

A DIFFERENT APPROACH TO TONSILLECTOMY

Discover the clinically proven benefits of BiZact™ 1-3,†



†Used in 48 cases, including adults (22+) US (18+) EU the use of the BiZact™ tonsillectomy device resulted in non-measurable bloodloss compared to published literature stating 10.83 ml for Coblator™, 27.08 ml for electrocautery [Roje], and 125 ml [Lachanas] with cold knife.

Medtronic
Further, Together



THE RIGHT TOOL MAKES ALL THE DIFFERENCE

Medical technology should improve outcomes, lower overall healthcare costs, and contribute to a positive patient experience. And those imperatives are most meaningfully achieved when we work together.

That's why we partnered with ENTs to engineer a device specifically for tonsillectomies, to deliver superior clinical outcomes that drive economic value.

The BiZact™ device has been clinically shown to:

- Nearly eliminate intraoperative blood loss^{1,†}
- Improve procedural efficiency^{1,4,5,‡}
- Reduce the incidence of postoperative hemorrhage^{6,7,§}

[†]Used in 48 cases, including adults (22+) US (18+) EU the use of the BiZact™ tonsillectomy device resulted in non-measurable bloodloss.

[‡]Used in 48 cases, including adults (22+) US (18+) EU. Average procedure time for the BiZact™ tonsillectomy device was 7 min. compared to published literature stating 14.8 (pediatric) and 20.5 (adult) min. [Lee] for electrocautery and 27.3 min. [Omran] for Coblator™.

[§]Used in 60 cases, including patients (age range 3-12yrs) in the U.S. There were no intra-operative or post-operative bleeding events, defined as bleeding events that required intervention, compared to secondary post-operative hemorrhage rates in published literature of 6.3% for electrocautery, 4% for cold dissection, and 2.4% for coblation [Francis].



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DESIGNED SPECIFICALLY FOR TONSILLECTOMY

The BiZact™ device:

- Optimizes transoral access with a 12 cm shaft
- Offers a curved-shape jaw that follows the tonsil bed
- Reliably seals vessels up to 3 mm⁸

OPTIMIZES THE PROCEDURE FROM START TO FINISH

Surgeons using the BiZact™ device are completing cases in about half the time^{1,4,5,†} compared to the Coblator™ device and electrocautery. Because the BiZact™ device:

- Offers a fast and easy setup^{9,‡}
- In-line activation facilitates efficient sealing and transection
- Nearly eliminates intraoperative bleeding^{1-3,§,Ω}

That means patients spend less time under anesthesia.^{1,4,5,†}
And your practice can perform more cases in a day.

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‡12 out of 12 surgeons and 13 out of 15 nurses surveyed agreed.

§Used in 48 cases, including adults (22+) US (18+) EU. The use of the BiZact™ tonsillectomy device resulted in non-measurable blood loss compared to published literature stating 10.83 ml for Coblator™, 27.08 ml for electrocautery [Roje], and 125 ml for cold knife [Lachanas].

ΩCompared to electrocautery, Coblator™, and cold knife.



BUILT FOR ONE PURPOSE

The BiZact™ device was designed in collaboration with ENTs, to optimize tonsillectomies



FAST EASY SETUP^{9,†}

Simple setup contributes to procedural efficiency — and it's easier than the Coblator™* device.⁹

†12 out of 12 surgeons and 13 out of 15 nurses surveyed agreed.

"Nurses are very happy with it."[‡]

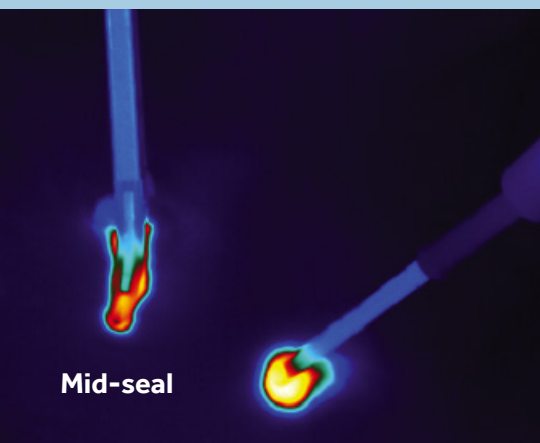
Dr. Eng Ooi

Head of Otolaryngology Head and Neck Surgery Unit at Flinders Medical Centre and Associate Professor, Flinders University, Adelaide, Australia

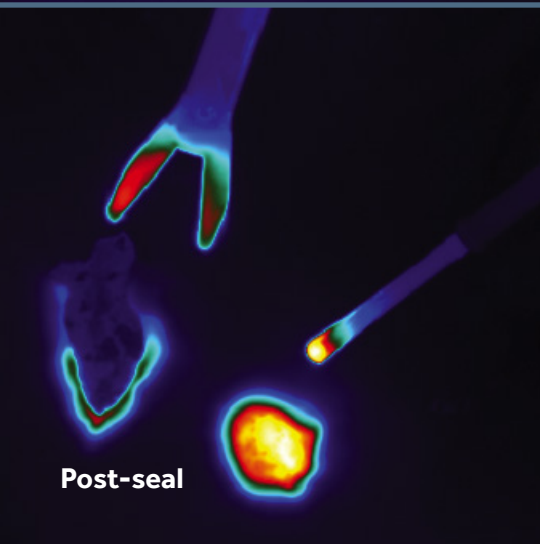
‡Feedback provided March 2017 after 30 procedures.



BiZact™ device vs. monopolar electrosurgery¹²



Mid-seal



Post-seal

LOW ENERGY LEVELS. HIGH CLINICAL VALUE.

The BiZact™ device is powered by Valleylab™ energy platforms that deliver consistent and reliable seals

The BiZact™ device uses advanced bipolar energy to permanently seal vessels up to and including 3 mm.⁸ It's powered by Valleylab™ energy platforms that:

- Continuously measure impedance of clamped tissue
- Appropriately adjust energy levels — in real time — to maintain the desired tissue effect
- Automatically stop energy delivery when the seal is complete

The clinical result is seals that withstand three times normal systolic blood pressure, and an average thermal spread of less than 1 mm.^{10,11,†}

[†]Based on internal bench testing, probability of burst ≥ 360 mm Hg is $\geq 96.1\%$.

DIFFERENT TECHNIQUE. BETTER RESULTS.

Compared to the Coblator™ device, the BiZact™ tonsillectomy device:

- Offers easier setup^{9,†}
- Reduces intraoperative bleeding^{1-3,‡}
- Reduces postoperative bleeding^{6,7,§}

Compared to an electrosurgical pencil, the BiZact™ tonsillectomy device provides:

- Less bleeding during and after surgery^{1-3,6,7,‡,§}
- Significantly lower maximum external jaw temperature¹²
- Significantly faster jaw cooldown time to 60 C¹²

†12 out of 12 surgeons and 13 out of 15 nurses surveyed agreed.

‡Used in 48 cases, including adults (22+) US (18+) EU the use of the BiZact™ tonsillectomy device resulted in non-measurable bloodloss compared to published literature stating 10.83 ml for Coblator™ and 27.08 ml for electrocautery [Roje] and 125 ml [Lachanas] with cold knife.

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EFFICIENT AND EFFECTIVE

"The removal is so efficient in terms of vessel sealing that it's quite rare for us to have to actually do anything once the tonsil's removed."

Dr. Ron J. Karni

Chief, Division of Head & Neck Surgical Oncology; Associate Professor, Department of Otorhinolaryngology – Head & Neck Surgery

University of Texas Medical School at Houston

Feedback provided March 2017 after 30 procedures

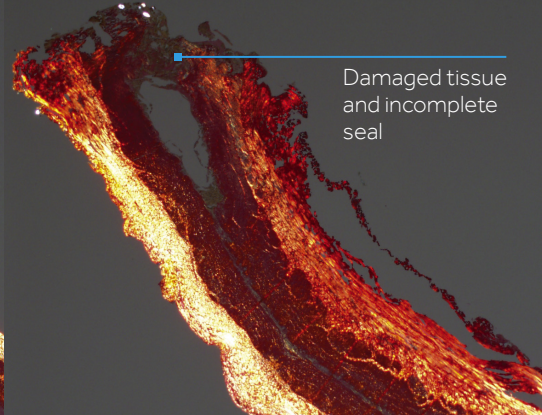
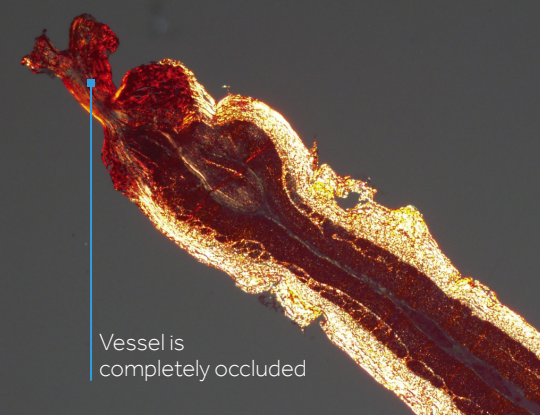
Picrosirius Red (PSR) Stained Images^{14,Ω}

Ω Damaged tissue is dark red and undamaged tissue is gold.

BiZact™ device

Monopolar electrosurgery

Coblator™ device

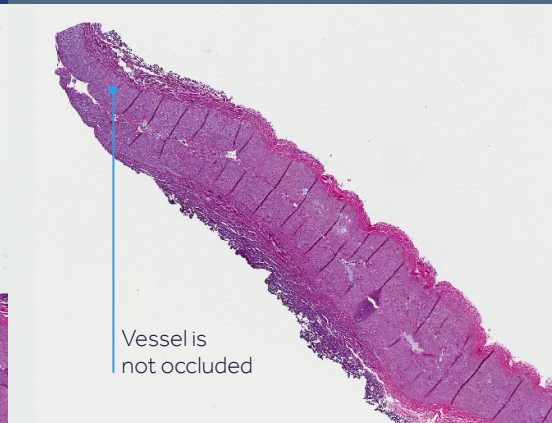
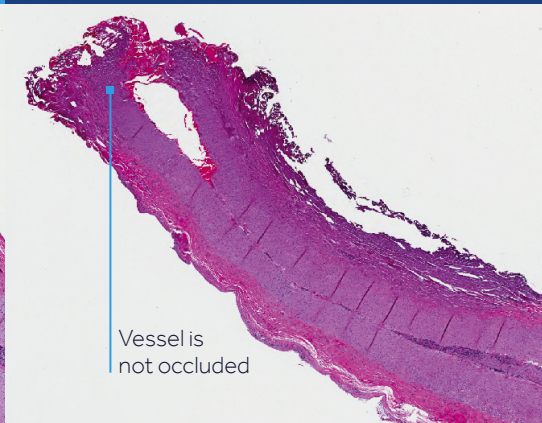
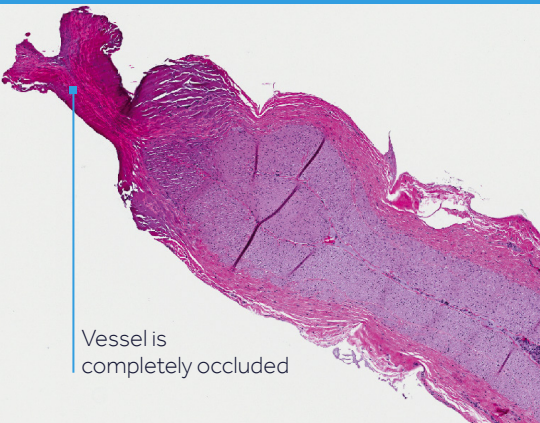


Hematoxylin and Eosin (H&E) Stained Images

BiZact™ device

Monopolar electrosurgery

Coblator™ device



INDICATIONS FOR USE

BZ4212

The BiZact™ device is a bipolar instrument intended for use in open surgical procedures where ligation and division of vessels, tissue bundles and lymphatics is desired.

The tissue fusion of the device can be used on vessels (arteries and veins) and lymphatics up to and including 3 mm diameter. The BiZact™ device is indicated for use in open general surgical procedures.

It's also indicated for adult, children and adolescent ENT procedures, including tonsillectomy, for the ligation and division of vessels, tissue bundles and lymphatics 2-3 mm away from unintended thermally sensitive structures.

The BiZact™ device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use for these procedures.



LET'S OPTIMIZE TONSILLECTOMY PROCEDURES

Contact your Medtronic sales
representative today to trial the
BiZact™ tonsillectomy device

Ordering information

BZ4212, six per case

800-722-8772

[medtronic.com/bizact](https://www.medtronic.com/bizact)



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