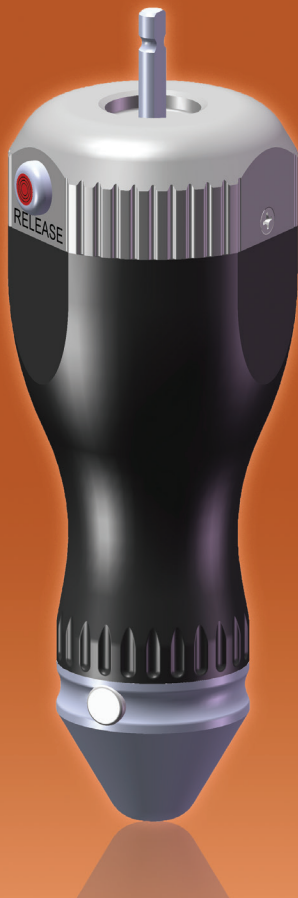




Pega Medical

FASSIER — DUVAL
TELESCOPIC
IM SYSTEM'S
**RESCUE
INSTRUMENTS 2.0**



The Rescue Instruments were conceived to retrieve components of the Fassier-Duval telescopic IM System after the treatment has been completed or in case of revision surgery.

SURGICAL TECHNIQUE

*FASSIER – DUVAL
TELESCOPIC IM SYSTEM'S
RESCUE INSTRUMENTS 2.0*

Surgical Technique



The Rescue Instruments were conceived to retrieve components of the Fassier-Duval telescopic IM system after the treatment has been completed or in case of revision surgery.

THIS METHOD IS NOT APPROPRIATE TO RETRIEVE OR REVISE AN IMPLANT IF PRIOR PERMANENT DEFORMATION OF THE NAIL HAS OCCURED.

REFER TO STEP 1 OF THE MALE RETRIEVER TECHNIQUE FOR FURTHER INFORMATION.

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STERILIZATION AND MAINTENANCE OF THE RESCUE INSTRUMENTS

The Male Retriever should be sterilized with all components disassembled as shown in the picture bellow. Sterilization should be performed by following the information included in the Guidance for Instrument Care and Instructions for Use pamphlets.

This instrument should be cleaned MANUALLY before it is cleaned with ultrasound. Completely dry the instrument once cleaned with the use of compressed air or drying oven.



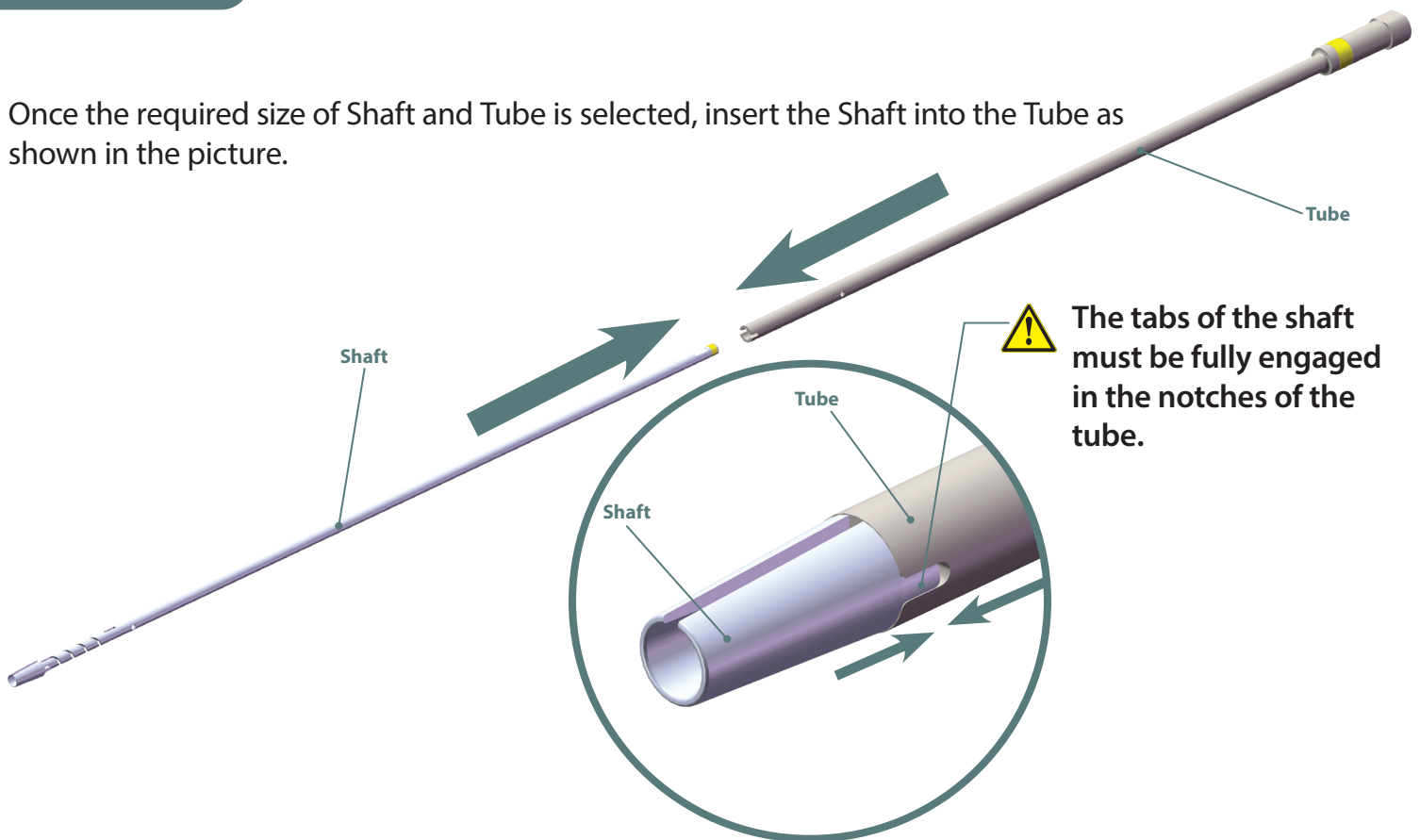
ASSEMBLY OF THE MALE RETRIEVER

Assembly of the Male Retriever components should be done after sterilization. The size of the Shaft and Tube correspond to the size of the implant to be retrieved. The size of each component of the Male Retriever is marked on each component and is identified by a color code as shown in the table below. Select the required size for use before starting the assembly process.

CATALOG #	IMPLANT SIZE	COLOR CODE
MR232	3.2 mm	Yellow
MR240	4.0 mm	Red
MR248	4.8 mm	Blue
MR256	5.6 mm	Black
MR264	6.4 mm	Rust

STEP 1

Once the required size of Shaft and Tube is selected, insert the Shaft into the Tube as shown in the picture.

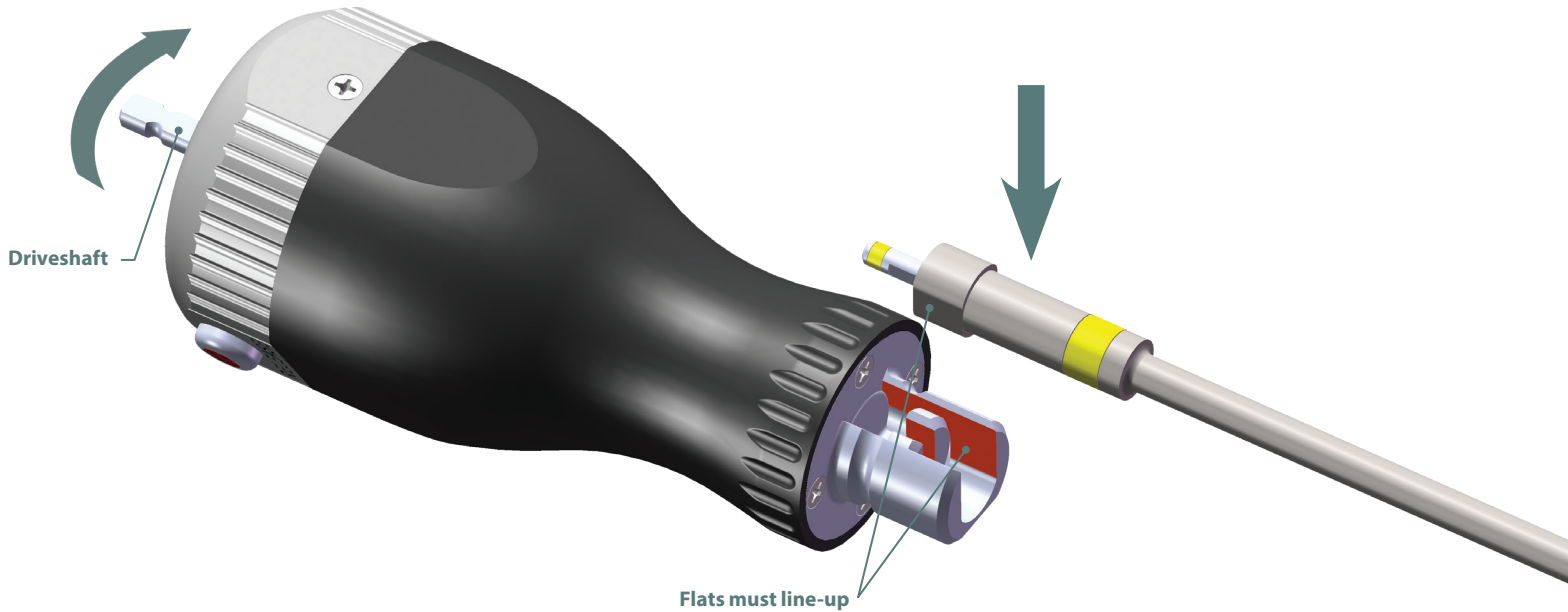


ASSEMBLY OF THE MALE RETRIEVER

STEP 2

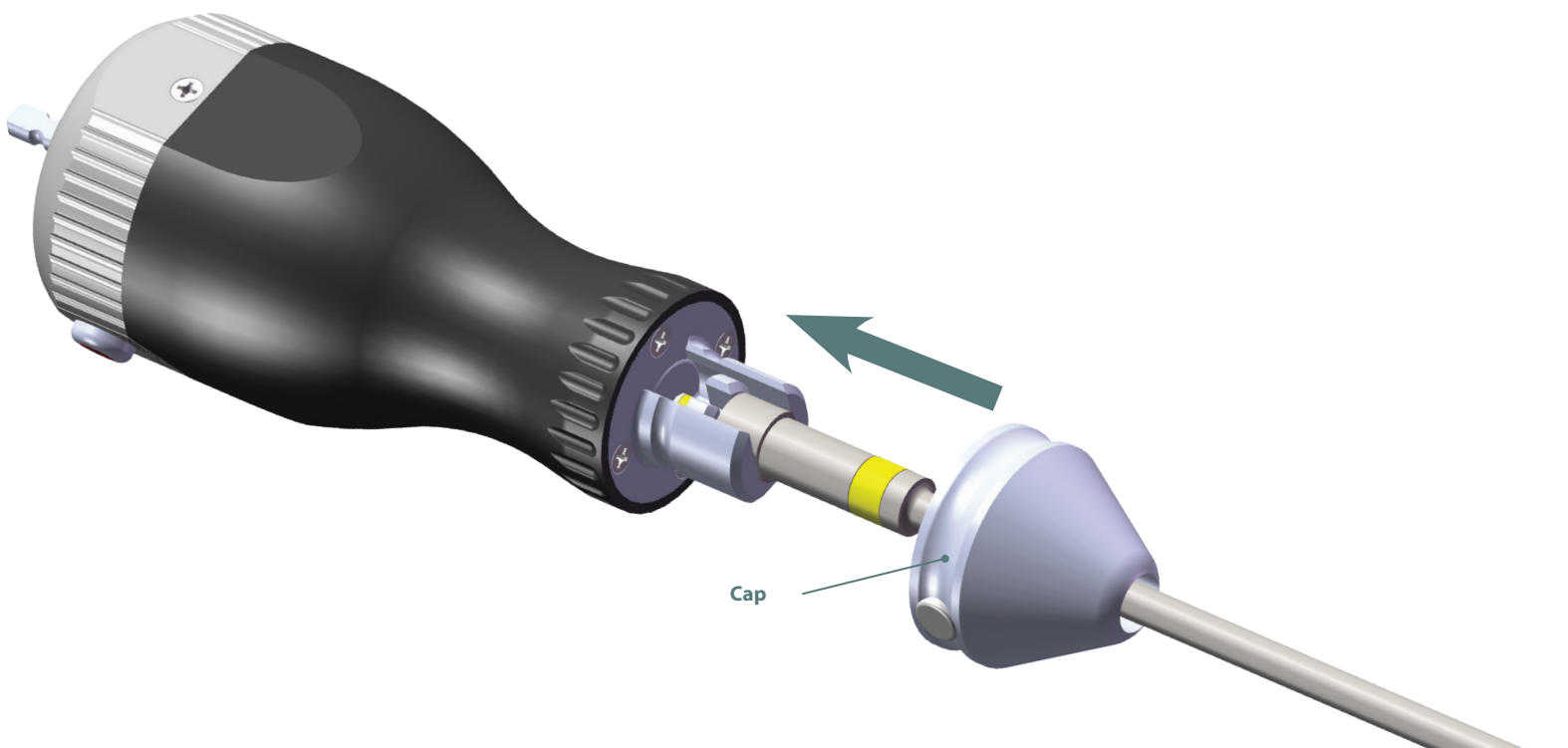
Verify that the flats on the Driveshaft are aligned with the flats on the Handle. If not, use the Torque Handle to turn the Driveshaft in a **counter-clockwise** direction until the flats line-up.

Insert the Shaft and Tube assembly into the Handle by lining up the flat surfaces.



STEP 3

Slide the Cap along the tube lining-up the flat surfaces. The Cap will «click» into position.



FEMALE RETRIEVAL TECHNIQUE

STEP 1

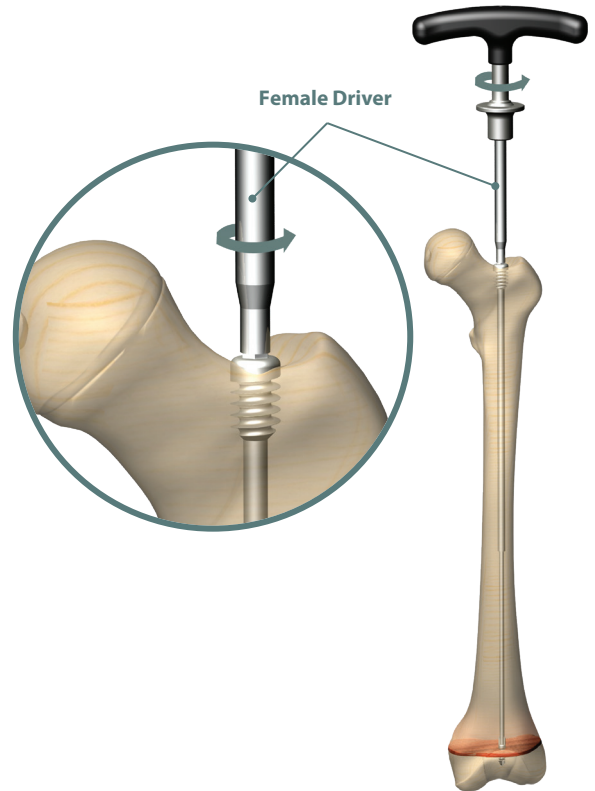
Use the Female Driver to unscrew the female component.

⚠ The Female Driver must be fully entered into the hexagonal drive of the implant. The instrument may break if rotated when partially entered or miss-aligned.

If the female component cannot be removed with the Female Driver use the Female Retriever to pull it out (see step 2).

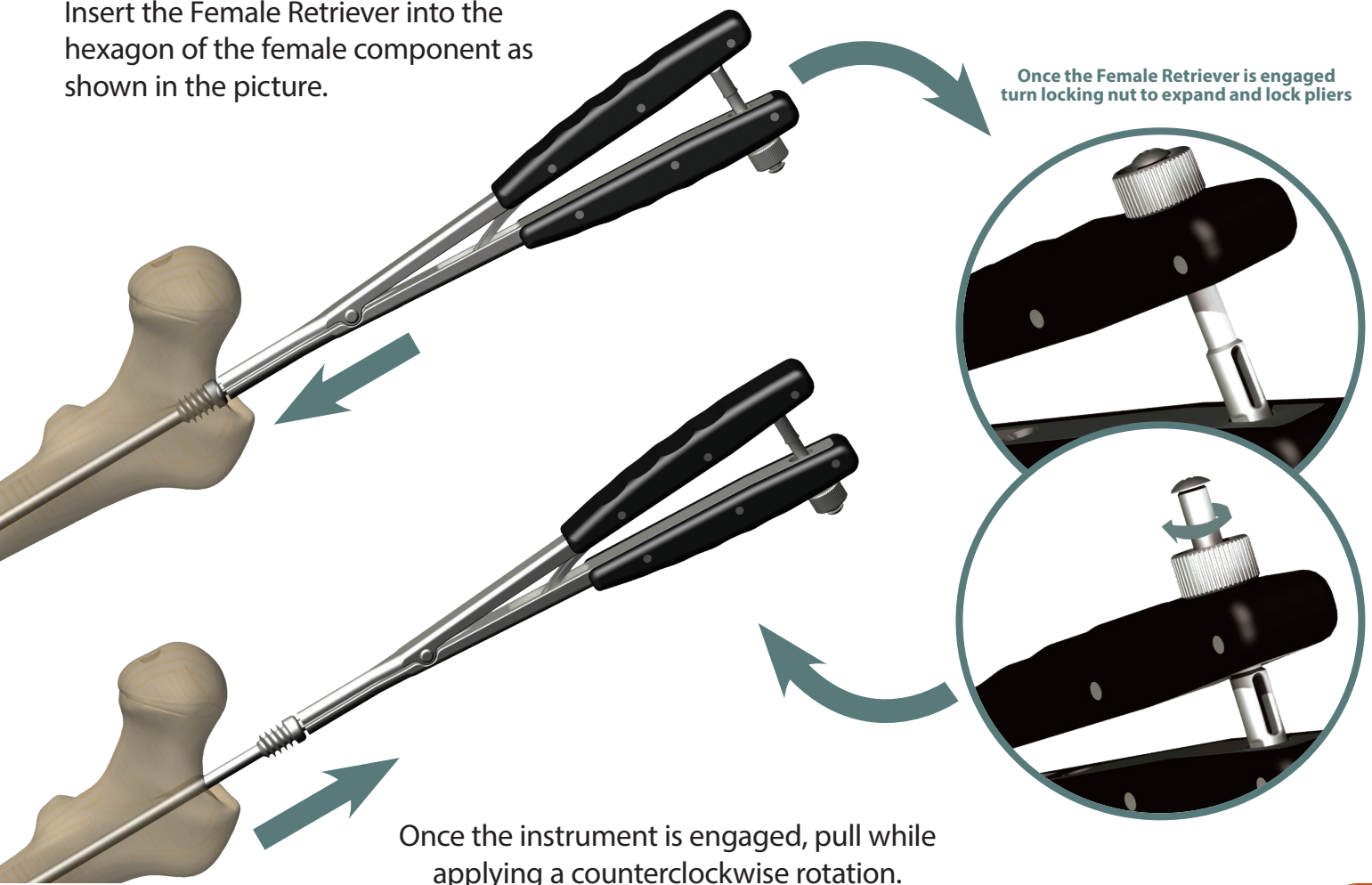
⚠ If bone has grown on top of the female head, reaming with a drill or trephine will be necessary to expose the female component.

IMPLANT SIZE	DRILL/TREPINE
3.2 mm	Ø 7.0 mm
4.0 mm	Ø 8.5 mm
4.8 mm	Ø 10.0 mm
5.6 mm	Ø 10.75 mm
6.4 mm	Ø 11.5 mm



STEP 2

Insert the Female Retriever into the hexagon of the female component as shown in the picture.



MALE RETRIEVAL TECHNIQUE

STEP 1



If the implant has been bent due to a recurrence of deformity or refracture, the nail will have to be removed through an osteotomy at the apex of the bend after cutting the male component in 2 segments: proximal and distal to the bend.

Both the Male Driver and Male Retriever can be used for removal of the male component. Insert the Male Driver through the intramedullary canal until it is fully engaged over the wings of the male component. It is important to note that, due to patient growth, the Male Driver may be too short to reach the implant's wings.



Partial engagement of the Male Driver onto the male component wings may lead to breakage of the instrument due to increased stress on the instrument.

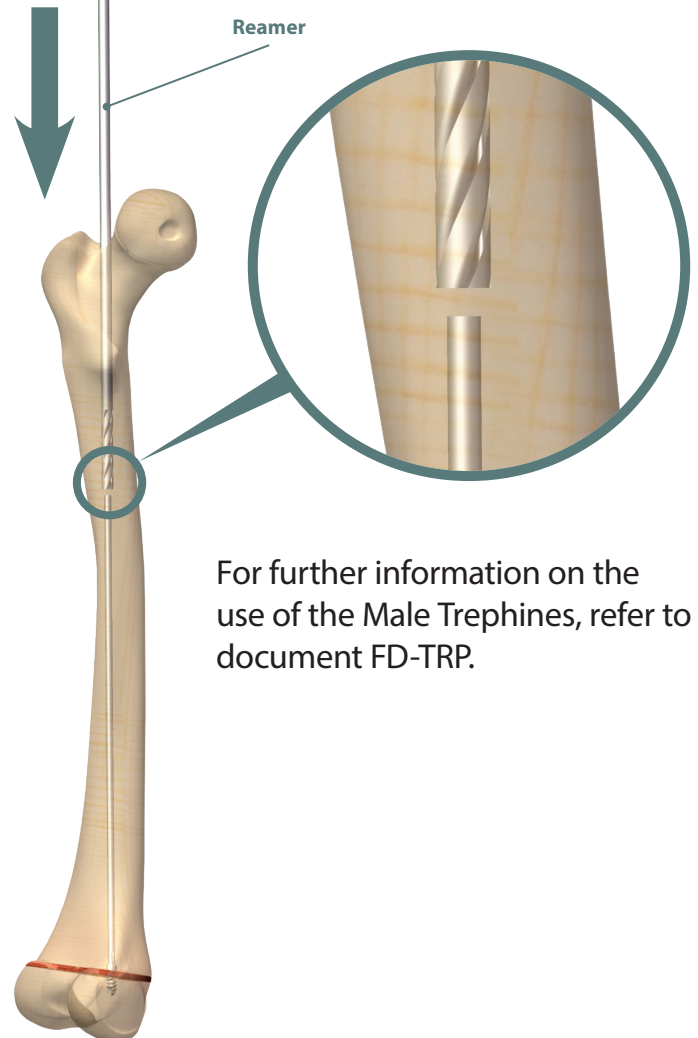
If proper engagement of the Male Driver cannot be achieved, it is recommended to use the Male Retriever. (See Step 2)



STEP 2

The Male Retriever has a larger outer diameter than the female component. Reaming to the tip of the male nail is necessary. The table below shows the drill size required for each size of implant to be removed. If the medullary canal is occluded or insertion of the instruments is difficult, use of the Male Trephines to clear a path is advised.

MALE RETRIEVER #	IF CLEARANCE REQUIRED
MR232	DR148 / TRP132
MR240	DR148 / TRP140
MR248	DR156 / TRP148
MR256	DR164 / TRP156
MR264	DR164 / TRP164



For further information on the use of the Male Trephines, refer to document FD-TRP.

MALE RETRIEVAL TECHNIQUE

STEP 3

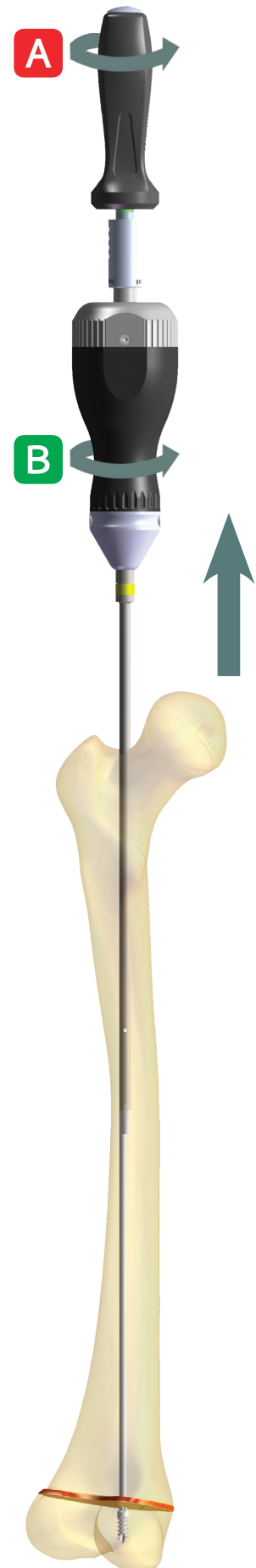
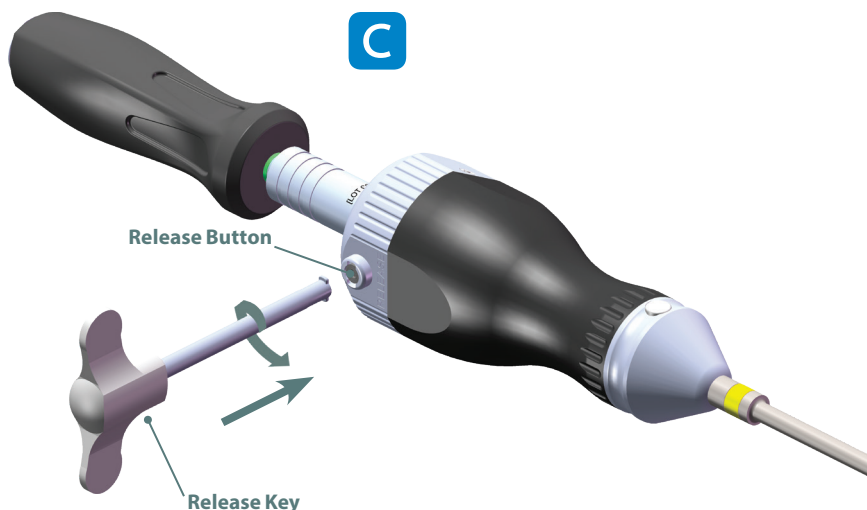
Under fluoroscopy, locate the end of the male component and mount the tip of the Male Retriever over it. **Make sure that the end of the male component is securely inserted into the Male Retriever Shaft before tightening with the Torque Handle.**

The hole in the tube should not be visible.



⚠ Tightening of the Male Retriever handle without the male component inside will result in damage to the shaft and render it unusable. A new Shaft will be necessary since they are single use instruments.

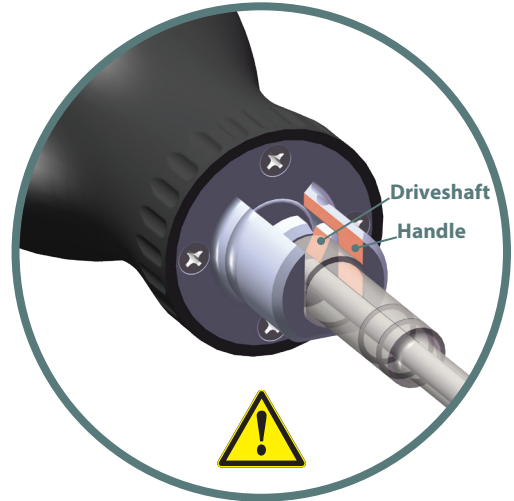
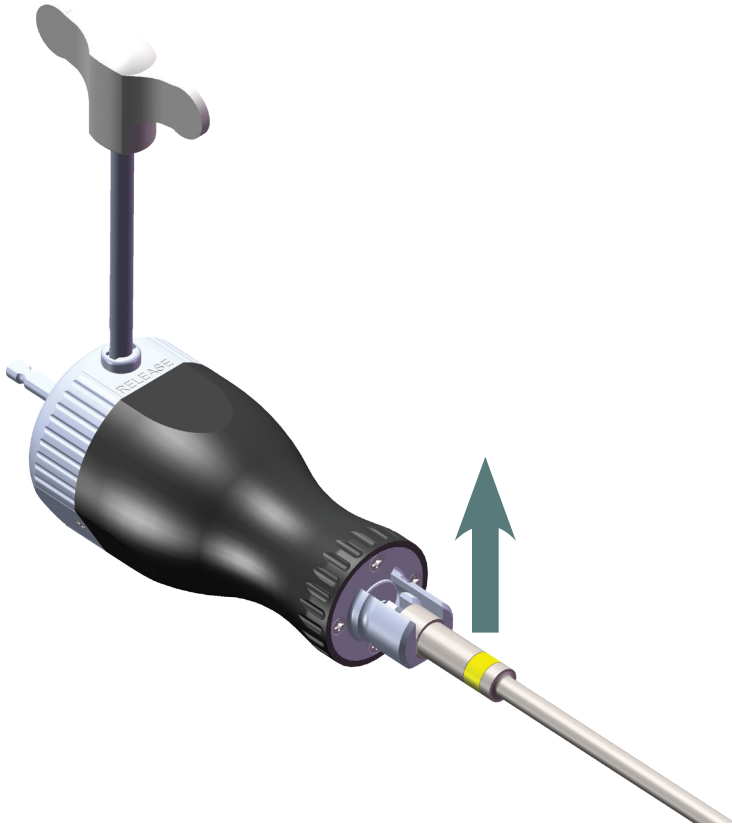
- A** Lock the Shaft over the male component by turning the Torque Handle **counterclockwise** until the torque limit is reached. Remove the Torque Handle after tightening.
- B** Once the male component is secured, turn the Male Retriever Handle in a counterclockwise direction. Simultaneous rotation and pulling might be necessary while the male component is unscrewed.
- C** To remove the retrieved implant from the Male Retriever, press the Release Button all the way down using the Release Key.



MALE RETRIEVAL TECHNIQUE

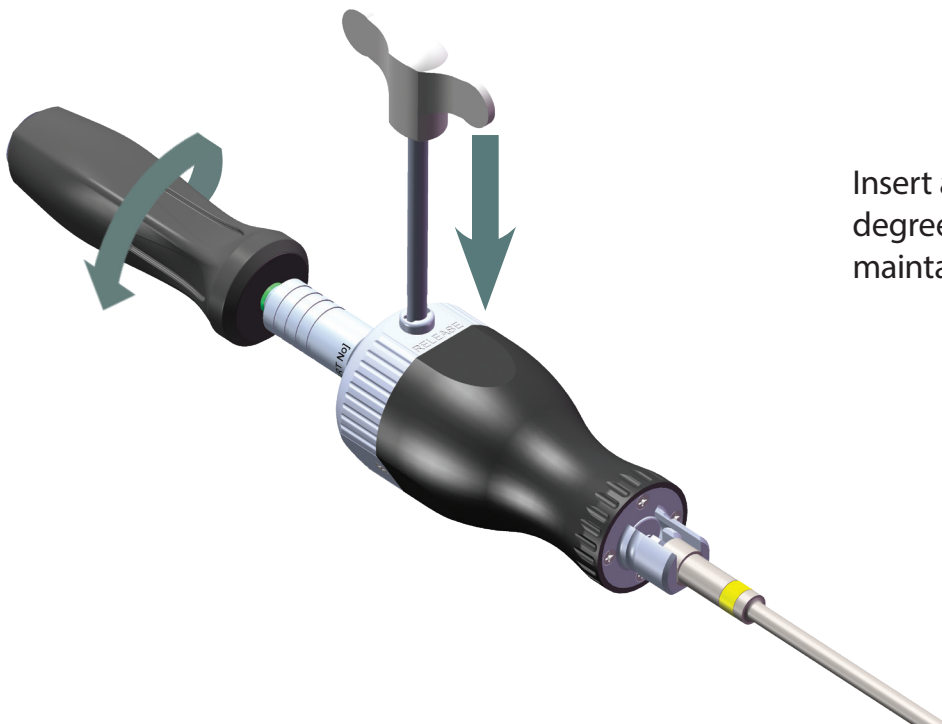
STEP 4

Disassembly of the Shaft and Tube from the Handle is done by pulling the components upwards after the Cap has been removed.



If the driveshaft flats are not parallel to the flat on the handle, the disassembly will not be possible.

To align the flats, maintain the Release Button depressed with the Release Key, then rotate the Driveshaft clockwise until the flats line-up. The Shaft and Tube assembly can then be pulled upwards.



Insert and Rotate the Release Key by 90 degrees inside the Release Button to maintain it depressed.



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