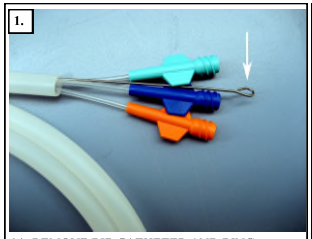
NuMED Bare Stent Mounting Procedure

1.

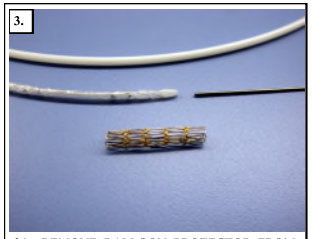


1.) REMOVE BIB CATHETER AND RING MANDRIL FROM PACKAGING HOOP

2.

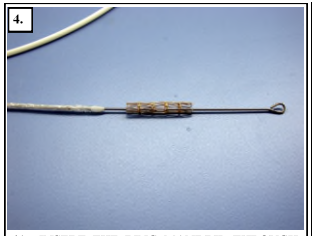
2.) REMOVE STENT FROM THE PACKAGING VIAL

3.



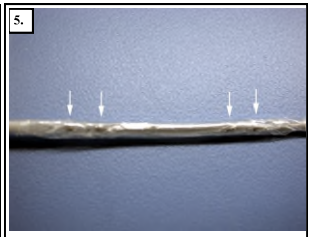
3.) REMOVE BALLOON PROTECTOR FROM BIB CATHETER AND ASSEMBLE MATERIALS (BIB CATH, RING MANDRIL, & STENT)

4.



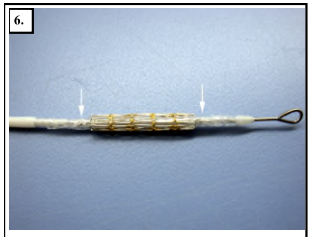
4.) INSERT THE RING MANDRIL THROUGH THE STENT AND INTO THE GUIDEWIRE LUMEN OF THE BIB CATHETER.

5.



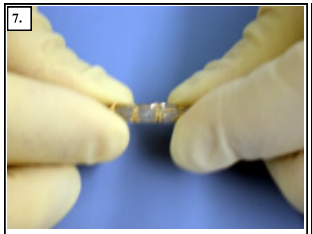
5.) LOCATE THE FOUR IMAGE BANDS ON THE BIB CATHETER

6.



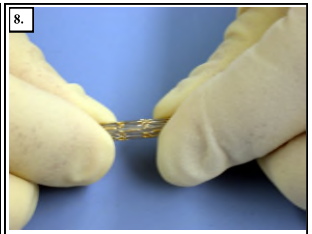
6.) POSITION THE STENT SO IT IS CENTERED BETWEEN THE TWO OUTER IMAGE BANDS

7.



7.) CRIMP THE STENT BY COMPRESSING IT TO THE BALLOON WITH PRESSURE GENERATED WITH THUMB AND FOREFINGER, AND A "ROLLING ACTION" TO EXERT EQUAL PRESSURE ON ALL SIDES OF THE STENT. DO NOT PINCH.

8.

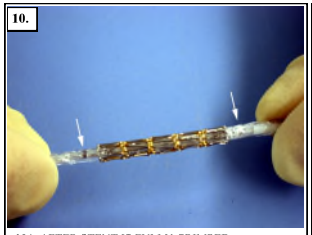


8.) ROTATE THE STENT 90 DEGREES AND REPEAT CRIMPING MOTION. REPEAT THIS STEP UNTIL ENTIRE CIRCUMFERENCE OF THE STENT IS CRIMPED.

9.

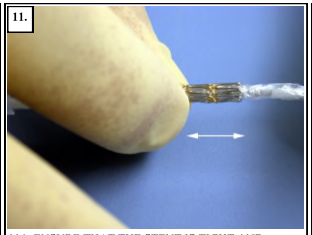
9.) ENSURE THAT THE CENTRAL AREA OF THE STENT IS CRIMPED.

10.



10.) AFTER STENT IS FULLY CRIMPED, VISUALLY INSPECT THE BALLOON / STENT ASSEMBLY TO ASSURE THE "ZIG" ROWS ARE EVENLY CRIMPED AND THE STENT IS CENTERED BETWEEN THE TWO IMAGE BANDS.

11.



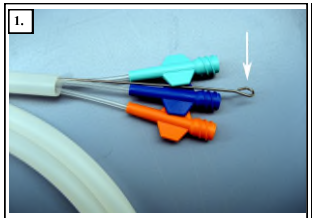
11.) ENSURE THAT THE STENT IS TIGHT AND SECURE ON THE BIB CATHETER.

HEMOSTASIS VALVE TOOLS.

REFER TO STEPS 11-15 ON OPPOSITE SIDE FOR PROPER USE OF THE HEMOSTASIS VALVE TOOLS

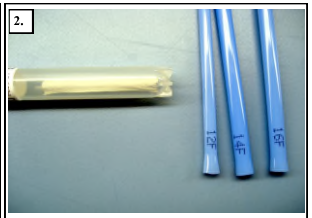
NuMED Covered Stent Mounting Procedure

1.



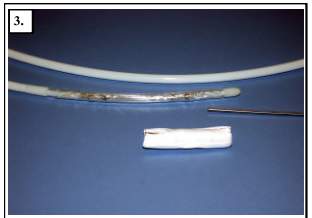
1.) REMOVE BIB CATHETER AND RING MANDRIL FROM PACKAGING HOOP

2.



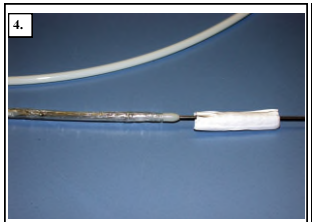
2.) REMOVE COVERED STENT FROM THE PACKAGING VIAL

3.



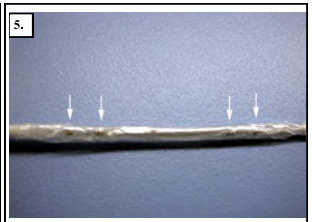
3.) REMOVE BALLOON PROTECTOR FROM BIB CATHETER AND ASSEMBLE MATERIALS (BIB CATH, RING MANDRIL, & COVERED STENT)

4.



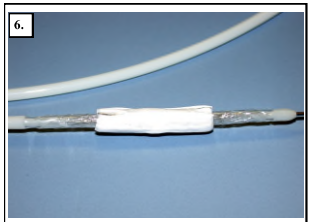
4.) INSERT THE RING MANDRIL THROUGH THE COVERED STENT AND INTO THE GUIDE-WIRE LUMEN OF THE BIB CATHETER.

5.



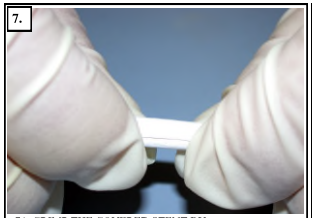
5.) LOCATE THE FOUR IMAGE BANDS ON THE BIB CATHETER

6.



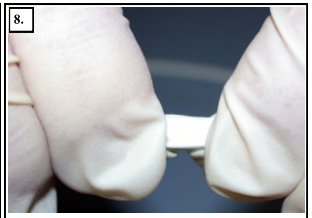
6.) POSITION THE COVERED STENT SO IT IS CENTERED BETWEEN THE TWO OUTER IM-AGE BANDS

7.



7.) CRIMP THE COVERED STENT BY COMPRESSING IT TO THE BALLOON WITH PRESSURE GENERATED WITH THUMB AND FOREFINGER, AND A "ROLLING ACTION" TO EXERT EQUAL PRESSURE ON ALL SIDES OF THE STENT. ROLLING ACTION SHOULD BE DONE IN THE SAME DIRECTION AS THE FOLDS OF THE COVERING. AVOID UNWRAPPING THE FOLDS IN THE COVERING AS THIS COULD CAUSE IT TO CATCH & TEAR OFF OF THE STENT. DO NOT PINCH.

8.

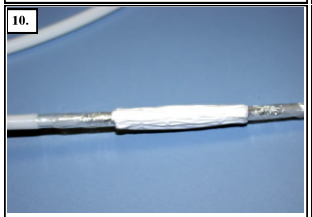


8.) ROTATE THE STENT 90 DEGREES AND REPEAT CRIMPING MOTION. REPEAT THIS STEP UNTIL ENTIRE CIRCUMFERENCE OF THE STENT IS CRIMPED.

9.

9.) ENSURE THAT THE CENTRAL AREA OF THE STENT IS CRIMPED AND THE COVERING IS TIGHTLY WRAPPED AROUND THE STENT.

10.



10.) AFTER STENT IS FULLY CRIMPED, VISUALLY INSPECT THE BALLOON / STENT ASSEMBLY TO ASSURE THE "ZIG" ROWS ARE EVENLY CRIMPED AND THE STENT IS CENTERED BETWEEN THE TWO IMAGE BANDS.

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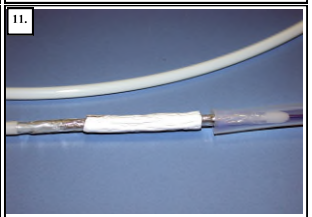
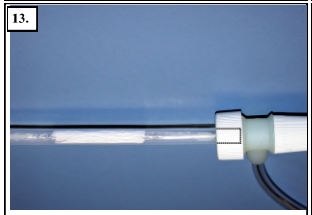


11.) CHOOSE THE APPROPRIATE INSERTION TOOL* TO BE USED FOR THE SELECTED INTRODUCER. THERE ARE THREE TUBES PROVIDED OR A SECTION OF THE APPROPRIATE SHEATH MATERIAL CAN BE USED.

12.

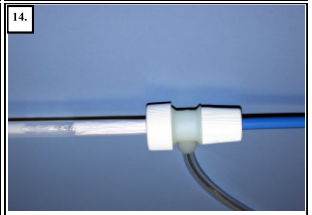
12.) CAREFULLY INSERT THE MOUNTED COVERED STENT INTO THE TOOL.

13.



13.) INSERT THE LEADING EDGE OF THE TOOL* INTO THE HEMOSTASIS VALVE OF THE SHEATH. THE TOOL MUST COLLAPSE THE ENTIRE HEMOSTASIS VALVE TO THE SIDES OF THE INTRODUCER TO ALLOW THE COVERED STENT TO PASS (APPROX 1 CM).

14.



14.) ADVANCE THE COVERED MOUNTED STENT THROUGH THE TOOL AND THE HEMOSTASIS VALVE.

15.

15.) AFTER THE COVERED STENT IS CLEAR OF THE HEMOSTASIS VALVE, THE TOOL MUST BE PULLED OUT OF THE VALVE.

* CLEAR TUBE SHOWN FOR VISUAL PURPOSES