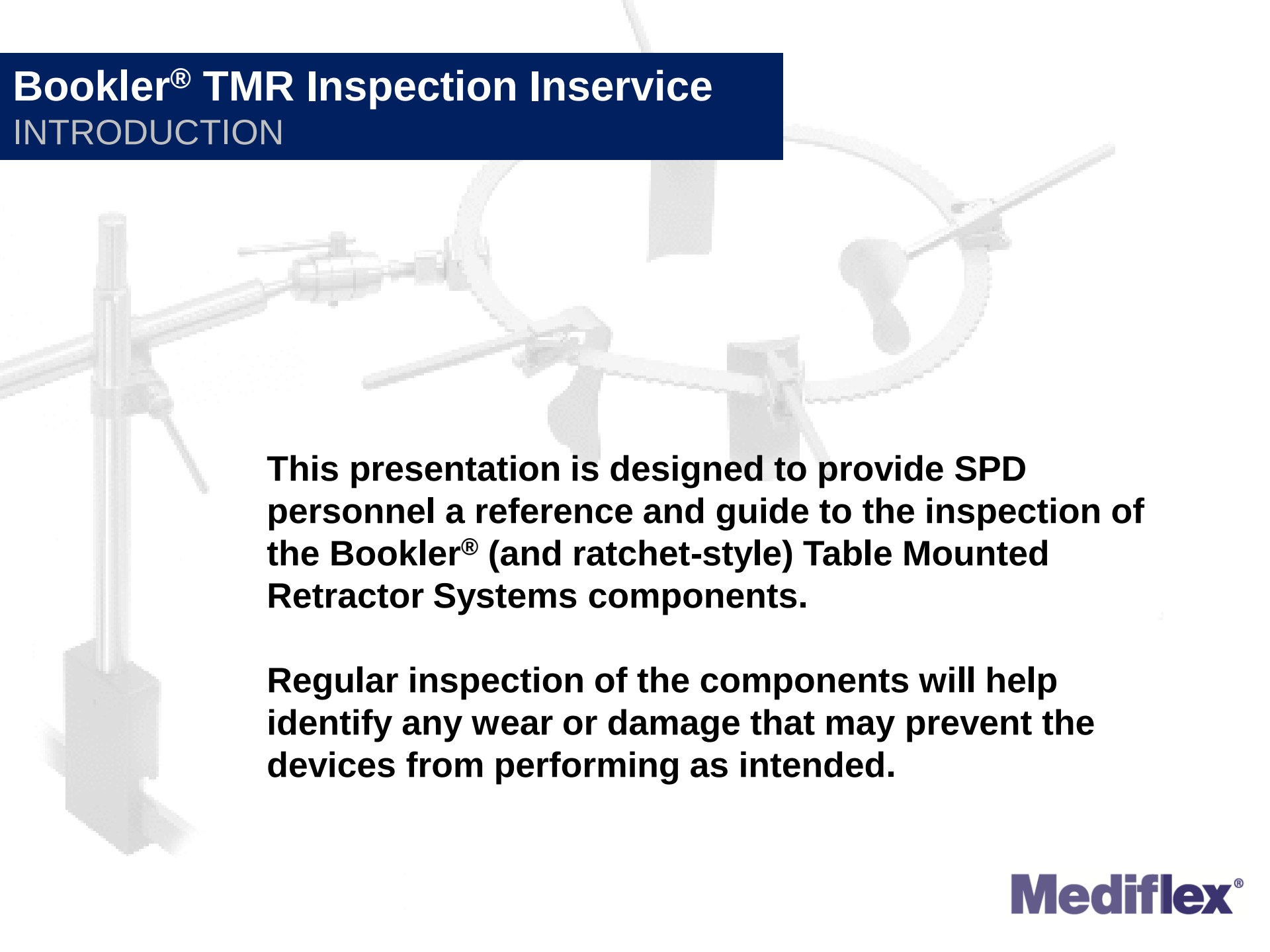




Recommendations for Inspection of Bookler® Table Mounted Retractor Systems During Decontamination and Cleaning

CEU INSERVICE FOR SPD



A faded, light gray image of a Bookler TMR inspection device is visible in the background. It features a vertical stand with a horizontal arm, a large circular scale with a pointer, and various adjustment knobs and levers.

Bookler® TMR Inspection Inservice

INTRODUCTION

This presentation is designed to provide SPD personnel a reference and guide to the inspection of the Bookler® (and ratchet-style) Table Mounted Retractor Systems components.

Regular inspection of the components will help identify any wear or damage that may prevent the devices from performing as intended.

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INSPECTION STEPS

1. Provide a visual inspection

- Look for corrosion (rust).

NOTE: Discoloration is not rust. Discoloration is caused by precipitate – minerals or chemical that were dissolved in fluid that the device came in contact with. When the fluid dried, the precipitate was left behind. Generally there are 2 sources: unrinsed detergent and sterilizer steam that is not properly filtered. There are 2 easy tests to verify if the discoloration is precipitate. First, is it Red or Red/Orange in color? If not, it is almost surely precipitate. The second test is to try to remove the discoloration. If it comes off easily (try using a pencil eraser) it is precipitate and not corrosion. Even iron oxide left as a precipitate will come off in this fashion. If it's rusty in color and you can not rub it off...send it in for repair. Remember, stainless steel is not rust-proof; it just resists rusting better than non-stainless steel.

2. Provide a tactile inspection

- The tactile inspection is looking for nicks, dings or gouges that result in an edge or a point that is sharp enough to snag and cut a surgical glove.

NOTE: If in doubt, rub a glove over the defect in question. If it snags, send it in for repair!

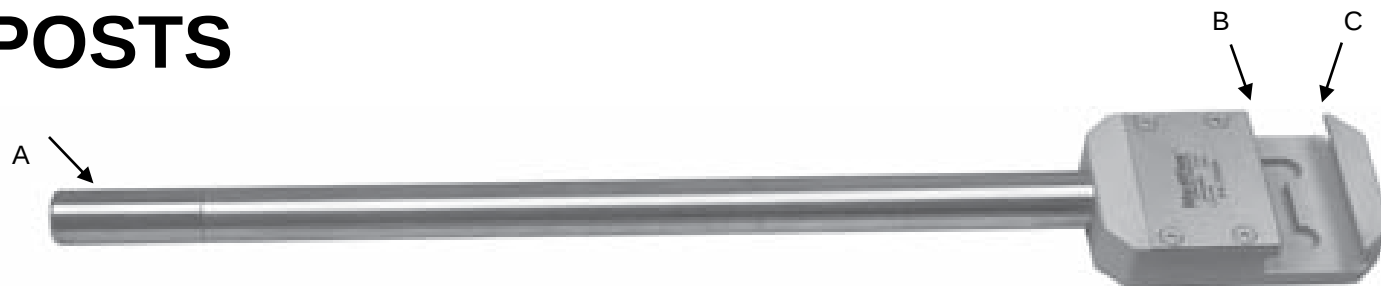
3. Look for any missing components

- Every Field Post, Coupler, Horizontal Bar and Ratchet is made up of parts that could, conceivably, come off. Missing parts will affect the functionality of every item. Use the photos in the accompanying guide to this presentation to compare to the items being inspected. Account for every part!

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INSPECTION STEPS

FIELD POSTS



1. Do the *Visual/Tactile* inspection previously described
2. Account for parts as described
3. Pull out the recessed turning handle (A)
 - a. Check to see that it slides in and out of its recess smoothly
 - b. Angle it down to 90° and do the visual and tactile inspection of the entire handle being sure to slide it back and forth
 - c. Check that the small plunge ball is in place and the screw holding it in is tight
4. Open and close the handle all the way both clockwise and counterclockwise
 - a. Make sure it doesn't bind or lock up before the upper jaw (B) is fully extended (approximately one inch) or fully retracted (it should be completely within the housing)
5. Examine the upper (B) and lower (C) jaws of the clamp, especially the leading edges. Look for any sharp defects or bent portions
6. If there is access to an OR table, attach the device to the table rail and tighten it in place. When tight, make sure it extends up at a 90° angle and does not move if you grab it and try to "wiggle" it around.

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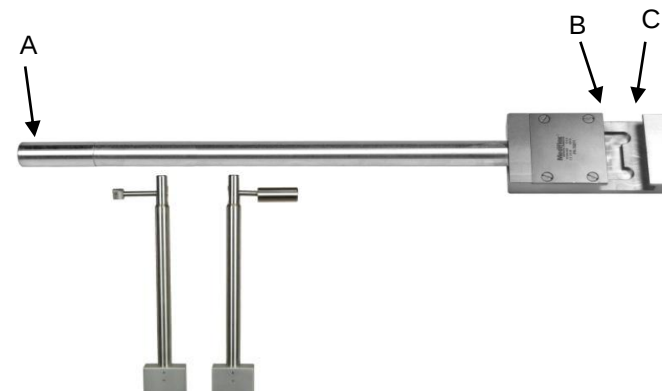
PRODUCT EVOLUTION

FIELD POST EVOLUTION

Generation 1: The post shown on right is typical of both the Mediflex and the Codman design that was offered for about 25 years. The majority of sets in hospitals will have this post.

Generation 2: In 2010, Mediflex added a Cap to the upper portion of the Post. This was to extend the 1" diameter all the way to the top and give surgeons 2 extra inches of height to be used if patient size required. There is really no change in how they should be decontaminated, inspected and sterilized. Points A, B and C remain the same. The photo to the right shows the 2 generations with the turning handle exposed.

Generation 3: In 2012, Mediflex reduced the weight of the posts about 30%. Some of this was accomplished with a redesign that is completely internal and invisible to the user. But, it is easy to identify this generation by the shape of the rail clamp. Material that was not needed for strength was removed giving the device a distinctly different shape. In all other aspects, the post is used and maintained the same way as the previous 2 generations

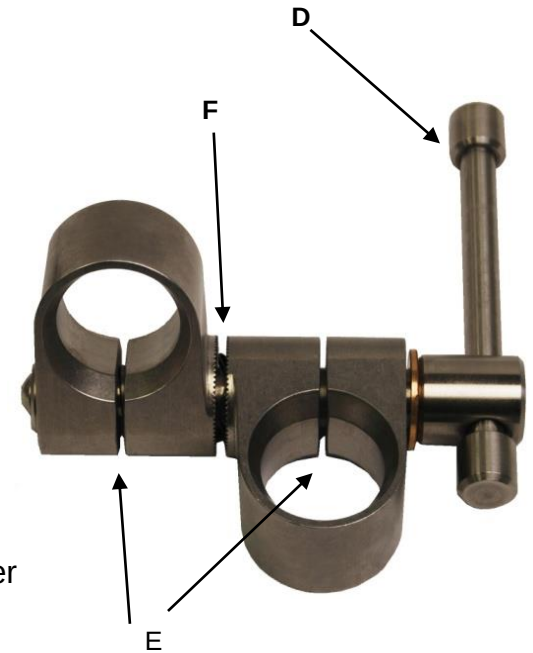


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INSPECTION PROCESS

COUPLERS

1. Do the *Visual/Tactile* inspection previously described
2. Account for parts as previously described
3. Make sure the slide bar (D) moves freely back and forth
4. Turn the Tightening Knob with the slide bar counter-clockwise to open the coupler completely
 - a. Determine that it opens enough for there to be about $\frac{1}{4}$ " between the two collar segments (E)
 - b. While it's open, examine the ridged teeth (starburst joint) (F)
 - c. Make sure there are no worn, bent or missing teeth
 - d. Using your hands, rotate one side against the other making sure that in every position the two halves mesh evenly
5. Now close the turning knob as far as possible
 - a. Verify that the split in both collars can be closed until they touch
 - b. Now open all the way and verify that the collars have rebounded
6. While it's still open, check to see that both sides fit onto and slide up and down a 1" diameter bar (the field post or horizontal bar)



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PRODUCT EVOLUTION

COUPLER EVOLUTION

Generation 1: The coupler shown is typical of both the Mediflex and the Codman design that was offered for about 25 years. The majority of sets in Hospitals will have this type of coupler. One major difference is that the Codman product comes apart into 3 separate pieces. The Mediflex Device was designed to open for adequate cleaning and sterilization, but to stay as one unit

Generation 2: This new, stainless steel Coupler was introduced in 2012 by Mediflex. While functionally identical to Generation 1, a few design changes were made:

- a. There is a more pronounced bevel on the inside of the two 1" rings. This allows it to be placed over the newer Field Posts more easily.
- b. The Slide Bar Tightening Rod was enlarged and fitted with more easily gripped ends.
- c. A brass washer was placed between the slide rod and the first ring to make the tightening process smoother.
- d. The teeth between the two halves were made slightly finer so that their number could be increased. This allows the surgeon the ability to lock the device in a greater number of positions.
- e. Finally, a circular leaf spring was placed between the 2 rings. This keeps the 2 halves open during cleaning and sterilization, even if the device is placed on its end. This allowed gravity to pull the two halves together and may have kept debris trapped between the parts.

However, all of the processing and inspection steps remain the same as with the original stainless steel coupler.

Generation 1



Generation 2



Mediflex®

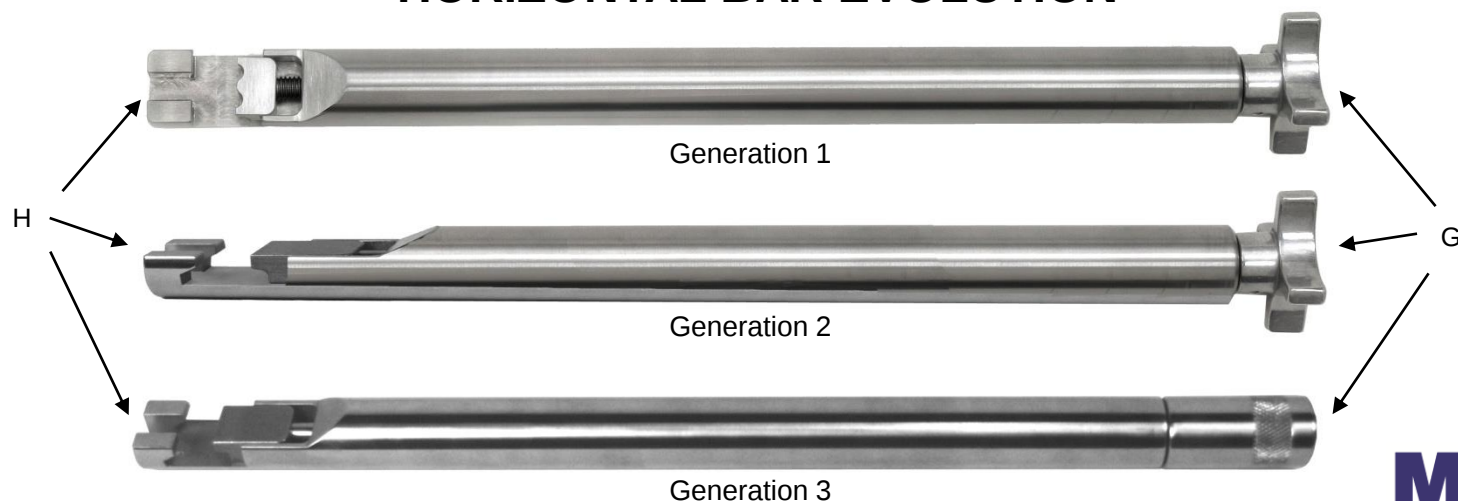
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INSPECTION PROCESS/ PRODUCT EVOLUTION

HORIZONTAL BAR

1. Perform the Visual/Tactile inspection previously described
2. Account for parts as previously described
3. Open and close the Tightening Knob (G)
 - a. Make sure it feels smooth in both directions and doesn't bind or lock up before the proximal jaw (H) is fully extended or fully retracted
 - b. Place a ring segment in the jaws and tighten down on it
 - c. When tight, check to see that the ring is securely captured and does not slide or wiggle (Note: be sure the proximal jaw lines up with the wave pattern on the ring. If not matched correctly, the ring will feel loose.)

HORIZONTAL BAR EVOLUTION

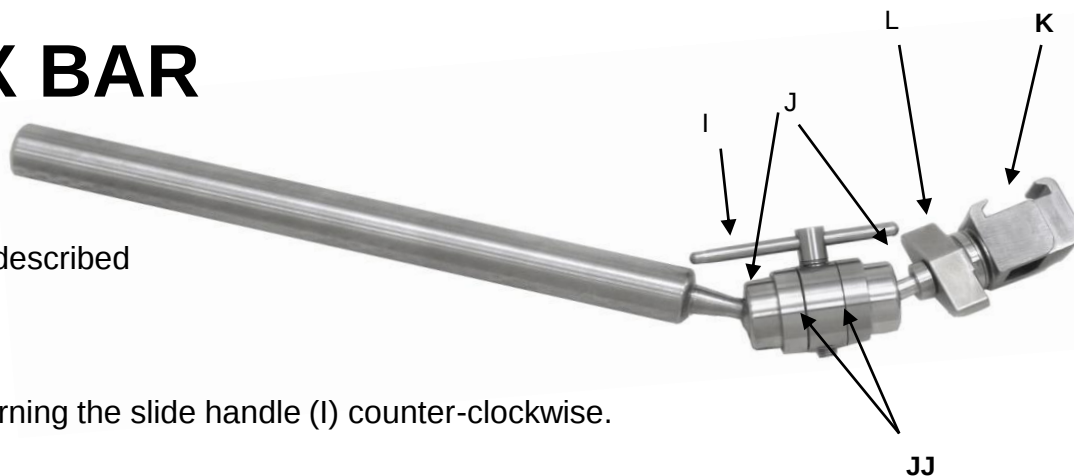


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INSPECTION PROCESS

HORIZONTAL FLEX BAR

1. Do the *Visual/Tactile* inspection previously described
2. Account for parts as described
3. Loosen the double ball joint assembly by turning the slide handle (I) counter-clockwise.
4. Check both ball joints (J) for full range of motions
 - a. Note the 2 joints labeled JJ. If there is a visible gap at either of these joints, it's an indication that an internal adhesive has begun to fail. The device needs to be repaired.
 - b. Also check the jaw assembly (K.) It should rotate freely on its axis
 - c. While you're at the jaw assembly, double check the jaw edges for any gouges, cracks or deformation
5. Tighten the double ball joints as tightly as you can by hand
 - a. As you tighten, be sure there is no binding or feeling of roughness
 - b. When tight, check to ascertain that the components have locked-up
6. Tighten and then loosen the jaw tightening knob (L)
 - a. Observe that the jaw closes and opens completely (The gap is just under 1" in the open position and less than ¼" in the closed position)
 - b. Check to be sure that there is no binding or rough feeling as you open and close
 - c. Make sure the jaws stay in parallel as they close
7. Place a ring segment in the jaw and close tightly
 - a. Check to be certain that the ring segment is held securely



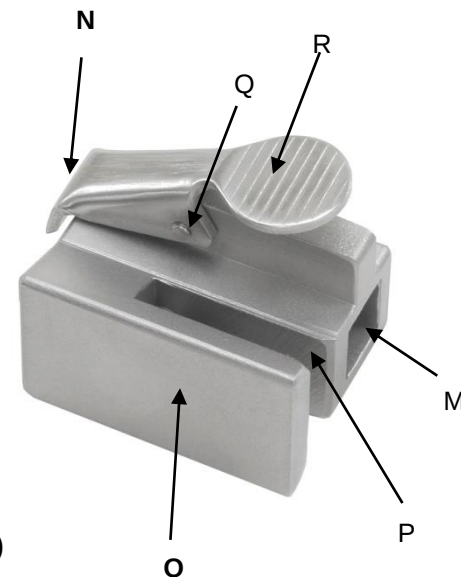
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INSPECTION PROCESS

RATCHETS

1. Do the *Visual/Tactile* inspection previously described
 - a. Be sure to look through the blade rack channel (M) for any chips or burrs on the inside
 - b. Carefully check the single tooth at the end of the ratchet lever (N) for wear or burrs
 - c. Check that the Base (O) has not been bent outward from the Ring Slot (P)
 - d. The ring slot should be the same width, on both sides for its entire length
2. Account for parts as described
3. Observe the pivot screw (Q) on the ratchet lever
 - a. It should not appear loose
 - b. The slot should not be damaged (a sign that someone tried to disassemble the ratchet)
4. Observe the small spring (not visible in this photo) under the Thumb Tab (R) of the ratchet lever
 - a. Check for corrosion or apparent damage
 - b. Watch for deformation as you press down on and release the thumb tab
 - c. Feel for smooth compression and steady rebound of the spring
5. Load a blade into the blade rack channel
 - a. Advance it one or two clicks then try to pull it out
 - b. Advance it about half way and try to pull it out
 - c. Advance it all the way in and try to pull it out (Note: occasionally the blade will advance to a point where the ratchet is between the last 2 teeth. While this feels loose, it is normal and would only occur just before the last exposed tooth)
6. Press the thumb tab and remove the blade
 - a. It should come out smoothly with no binding

Note: Any test done to a ratchet using a blade that results in a failure may be the fault of the blade, not the ratchet. For example, if the toothed rack of a blade is bent, the ratchet may fail step 4 or 5 above. But it is the fault of the blade, not the ratchet. Test several blades if there is a question.



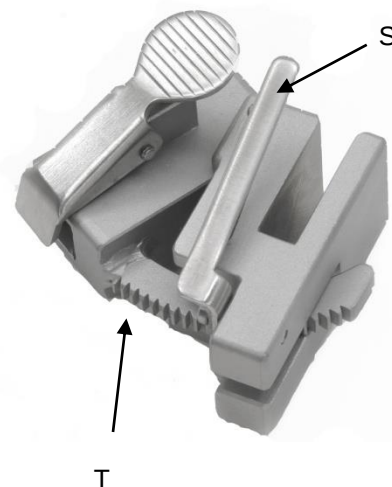
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INSPECTION PROCESS

TILT RATCHETS

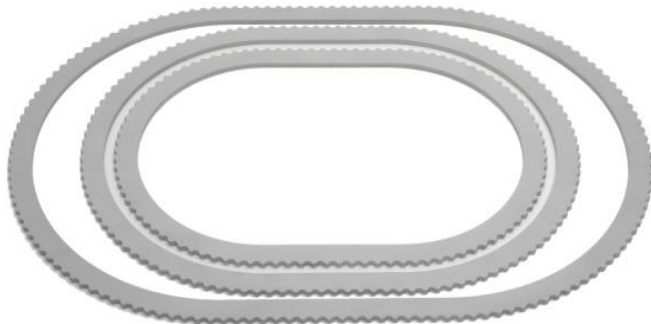
Steps 1 through 6 are identical to the ratchet instructions previous described

7. Press the Tilt Ratchet Release Lever (S) and open the tilt housing **past** the last ratchet.
 - a. This will expose:
 - i. the toothed rack (T),
 - ii. the tilt release lever ratchet (not visible in this picture)
 - iii. the pivot screw (not visible in this picture) for the tilt release lever
 - b. It will also allow a visual examination of the space between the 2 halves of the device
8. Check the toothed rack for:
 - a. worn or missing teeth
 - b. bends in the length of the rack or total misalignment
9. Check the tilt ratchet release lever for
 - a. smooth in and out movement
 - b. excessive wear on the ratchet portion where the teeth make contact
10. Press the tilt ratchet release lever and return the device to its untilted position
11. Insert a blade about 1/2 way and place the ratchet on a ring segment
 - a. Press down on the blade to cause the ratchet to tilt inward
 - b. Check that it holds position at each tooth

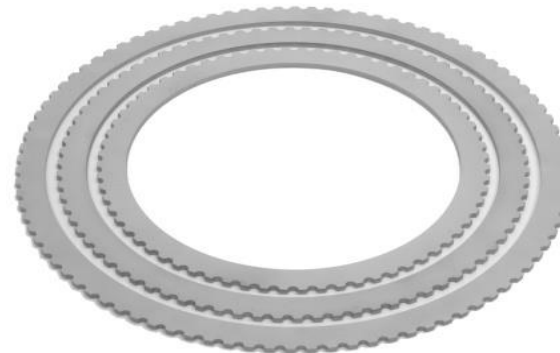


SOLID RINGS

1. Do the *Visual/Tactile* inspection previously described
2. Now hold the ring at eye level with it parallel to the ground
 - Check to ascertain that there is no distortion or warpage



Oval Solid Rings



Round Solid Rings

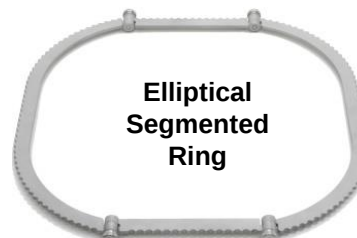
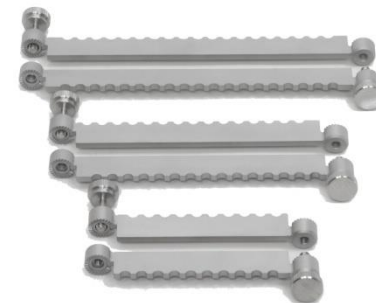
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INSPECTION PROCESS

SEGMENTED RINGS

1. Do the *Visual/Tactile* inspection previously described
2. Disassemble the ring
 - a. Check each segment for distortion or warpage
3. Check the Starburst (U) found on both ends of every segment
 - a. Inspect for worn or missing teeth
4. Ascertain that each segment has its attached screw (V) Note: The screws are designed to stay on the ring segment during cleaning and sterilization. However, some hospitals have discovered they can be removed and therefore do remove them for sterilization. In these cases, make sure that there are the appropriate number of screws present and test that each one will thread into a starburst joint. Then proceed with step 5.
5. Test that each segment will attach to all other segments
 - a. Observe that the screw threads smoothly into the internal threads
 - b. Observe that the teeth of the star burst align cleanly through 360°

Straight Ring Segments

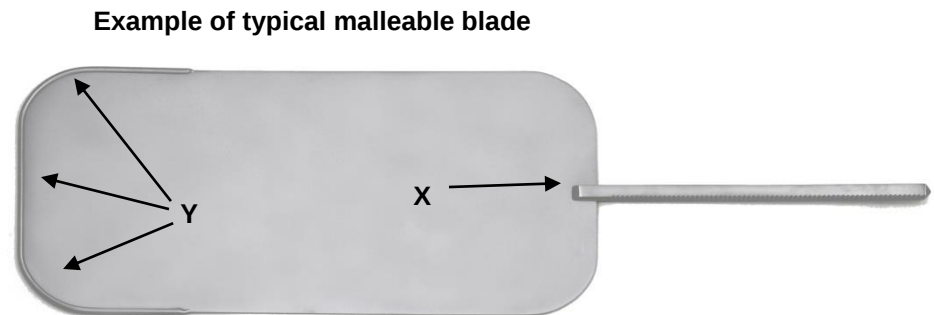
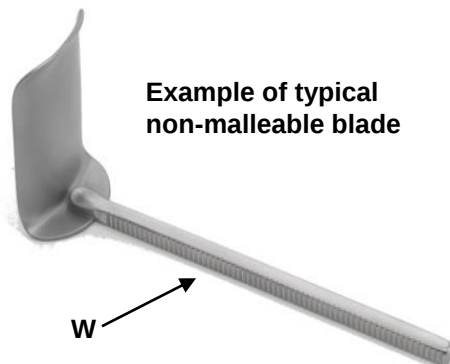


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INSPECTION PROCESS

RETRACTOR BLADES

1. Do the *Visual/Tactile* inspection previously described
 - a. Pay particular attention to all of the blade edges
 - b. Look for any burrs or dings that result in a sharp point
2. Inspect the Toothed Rack (W) portion
 - a. Check that the entire rack is perfectly straight by holding it up against a flat surface (table top, metal ruler, etc)
 - b. Check teeth for worn, broken or missing teeth
3. In all non-malleable blades, check the blade surface for signs of bending or cracks
4. In all malleable blades
 - a. Check for cracks near where the toothed rack is joined to the flat of the blade (X)
 - b. Check for signs of pitting or corrosion where the protective edge is joined to the flat of the blade (Y)



Certificate of Attendance

This is to Certify that

completed the Mediflex® SPD program:
Recommendations for Inspection of Bookler®
(and Ratchet-Style) Table Mounted Retractor Systems During
Decontamination and Cleaning

Contact Hours: 1
Certification Board for Sterile Processing and Distribution (CBSPD)
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