ALTERNATE INSERTION INSTRUCTIONS

USING THE GRAETHER SIDEPORT MANIPULATOR

GRAETHER 2000™ PUPIL EXPANDER SYSTEM

STERILE R ⊘ CE 0473

PATENT NUMBERS 5,267,553 & 5,634,884
AND OTHER PATENTS PENDING

Physicians should be aware that all information such as *"Description, Indications for use, Contraindications, Preparation, Conditions Encountered and Their Solutions, Cautions, Warnings"* etc. contained in the "Physician Instruction, Graether 2000 Pupil Expander System" No.930066 CID 764 **applies to this instruction**, with the exception of those references describing the IGR (Iris Glide Retractor) and usage of it.

The Alternate Insertion Instruction does not include the use of the IGR component. Without the IGR, the insertion technique varies and is described with the usage of a Sideport Manipulator instrument in the following steps.

1. The surgeon should make his usual incision of at least 2.5mm and a sideport incision of 1mm on the side of his non-dominant hand.
2. Remove the pupil expander (on the insertion tool) from the container and examine it under the microscope to make sure that the expander is in place. Note the folded tip, fenestrated tabs at the open ends of the ring, and the release button on the handle.
3. Fill the anterior chamber with Viscoat or other dispersive viscoelastic agent but do not overfill the chamber, especially in Flomax (tamsulosin) "floppy iris" cases.
4. Place the pupil expander mounted on the insertion tool into the AC by tipping the tool on its side to pass it through the incision and over the iris. *(Fig. 1)*
5. Engage the sphincter with the folded tip of the pupil expander opposite the incision and push the expander ring into the chamber until the tabs are visible through the cornea near the incision. The distal portion of the sphincter will be near the limbus and the proximal portion will lie under the tool. *(Fig. 2)*
6. Insert the sideport manipulator (ASICO AE-2504) through the sideport incision and place the olive tip of the tool inside the sphincter edge alongside the expander. *(Fig. 3)*
7. With the insertion tool (and expander ring) held in a stationary position within the chamber, move the olive tip of the sideport instrument toward the incision until the stretched sphincter clears the end of the expander ring. *(Fig. 4)*
8. Move the olive tip perpendicular to the axis of the tool across the end of the ring so that the sphincter edge is elevated to the plane of the pupil expander ring on both sides. The fenestrated tabs on the ring should now lie against the surface of the iris. *(Fig. 5 shown without the inserter)*
9. Reverse the path of the olive tip so that it is free from the sphincter but remains in the chamber.
10. After ascertaining that both ends of the ring are engaged, release the pupil expander from the tool by pressing the button on the handle with the forefinger.
11. As the pupil expander resumes a circular shape and engages the sphincter margin, guide the edges onto the sphincter with the sideport manipulator as required. *(Fig. 6)*
12. Remove the carrier insertion tool and discard it.
13. If one side of the pupil expander ring misses the sphincter edge, push it back into the pupil space and let it expand onto the sphincter. *(Fig. 7)*
14. If the pupil is not fully dilated, add more Viscoat or use one or two instruments within the ring to expand it further. Be careful not to overinflate the chamber.
15. The pupil will now remain dilated to approximately 6.3mm throughout the procedure, and the entire pupil can be transposed en masse by pressure on the ring to expose the equator of the lens. If hydrodissection of the nucleus is employed, release fluid from the capsule during the irrigation to avoid a pupil block.
16. To remove the ring, push the strap into the pupil until both ends are free of the sphincter and pull the pupil expander from the eye. This step should be done before removing the viscoelastic. *(Figs. 8, 9)*

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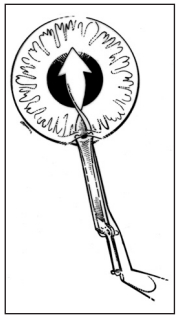

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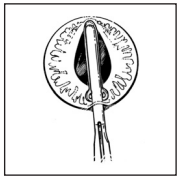

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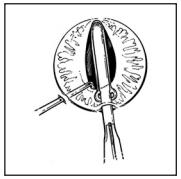

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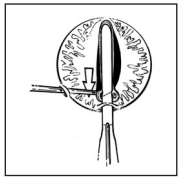

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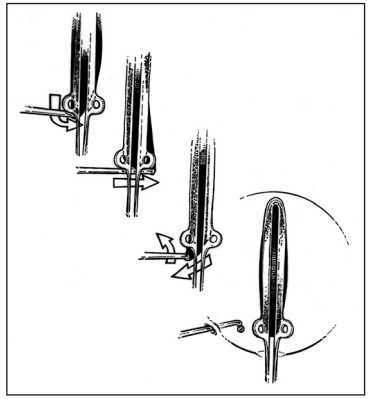

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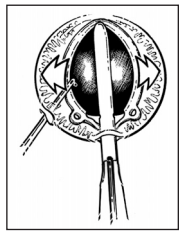

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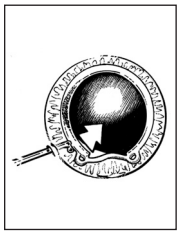

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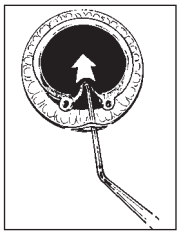

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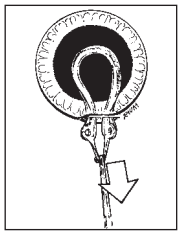

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