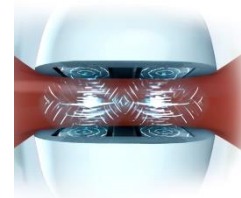
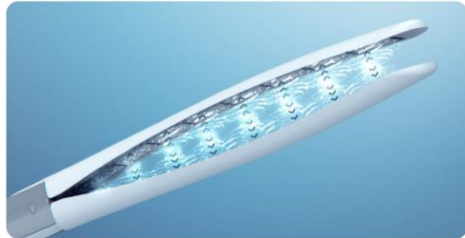


Novuson Direct Therapeutic Ultrasound (DTU)

Technical and Clinical Advantages Summary

July 2025



Executive Summary

Novuson's DTU technology represents a category-defining advancement in surgical energy devices. By leveraging ultrasonic wave interference combined with precise mechanical compression, DTU achieves unparalleled sealing and dissection performance characterized by:

- **Exceptional thermal precision** with a minimal 0.5 mm lateral thermal spread, outperforming traditional ultrasonic and bipolar RF systems (typical spreads 1.7 – 3.0 mm).
- **Virtually non-existent surgical smoke**, addressing major occupational hazards and regulatory mandates as well as intra-operative safety.
- **Robust, uniform vessel sealing ($\geq 7\text{mm}$) with high burst pressures ($>240\text{ mmHg}$)**
- **Electrically neutral** – does not require grounding pad or other kinds of return electrode
- **Functions in fluid-rich environments**, unlike RF systems susceptible to arcing or dampening effects.
- **The ONLY 3mm sealer/divider** – first to enable CUT in a 3mm sealer

This unique combination optimizes patient safety, reduces complication rates, simplifies smoke-related compliance, and expands clinical applications in delicate and challenging surgical environments.

Brief Technical summary

All surgical energy systems currently on the market work on the principle of conductive heat transfer through tissue. Heat is generated at the device/tissue interface and must be “pushed” deeper into tissue to get the intended effect. As tissue at the device interface heats up, however, it also desiccates and becomes more resistant to the conductive transfer of energy, requiring an increase in power. This results in excessively high temperatures, burning and charring of tissue, and smoke.

DTU on the other hand works “from the inside – out”. The ultrasonic waves easily penetrate through tissue from opposing jaws and generate heat only where they intersect at the midplane. The heat generated is enough to get the job done, and no more.

1. Patient Safety and Clinical Outcomes

1.1 Minimal Thermal Spread Preserves Critical Structures

- DTU's focused ultrasound energy creates heat at the midplane of the jaws, where the ultrasonic waves intersect, creating an "Inside --> Out" thermal lesion development which confines heat within approximately 0.5 mm of tissue, vastly reducing collateral thermal injury compared to Harmonic Ace (~1.7 mm) and LigaSure (~2.2–3.0 mm).
- This minimized lateral heat can protect adjacent nerves, vasculature, and delicate organs during procedures like thyroid/parathyroid surgery, head & neck cancer resections, prostate resection, colorectal surgery, and gynaecologic oncology.
- Clinical implications include dramatically reduced rates of nerve palsy (e.g., recurrent laryngeal nerve) and better preservation of organ function.

1.2 Reliable and Secure Tissue Sealing

- DTU has been shown to deliver robust seals with burst pressures exceeding FDA requirements-- porcine studies demonstrate >240 mmHg.
- Its sealing efficacy is maintained in fluid-rich or bloody environments where RF systems may fail due to electrical arcing, and ultrasonic (Harmonic) devices lose efficiency due to the heat sink effect.
- This will result in improved haemostasis and a reduction in postoperative complications such as bleeding and hematoma.

1.3 Smoke-Free Operation Mitigates Risks and Occupational Hazards

- Unlike bipolar RF or ultrasonic cutters, DTU produces no surgical smoke or carcinogenic particulates, eliminating patient and staff exposure to carcinogens (benzene, formaldehyde), infectious agents (viable HPV, bacteria), and toxic gases.
- Surgical smoke is associated, albeit indirectly, with increased surgical site infections (SSIs), delayed wound healing, DNA damage in OR personnel, and respiratory symptoms. DTU eradicates this risk by design.
- Smoke-free conditions reduce chronic occupational injuries, aligning with emerging regulatory mandates in 18 US states that require smoke evacuation.

1.4 MiniLS 3mm diameter enables less invasive procedures

- Seal and cut capabilities combined in a 3mm diameter instrument, when associated with the use of a "nano-scope" of 3mm or less, allows some procedures to be performed entirely percutaneously, greatly reducing morbidity and increasing the efficiency of ambulatory surgery.

2. Surgical Precision and Dissection Capability

2.1 Superior Tissue Handling in Confined and Complex Anatomy

- DTU's small 3mm handpieces can afford unparalleled access in tight surgical fields. This will become even more relevant in robotic single-port, and endoscopic procedures.
- Mechanical compression combined with ultrasonic wave interference allows precise coagulation with consistent tissue apposition and no charring or sticking.
- The absence of smoke improves visualization, reducing surgeon fatigue and technical errors during dissection and preparation.

2.2 Precise, Controlled Dissection with Minimal Collateral Damage

- DTU enables effective separation of tissues via clean sealing and division, unlike traditional bipolar RF devices that primarily coagulate, or ultrasonic systems where cutting is integrated but impacted by blade size and smoke.
- Fluid tolerance allows consistent performance in blood- or fluid-rich operative sites such as liver, trauma, and pelvic surgeries, where other platforms may falter.

2.3 Enhanced Ergonomics and Handling

- The lightweight, compact device design delivers good tactile feedback and surgeon control, essential for delicate minimally invasive procedures.
- Articulating jaw designs (e.g., in Caiman) offer excellent angles but coupled with smoke and larger profiles; DTU balances size, dexterity, and smoke avoidance.

3. Workflow Efficiency and Operating Room Economics

3.1 Eliminates Need for Smoke Evacuation Systems

- Traditional current devices necessitate costly smoke evacuation infrastructure (\$8,000–\$120,000 per OR initial setup plus \$8,000–\$10,000 yearly filter costs and disposables).
- DTU's smoke-free operation eliminates these cost and logistical burdens leading to estimated savings of \$19,000 per OR annually in consumables and compliance costs.
- Clear surgical fields reduce procedure time by decreasing smoke clearance delays (5–12 minutes per surgery).

3.2 Faster and Reliable Sealing Reduces Procedure Times

- The device seals vessels in 2–3 seconds, comparable or faster than LigaSure (2–4 seconds) and Harmonic Ace (4.5 seconds), improving OR turnover and throughput.
- Reduced instrument exchanges due to DTU's capacity to seal and divide efficiently contribute to streamlined workflows in minimally invasive surgeries.

3.3 Regulatory and Compliance Advantages

- DTU meets smoke evacuation mandates in states such as Colorado, Rhode Island, and 16 others without retrofitting or added infrastructural investment.
- Early adoption provides a competitive advantage and positions hospitals to avoid penalties or legal liabilities linked to surgical smoke exposure.

4. Clinical Application Expansion and Strategic Market Positioning

4.1 High-Value Specialties with Expected Benefit

Clinical Area	DTU Advantages	Clinical Impact
Thyroid/Parathyroid	Minimal thermal spread, nerve preservation	Reduced RLN nerve palsy and hypoparathyroidism
Trauma/Hepatic Surgery	Functional in bloody fields, reliable sealing	Safer hemostasis in challenging environments
Robotic Surgery	Small profile, smoke-free, ergonomic	Enhanced precision and OR efficiency
Head & Neck Oncology	Thermal safety, smoke elimination	Improved visibility, lower nerve injury
Trauma	Remains fully functional in fluid (blood and/or saline) environments	Improved speed and efficacy in trauma surgery
Gynecology	Reduced tissue stickiness, precise sealing. Enables percutaneous procedures.	Protection of pelvic nerves and ureters. Less invasive, elimination of scars.

4.2 Compatibility with Robotic Platforms

- DTU transducer technology can be built into robotic platform end-effectors, providing all the DTU advantages as part of a co-development or licensing agreement.
- The 3mm ultra-slim DTU handpiece can be used percutaneously, in conjunction with robotic systems, facilitating minimally invasive and endoscopic surgeries.
- Enables advanced surgical tasks in tight anatomical corridors, with smoke-free visualization critical for precision oncology and nerve-sparing procedures.

4.3 Potential for Future Innovation

- DTU's energy delivery mechanism is adaptable for AI-guided and sensor-augmented surgical systems enabling personalized, real-time energy modulation and tissue characterization.
- Support for integration with imaging, navigation, and emerging functional surgery techniques fosters evolutionary steps in minimally invasive oncology and reconstructive procedures.

5. Summary Comparison Table (DTU vs. Leading Seal & Cut Systems)

Parameter	Novuson DTU	Aesculap Caiman (Advanced Bipolar)	J&J Harmonic Ace (Ultrasonic)	Medtronic LigaSure (Bipolar RF)
Energy Source	Focused ultrasound wave interference (internal heat)	Bipolar RF current	Ultrasonic blade friction	Bipolar RF current
Smoke Production	None	Minimal	Moderate	High
Thermal Spread	~0.5 mm	<1.0 mm	1.7 mm	2.2–3.0 mm
Max Vessel Diameter	≥7 mm	Up to 7 mm	Up to 7 mm	Up to 7 mm
Sealing Time	2–3 seconds	2–4 seconds	4.5 seconds	2–4 seconds
Fluid Compatibility	Fully functional (blood/fluid)	Variable	Reduced efficiency	Risk of arcing
Instrument Profile	3 mm / 5 mm small diameter	Larger jaw, articulating design	Blade/scissor format	Bulkier jaws
Dissection Capability	High precision, smoke-free	Good articulation/dissection	Good sharp dissection	Moderate
Regulatory Compliance	Fully smoke-free, no evacuation	Partial, smoke generated	Smoke produced	Smoke produced
Cost Implications	Lower OR cost (no evacuation needed)	Moderate	Moderate	High due to smoke control

Conclusion

Novuson’s Direct Therapeutic Ultrasound (DTU) technology offers a profound step forward in surgical energy devices by combining:

- **Sub-millimeter thermal spread**, dramatically improving precision and reducing collateral injury risks,
- A **smoke-free** mechanism, significantly enhancing patient and staff safety and regulatory compliance,
- **Consistent, robust vessel sealing** even in fluid environments,
- **Percutaneous** vessel sealing and division capabilities
- **Superior tissue dissection capability** through precise energy delivery and small, ergonomic instrument profiles, and
- **Operational efficiencies** through time savings and elimination of costly smoke evacuation

DTU is uniquely positioned to disrupt the surgical energy market dominated by bipolar RF and “ultrasonic” platforms. Its application spans a broad range of clinical specialties, with especially compelling benefits in oncologic, endocrine, trauma, and minimally invasive surgeries.

Hospitals and surgical teams adopting DTU can expect improved clinical outcomes, operational cost savings, and compliance readiness—making this technology a strategic investment in the future of advanced surgical care.