MORE EFFICIENT TONSILLECTOMIES $^{1-4,\dagger}$

A procedural solution from Valleylab™ energy, the BiZact™ device is designed for tonsillectomies.

$^\dagger$ Used in 37 cases, average procedure time for the BiZact™ tonsillectomy device was 9.35 minutes, compared to 14.8 (pediatric) and 20.5 (adult) minutes for electrocautery and 16.32 minutes for the Coblator™ device.
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LESS BLEEDING.²,₅,₆,‡ MORE IDEAL OUTCOMES.

We believe there is a better tonsillectomy procedure — for surgeons and patients entrusted in their care. It’s now possible with the BiZact™ tonsillectomy device, in surgeons’ hands.

The BiZact™ tonsillectomy device:
• Reduces bleeding during surgery²,₅,₆,‡
• Provides faster setup and more efficient procedures¹-⁴,†

With a 3 mm vessel-sealing indication⁷ and curved jaws that follow the shape of the tonsil bed, the BiZact™ device is designed specifically for tonsillectomy procedures.

It’s the latest surgical innovation from the Valleylab™ energy portfolio, borne out of our commitment to continually advance patient care, together.

‡ Average intraoperative bleeding in 17 cases was 7.3 mL for BiZact™ device, compared to published literature results for Coblator™ device (10.83 mL) and electrocautery (27.08 mL) and cold knife (73 mL).

† Average procedure time in 17 cases for the BiZact™ tonsillectomy device was 9.35 minutes, compared to published literature results for electrocautery (14.8 minutes pediatric, 20.5 minutes adult) and the Coblator™ device (16.12 minutes).
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 3 mm. 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 withstand three times normal systolic blood pressure, and minimal thermal damage to tissue.

The clinical benefit is less intraoperative blood loss and more efficient procedures. Patients may also experience less postoperative pain due to low thermal damage.

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€ Based on internal bench testing, probability of burst ≥ 360 mm Hg is ≥ 96.1%.
† Average intraoperative bleeding in 17 cases was 7.3 mL for BiZact™ device, compared to published literature results for Coblator™ device (10.85 mL) and electrocautery (27.08 mL) and cold knife (73 mL).
‡ Average procedure time in 17 cases for the BiZact™ tonsillectomy device was 9.35 minutes, compared to published literature results for electrocautery (14.8 minutes pediatric, 20.5 minutes adult) and the Coblator™ device (16.32 minutes).
* Low thermal damage has been shown in studies to result in less postoperative pain. The BiZact™ device has been shown to produce <1 mm thermal spread, but has not been directly evaluated for pain reduction.
DESIGNED FOR TONSILLECTOMIES

Seal and divide tonsil tissues in one step

12 cm shaft
provides optimal access

In line activation
facilitates intuitive control and efficient sealing and transection

Curved jaw
follows the shape of tonsil bed

Ergonomic handle
ensures comfort in either hand

FAST EASY SETUP\textsuperscript{1,2}

Simple setup contributes to procedural efficiency — and it’s easier than the Coblator™ device.\textsuperscript{1}

“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

\textsuperscript{1} Feedback provided March 2017.

\textsuperscript{2} 12 out of 12 surgeons and 13 out of 15 nurses surveyed agreed.
NEW TECHNIQUE. 
BETTER RESULTS.

Compared to the Coblator™ device, the BiZact™ tonsillectomy device:
- Offers easier setup
- Reduces intraoperative bleeding

Compared to an electrosurgical pencil, the BiZact™ tonsillectomy device provides:
- Less bleeding during surgery
- Significantly lower maximum external jaw temperature
- Significantly faster jaw cooldown time to 60°C

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

‡ Average intraoperative bleeding in 17 cases was 7.3 mL for BiZact™ device, compared to published literature results for Coblator™ device (10.83 mL) and electrocautery (27.08 mL) and cold knife (73 mL).

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 is 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

Picrosirius Red (PSR) Stained Images

BiZact™ device
Monopolar electrosurgery
Coblator™ device

Damaged tissue and incomplete seal
Vessel is completely occluded

Hematoxylin and Eosin (H&E) Stained Images

BiZact™ device
Monopolar electrosurgery
Coblator™ device

Damaged tissue and incomplete seal
Vessel is completely occluded

¥ Damaged tissue is dark red and undamaged tissue is gold.
INDICATIONS FOR USE

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 function 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 is also indicated for adult 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.
PRODUCT REQUEST FORM

I’m requesting the following instrument to convert my practice to the BiZact™ tonsillectomy technique:

**BiZact™ tonsillectomy device (BZ4212A)**

The BiZact™ device:

- Reduces bleeding during surgery\(^1\)\(^-\)\(^3\),\(^\dagger\)
- Provides efficiency throughout the procedure\(^1\)\(^,\)\(^4\)\(^-\)\(^6\),\(^\ddagger\)

With a 3 mm vessel-sealing indication\(^1\) and curved jaws that follow the shape of the tonsil bed, the BiZact™ device is designed specifically for tonsillectomy procedures.

The minimal thermal damage to tissue may also help reduce postoperative pain for patients.\(^5\)\(^-\)\(^10\),\(^\€\)

Thank you for reviewing this information. Please feel free to contact me if you have any questions.

Sincerely,

**Additional comments:**

References

1. Based on internal test report #RE000036877, Data collected during 17 procedures for product introduction. April–June 2017.

\(^\dagger\) Average intraoperative bleeding in 17 cases was 7.3 mL for BiZact™ device, compared to 10.83 mL for Coblator™ device and 27.08 mL for electrocautery\(\ddagger\) and 125 mL with cold knife.\(^\ddagger\)

\(^\ddagger\) Used in 17 cases, average procedure time for the BiZact™ tonsillectomy device was 9.35 minutes, compared to 14.8 (pediatric) and 20.5 (adult) minutes for electrocautery\(\ddagger\) and 16.32 minutes for the Coblator™ device.\(^\ddagger\)

\(\€\) Low thermal damage has been shown in studies to result in less postoperative pain. The Bizact™ device has been shown to produce <1 mm thermal spread, but has not been directly evaluated for pain reduction.

\(\£\) Based on internal bench testing, probability of burst ≥ 360 mm Hg is ≥ 96.1%.

For more information, please visit [medtronic.eu/product-catalog](http://medtronic.eu/product-catalog)
LET’S OPTIMIZE
TONSILLECTOMY PROCEDURES

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

Ordering information
BZ4212A, six per case
medtronic.eu/product-catalog

References

2. Based on internal test report #RE000036877, Data collected during 17 procedures for product introduction. April–June 2017.

IMPORTANT: Please refer to the package insert for complete instructions, contraindications, warnings and precautions.

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