MORE EFFICIENT TONSILLECTOMIES$^{1-4,†}$

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

† 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$^3$ and 16.32 minutes for the Coblator™ device.$^4$
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LESS BLEEDING.\textsuperscript{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 surgery\textsuperscript{2,5,6,†}
- Provides faster setup and more efficient procedures\textsuperscript{1-4,†}

With a 3 mm vessel-sealing indication\textsuperscript{7} 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.

\textsuperscript{†}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).

\textsuperscript{‡}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 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 (10.83 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 (16.32 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 SETUP¹,²
Simple setup contributes to procedural efficiency — and it’s easier than the Coblator™ device.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

¹Feedback provided March 2017.

*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 setup1,2
- Reduces intraoperative bleeding2,3,4

Compared to an electrosurgical pencil, the BiZact™ tonsillectomy device provides:
- Less bleeding during surgery2,3,4
- Significantly lower maximum external jaw temperature12
- Significantly faster jaw cooldown time to 60°C12

112 out of 12 surgeons and 13 out of 15 nurses surveyed agreed.
1 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

PDF

Vessel is completely occluded

Damaged tissue and incomplete seal

Damaged tissue and incomplete seal

Vessel is completely occluded

Vessel is not occluded

Vessel is not occluded

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

Picrosirius Red (PSR) Stained Images13

Hematoxylin and Eosin (H&E) Stained Images13

†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\(^1\)–\(^3\),\(^†\)
- Provides efficiency throughout the procedure\(^1\),\(^4\)–\(^6\),\(^‡\)

With a 3 mm vessel-sealing indication\(^7\) 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\(^8\)–\(^10\),\(^€\).

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

Sincerely,

Additional comments:

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**References**


\(^†\) 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\(^7\) and 125 mL with cold knife\(^8\)

\(^‡\) 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\(^7\) and 16.32 minutes for the Coblator™ device\(^8\).

\(^€\) 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%.

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LET’S OPTIMIZE TONSILLECTOMY PROCEDURES

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

Ordering information
BZ4212A, six per case
800-722-8772
medtronic.com/bizact

References

Photo credit Getty Images

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June 8, 2017

Covidien
Ms. Sharon McDermott
Senior Specialist Regulatory Affairs
5920 Longbow Drive
Boulder, Colorado 80301

Re: K171066
  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: April 7, 2017
  Received: April 10, 2017

Dear Ms. McDermott:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure