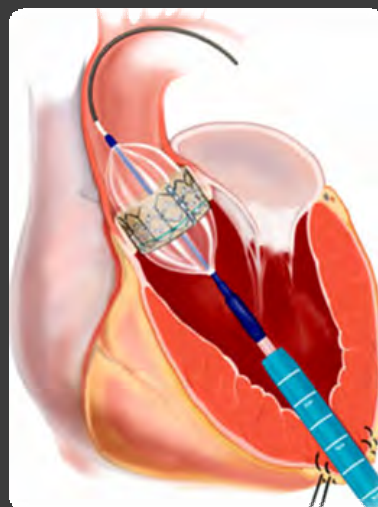




Edwards SAPIEN transcatheter Heart Valve

Crimping Process for the Transapical Procedure



CERTIFICATE OF ACHIEVEMENT

Presented to

Mr. Antonino Carmeci

*in recognition of the successful completion of
Edwards SAPIEN™ valve and device preparation training
for Transcatheter Heart Valve procedure*

TRANSAPICAL & TRANSFEMORAL CERTIFIED



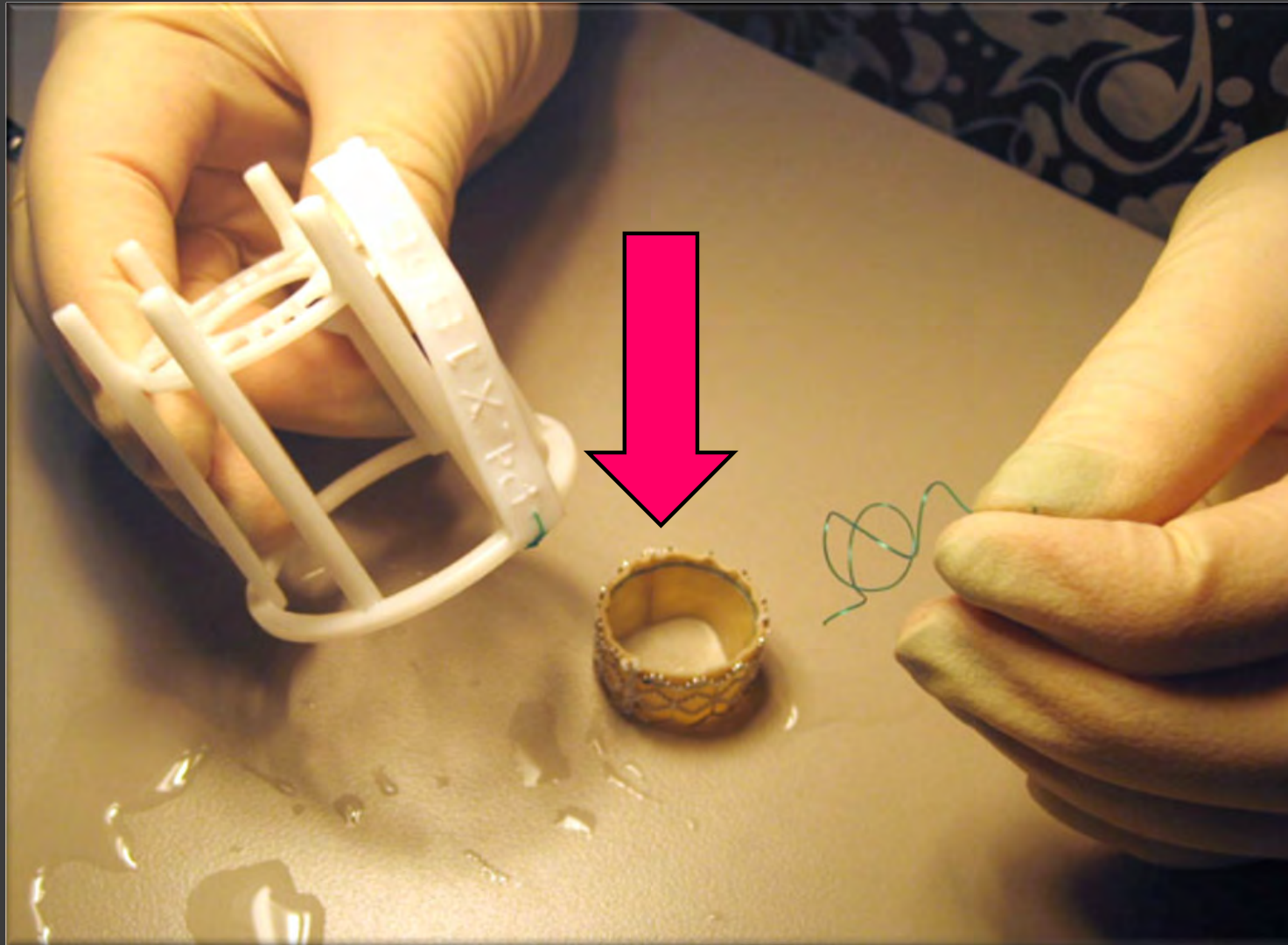
October 2009



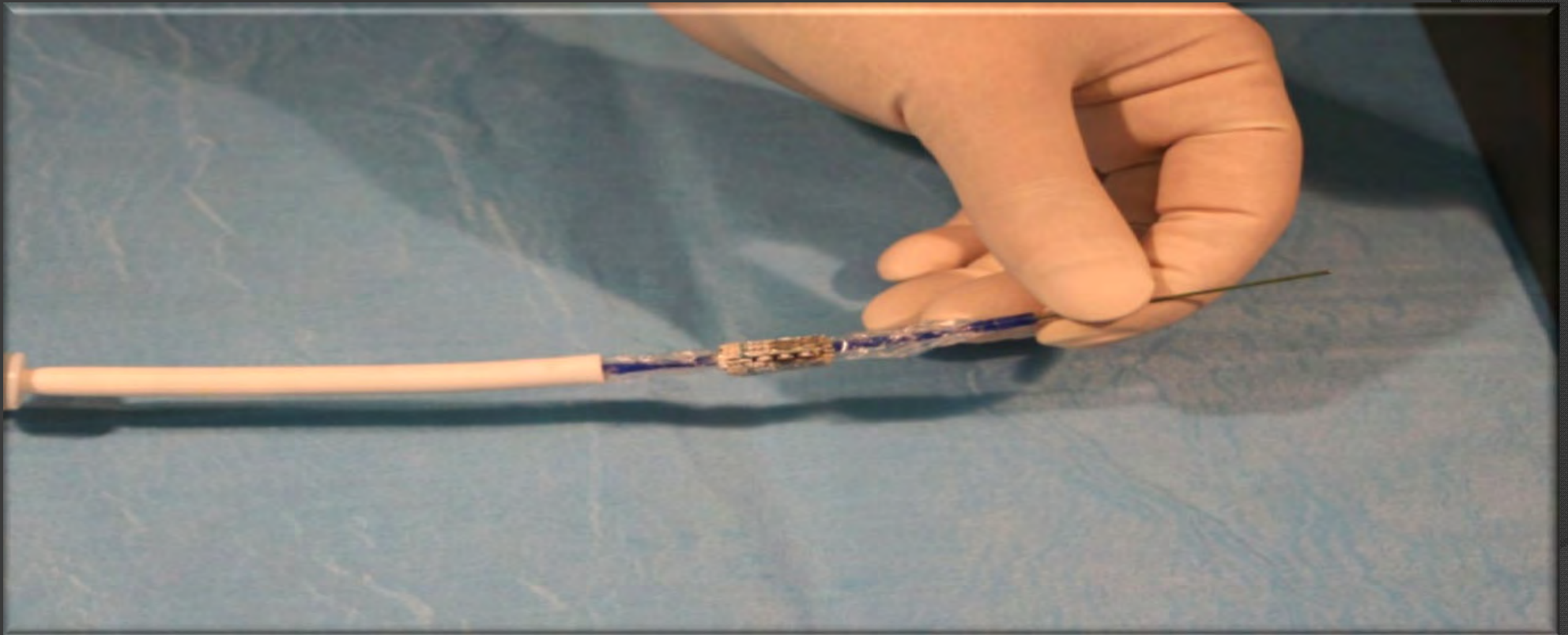
Edwards

31/8/2010 14:45
Nathalie Freysz
THV Director Professional Education

Edwards SAPIEN transcatheter Heart Valve



Edwards SAPIEN transcatheter Heart Valve



Composizione del kit per l'impianto transapicale



Viola
26 mm



Verde
23mm

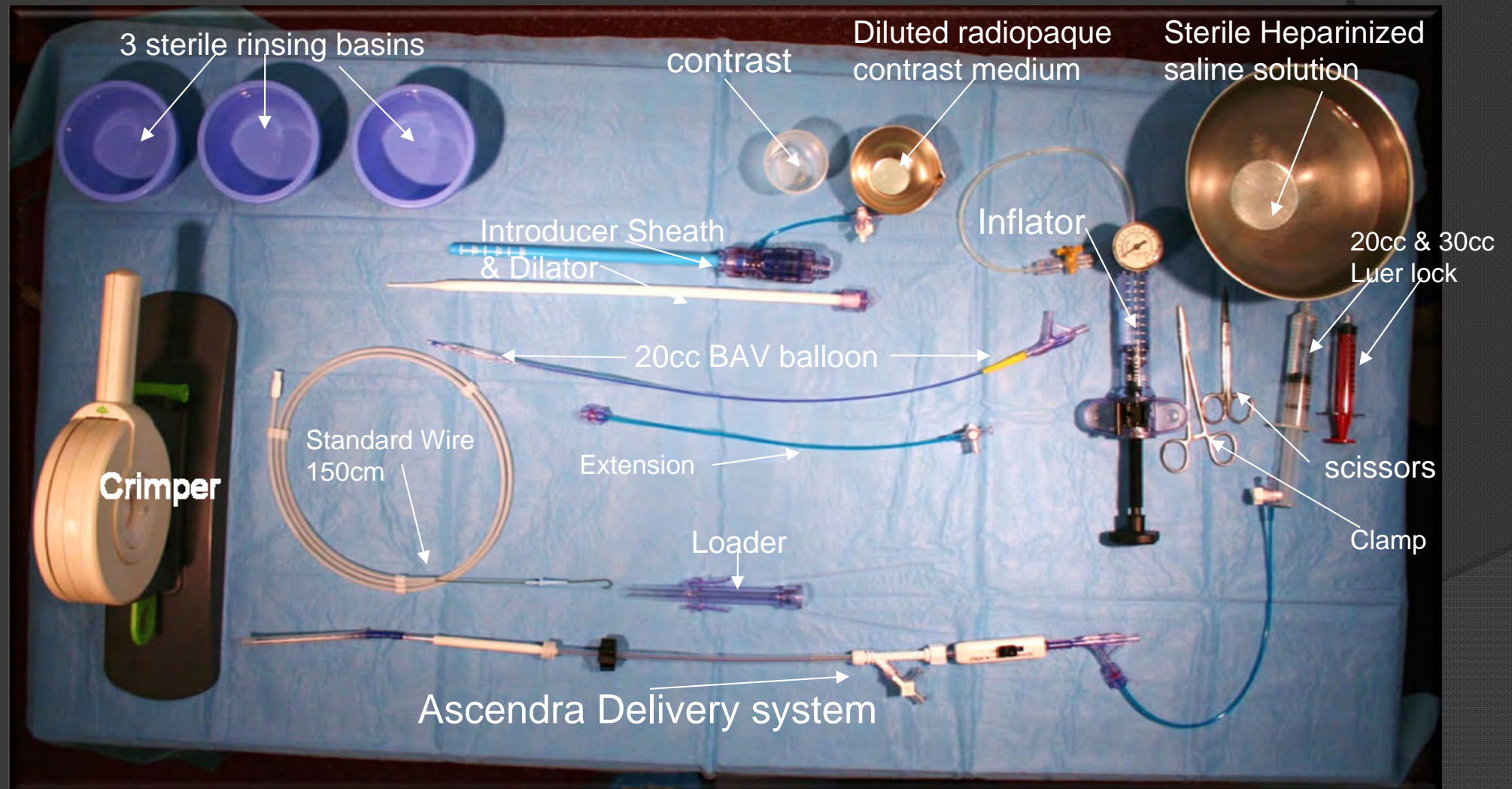


9100CR26, CR23
26mm or 23mm Crimper

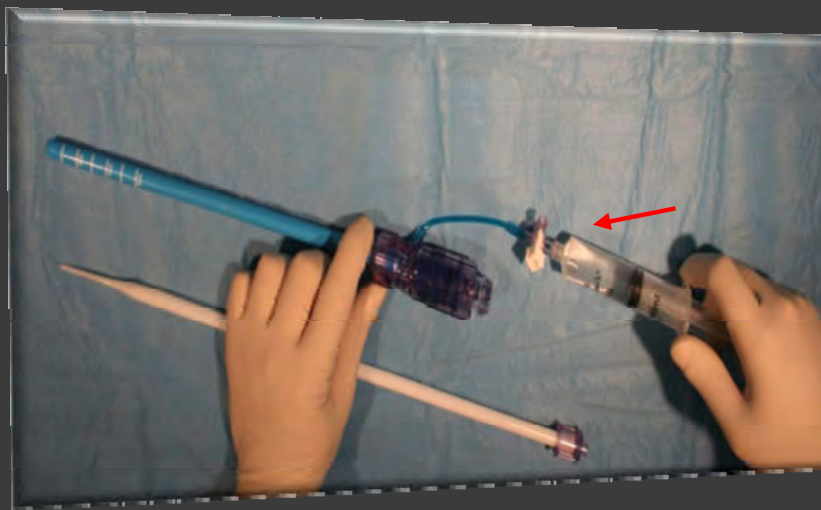


90302
Atrion inflation
devices (x2)

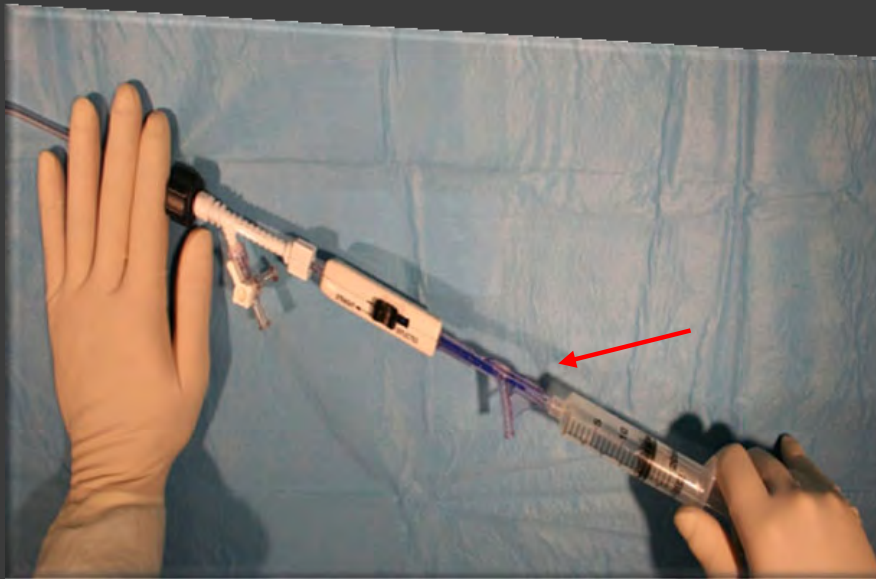
Crimping table (1,30m) for a Transapical procedure



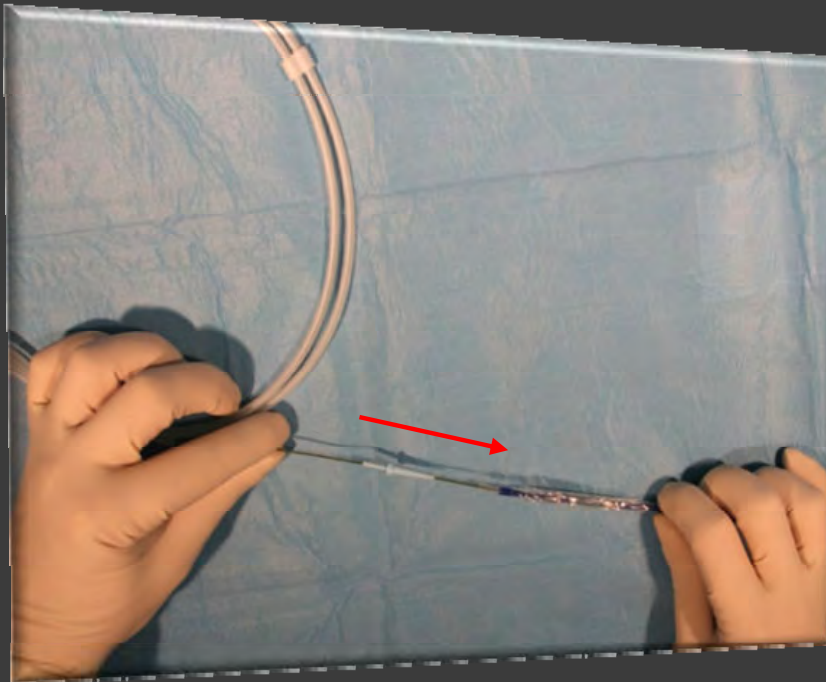
Flush Sheath Introducer (26Fr.) & Dilator



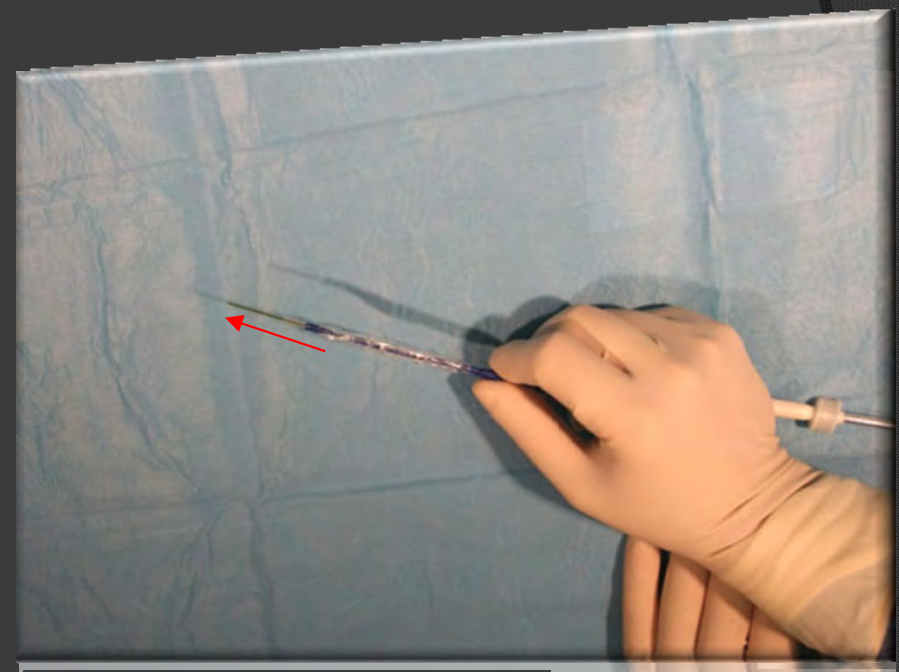
Flush the Ascendra Delivery system



Insert the Guidewire (Standard 1,50m) into the Ascendrea Delivery System



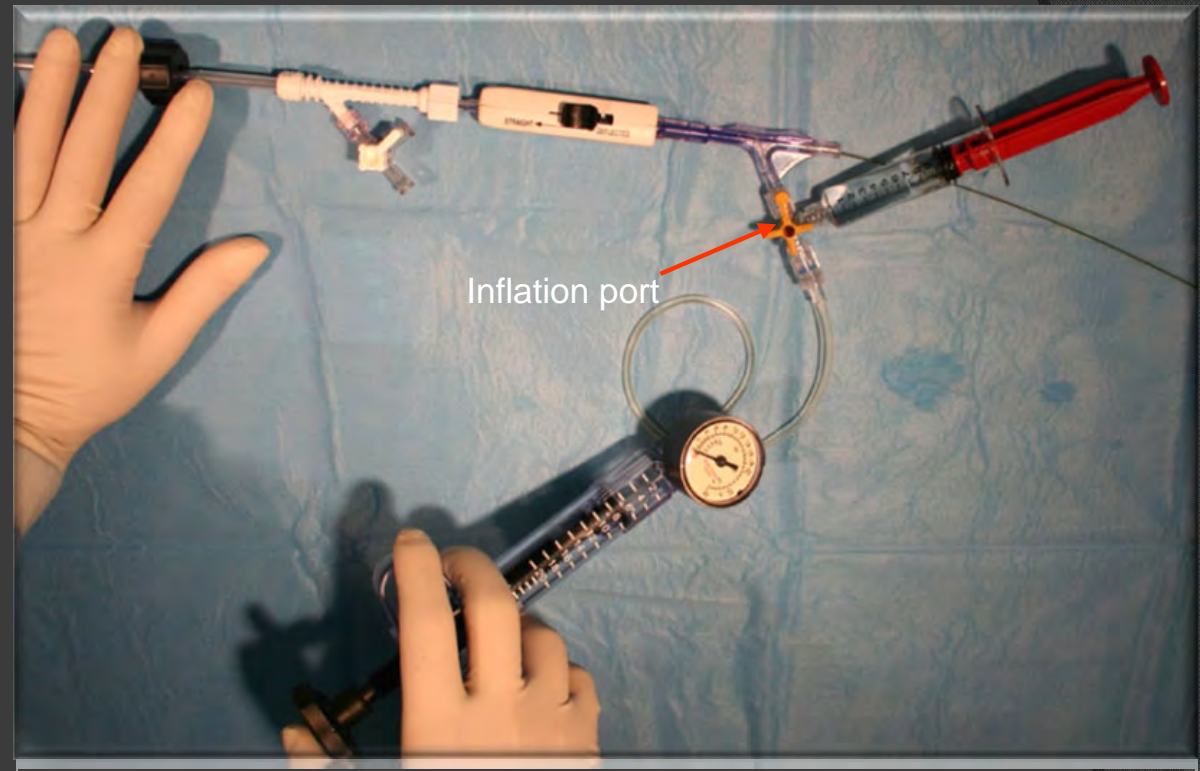
Insert first the Distal flexible end of the wire



Straight proximal end of the wire must be outside

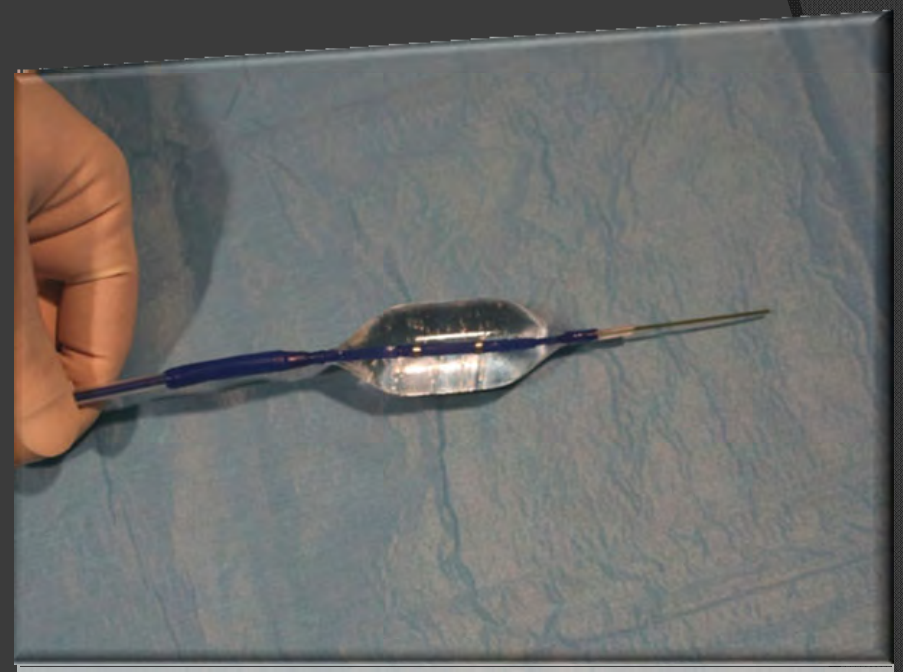
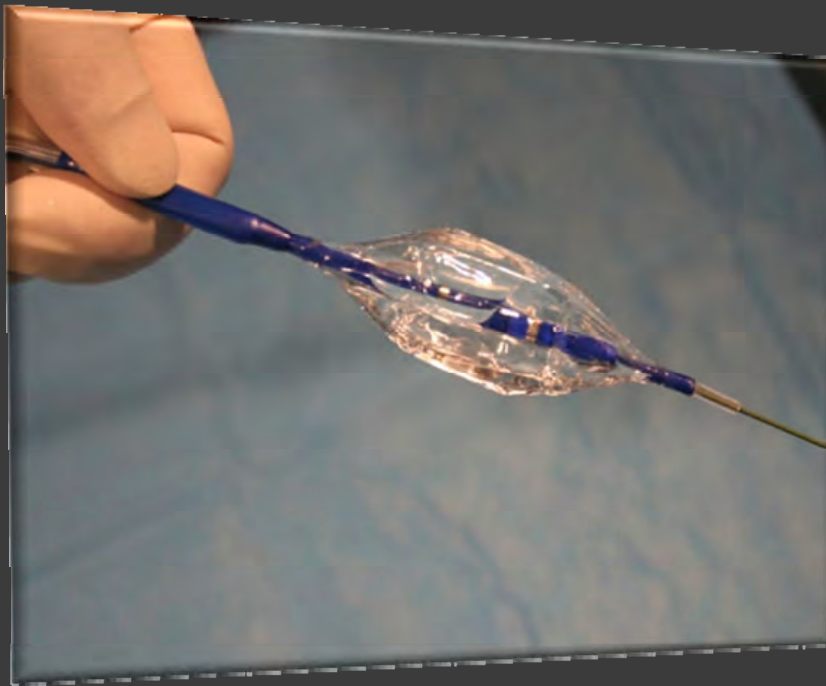
Crimp Balloon Preparation

- Attach the stopcock to the Inflation Lumen
- Attach the Inflation Syringe (25cc) to the Stopcock and a 10 cc syringe with Luer lock
- Close the stopcock on the inflation port
- Remove the syringe and purge the air
- Reattach the syringe. Open and again induce negative pressure, pulling the syringe plunger as far back as possible
- Close the stopcock to the inflation lumen and remove the syringe
- Note: To ensure air contained in the balloon and inflation lumen is removed, it is recommended that negative pressure be induced twice or more. Open the stopcock only when the syringe is in place with negative pressure induced
- Fill the Crimp balloon with a 15% max. solution of contrast medium and sterile saline.



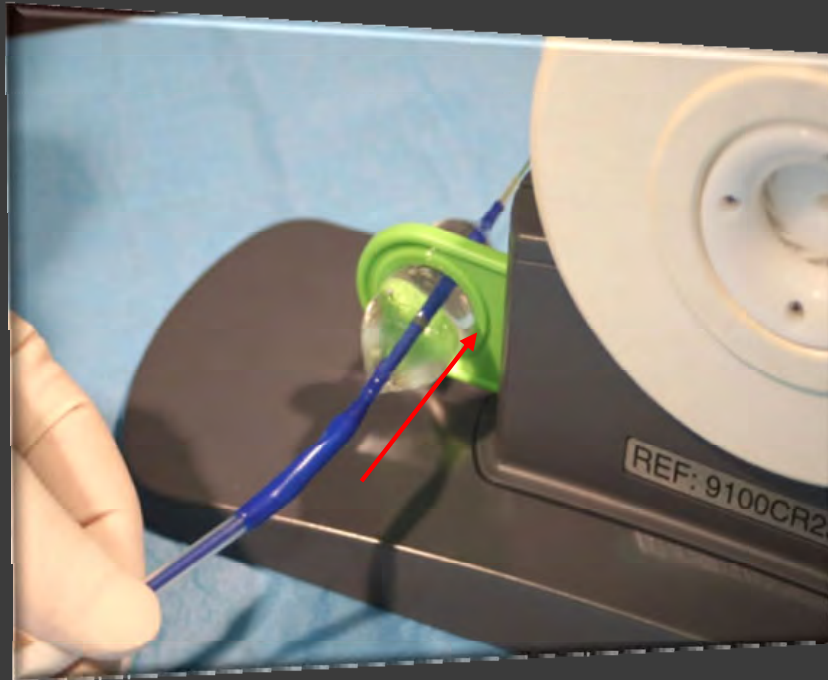
→ 15cc Contrast + 85cc Sterile saline solution

Purge the Crimp Balloon



Make sure there are no air bubbles

Insert the Crimp Balloon into the Balloon Gauge

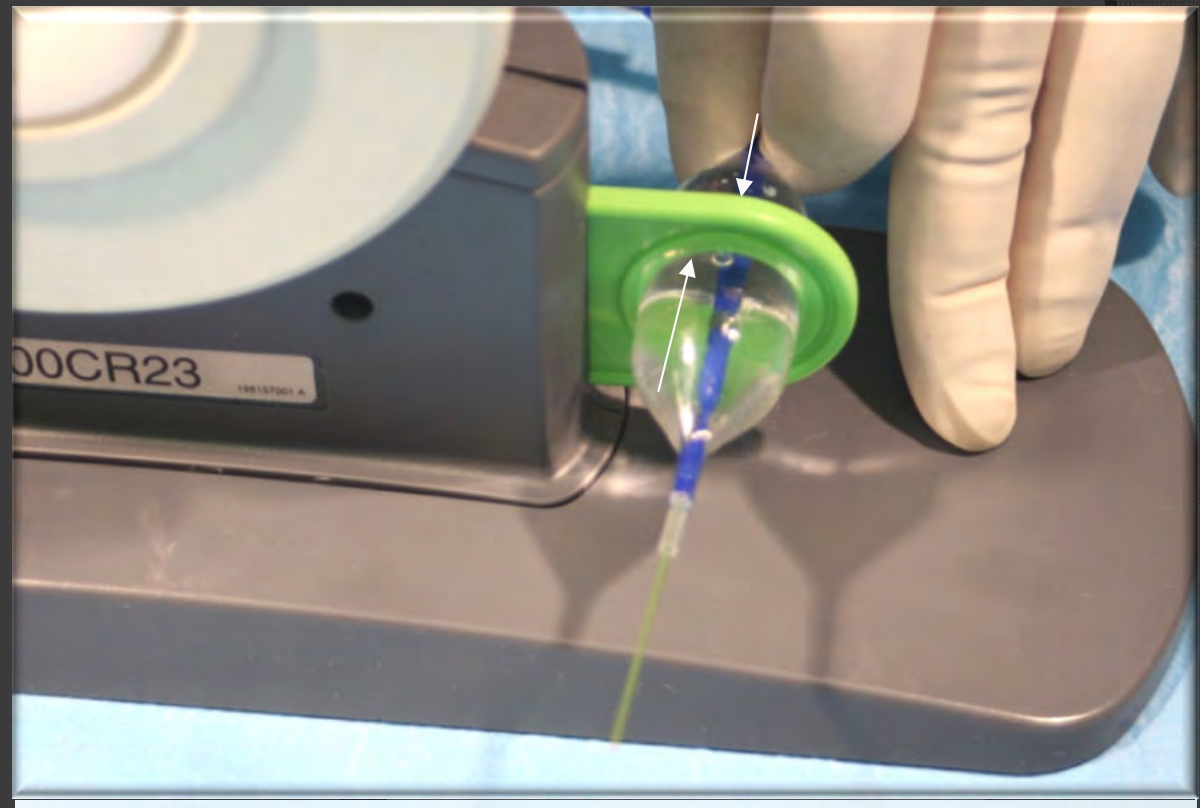


Balloon preparation

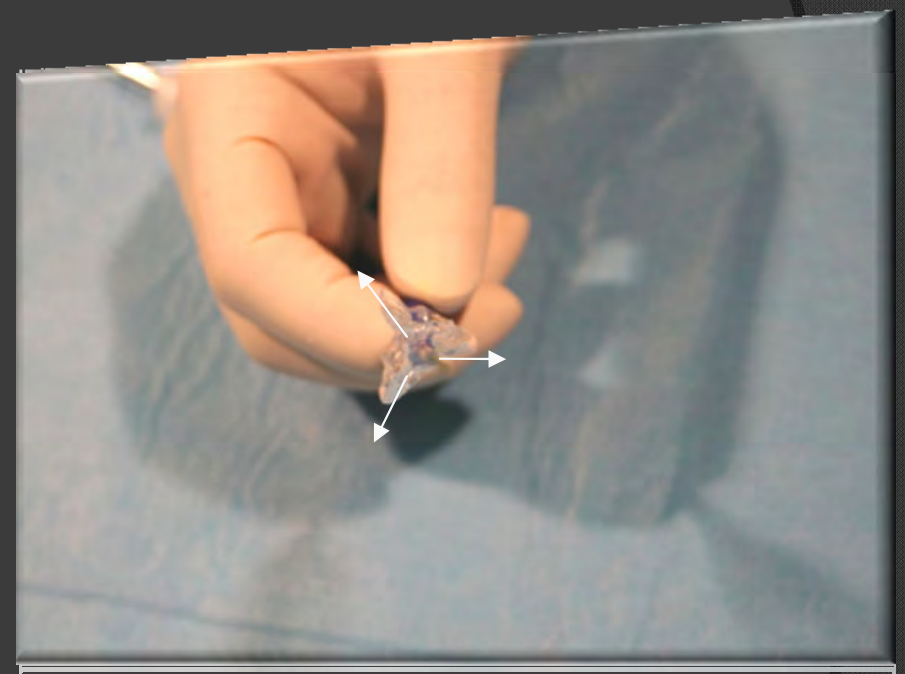
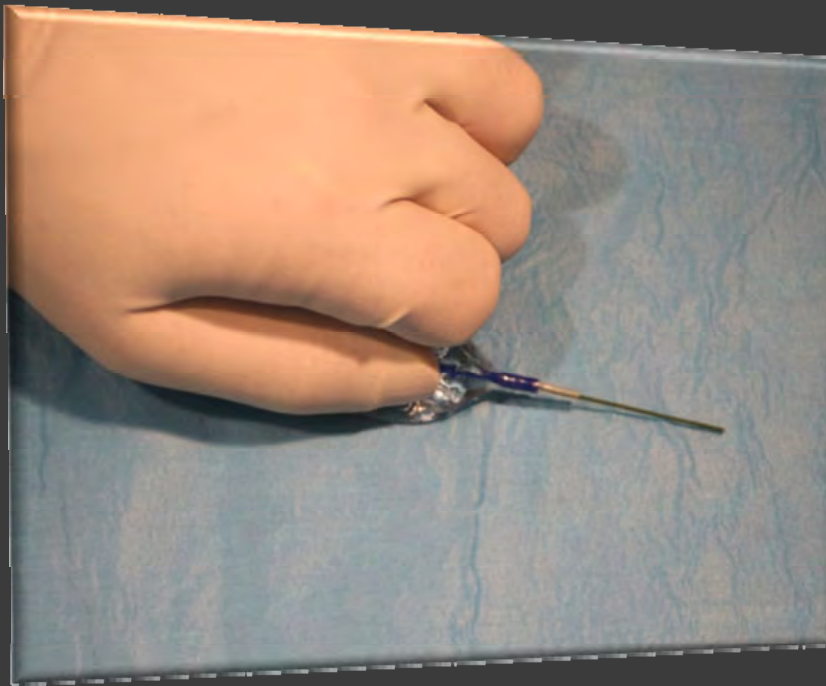


- Inflate the Balloon and make sure its diameter fits the Gauge with minimal friction
- While gently pulling and pushing the Balloon, verify that the balloon moves with little resistance to the measuring ring
- If the Balloon does not reach the correct diameter when fully inflated, add or discard of the inflating solution in the syringe
- **Make sure there are no air bubbles in the balloon catheter. If a small air bubble is detected, eliminate it while deflecting the balloon**
- **The syringe must remain connected to the delivery balloon throughout the rest of the procedure**

Correct Balloon Sizing is critical to successful valve deployment and Valve function

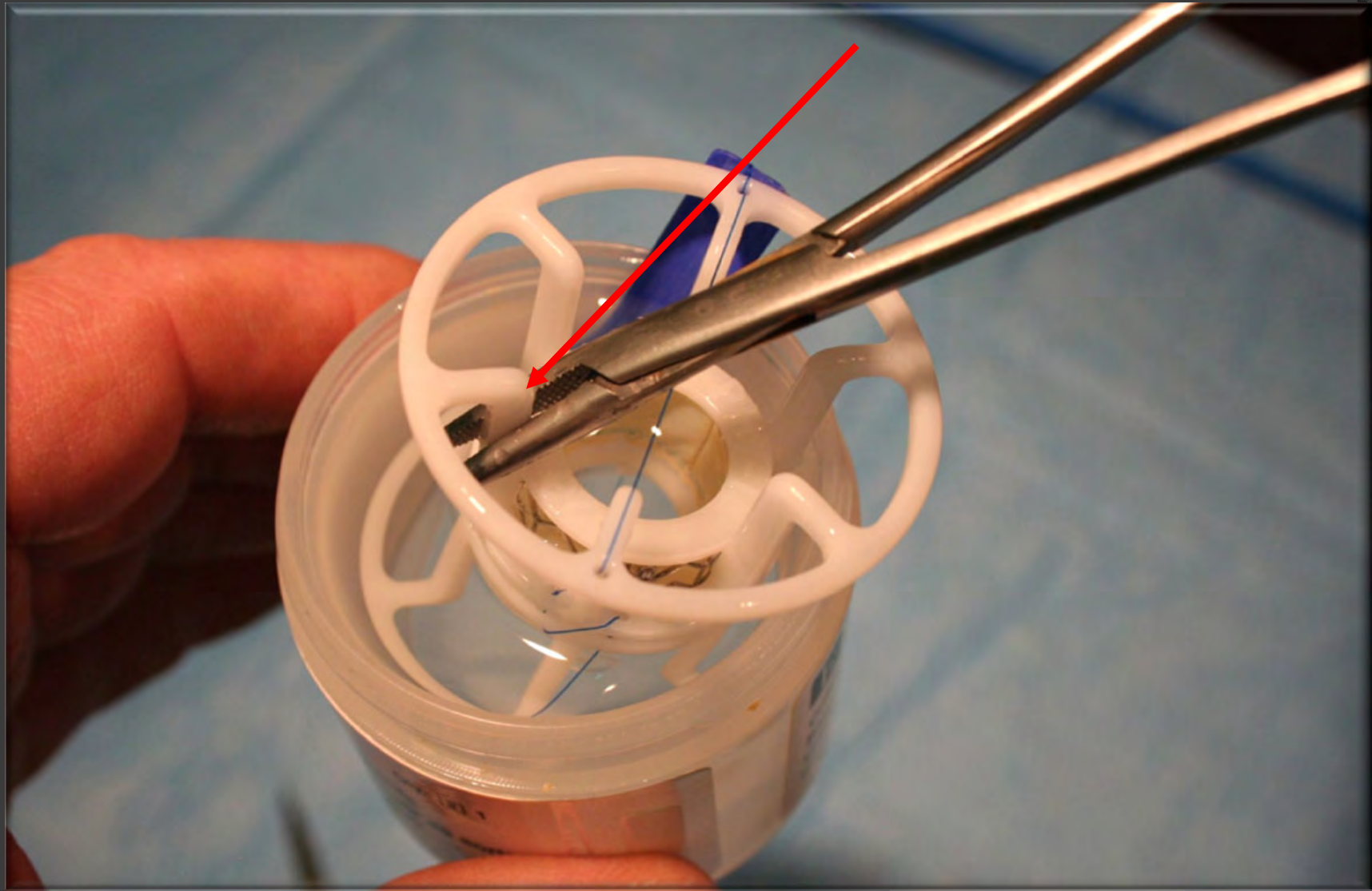


3 wings fold configuration



Deflate the Balloon, using your fingers to create a 3 wings fold configuration

**Remove the Holder from the jar
only with a clamp**



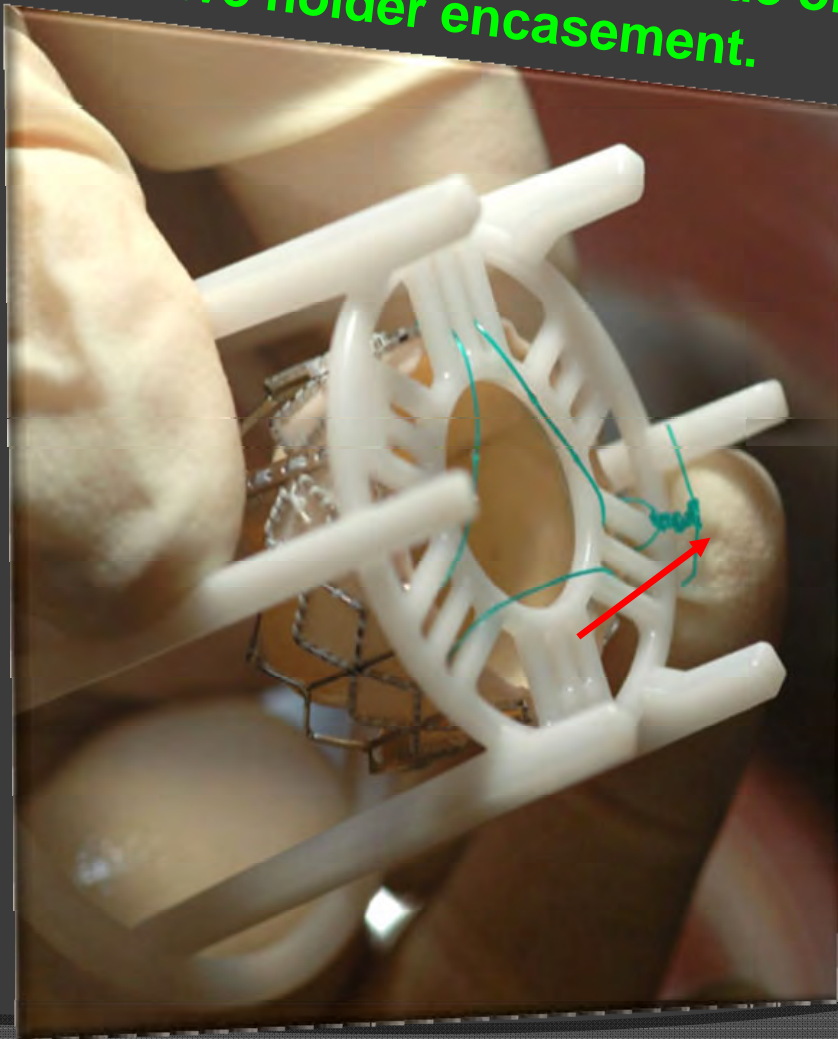
Single piece Valve Holder



Valve Holder



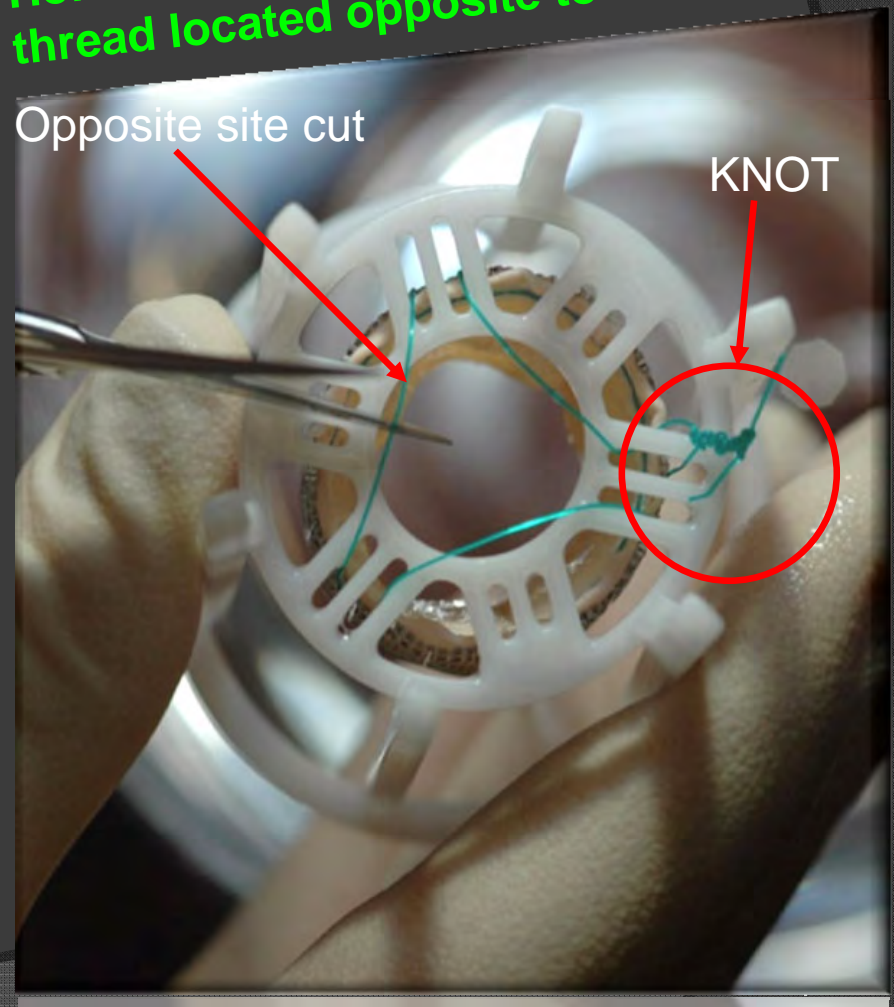
Knot is located on the outside of the valve holder encasement.



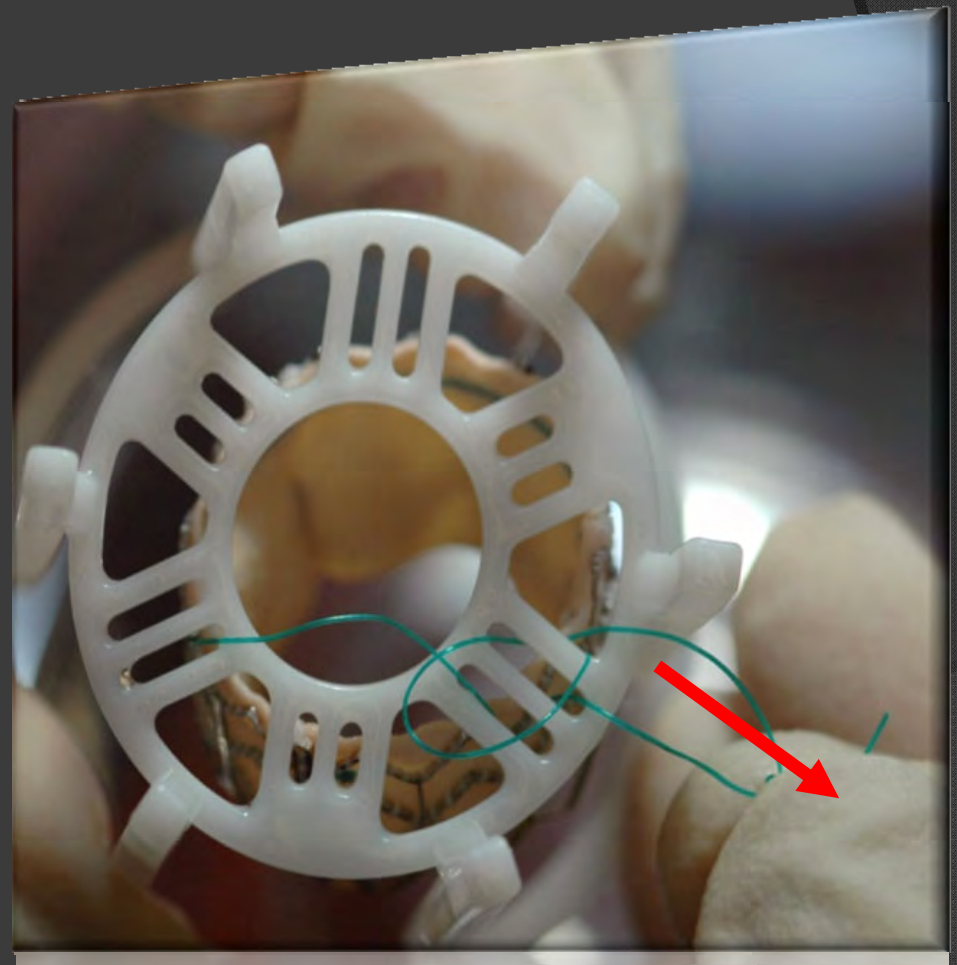
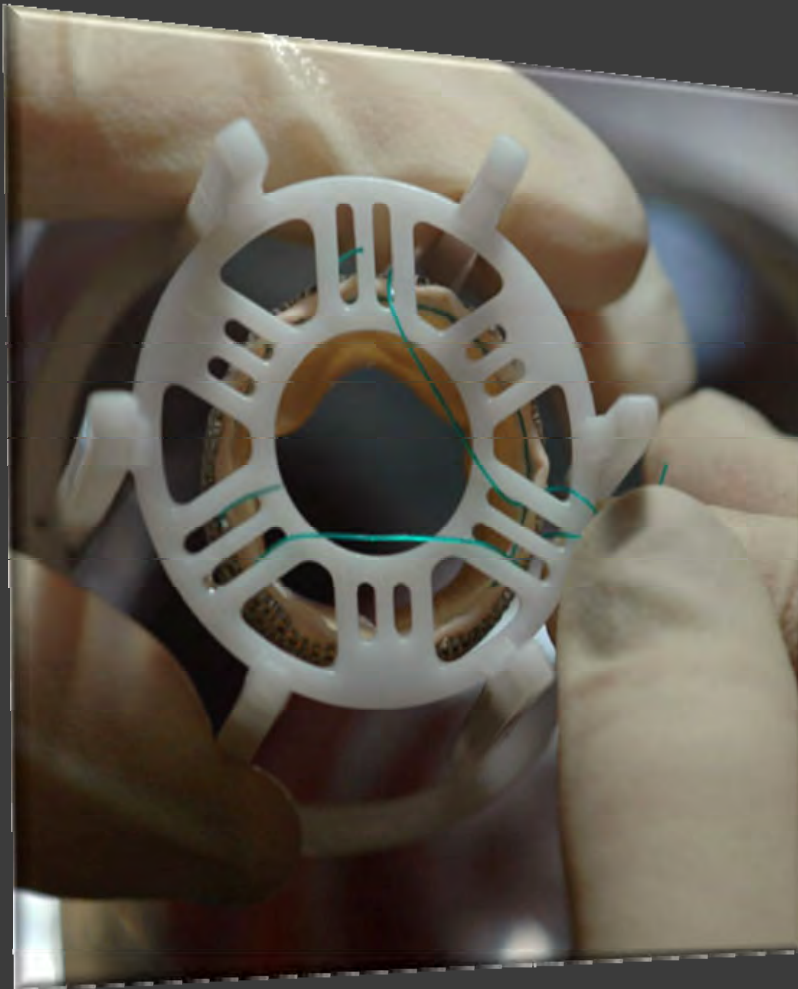
Hold encasement with hand and cut the thread located opposite to the knot

Opposite site cut

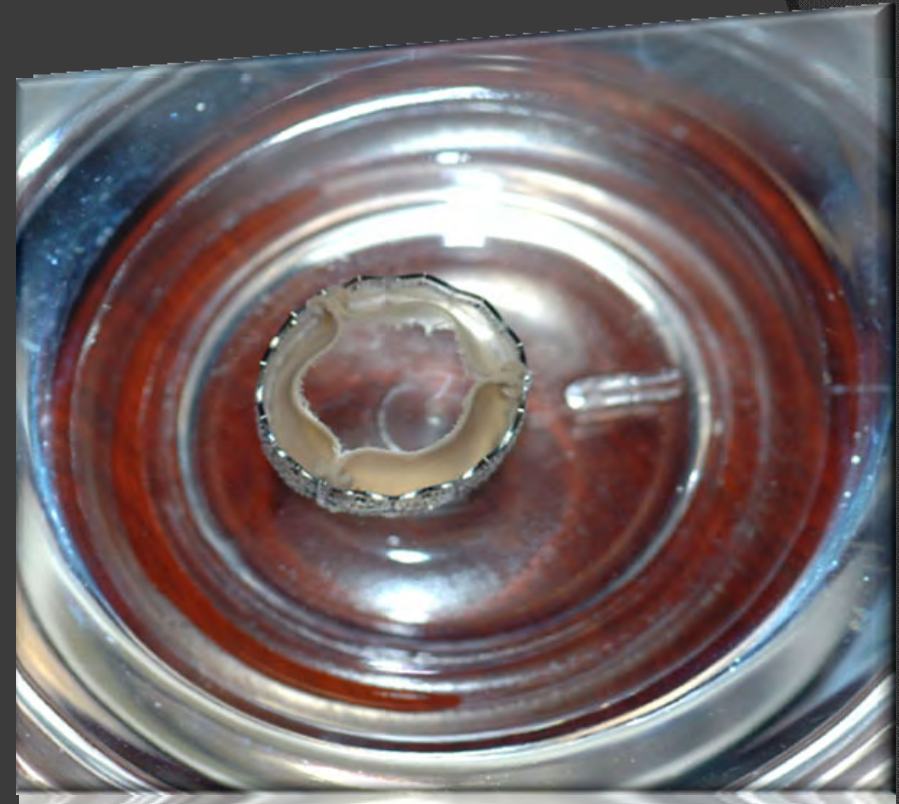
KNOT



Once you have cut the thread, take knot and pull thread completely through holder



**Once thread has been removed,
valve will easily release from
holder.**

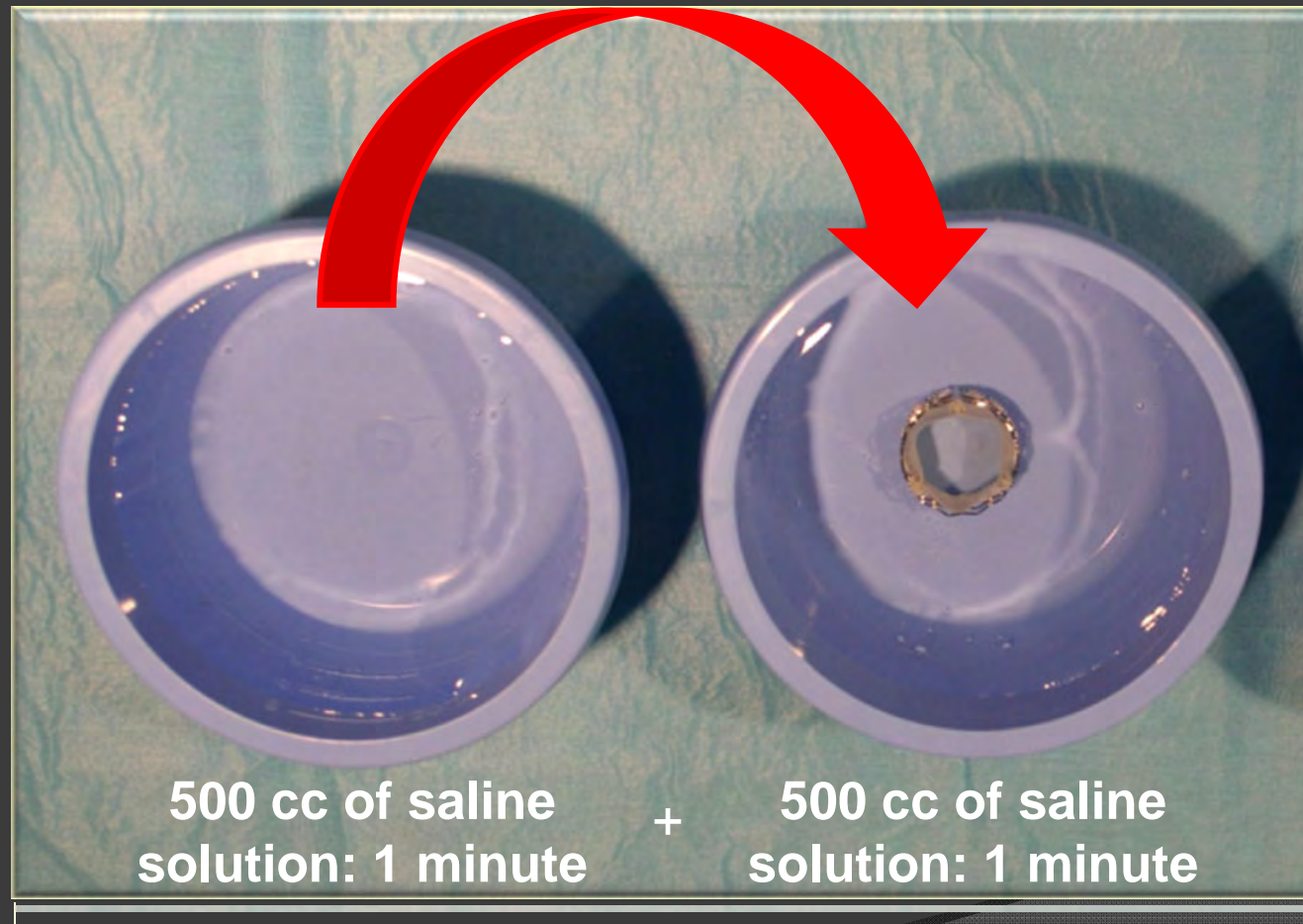


Rinse the Glutaraldehyde sterilant from the Bioprothesis

Rinsing the Bioprosthesis: 2 X 1 minute

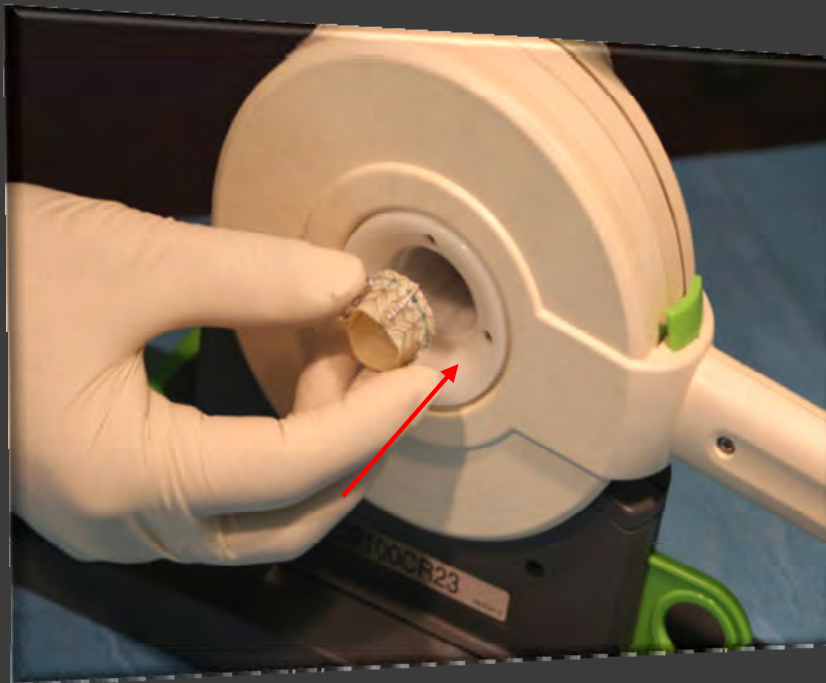


The bioprosthesis should be kept hydrated throughout the rest of the preparation procedure to prevent the tissue from drying

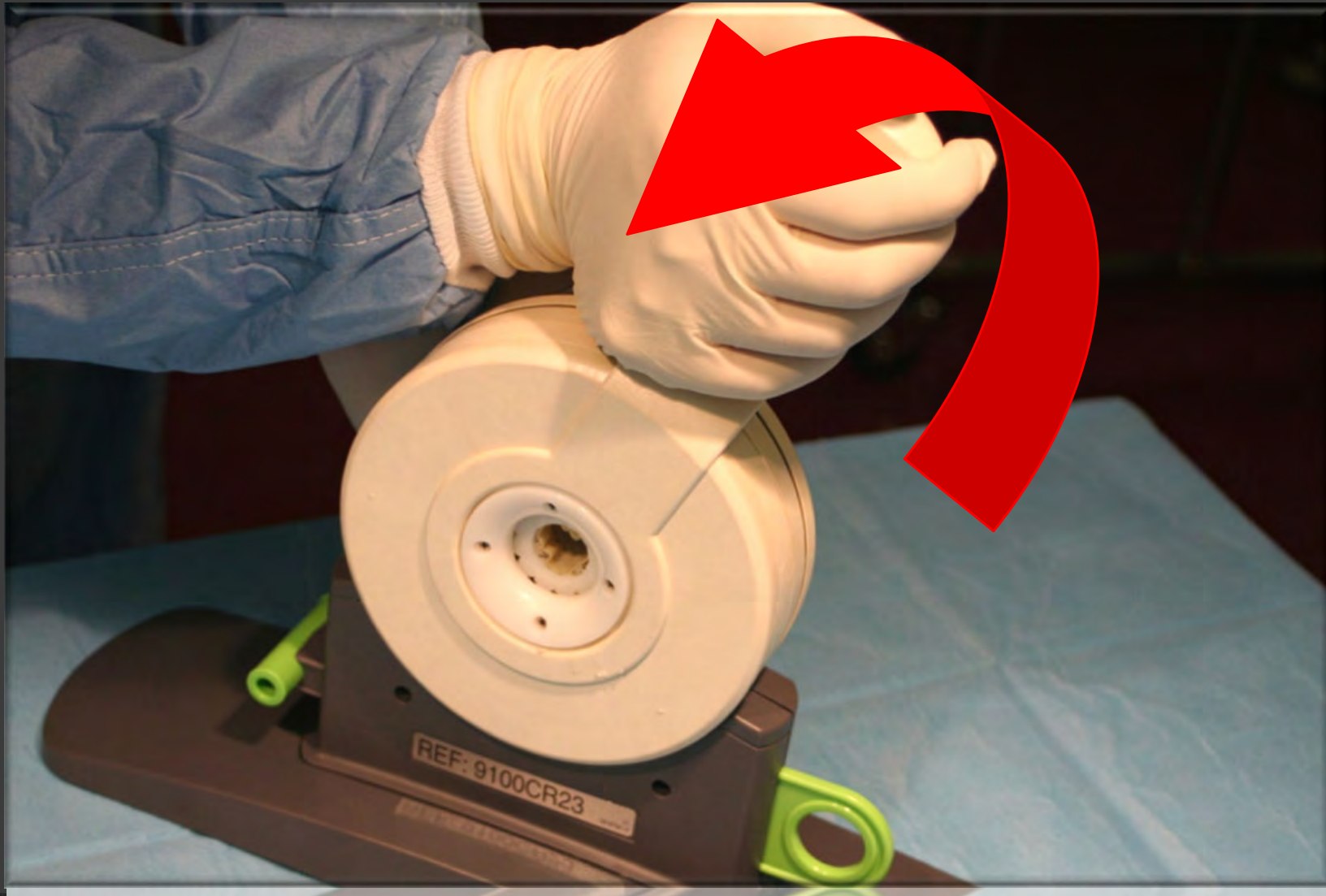


The saline solution should completely covers the bioprosthesis

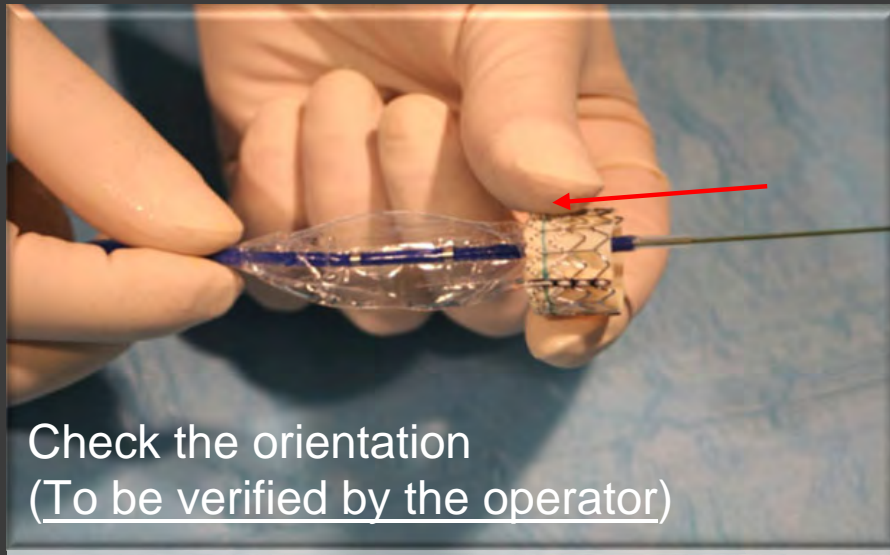
**Place the Bioprosthesis gently
into the Crimper aperture**



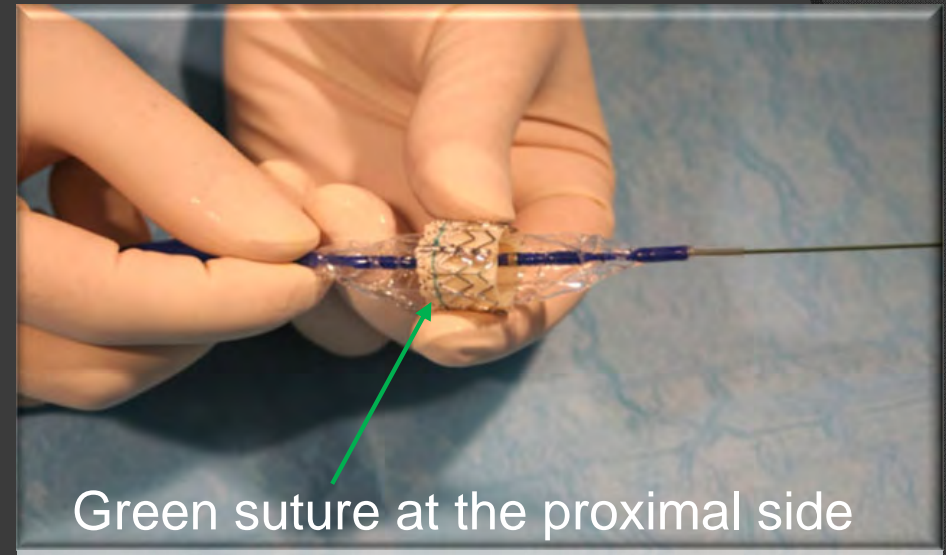
**Gradually crimp the
Bioprosthesis to a diameter of
approximately 12mm**



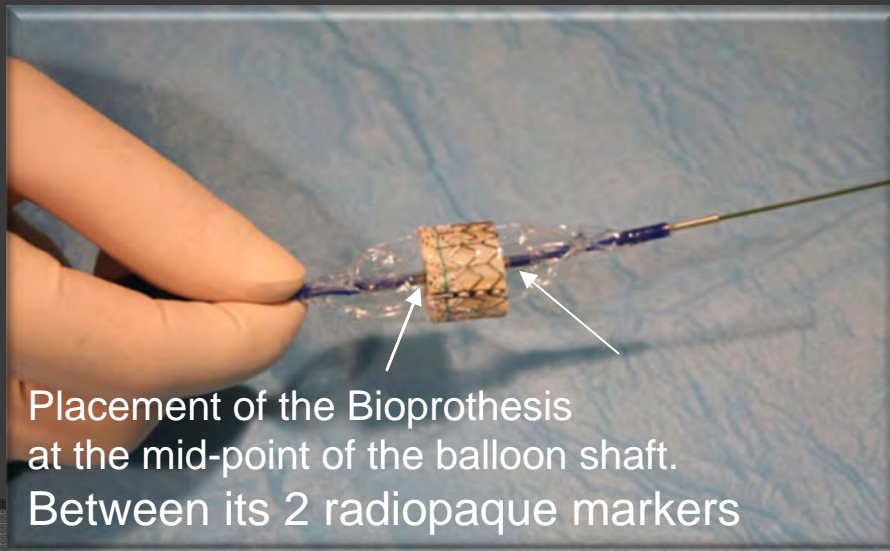
Bring gently the Bioprosthesis on the balloon



Check the orientation
(To be verified by the operator)



Green suture at the proximal side

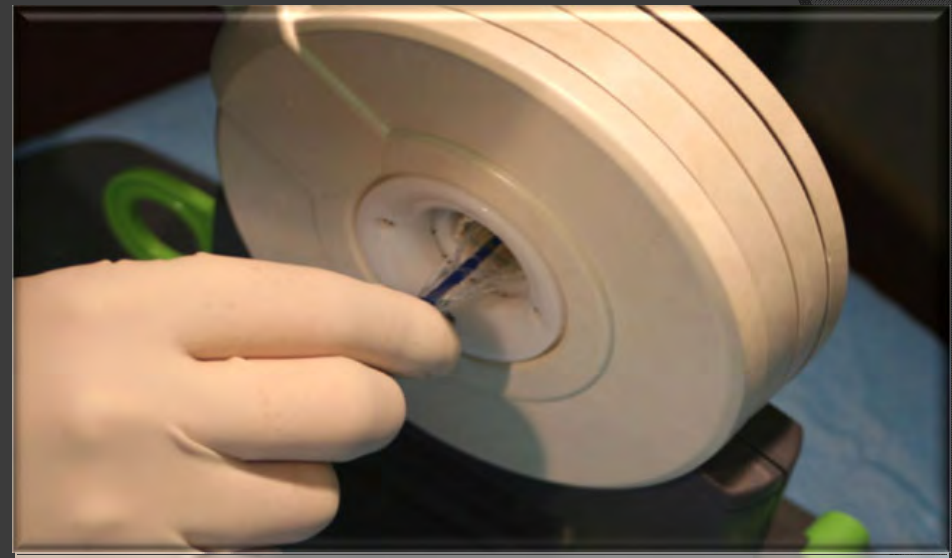
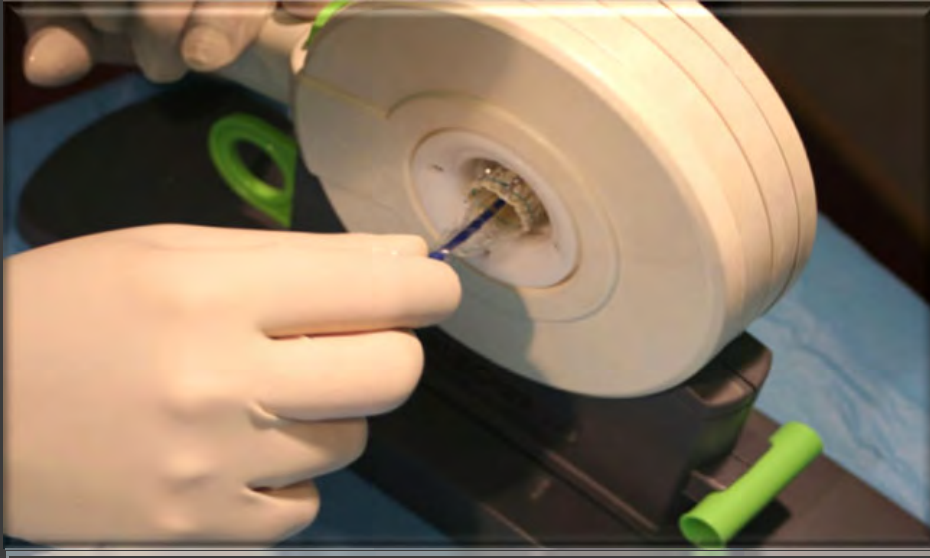


Placement of the Bioprosthesis
at the mid-point of the balloon shaft.
Between its 2 radiopaque markers

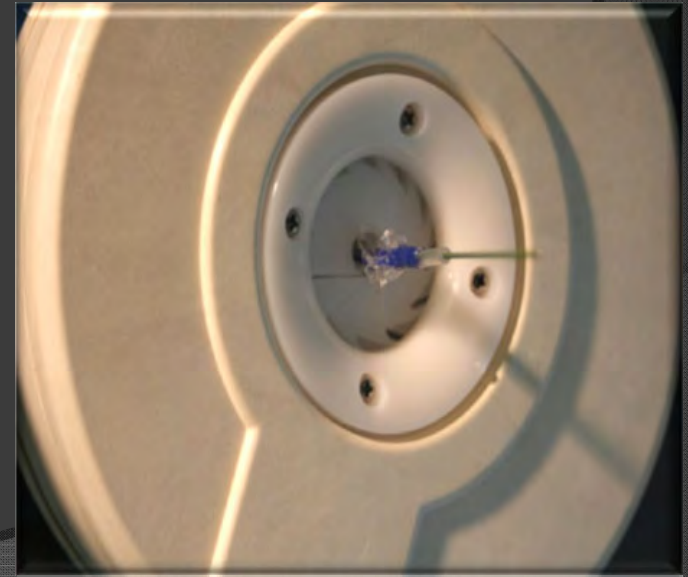
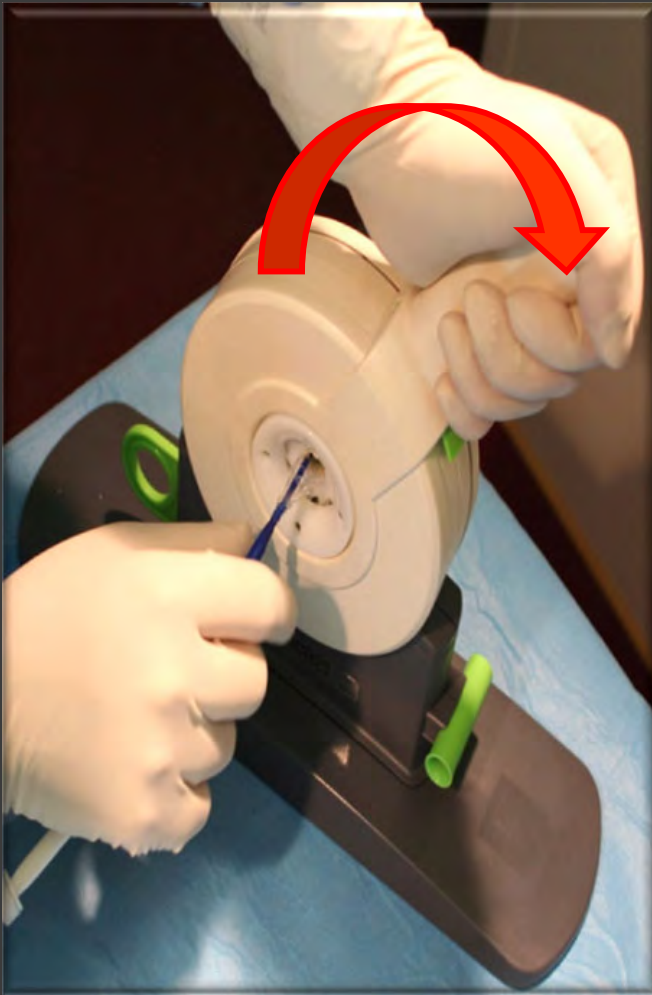
Caution: Special attention should be taken when placing the Bioprosthesis on the balloon catheter

Caution: it is recommended that a second operator verify correct mounting / orientation of the Bioprosthesis prior to its implantation

Place the Bioprosthesis / Balloon assembly back in the Crimper aperture



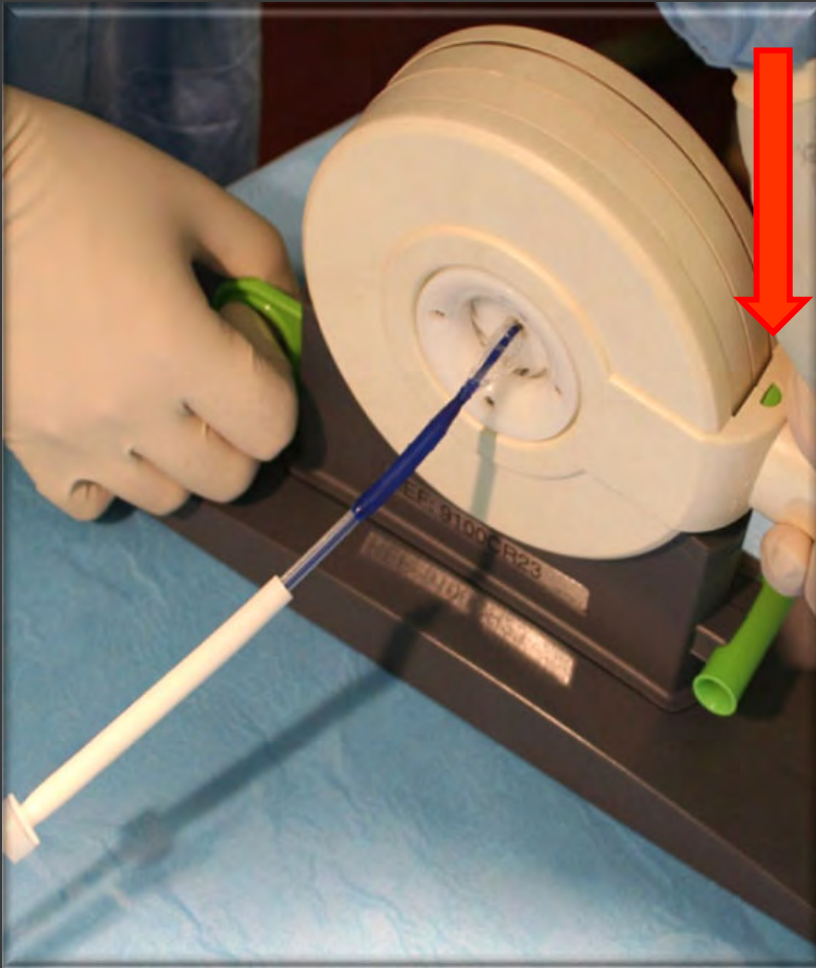
Gradually, continue to crimp



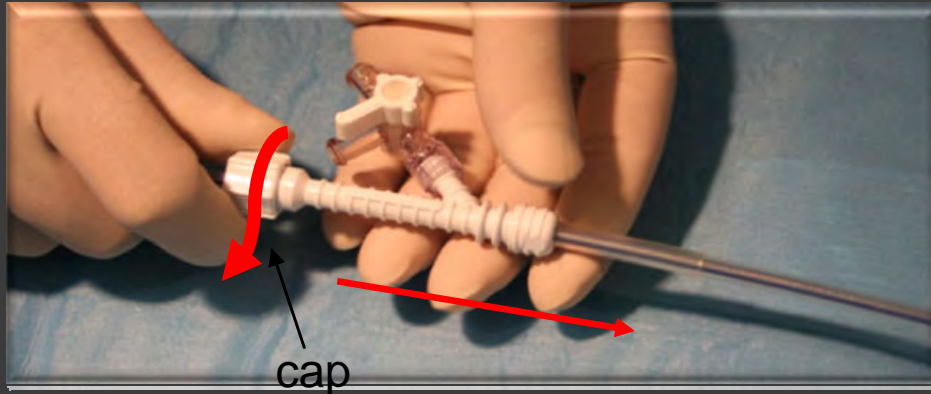
Insert the crimped Bioprosthesis / balloon assembly without passing it completely through the gauge



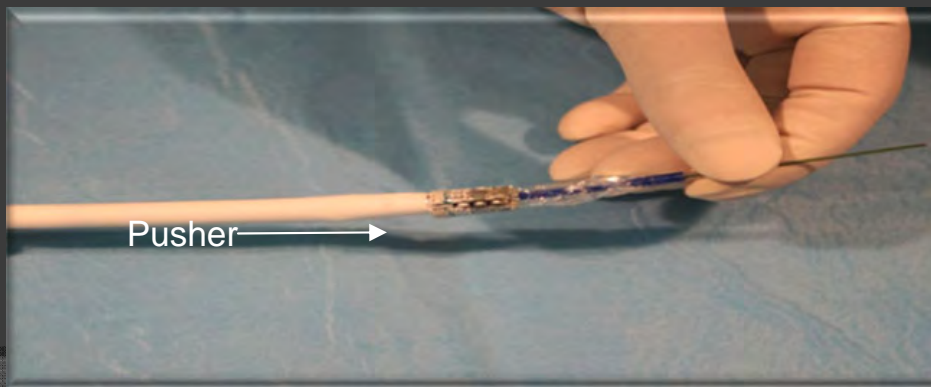
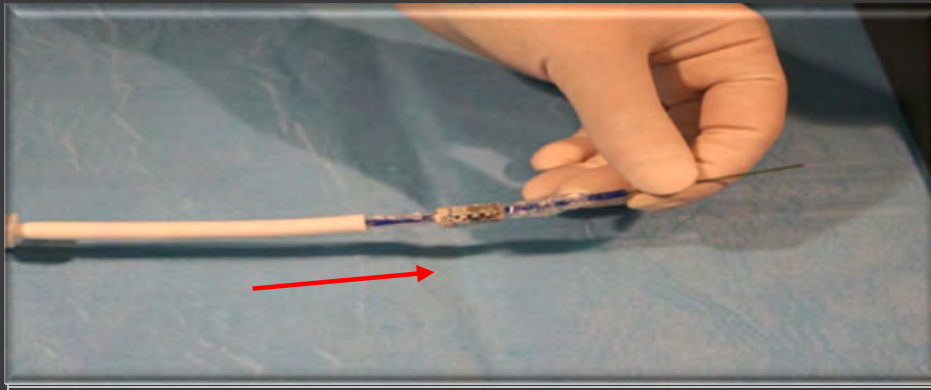
If needed, give an additional pressure to cross the crimp gauge



Ascendra Delivery System assembly



Advance the Pusher and connect the cap



The Pusher must be in contact with the crimped valve

Loader insertion



1. Insert gently the Loader

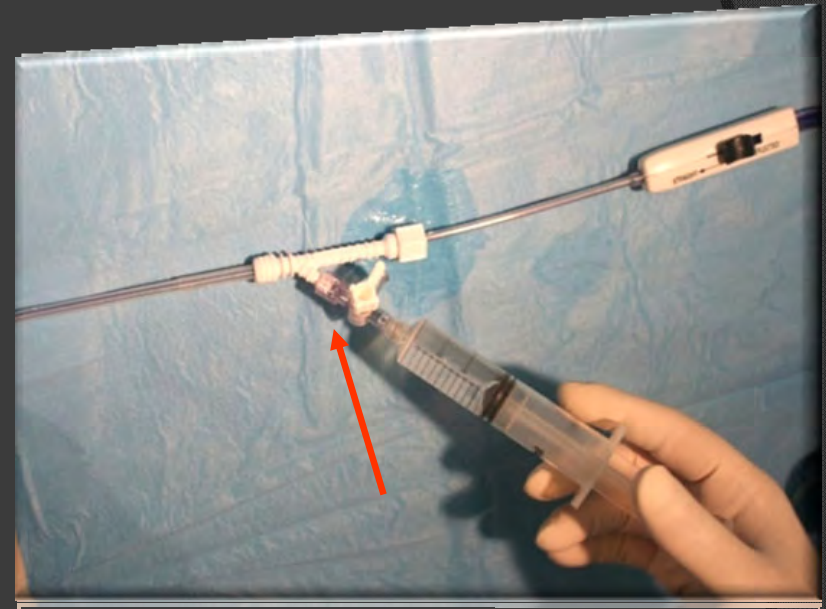
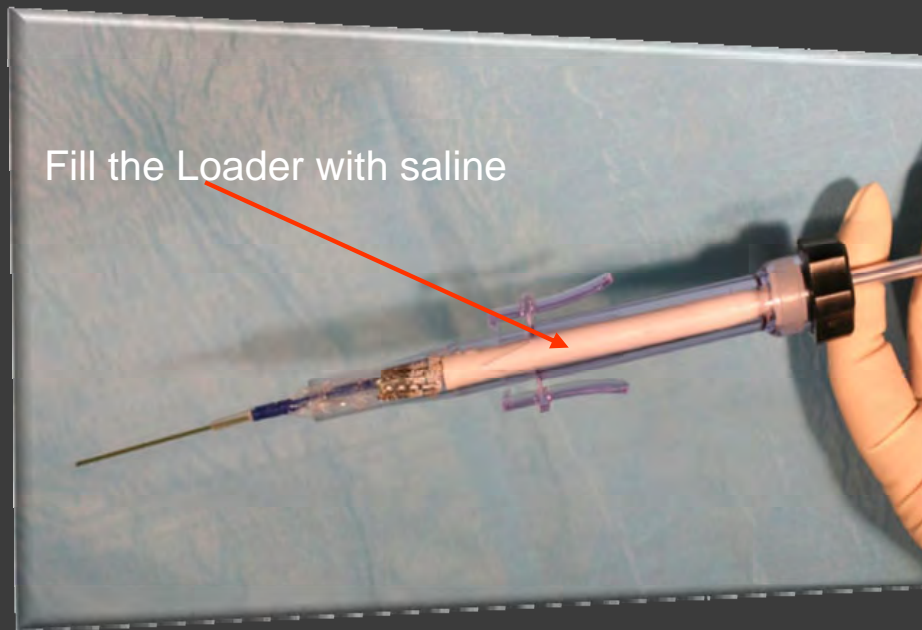


2. Push the Ascendra Delivery System into the Loader



3. Connect the cap to the Loader

Flush again the RetroFlex catheter



Always maintain hydration of the Bioprosthesis by flushing

GRAZIE
DELL'ATTENZIONE

