

⚠ Warning Adequate Intraocular Pressure (IOP) is critical to performing a successful keratectomy. If the tonometer reading remains questionable (less than 2.6 in. Hg/65.0 mm Hg), do not proceed with the procedure. Doing so could result in possible serious permanent patient injury.

In the case of soft eye, precaution should be exercised if attempting surgery at high altitude where the available vacuum is reduced.

19. Do not conduct surgery without first conducting and passing all tests outlined in chapter 4, Set-Up and Testing in this manual.

20. Do not modify the Bausch & Lomb Surgical Hansatome® microkeratome in any way. Modifications will void the product warranty.

⚠ Warning Modifications could damage the Bausch & Lomb Surgical Hansatome® microkeratome. Such damage could result in possible serious permanent patient injury.

21. **⚠ Warning** Never permit extraneous foreign materials of any kind (unless specifically indicated in this manual) to be put on the blade or Hansatome® microkeratome. These materials could clog the Hansatome® microkeratome and during sterilization, could harden and become permanently lodged. Such materials could get into the interface between the cap and stromal bed. Such materials could also cause the microkeratome to malfunction and could result in possible serious permanent patient injury.

22. **⚠ Warning** The forward and reverse travel of the Hansatome® microkeratome across the suction ring must be free of visual and audible warning indications. If there is any such warning, the problem must be resolved prior to any surgical procedure. If cleaning and/or a blade change does not resolve the problem, do not proceed with surgery. Doing so could result in possible serious permanent patient injury.

23. **⚠ Warning** Do not use the Hansatome® microkeratome if each of the assembly and functional tests have not been successfully completed in sequence. Use of the Hansatome® microkeratome when each test was not successfully completed in sequence could result in possible serious permanent patient injury. Contact Bausch & Lomb Surgical Refractive Customer Service (see page 5-1) to schedule an inspection and/or service.

Procedural

24. Each day after turning on the Hansatome® microkeratome, always run the test procedures described in chapter 4, Set-up and Testing. Do not attempt to use the Hansatome® microkeratome if there are any failures in these procedures.

25. **⚠ Warning** Do not reactivate the motor footswitch until the Hansatome® microkeratome head has been removed from the patient. Doing so could transect the partial corneal flap, leading to possible serious permanent patient injury.

26. **⚠ Warning** *It is important to follow proper surgical procedure and carefully drape the eyelids and lashes. Failure to do so could result in possible serious permanent patient injury.*

⚠ Warning *Failure to achieve proper suction could result in possible serious permanent patient injury.*

27. **⚠ Warning** *If vacuum seal to the patient's eye is lost during a cut, never attempt to regain suction and continue, or to immediately repeat the procedure. Doing so could result in serious permanent patient injury.*

28. If through manipulation, vacuum reserve is lost in the attempted fixation of the suction ring to the eye prior to commencing a cut, press the vacuum footswitch to return from OPERATING mode to READY mode. Wait for the vacuum reserve to build up. Re-depress and release the vacuum footswitch and wait until the green light comes on in the OPERATING mode.

⚠ Warning *Never attempt a keratectomy when the display indicates the READY mode. Doing so would cause the blade to run in the absence of vacuum seal to the patient eye, which could result in possible serious permanent patient injury.*

29. NOTE: Do not turn the main power off while in OPERATING mode, except to run short tests of the battery back-up feature of the *Hansatome®* microkeratome. This would eventually deplete the battery energy, requiring factory replacement. Always return from OPERATING mode to READY mode when turning off the power to the *Hansatome®* microkeratome. With isolated use, the back-up batteries will last over 10 years.

30. **⚠ Warning** *The suction handle to the suction ring must be held firmly during the keratectomy to prevent counter rotation of the suction ring. Counter rotation of the suction ring in the scleral ridge could result in possible serious permanent patient injury.*

31. If the Bausch & Lomb Surgical *Hansatome®* microkeratome stops during the forward pass of a keratectomy, remove the foot from the motor footswitch, then re-depress the forward footswitch. Re-depression of the motor footswitch will provide a surge of additional power to the *Hansatome®* microkeratome, enabling continued travel through a minor jam. It could be necessary to depress the motor footswitch multiple times.

NOTE: Any tissue lodged in the *Hansatome®* microkeratome head should be removed immediately. This will prevent the tissue from hardening or becoming lodged in the cavity of the *Hansatome®* microkeratome head.

⚠ Warning *Never go forward-reverse-forward. Forward-reverse-forward will result in an uneven or irregular stromal bed. If the source of the jam presents with too great of resistance (eg., the *Hansatome®* microkeratome head travel is impeded by drape), it will be necessary to turn off the vacuum and gently slide the *Hansatome®* microkeratome assembly away from the hinge.*

32. The *Hansatome®* microkeratome is always in the READY mode while performing diagnostic tests with the exception of testing the patient vacuum with the suction tubing attached.

Warning Failure to fully engage the blade drive pin into the non-oscillating blade could lead to an adverse surgical outcome and possible serious permanent patient injury.

Caution Forcible tightening could cause damage which would require factory service.

33. **Warning** When the **READY** mode is displayed, there is no vacuum, however, the Hansatome® microkeratome can be engaged for test purposes. Prior to performing the lamellar cut, visually verify the LED display reads **OPERATING** mode. Loss of vacuum during a procedure would result in Error 33 on the display and forward pass of the Hansatome® microkeratome head would be terminated and could result in possible serious permanent patient injury.

Cleaning and Disinfection

Perform Cleaning, Disinfection, and Sterilization in accordance with chapter 3 of this manual.

34. **Warning** The Hansatome® microkeratome must be cleaned, disinfected, and/or sterilized according to the instructions provided in this manual. Failure to properly clean, disinfect, and sterilize equipment could result in possible serious permanent patient injury.
35. **Warning** If the rolling gear does not spin freely after repeated cleaning, it could be damaged and require factory service. In such a case, do not use the Hansatome® microkeratome, as possible serious permanent patient injury could result. Contact Bausch & Lomb Surgical Refractive Customer Service (see page 5-1) to schedule an inspection and/or service.
36. **Warning** Any delay in cleaning can allow residual debris from the procedure to adhere to the Hansatome® microkeratome. Such debris could clog the Hansatome® microkeratome and during sterilization, could harden and become permanently lodged. Debris allowed to build up on the Hansatome® microkeratome components could affect the performance of the system resulting in system malfunction and possible serious permanent patient injury.
37. **Caution** Do not bring any chemicals, solvents or chemical solvent vapors in contact with the Hansatome® microkeratome components other than those specified in this manual. Damage caused by these items would require major factory service that is not covered by the product warranty.
38. **Caution** Do not use acetone when cleaning the Hansatome® microkeratome. Acetone may cause damage to the Hansatome® microkeratome and would void the product warranty.
39. **Warning** Do not immerse the electrical cords or motor in any fluid. If the electrical cords or motor are immersed in a fluid, do not use the microkeratome as internal damage could have occurred, even if no abnormality of function is evident. Such damage could present itself at a future time leading to a potential

malfunction during surgery which could result in possible serious permanent patient injury. Contact Bausch & Lomb Surgical Refractive Customer Service (see page 5-1) to schedule an inspection and/or service.

⚠ Warning Do not immerse the Hansatome® microkeratome power/suction supply unit in any fluids. Do not autoclave the Hansatome® microkeratome power/suction supply unit. If the power suction supply unit is immersed in a fluid or is autoclaved, do not use the microkeratome as internal damage could have occurred, even if no abnormality of function is evident. Such damage could present itself at a future time leading to a potential malfunction during surgery which could result in possible serious permanent patient injury. Contact Bausch & Lomb Surgical Refractive Customer Service (see page 5-1) to schedule an inspection and/or service.

⚠ Warning Do not immerse or store the Hansatome® microkeratome motor in any fluid. If the Hansatome® microkeratome motor is immersed in a fluid, do not use the Hansatome® microkeratome as internal damage could have occurred, even if no abnormality of function is evident. Such damage could present itself at a future time, leading to a potential malfunction during surgery which could result in possible serious permanent patient injury. Contact Bausch & Lomb Surgical Refractive Customer Service (see page 5-1) to schedule an inspection and/or service.




⚠ DANGER Alcohol used for disinfection purposes is flammable.

⚠ Warning Never use powdered gloves or finger cots while handling or operating the Hansatome® microkeratome. Powder free (talc free) surgical gloves should be worn during preparation, use, and cleaning of the Hansatome® microkeratome. Talc could enter the Hansatome® microkeratome and/or could enter the stromal interface of the eye and could cause possible serious permanent patient injury.



⚠ Warning Following the use of the Hansatome® microkeratome in a wet lab procedure, clean, disinfect/sterilize all parts in accordance with the instructions in chapter 3. Failure to properly clean, disinfect/sterilize the Hansatome® microkeratome and its parts could result in possible serious permanent patient injury.

Sterilization

40. **Caution** Before sterilization, the white foam pad must be removed from the sterilization/storage tray. Do not throw away the white foam pad. Keep this for future use to transport the sterilization/storage tray and components.
41. **⚠ Warning** Failure to properly sterilize the Hansatome® microkeratome parts could result in possible serious permanent patient injury.
42. **⚠ Warning** Items processed by flash sterilization (unwrapped method) require aseptic handling and should be used immediately following sterilization to avoid potential recontamination.

43.  **Warning** Do not sterilize the Hansatome® microkeratome head with the AccuGlide blade installed. This could result in the blade becoming wedged in the head or result in damage to the head. Damage of this nature could result in possible serious permanent patient injury.
44.  **Warning** Do not autoclave the motor, motor cord, power/suction supply unit, footswitches, or power cord. Excessive heat or moisture could cause damage to these components. Damage of this nature could lead to a potential malfunction during surgery, which could result in possible serious permanent patient injury.
- Caution** Do not autoclave the tonometer or black suction ball. Autoclaving could cause the tonometer and/or black suction ball to melt or warp due to the extreme heat.
45.  **Warning** Never disassemble the Hansatome® microkeratome head. The Hansatome® microkeratome head has been carefully calibrated; the calibration is lost if disassembled. Do not use the Hansatome® microkeratome if the microkeratome head has been disassembled. Doing so could result in possible serious permanent patient injury.

General Precautions

46. The Hansatome® microkeratome is a precision-manufactured device which has been carefully calibrated.
-  **Warning** Do not use the Hansatome® microkeratome if it or an individual part or parts of it are dropped. If the Hansatome® microkeratome is dropped or an individual part or parts of it are dropped, damage could have occurred, even if no abnormality of function is evident. Such damage could present itself at a future time, leading to malfunction during surgery which could result in possible serious permanent patient injury. Contact Bausch & Lomb Surgical Refractive Customer Service (see page 5-1) to schedule an inspection and/or service.
47. Follow local governing ordinances and recycling plans regarding disposal or recycling of disposable Hansatome® microkeratome components.
48.  **DANGER FLAMMABLE:** Do not use the Hansatome® microkeratome in the presence of flammable anesthetics or vapors.

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