



Manufactured by LA Eye, LLC
109 Lake Forest Dr, St Louis, MO 63117, USA
contact@macularbuckle.com

PRODUCT INFORMATION (Surgery Instructions on back)

Akduman Titanium Scleral Buckle (TSB)

**PLEASE COMPLETE THE PATIENT/SURGERY/IMPLANT NOTIFICATION FORM AND RETURN IT TO THE MANUFACTURER IN THE PROVIDED ENVELOPE
(or enter the information at macularbuckle.com/re/form-1 or by scanning the QR code)**



Caution: Rx only; Federal (USA) law restricts this device to sale or on the order of a physician.

NOTE: The manufacturer disclaims all warranties expressed or implied, including but not limited to suitability for a particular purpose.

Description

The Akduman Titanium Scleral Buckle (TSB) is a medical implant grade titanium device designed to provide a buckling effect in the macular area for the surgical repair of retinal detachment involving the macular area. The device is for single use only, and permanent once implanted.

Indication

Retinal detachment.

Contraindications

Active infections of the eye or the body.

No light perception eyes.

Extremely thin sclera where suturing for a scleral buckle is not appropriate.

Possible Complications and Adverse Reactions

Conjunctival and scleral erosion.

Choroidal detachment or hemorrhage.

Change in the refraction.

Warnings and Precautions

Do not use the device if the sterile package integrity has been compromised. Do not re-sterilize the implant.

It should be implanted by a surgeon familiar with scleral buckle suturing. The device is MRI conditional.

If the sterility is compromised, or any part of the implant is broken during the implantation, discard the implant or contact the company for possible exchange.

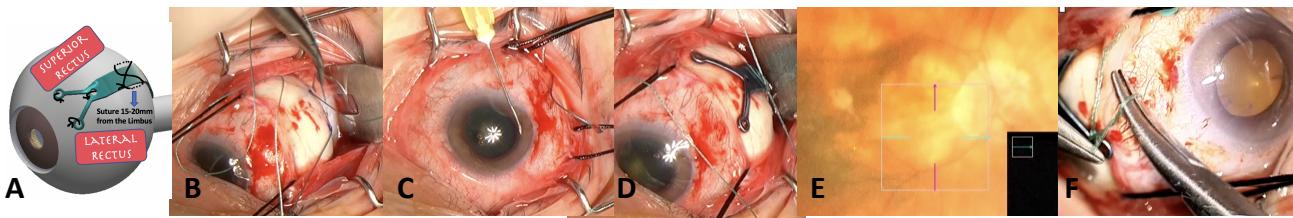
Consider adjusting the body curvature of the implant for obtaining a desired postoperative axial length as suggested in the surgery instructions.

Contents List

- The implant in a sterile double pouch packaging.
- Product Information/surgery instructions sheet (front and back). (These are also available via the QR code scanning on the box).
- Product information labels.
- Patient/Surgery/Implant notification form to be returned to the manufacturer (Postage paid pre addressed envelope (alternatively this information can be entered online – QR code and web address on the card)).
- Patient ID card.

The implant has been terminally stabilized by Gamma Radiation. Sterility is assured provided that the peel pouch has not been opened, and the sterility expiration date has not lapsed. The peel pouch is intended to be opened using sterile technique, allowing the implant to be dropped into the sterile field.

SURGERY INSTRUCTIONS (Product information on back)



- a. **Schematic placement of the implant on the eye.**
- b. **Place 5/0 Mersilene in the superotemporal (ST) quadrant 15-20 mm from the limbus.**
 - i. Perform a peritomy at the limbus, centering the superotemporal quadrant for 180 degrees.
 - ii. Bluntly and thoroughly dissect the Tenon's in the superotemporal quadrant to create a relaxed space extending all the way to the retrobulbar area.
 - iii. Place a 5/0 mersilene double-arm mattress suture at a 90-degree angle to the limbus, precisely in the middle of the superotemporal quadrant. The anterior bite should be 15-20 mm away from the limbus, with 5 mm apart bites, deep enough in the sclera (about 2/3 of the scleral thickness). Aim for a bite length of approximately 3-4 mm.
 - iv. Insert a trocar (a valved trocar is recommended) into the pars plana of an easily accessible quadrant of choice, preferably superonasal or inferonasal.
- c. **Reduce IOP.** Perform a paracentesis with a side-port blade to empty the anterior chamber almost completely, ensuring sufficient hypotony.
- d. **Tightly suture implant.** Insert the implant through the preplaced Mersilene and gently push it as posteriorly as possible until you encounter some resistance. At that point, securely tie the Mersilene to fixate the body of the implant.
- e. **Adjust placement of TSB.** Insert a light pipe (a chandelier light source is recommended) into the preplaced nasal valved trocar. Use a wide-angle operating microscope (e.g., BIOM, Resight, or EIBOS) to visualize whether the implant indents the desired area. If necessary, make fine adjustments by manipulating it through the anterior horns.
- f. **Fixate arm to the adjusted position.** Finally, fixate the implant in the adjusted position by placing additional suture(s) in one or more of the three holes in its anterior section.

SUGGESTED ADJUSTMENTS FOR APPROXIMATING TO THE DESIRED POSTOPERATIVE RESULTANT AXIAL LENGTH

**NOTE: STRETCH THE IMPLANT BODY TO ADJUST.
DO NOT BEND THE HORNS.**

The postoperative axial length may vary depending on the tightness of the surgical suture and the individual technique employed by the surgeon.

The implant in the original packaging has an End-to-End distance of 22 mm, which is estimated to provide a target post-operative axial length of 25 ± 1 mm, regardless of the pre-operative axial length (refer to the image on the top).

In cases where the desired final axial length differs from this target, especially when a significant reduction in axial length may adversely affect post-operative refraction (e.g., pseudophakic eyes), a lesser indentation, such as shortening the axial length by 2 mm with the implant, is likely to achieve the desired improvement in macular pathology. To determine the recommended modification for the End-to-End distance in such situations, please refer to the table.

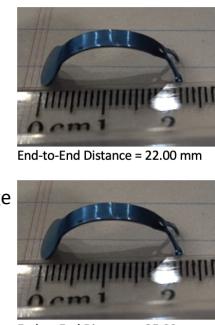
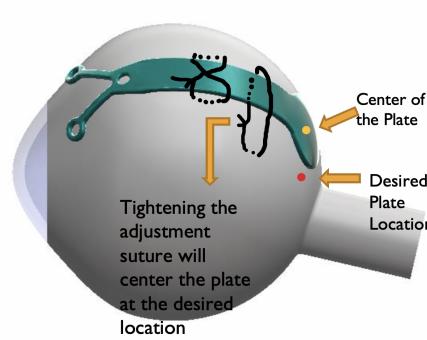


TABLE:

Desired Postoperative Axial Length (mm) Regardless of the preoperative axial length.	Recommended End-to-End Distance (mm)
25 ± 1	22.00
26 ± 1	22.50
27 ± 1	22.75
28 ± 1	23.25
29 ± 1	23.75
30 ± 1	24.25
31 ± 1	24.50
32 ± 1	25.00
33 ± 1	25.25
34 ± 1	25.50
35 ± 1	25.75
36 ± 1	26.00
37 ± 1	26.25
38 ± 1	26.50

SUGGESTED TECHNIQUE FOR FURTHER ADJUSTING THE PLATE LOCATION IF DESIRED



Scan the QR code or visit macularbuckle.com/re/tmb-placement for a 40-second surgical technique video.



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