A DIFFERENT APPROACH
TO TONSILLECTOMY

A procedural solution from the Valleylab™ energy portfolio, the BiZact™ device is designed for tonsillectomy.
LESS BLEEDING.1,†
FASTER PROCEDURES.1-3 ‡
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 has been shown to:

• Result in no measurable intraoperative bloodloss, based on a prospective study with 48 adult patients1,†

• Provides faster setup and more efficient procedures1-4,‡,§

In some studies, technology similar to the BiZact™ device helped tonsillectomy patients experience less pain.5,Ω

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

†Adults 22 and older in the United States and 18 and older in the European Union. Compared to conventional techniques and Coblation™.
‡Used in 48 cases, including adults (22+) US (18+) EU. Average procedure time for the BiZact™ tonsillectomy device was 6 min. compared to published literature stating 14.8 (pediatric) and 20.5 (adult) min. [Lee] for Electrocautery and 27.3 min. [Omran] for Coblator™.
§11 out of 12 surgeons 13 out of 15 nurses surveyed agreed.
ΩCompared to conventional techniques. BiZact™ was not a part of this meta-analysis.
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. 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.

†Based on internal bench testing, probability of burst ≥ 360 mm Hg is ≥ 96.1%.
‡The average thermal spread of the BiZact™ device is less than 1 mm.
DESIGNED FOR TONSILLECTOMY

Seal and divide tonsil tissue 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

Simple setup contributes to procedural efficiency — and it’s easier than the Coblator™ device.†

†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.
Device Performance

DIFFERENT TECHNIQUE. BETTER RESULTS.

Compared to the Coblator™ device, the BiZact™ tonsillectomy device:
- Offers easier setup $^{4,1}$
- Reduces intraoperative bleeding $^{10-12,1}$

Compared to an electrosurgical pencil, the BiZact™ tonsillectomy device provides:
- Less bleeding during surgery $^{10-12,1}$
- Significantly lower maximum external jaw temperature 7
- Significantly faster jaw cooldown time to 60 C 7

$^{1}$12 out of 12 surgeons and 13 out of 15 nurses surveyed agreed.
$^{2}$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). 7

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

Picosirius Red (PSR) Stained Images $^{11,4}$

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<thead>
<tr>
<th>BiZact™ device</th>
<th>Monopolar electrosurgery</th>
<th>Coblator™ device</th>
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<td>Vessel is completely occluded</td>
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Hematoxylin and Eosin (H&E) Stained Images

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$^{4}$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 and adolescent ENT procedures (12 years of age and above), 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:

- Resulted in non-measurable intraoperative blood loss, based on a prospective study including 48 adults patients.†
- Provides efficiency throughout the procedure.‡

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

In some studies, technology similar to the BiZact device helped tonsillectomy patients experience less pain.§

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

Sincerely,

Additional comments:

†Adults 22 and older in the United States and 18 and older in the European Union.
‡Used in 48 cases, including adults (22+) US (18+) EU. Average procedure time for the BiZact™ tonsillectomy device was 6 mins compared to published literature stating 14.8 (pediatric) and 20.5 (adult) min. [Lee] for Electrocautery and 16.32 min. [Omrani] for Coblator™.
§Compared to conventional techniques. BiZact™ was not a part of this meta-analysis.
ΩBased on internal bench testing, probability of burst ≥ 360 mmHg is ≥ 96.1%.

References
References


7. Based on internal test report #RE00011247, Benchtop testing comparing the BiZact™ tonsillectomy device with the E1551X Valleylab™ Hex-locking blade electrode. March 23, 2017.


Photo credit Getty Images

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510(k) CLEARANCE

Covidien, LLC
Rebecca Clark
Senior Regulatory Affairs Specialist
5920 Longbow Drive
Boulder, CO 80301

Re: K182451
   Trade/Device Name: BiZact Tonsillectomy Device Advanced Bipolar Tissue Sealer/Divider
   Regulation Number: 21 CFR 878.4400
   Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
   Regulatory Class: Class II
   Product Code: GEI
   Dated: September 6, 2018
   Received: September 7, 2018

Dear Rebecca Clark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose, and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health