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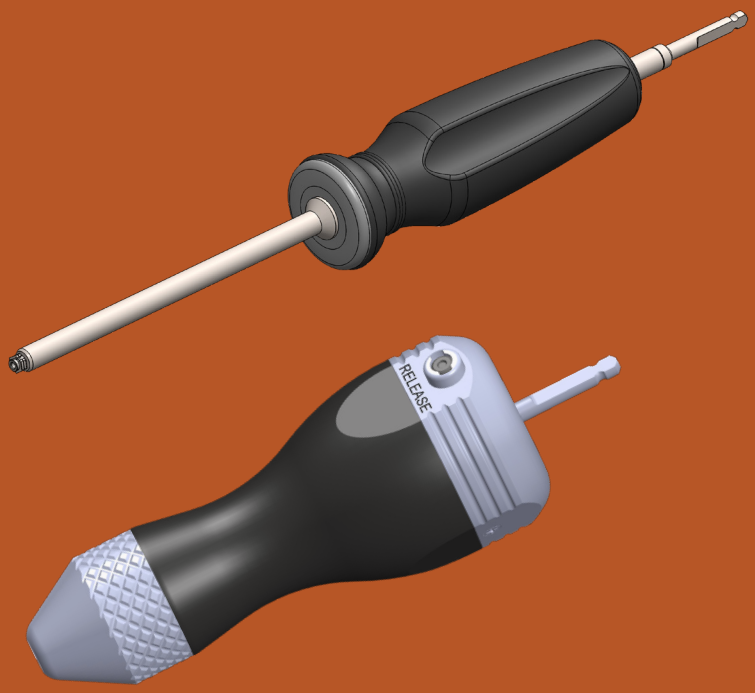
FASSIER — DUVAL TELESCOPIC IM SYSTEM

RESCUE INSTRUMENTS 3.0



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

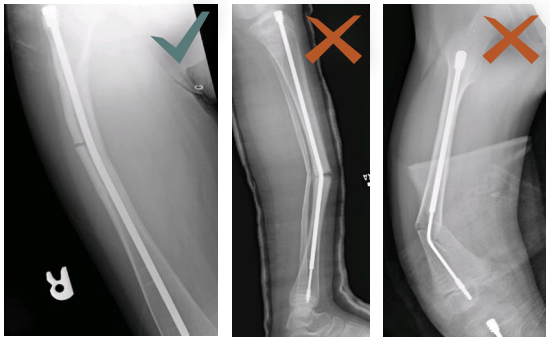
SURGICAL TECHNIQUE

FASSIER – DUVAL TELESCOPIC IM SYSTEM'S RESCUE INSTRUMENTS 3.0

Surgical Technique

The Rescue Instruments were designed 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 approriate to retrieve or revise an implant if permanent deformation (bending) has occured.**



⚠ **If the implant has been bent due to recurrence of deformity or refracture, the nail will have to be removed through and osteotomy at the apex of the bend after cutting implant into two segments: proximal and distal to the bend.**

If the implant is interlocked with Pega PEGS, first start by removing them.

If bone has grown over the Female Component, ream with the recommended Female Trephine (see table) to expose the head.

The Table below shows maximum size required. Progressive reaming starting with a smaller drill or Trephine is recommended to minimize bone removal and maximize purchase of replacement implant.

IMPLANT SIZE	FEMALE TREPHINE/ DRILL Ø	FEMALE TREPHINE CATALOG #	COLOR
3.2 MM	7 MM	FTRP107	YELLOW
4.0 MM	8 MM	FTRP108	RED
4.8 MM	9 MM	FTRP109	BLUE
5.6 MM	10 MM	FTRP110	BLACK
6.4 MM	11 MM	FTRP111	RUST / BROWN

Advance a 1.6mm Guide Wire [G-WIRE 016] until it engages the cannulation of the Female Component to provide alignment.

A 2.0mm Guide Wire (not provided) can also be used for the Trephine Step. Please note that the Female Retriever can only fit over a 1.6mm Wire.

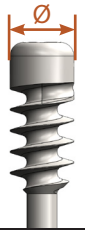
Slide the Female Trephine over the Guide Wire.

Use the Female Trephine (manually or on power) to remove bone up to the head of Female Component.

Alternatively, drills of the recommended size can be used but are not included with the system.

If advancement becomes difficult or overheating of the instrument is observed, back-out the Female Trephine and clean the teeth and core.

The use of a Female Trephine can affect the purchase of the subsequent nail. Verify head specifications in the table below. The use of Pega PEGS for interlocking subsequent nails is advisable.

IMPLANT SIZE	FEMUR		TIBIA/HUMERUS	
3.2 MM		Ø7		Ø7
4.0 MM		Ø8.5		Ø8
4.8 MM		Ø10		Ø9
5.6 MM		Ø10.75		Ø9.75
6.4 MM		Ø11.5		Ø10.5

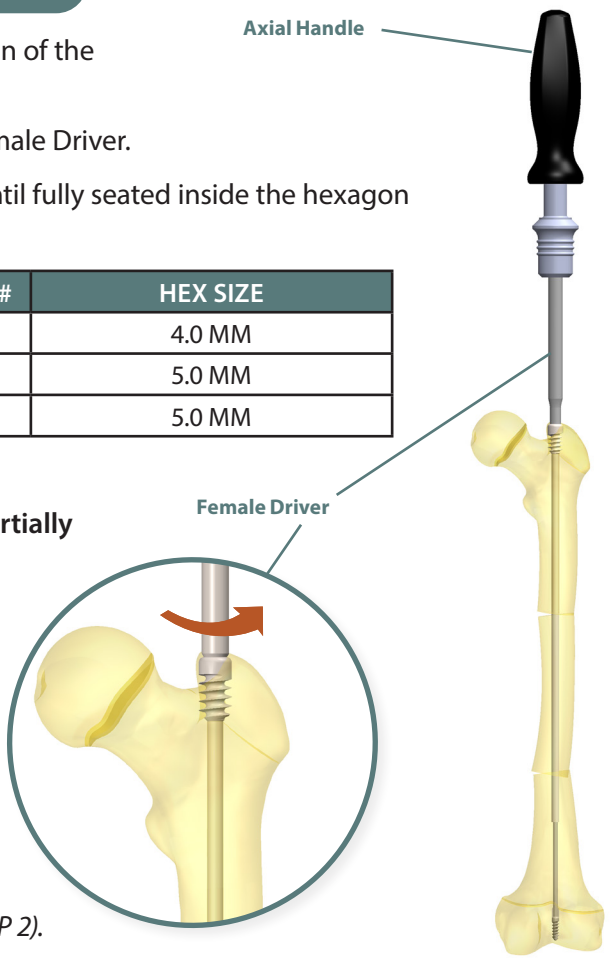
STEP 1 - UNSCREWING WITH FEMALE DRIVER

Place a 1.6mm Guide Wire [G-WIRE 016] into the canulation of the Female Component to provide ideal hexagon alignment.

Assemble the Axial Handle [FD-AXIALHANDLE] to the Female Driver.

Slide the Female Driver (see table) over the Guide Wire until fully seated inside the hexagon of the Female Component.

IMPLANT SIZE	FEMALE DRIVER CATALOG #	HEX SIZE
3.2 MM	FDR100	4.0 MM
4.0 - 4.8 MM	FDR102	5.0 MM
5.6 - 6.4 MM	FDR101	5.0 MM



The Female Driver must be fully seated flush inside the hexagon. The instrument may break if rotated when partially entered or miss-aligned.

To clear the hexagon of bone debris, a curette or small drill can be used taking care not to damage the Hex.

Unscrew the Female Component by rotating counterclockwise.

Use fingers or other gripping tools (not included) to pull out the Female Component once unscrewed.

If the Female Component cannot be unscrewed with the Female Driver, use the Female Retriever to pull it out (see STEP 2).

STEP 2 - REMOVAL WITH FEMALE RETRIEVER

There are two generations of the Female Retrievers. Follow the option that correspond to the Female Retriever you have. For the Gen2 (Series 100) go to option A. For the Gen3 (series 200), go to Option B.

Option A: Use of Gen2 Female Retriever

Insert the appropriate Female Retriever (see table) over the 1.6mm Guide Wire into the hexagon of the Female Component.

IMPLANT SIZE	FEMALE DRIVER CATALOG #
3.2 MM	FRT100
4.0 - 6.4 MM	FRT101

The Female Retriever must be fully seated inside the hexagon of the implant for optimal pull-out strength.

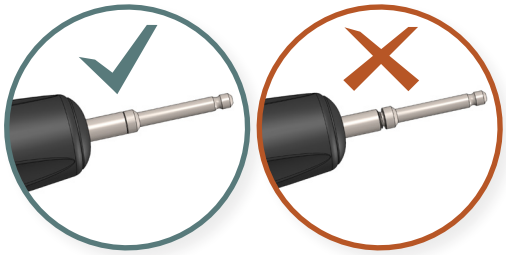
Once engaged, squeeze the handles, turn the locking nut to expand and lock the pliers.

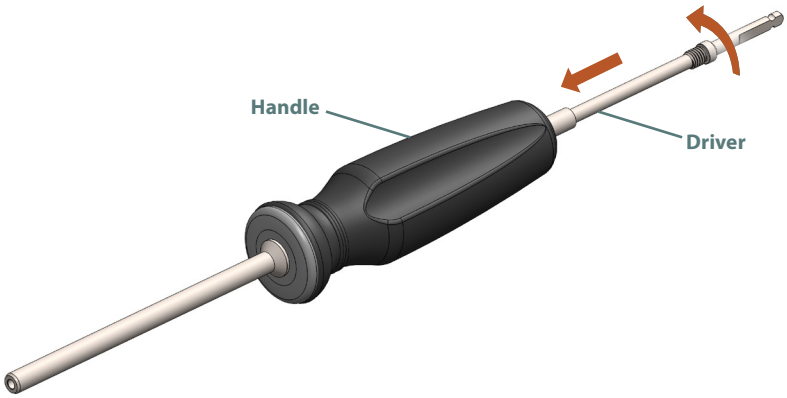
Unscrew the Female Component counterclockwise while applying a steady pulling force.

Option B: Use of Gen3 Female Retriever

ASSEMBLY OF THE FEMALE RETRIEVER

Insert the Female Retriever Driver [FRT220] into the back of the Female Retriever Handle [FRT210] and fully thread it with a clockwise rotation.



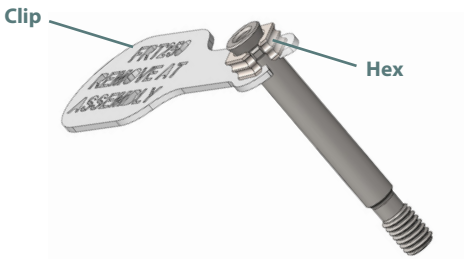


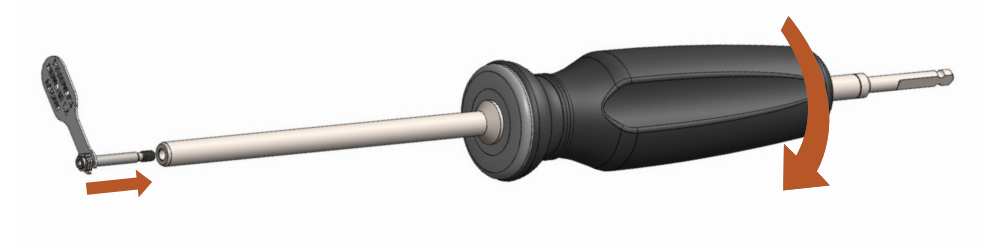
Insert the appropriate Cartridge (see table) into the front end of the Driver. Hold the Cartridge, thread the Handle counterclockwise until finger-tight, without pre-expending the Hex.

IMPLANT SIZE	CARTRIDGE
3.2 MM	FRT240
4.0, 4.8, 6.5, 6.4 MM	FRT250

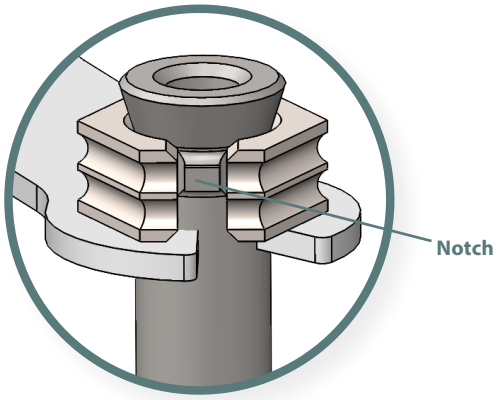
The Cartridge is threaded counterclockwise into the Female Retriever.

Stop threading when you feel presure. Do not overtighten as this poses a rick of pre-expanding the Hex.

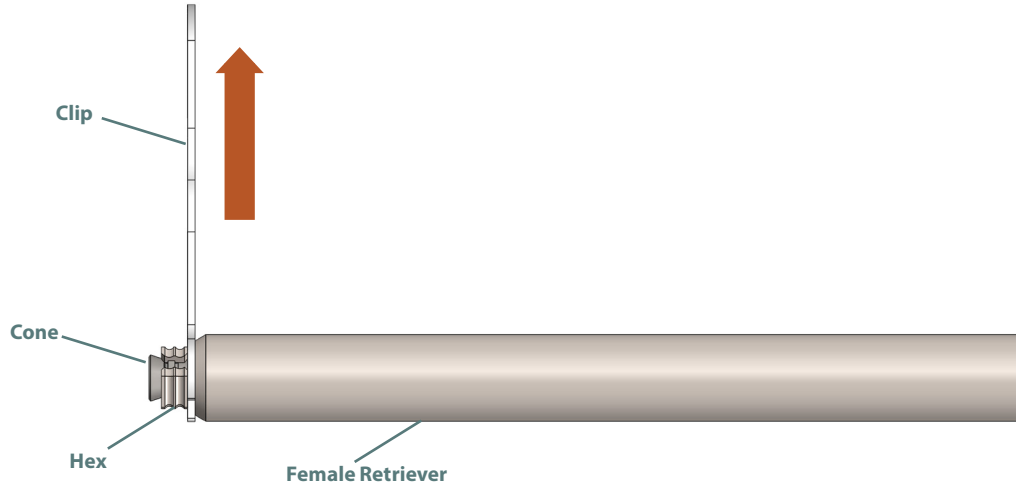




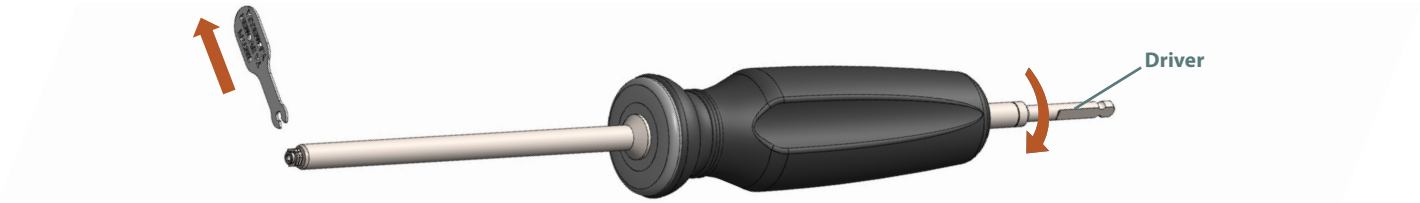
Ensure that the notch of the Cone Shaft is aligned properly with the Hex. If the Clip moves and the Hex falls of the notch, it is important to reassemble it properly before continuing with the next steps.



Remove the Clip perpendicular to the axis of the Female Retriever. DO NOT twist off the Clip. Avoid pushing the Hex onto the cone as it will expand.



To eliminate any gap between the Cartridge and the tip of the Driver, carefully rotate the end of the driver, with fingers only, while avoiding pre-expanding the Hex. Stop when resistance is felt.

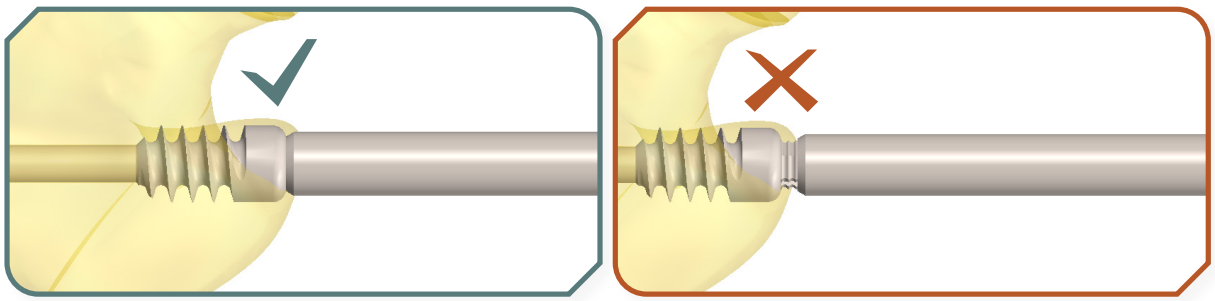


DO NOT assemble the Torque Handle until the Female Retriever is engaged into Female Component. The Cartridge is single use. Expansion prior to insertion will permanently deform the Hex and render the Cartridge unusable.

For further information on the assembly and disassembly of the Female Retriever Generation Gen3, refer to document FD-FRT200

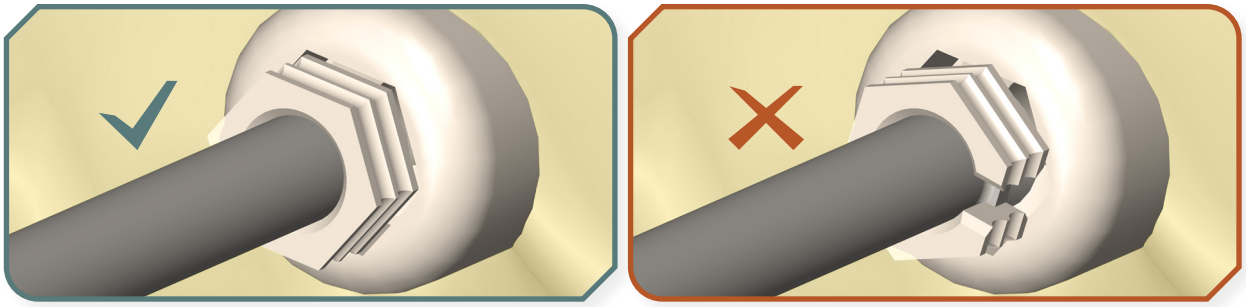
Insert the Female Retriever over the 1.6mm Guide Wire until fully seated inside the hexagon of the Female Component.

Confirm placement in both the AP and lateral views under image intensification (C-arm).



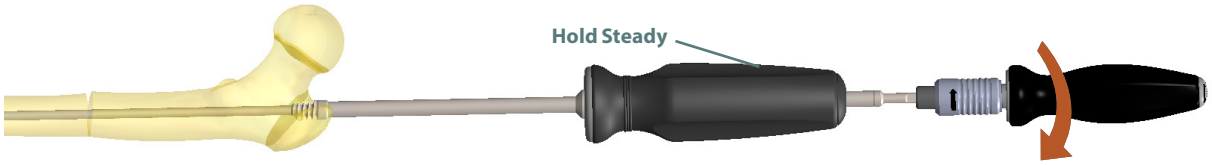
If the Female Retriever does not engage, rotate counterclockwise while applying a light pressure until the hexagons align and the retriever engages.

If assembly remains difficult, cleaning out the hexagon of the Female Component may be required.

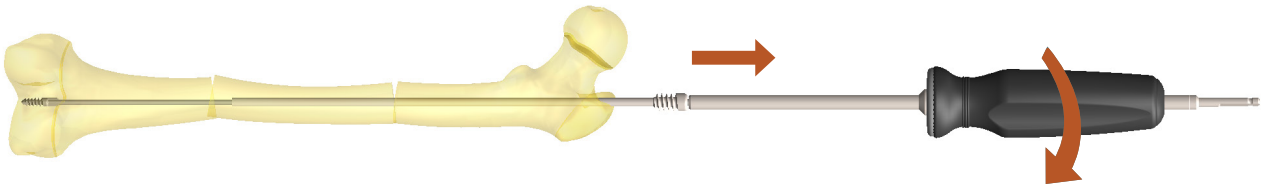


Remove Guide Wire. Attach the Torque Handle [MRT-HANDLE] to the back end of the Driver taking care to not disengage the Female Retriever from the Female Component.

Hold the Female Retriever steady while applying light pressure against the implant. Apply a counterclockwise rotation on the Torque Handle until the torque limit is reached to expand the Hex. An audible click will be heard when the limit is reached.



Remove the Torque Handle to avoid rethreading the Driver and releasing the expanded Hex. Unscrew the Female Component while applying a steady pulling force in the axis of the nail.



REMAIN ALIGNED with the axis of the implant. Avoid oscillation as it might causes the Female Retriever to detach from the implant. If this happens, try to reinsert the Female Retriever into the implant and use the torque handle to reexpand the Hex. If this does not work, restart the retrieval process with a new Cartridge.

To disassemble the Female Retriever and implant, rethread clockwise the Driver into the Handle to relieve any expansion of the Hex and pull-off the Female Component. The Cartridge can then be unscrewed clockwise from the Driver, and the Driver counterclockwise from the Handle. The Cartridge is single-use; discard accordingly.

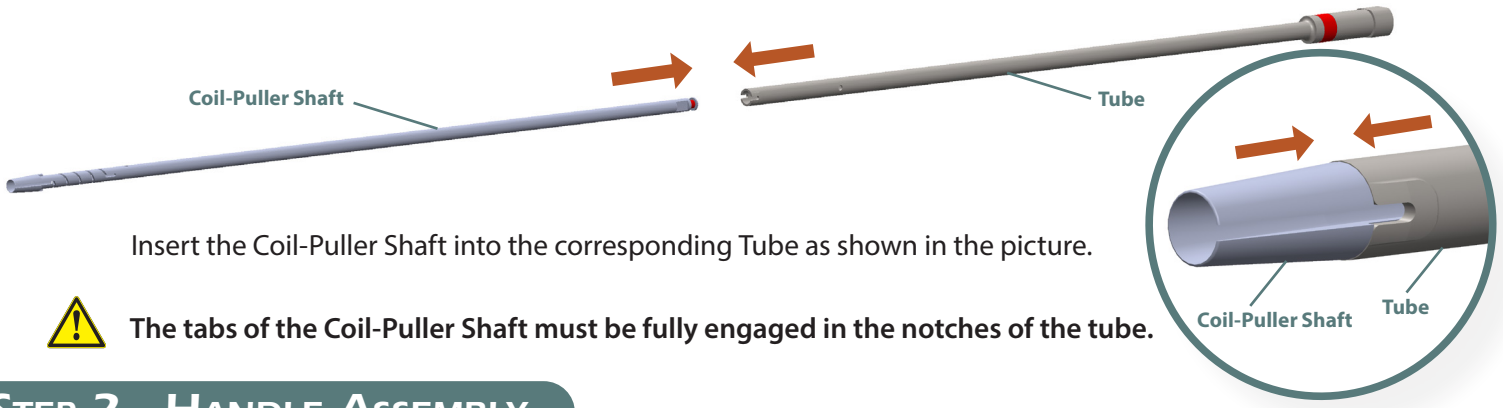
ASSEMBLY OF THE MALE RETRIEVER

The size of the Coil-Puller Shaft and Male Retriever Tube correspond to the size of the implant to be retrieved (see table). Select the appropriate size for use before starting the assembly process.

IMPLANT SIZE	COIL-PULLER SHAFT CATALOG #	TUBE CATALOG #	COLOR CODE
3.2 MM	MR232-S	MR232-T	YELLOW
4.0 MM	MR240-S	MR240-T	RED
4.8 MM	MR248-S	MR248-T	BLUE
5.6 MM	MR256-S	MR256-T	BLACK
6.4 MM	MR264-S	MR264-T	RUST / BROWN

The Coil-Puller Shafts are single-use and cannot be reused. All other components of the Male Retriever assembly are reusable.

STEP 1 - COIL-PULLER SHAFT AND TUBE ASSEMBLY



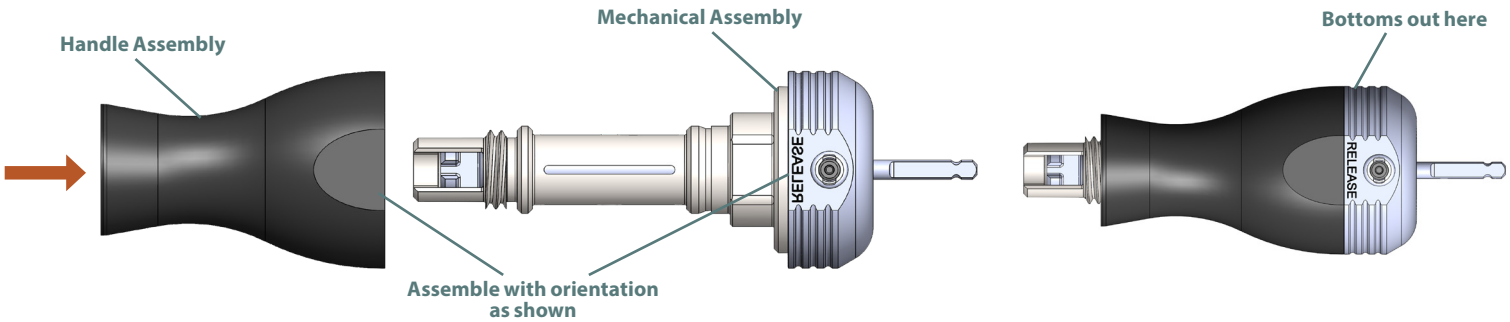
Insert the Coil-Puller Shaft into the corresponding Tube as shown in the picture.

The tabs of the Coil-Puller Shaft must be fully engaged in the notches of the tube.

STEP 2 - HANDLE ASSEMBLY

There are two generations of the Male Retriever: GEN2 [MR200] and GEN3 [MR300]. If using the GEN2 Male Retriever [MR200], skip this Step.

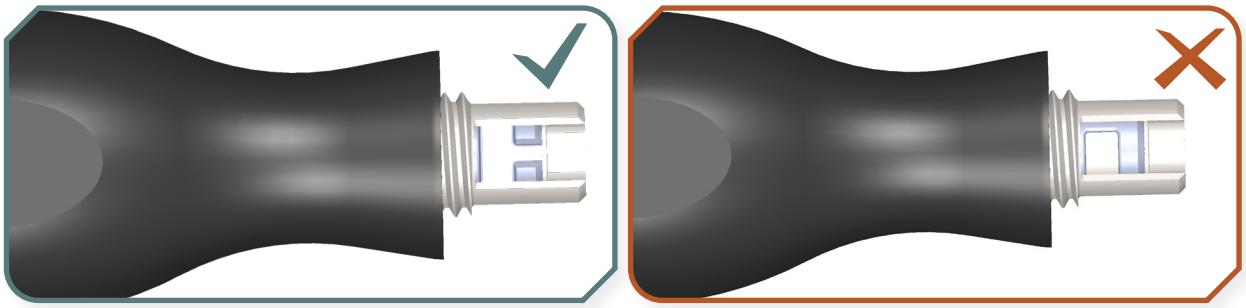
For GEN3 Male retriever [MR300], slide the Handle Assembly [MR320] onto the Mechanical Assembly [MR310] until it bottoms out.



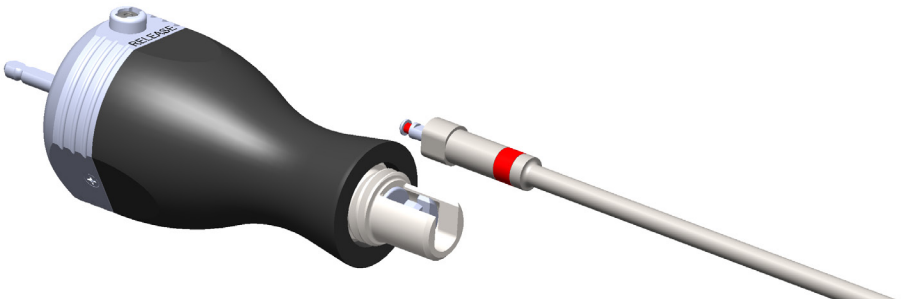
Ensure flat of the Handle Assembly with no markings and the “RELEASE” on Mechanical Assembly line up.

Step 3 - Male Retriever Assembly

Verify that the flats on the Driveshaft are aligned with the flats on the Handle.



If the assembly is difficult, verify alignment of flat surfaces.

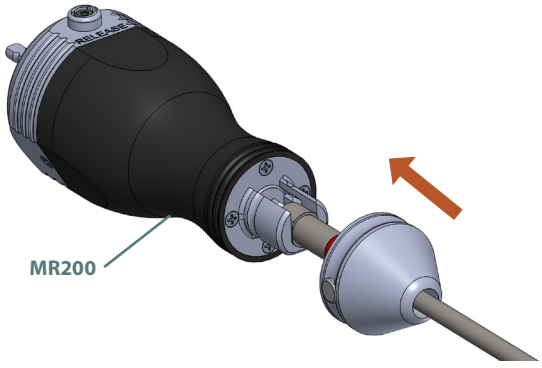


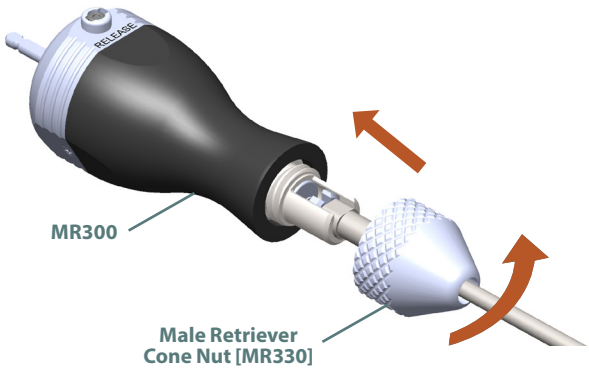
If not, use the Torque Handle to turn the Driveshaft in a counterclockwise direction until the flats align.

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

Step 4 - Cap Assembly

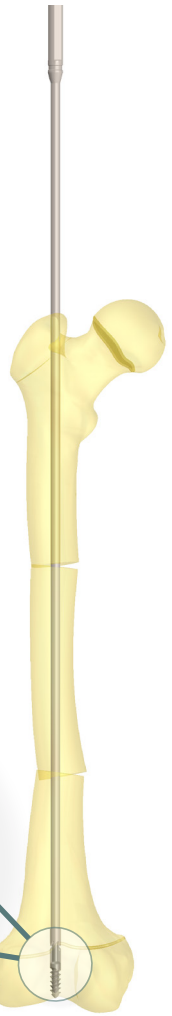
Attach the cap by either clipping it (Gen2) or threading it (Gen3) into place.





This method is not approriate to retrieve or revise an implant if prior permanent deformation has occured.

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.



Step 1 - Use Of Male Trephines

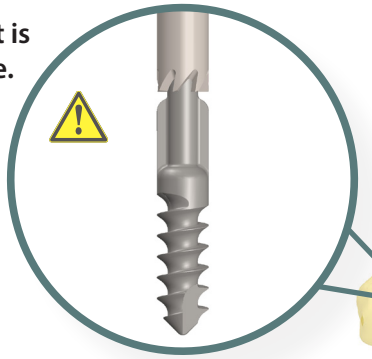
Advance a 1.6mm Guide Wire [G-WIRE 016] contacts the Male Component to provide alignment.

Slide the Trephine over the Guide Wire.

Since the diameter of the Male Retriever is larger than the Female Component, use the recommended Male Trephine (manually or on power) to remove bone up to the proximal end of the Male Component to fit the Male Retriever into the canal.

IMPLANT SIZE	MALE RETRIEVER #	MALE TREPHINE	DRILL
3.2 MM	MR232	TRP132	DR148
4.0 MM	MR240	TRP140	DR148
4.8 MM	MR248	TRP148	DR156
5.6 MM	MR256	TRP156	DR164
6.4 MM	MR264	TRP164	DR164

If advancement becomes difficult or overheating of the instrument is observed, back-out the Male Trephine and clean the teeth and core.



When necessary to remove bone to create a path for the male component wings, use Male Trephine over the Male Component shaft to clear the path.

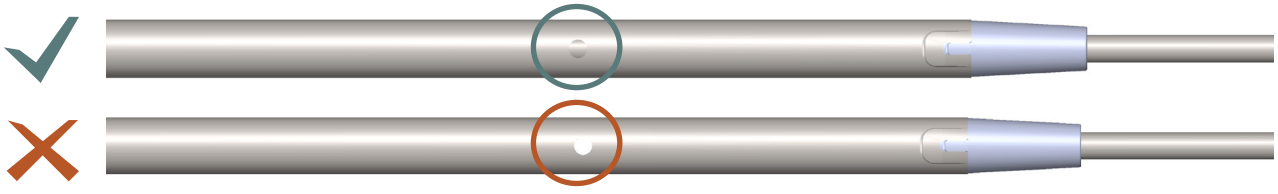
Take care not to hit the wings of the male component when advancing the Male Trephine. It is recommended to finish the removal of bone near the wings manually with a Jacobs Chuck.

Alternatively, drills of the recommended size can be used up to the proximal end of the Male Component but are not included with the system.

Step 2 - Final Assembly

Under fluoroscopy, locate the end of the Male Component and mount the Male Retriever over it. Verify that 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 under imaging.



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

Step 3 - Retrieve Male Component

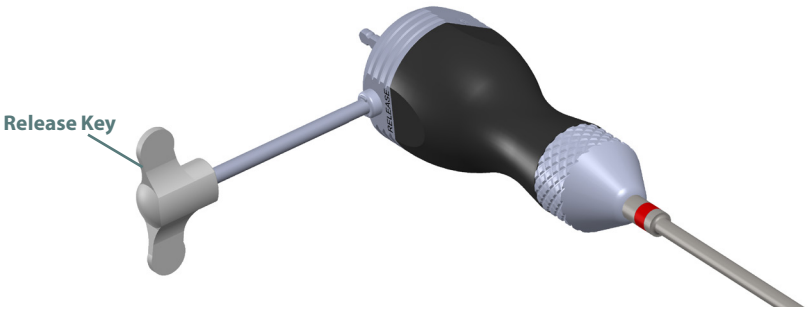
Attach the Torque handle onto the Male Retriever.

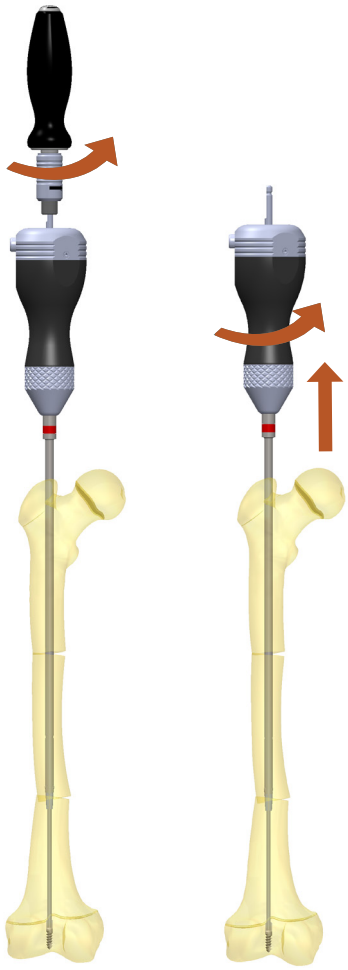
Lock onto the male component by holding the Male Retriever steady and turning the Torque Handle counterclockwise until the torque limit is reached. Remove the Torque Handle after tightening.

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.

To remove the implant from the Male Retriever, press the Release Button all the way down using the Release Key [RLK100].

Push down and rotate 90° to lock the Release Key into position.





If Male Retriever is unavailable or unsuccessful in removing Male Component, the Male Driver (not included) can be used to unscrew the implant.

Step 4 - Optional Use Of Male Driver

If the Male Component has been retrieved, skip this step.

The Male Drivers are not included in the Rescue Case.

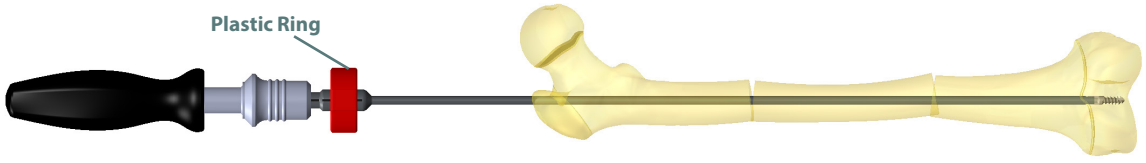
Insert appropriate Male Driver (see table) through the intermedullary canal until it is fully engaged over the wings of the Male Component.

IMPLANT SIZE	DRIVER	COLOR
3.2 MM	MDR132-L	YELLOW
4.0 MM	MDR140-L	RED
4.8 MM	MDR148-L	BLUE
5.6 MM	MDR156-L	BLACK
6.4 MM	MDR164-L	RUST BROWN

Due to patient growth, the Male Driver may be too short to reach the implant's wings

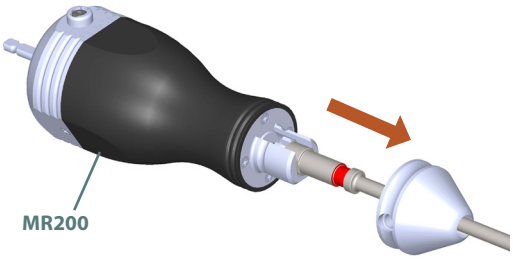
Partial engagement of the Male Driver onto the Male Component wings may lead to breakage of the instrument due to increased stress on it.

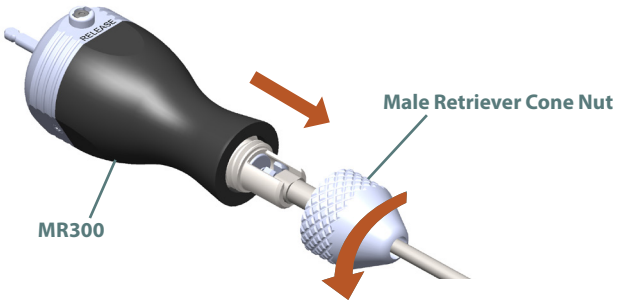
To lock the Male Driver onto the Male Component, rotate the plastic ring to the LOCK position with reference to the line on the metal shaft of the Male Driver.



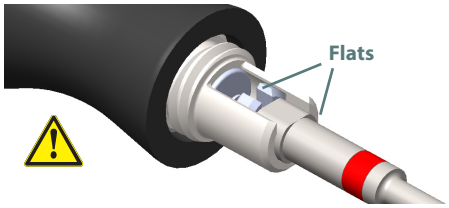
STEP 5 - DISSASSEMBLY

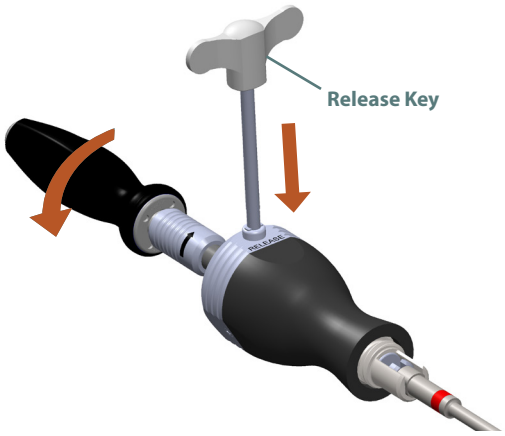
Remove the Cap by either pulling it off (GEN2) or unthreading it (GEN3).





Once the Cap has been removed, the flats need to be aligned in order to disassemble the Coil-Puller Shaft and Tube from the Handle





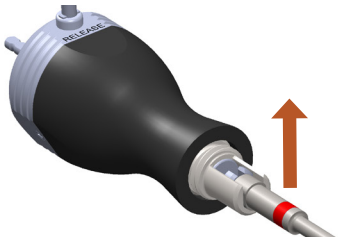
To align the flats, maintain the Release Button depressed with the Release Key. Insert and Rotate the Release Key by 90 degrees inside the Release Button to maintain it depressed.

Use the Torque Handle to rotate clockwise until the flats line-up.

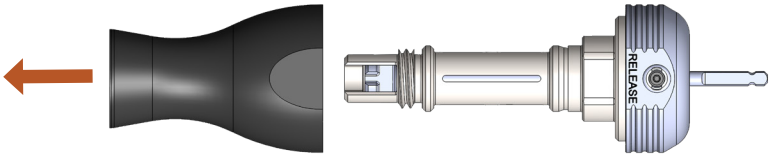
The Shaft and Tube assembly can then be pulled upwards.

If the flats are not parallel, the disassembly will not be possible.

Once the flats are aligned, the Coil-Puller Shaft and Tube can be removed by pulling them upwards.



For the GEN3 Male Retriever only, pull off the Handle Assembly while holding the Mechanical Assembly.



The Coil-Puller Shafts are single-use instruments and cannot be reused. All other components (Tubes, Handle, etc.) are reusable.

For further information on the assembly and disassembly of the Male Retriever 3rd Generation, refer to document FDRS-MR300-ASM.

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