATOR USES THE RuSI™

The operator switches to the RuSI™ for dynamic tracheal access, actively navigating the serpentine path using VL for visualization.

CAUTION

Respect the 3+1 attempt ceiling and call for experienced help early. Do not force tracheal access if resistance is encountered.

Use case 4 · Cervical spine pathology / restricted neck mobility

CLINICAL SCENARIO

Manual in-line axial stabilization (MIAS) or anatomical limitation of neck mobility prevents the neck positioning that a static introducer relies on to navigate the airway.

Example Video of RUSI™ in a Fused Neck

GUIDELINE AND PUBLISHED LITERATURE SUPPORT

Lenhardt et al. (RCT, Anesth Analg 2014) specifically reported that the four patients rescued with a dynamic device after static-stylet failure all had cervical spine pathology; overall tracheal intubation success probability for cervical spine patients was 100% (20/20) with the dynamic tracheal access technique vs. 80% (16/20) with the rigid stylet (95% CI for difference: 2%–42%). Ganom et al. (WAMM poster 2025) reported 94.4% FPS and 94.4% overall success for the unstable cervical spine subgroup (n=18; conference poster).

HOW THE OPERATOR USES THE RuSI™

The operator uses tip articulation to follow the airway's serpentine geometry using VL for visualization, without depending on neck movement or repositioning of airway geometry. The shaft conforms to the path rather than the patient being moved to accommodate the device.

CAUTION

Follow institutional cervical spine protocols throughout; the RuSI™ does not alter immobilization requirements. Do not force tracheal access if resistance is encountered.

Use case 5 · Single-operator combined technique

CLINICAL SCENARIO

A combined technique (VL plus dynamic introducer) is indicated, but a second operator or a flexible intubating scope (FIS) is not immediately available to be used as a dynamic introducer.

Example Video of Single Operator Use

GUIDELINE AND PUBLISHED LITERATURE SUPPORT

ASA (2022) describes a single-view / single-operator configuration of the combined technique using a purpose-built, single-handed dynamic introducer. Ganom et al. (WAMM poster 2025) reported 93.2% FPS and 98.1% overall success for novice operators using the single-operator combined technique in a six-year retrospective review (n=103; conference poster).

HOW THE OPERATOR USES THE RuSI™

Because the shaft is designed to be advanced one-handed on the handle, a single clinician can hold the VL and steer the RuSI™ simultaneously — the RuSI™ in the right hand and the VL in the left hand — enabling the combined technique without a second operator.

CAUTION

Do not force tracheal access if resistance is encountered.

Use case 6 · Awake intubation for the anticipated difficult airway

CLINICAL SCENARIO

An awake, topicalized/sedated intubation is planned for a patient with a predicted difficult laryngoscopy or difficult tracheal access, using VL as the primary visualization strategy rather than awake fiberoptic bronchoscopy (FOB).

Video Example of Awake Intubation with RuSI™

Use case 6 · Awake intubation for the anticipated difficult airway

GUIDELINE AND PUBLISHED LITERATURE SUPPORT

ASA (2022) supports awake intubation as a strategy for the anticipated difficult airway; awake VL is an accepted alternative to awake FOB. Ganom et al. (WAMM poster 2025) reported 100% FPS and 100% overall success in the awake-intubation subgroup (n=4; conference poster).

HOW THE OPERATOR USES THE RuSI™

The operator maintains glottic visualization with VL and uses the RuSI™ for precise, dynamic tracheal access. The ability to preload the ETT behind the handle, and if needed to exchange ETT size, may reduce the number of passages in the awake patient.

CAUTION

The awake use of this technique requires appropriate topicalization and/or sedation per institutional protocol. Report from Ganom et al. is very small (n=4); present as illustrative only until further evidence is available. Do not force tracheal access if resistance is encountered.

Use case 7 · Pediatric single-lumen intubation (age ≥2 years)

CLINICAL SCENARIO

A pediatric patient (2 years or older) requires single-lumen endotracheal intubation, and the operator plans to use a dynamic steerable introducer sized appropriately for the child.

GUIDELINE AND PUBLISHED LITERATURE SUPPORT

IFU-indicated: the product family includes subtypes and sizes for single-lumen tubes in pediatric patients aged ≥2 years. Stein et al. (Pediatric Difficult Intubation [PeDI] Registry analysis, Anaesthesia 2023) reported that a hybrid technique (simultaneous VL and flexible bronchoscopy as a dynamic introducer) in children with difficult direct laryngoscopy achieved first-attempt success of 70% (98/140) compared with 63% (352/560) for flexible bronchoscopy alone (odds ratio 1.4, 95% CI 0.9–2.1; P=0.1 — not statistically significant); eventual success was 90% vs. 89%; complication rates were similar (15% vs. 13%). The hybrid technique was used as a rescue technique more frequently (39% vs. 25%, P<0.001). Important limitation: the hybrid device in that study was an FOB, not a purpose-built single-handed introducer. Adult difficult-airway guidelines (ASA 2022, DAS 2025) do not cover pediatric practice — follow applicable pediatric-specific difficult-airway guidance.

HOW THE OPERATOR USES THE RuSI™

The operator selects the pediatric-appropriate RuSI™ subtype and size, steers under VL visualization, and uses the color-zone depth indicator to manage tip depth in the smaller airway.

CAUTION

Contraindicated in children under 2 years of age. Confirm that the selected subtype and size are appropriate for the patient's age and ETT. Do not force tracheal access if resistance is encountered.

Use case 8 · Nasotracheal intubation (NTI)

CLINICAL SCENARIO

When a nasotracheal intubation is planned — for example, in oropharyngeal or maxillofacial surgery, or for an anticipated difficult airway — where maximizing first-attempt success and minimizing soft-tissue trauma and nasal bleeding are clinical priorities.

Video example of Nasotracheal intubation with RuSI™

GUIDELINE AND PUBLISHED LITERATURE SUPPORT

IFU-indicated: the intended use covers nasal as well as oral endotracheal intubation. Kumar et al. (BMJ Case Rep 2020) described a dynamic steerable introducer facilitating VL-guided nasotracheal intubation (NTI) in an anticipated difficult airway (oropharyngeal carcinoma), aiming to reduce soft-tissue trauma compared with Magill forceps or other adjuncts — single case report, illustrative only. Ganom et al. (WAMM poster 2025) reported 80% FPS and 100% overall success for the nasal intubation subgroup (n=10; conference poster).

HOW THE OPERATOR USES THE RuSI™

The operator advances the RuSI™ via the selected nostril under VL visualization, steering the articulating tip through the nasal cavity, nasopharynx and glottis, then passes the nasal ETT over the shaft under indirect vision.

CAUTION

Contraindicated via the nasal route in patients with abnormal coagulation or midface trauma. Do not force if resistance is encountered.

Use case 9 · Double-lumen tube (DLT) placement / lung isolation (adults)

CLINICAL SCENARIO

An adult patient requires a DLT for lung isolation (e.g., video-assisted thoracoscopic surgery [VATS] or other thoracic surgery procedure) and difficult laryngoscopy makes DLT tracheal access challenging.

Example Video of DLT Placement with RuSI™

GUIDELINE AND PUBLISHED LITERATURE SUPPORT

IFU-indicated: the product family includes subtypes for 35 Fr, 37 Fr, 39 Fr, and 41 Fr DLT placement (tracheal access) in adult patients. Pollard et al. (BMJ Case Rep 2021) described VL combined with a dynamic steerable introducer to achieve tracheal access with a 39 Fr left-sided DLT in a patient with a history of difficult intubation (Cormack-Lehane [CL] grade IV on first attempt) — single case report, illustrative only. Ganom et al. (WAMM poster 2025) reported 66.7% FPS and 100% overall success for the DLT subgroup (n=3; conference poster).

HOW THE OPERATOR USES THE RuSI™

The operator obtains the glottic view with VL, steers the RuSI™ into the trachea under indirect vision, then passes the DLT over the shaft before removing the introducer and positioning the DLT in the left (or right) main bronchus by standard technique.

CAUTION

Confirm that the selected RuSI™ subtype is rated for the intended DLT size. Do not force tracheal access if resistance is encountered.

Contraindications (per current IFU)

- The entrance to the trachea cannot be visualized at laryngoscopy — Cormack–Lehane (CL) grade III or IV.
- A laryngoscope cannot be placed in the airway, or the color-depth zone cannot be visualized throughout the procedure.
- Abnormal tracheal anatomy, or existing or potential tracheal trauma.
- Children under 2 years of age.
- Nasal route: not in patients with abnormal coagulation or midface trauma.

Key safety caution

Excessive force must be avoided at all times. Do not force tracheal access if resistance is encountered. If resistance continues, remove the introducer, ventilate the patient, and reassess the intubation plan. Use only when the tracheal entrance and the color-depth zone can be visualized.

Evidence, with limitations

Every figure is stated in the source's own wording with its study type and limitations. Outcomes labeled 'first-pass' or 'first-attempt success' in the source literature are outcomes of successful tracheal access on the first attempt. *Note: the Dallyn et al. (2025) manikin study is cited honestly — the dynamic introducer did not achieve the highest first-attempt success on the manikin; the force-sparing hypothesis is labeled as a hypothesis throughout. Pediatric, nasal, and DLT use cases rest on the IFU and limited reports, not on comparative clinical trials.*

Theme	What was reported	Source and limitations
Combined technique vs. fiberoptic bronchoscopy as primary approach	In a retrospective single-center comparative analysis, a combined technique — video laryngoscope (VL) for visualization and a dynamic steerable introducer for tracheal access — demonstrated a higher first-pass rate (88.7%) than awake fiberoptic bronchoscopy (FOB) (74.2%, P<0.001) and asleep FOB (80.7%, P=0.06). In anticipated difficult intubations, failure to intubate was lowest in the combined-technique group (1.8%). Within the combined group, the dynamic-introducer subgroup was rated 'easy' and 'atraumatic' more often than VL plus FOB, although this difference did not reach statistical significance.	Shah et al., Open Anesthesiol J 2023 — retrospective, single-center; not a randomized controlled trial (RCT).
First-attempt tracheal intubation success: dynamic vs. rigid introducer (RCT)	In an RCT of 158 patients with anticipated difficult airways, a combined technique (VL plus a flexible dynamic introducer used without internal optics) achieved higher first-attempt tracheal intubation success — the study's pre-specified primary outcome — compared with VL plus a rigid stylet (91% vs. 67%; P=.001; fragility index 8). The dynamic-introducer group also demonstrated a roughly tenfold lower airway-injury rate (1% vs. 11%; P=.035) and faster intubation.	Mazzinari et al., Anesth Analg 2019 — single-center RCT; the dynamic introducer was a flexible intubating scope (FIS) used as a steerable introducer with optics off, not a purpose-built single-handed introducer.
Tracheal access as the predominant VL failure mode	In the VL subgroup of Prekker et al., intubation failure due to tracheal access (n=49; 46.7%) was approximately twice as common as failure due to inadequate visualization (n=26; 24.8%). In Kriege et al., tracheal access failure accounted for 86% (n=48) of VL failure attempts; inadequate visualization of the glottis accounted for 14% (n=8). Conversely, in the direct laryngoscopy (DL) subgroup of Prekker et al., inadequate visualization (n=123; 59%) was approximately twice as common as failure to access the trachea (n=51; 24%). First-pass success (ED/ICU): DL 70.8%, VL 85.1% (Prekker et al.).	Prekker et al., N Engl J Med 2023 — large multicenter study (ED/ICU setting). Kriege et al., Anaesthesia 2023 — operating room setting.
Single-operator combined technique: six-year use-pattern review	In a retrospective review of 27,841 consecutive intubation notes from a large academic medical center (December 2017 to September 2023), VL combined with a single-handed steerable introducer was used across a range of indications. Reported first-pass success (FPS) and overall success rates by indication: anticipated difficult intubation, 88.9% FPS and 95.8% overall (n=126/358); novice operator, 93.2% FPS and 98.1% overall (n=103); unstable cervical spine, 94.4% FPS and 94.4% overall (n=18); nasal intubation, 80.0% FPS and 100% overall (n=10); awake intubation, 100% FPS and 100% overall (n=4); double-lumen tube (DLT) placement (tracheal access), 66.7% FPS and 100% overall (n=3); glottic edema, 100% FPS and 100% overall (n=4).	Ganom, Pollard, Shah & Norris — conference poster, World Airway Management Meeting (WAMM), Florence 2025; retrospective, single-center, IRB-approved; not peer-reviewed as a full journal article.
Combined technique in head and neck surgery (prospective observational)	In a prospective observational study of 30 patients undergoing head and neck surgery at an ear, nose and throat (ENT) surgical unit, a combined technique (VL plus flexible fiberscope) achieved first-attempt tracheal intubation success in 29 of 30 patients (96.7%), with a mean intubation duration of 9.56 ± 4.07 seconds. No post-procedural complications were recorded.	Ottoveggio et al., Curr Probl Surg 2025 — prospective observational, single-center, no control group; n=30; ENT setting with two experienced anesthesiologists.
Rescue success after failed intubation	A retrospective consecutive case series reported successful rescue in 100% of cases in which both VL and DL had already failed. The authors reported that the success rate of VL plus a dynamic introducer 'is similar to published success rates of classic combined techniques utilizing VL plus FOB.'	Shah et al., A&A Practice 2021 — retrospective consecutive case series; uncontrolled, single-center, small n. Hypothesis-generating only.
Dynamic rescue after static-introducer failure	In an RCT of 140 patients with anticipated difficult airways, no statistically significant difference in overall first-attempt tracheal intubation success or time to intubation was found between VL plus rigid stylet (control) and VL plus a flexible tracheoscope used as a steerable introducer (intervention). However, four patients with cervical spine pathology could only be successfully intubated with VL and the dynamic technique after three failed attempts with VL and a rigid stylet. Overall success probability for cervical spine patients was 100% (20/20) in the dynamic-introducer group vs. 80% (16/20) in the rigid-stylet group (95% CI for difference: 2%–42%).	Lenhardt et al., Anesth Analg 2014 — single-center RCT; the cervical spine rescue observation is a subgroup finding, not a powered primary outcome; the dynamic device was an FIS (aScope®), not a purpose-built single-handed introducer.

Theme	What was reported	Source and limitations
Pediatric combined technique (hybrid VL plus flexible bronchoscopy)	In an analysis of the international Pediatric Difficult Intubation (PeDI) Registry from 2017 to 2021, the hybrid technique (simultaneous VL and flexible bronchoscopy) achieved a first-attempt success of 70% (98/140) compared with 63% (352/560) for flexible bronchoscopy alone (odds ratio 1.4; 95% CI 0.9–2.1; P=0.1 — not statistically significant). Eventual success rates were 90% (126/140) hybrid vs. 89% (499/560) flexible bronchoscopy. Complication rates were similar (15% vs. 13%). The hybrid technique was more commonly used as a rescue technique (39% vs. 25% of cases; P<0.001).	Stein et al., Anaesthesia 2023 — retrospective registry analysis, propensity-score matched; hybrid technique used a flexible bronchoscope with VL, not a purpose-built single-handed introducer; not an RCT.
Stylet-associated subglottic injury during videolaryngoscopy	In an RCT of 104 patients with Mallampati grade III or IV undergoing intubation with a McGrath® MAC video laryngoscope, the incidence of subglottic injury was significantly higher in patients intubated with a stylet compared with those without (65.4% vs. 42.3%; P=0.030).	Yoon et al., BMC Anesthesiol 2019 — single-center RCT; used a Macintosh-type (non-hyperangulated) blade; subglottic injury was a secondary outcome. Cited to contextualize the force-sparing hypothesis; not a claim about any specific introducer product.
Introducers are not interchangeable: bench evidence	In a manikin study (C-MAC® D-blade), five introducers, standard and difficult airways. First-pass success — difficult airway, ranked: **C-MAC stylet 93%; Runnels TCI (RuSI™) 87%; USB 73%; STIG 60%; Portex static bougie 33%.** Standard airway (same order): 100% / 90% / 93% / 80% / 57%. Overall, both scenarios: 97% / 88% / 83% / 70% / 45%. **First-pass success — statistics:** the C-MAC stylet, USB and TCI **(RuSI™)** were statistically indistinguishable from one another and each significantly better than the Portex static bougie. The TCI **(RuSI™)** showed the smallest fall from standard to difficult (−3 points), the most robust of the five. **Time to intubation and ease of intubation:** the C-MAC stylet, USB and TCI **(RuSI™)** were each significantly better than the STIG and the Portex bougie (exact values not labelled on the poster charts). Note: Manikins are force-insensitive, which advantages a rigid stylet; the force-sparing hypothesis is offered to explain why patient data may diverge from the manikin ranking (a hypothesis, not a proven outcome). Values read from the study poster; verify against the full article (Anesthesia 2025;80:1074–82). “Runnels Total Control Introducer (TCI)” is the study’s name for the device now marketed as RuSI™.	Dallyn et al., Anaesthesia 2025 — manikin (bench) study; a force-insensitive model in which rigidity is advantaged; findings may not translate to patient outcomes. See force-sparing hypothesis below.
Force-sparing hypothesis (labelled)	Hypothesis (founder's model): in patients, an introducer that navigates the serpentine airway path with less applied force may be associated with higher first-attempt tracheal intubation success and lower airway injury — proposed to explain why rigid tools may perform well in force-insensitive manikins yet dynamic navigation is favored in patient data.	Founder's serpentine/force-sparing framework — a hypothesis, not a proven clinical outcome. Consistent with Mazzinari et al.'s tenfold injury-rate reduction and Yoon et al.'s stylet-associated subglottic injury findings (both cited above with limitations).
Nasotracheal intubation case report	A case report described a dynamic steerable introducer used to facilitate videolaryngoscope-guided nasotracheal intubation (NTI) in an anticipated difficult airway (carcinoma of buccal mucosa), with the aim of reducing soft-tissue trauma and blood loss compared with alternative adjuncts.	Kumar et al., BMJ Case Rep 2020 — single case report; illustrative only.
Double-lumen tube placement case report	A case report described the combined use of VL and a dynamic steerable introducer to facilitate tracheal access (placement) of a 39 Fr left-sided double-lumen tube in a patient with a history of difficult laryngoscopy (Cormack-Lehane [CL] grade IV on first attempt) undergoing video-assisted thoracoscopic surgery (VATS).	Pollard et al., BMJ Case Rep 2021 — single case report; illustrative only.
Why first-attempt success and attempt limitation matter: cost model	A decision-analysis model estimated that raising first-pass success in emergent (non-operative room) endotracheal intubation from 84% toward 100% could avoid approximately 167,594 peri-intubation complications and approximately $890 million per year (2018 USD) for US providers.	Schilling, Runnels & Hollenbeak — conference poster; decision-analysis model using expected-value methods; emergent non-OR setting; US cost estimates; a modeled projection, not a measured outcome.

Force-sparing hypothesis: the founder proposes that navigating the serpentine airway path with guidance rather than force may be associated with higher first-attempt tracheal intubation success and lower airway injury — a hypothesis, not a proven clinical outcome. Consistent with Mazzinari et al.'s tenfold injury-rate reduction and Yoon et al.'s stylet-associated subglottic injury finding.

Product notice (US / FDA-governed territories)

For healthcare professional use. Follow the Instructions for Use. The RuSI™ is intended to facilitate oral or nasal endotracheal intubation with a video laryngoscope or direct laryngoscope: single-lumen tubes in adult and pediatric patients (aged ≥2 years), and double-lumen tubes in adults, using the appropriate subtype and size. Contraindicated when the tracheal entrance or color-depth zone cannot be visualized; in Cormack–Lehane grade III–IV laryngoscopic views; in abnormal tracheal anatomy or existing/potential tracheal trauma; in children under 2 years of age; and, via the nasal route, in patients with abnormal coagulation or midface trauma. Excessive force must be avoided — do not force tracheal access if resistance is encountered.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. Verify all wording, indications, contraindications, and age thresholds against the current cleared RuSI™ IFU with Regulatory and Legal. Guidelines and studies support the category of technique, not the specific product. Pediatric, nasal, and DLT use cases rest on the IFU and limited published reports, not on adult difficult-airway guideline endorsement. AI drafts; humans clear. Through The Cords LLC — Precision tracheal intubation. Harmonized to IFU 001042.D (February 2026). Draft vX.X · Owner: [name] · Confidential.