First results of the new GORE TIPS Set to deliver the GORE® VIATORR® TIPS Endoprosthesis

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Disclosure

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I have the following potential conflicts of interest to report:

- Consulting, Speaker for: Visage Imaging, Merit Medical, Siemens Healthcare, W. L. Gore, Bard
Content of my presentation

• GORE TIPS Set - Technical description of the components
• Use of the GORE TIPS Set in two cases:
  • Case 1: Liver cirrosis + GI bleeding
  • Case 2: Budd-chiari-Syndrome
    (GORE® VIATORE® in BCS is of-label use)
GORE TIPS Set

GORE® TIPS Sheath
with dilator

GORE® TIPS Needle
with guiding catheter
GORE® TIPS Sheath

Radio-opaque Sheath
- 10 F, 40 cm working sheath length
- Multi-layered and coil reinforced introducer sheath shaft design provides both flexibility and kink resistance
- Clear view of components under fluoroscopy
- Curved leading end
GORE® TIPS Sheath – Sheath Hub

Transparent & Tapered Sheath Hub
• Provides procedural ease during insertion of GORE® VIATORR® TIPS Endoprosthesis
• For a smooth insertion
• Minimizes potential for premature device deployment
GORE® TIPS Sheath – Sheath Dilator

Sheath Dilator
• 10Fr - Sized for use with the GORE® TIPS Sheath
• Gray color-coded
• Curved leading end aligned with directional indicator
• 0.035” Wire Compatible

Directional Indicator
Provides awareness of component alignment and direction during device preparation. Directional indicators are relevant for device preparation and initial insertion only. Once the components are in the patient, directional indicator’s relevance cannot be guaranteed.
IFU: “Advance, remove and verify position of devices only under fluoroscopic guidance.”
GORE TIPS Needle – 16 Gauge Needle

**16 Gauge Stainless Steel Needle**
- High-strength, stiff needle shaft
- Compatible with 0.035” guide wires
- 35° curved leading end aligned with directional indicator of the grip
- 56cm effective length
- “**Status band**”: marker to assure that the sharp needle tip is covered by the guiding catheter
GORE TIPS Needle – 16 Gauge Needle

16 Gauge Stainless Steel Needle
- Sharp beveled tip
- Echogenic
GORE TIPS Needle – Guiding Catheter

Guiding Catheter

• Sized for use with GORE® TIPS Sheath (10Fr)
• Blue color-coded
• Provides protection from sharp distal needle tip during access for patient safety
• Curved leading end aligned with directional indicator
• Inner Diameter 5.5French
Use of the GORE TIPS Set in daily practice

Case 1
• 51 y/o patient
• NASH cirrhosis
• reccurent GI bleeding from esophageal varices
Case 1: TIPS in GI Bleeding

- Venous access right jugular vein - 10F short Sheath (Cordis), Guidewire below the diaphragm in ICV
- GORE TIPS Needle „shaping“ (non-IFU)
Case 1: TIPS in GI Bleeding

GORE TIPS Needle covered by GORE Guiding Catheter is introduced
Case 1: TIPS in GI Bleeding

How to probe the right liver vein within 1 min
Case 1: TIPS in GI Bleeding

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How to probe the right liver vein within 1 min
Case 1: TIPS in GI Bleeding

GORE TIPS Needle covered by GORE Guiding Catheter is pulled back and „jumps“ into the right liver vein.
Case 1: TIPS in GI Bleeding

GORE Guiding Catheter is pulled back and GORE TIPS Needle is getting sharp
Anterotate the needle against the liver vein wall to exit – rotate slightly to the right
Case 1: TIPS in GI Bleeding

0.035” guide wire (Terumo) is placed in the portal vein
5 French Pigtail-Katheter is introduced through the GORE TIPS Guiding catheter. Pressure measurement + Angiogram – Amplatz Guide wire is inserted.
Case 1: TIPS in GI Bleeding

How we prepare the sheath

TIPS Sheath
+ TIPS Sheath introducer
get shaped (~80°)
→ less stiff
Case 1: TIPS in GI Bleeding

Amplatz Guide wire – GORE TIPS Sheath is inserted
(by use of a 8x40mm balloon if you do not jet want to dilate the tract)
Case 1: TIPS in GI Bleeding

Tri-axial System 6F RDC guiding catheter + 5F cobra / 12mm Amplatz Plug Type 2
Case 1: TIPS in GI Bleeding

Tract dilatation (8x40mm balloon) – Insertion of GORE TIPS sheath
Case 1: TIPS in GI Bleeding
Case 1: TIPS in GI Bleeding

GORE VIATORR (10x80mm) Insertion via GORE TIPS sheath
Case 1: TIPS in GI Bleeding

Post TIPS Angiogram (Gradient 34cm H₂O → 8cm H₂O)
Use of the GORE TIPS Set in daily practice

Case 2

- 34 y/o female
- Polycythemia vera
- Budd-chiari-syndrome
- massive refractory ascites
Case 2: TIPS in BCS

Activation of 3D Guidance (Siemens Pheno) to visualize the level of the liver veins
Case 2: TIPS in BCS

GORE TIPS Needle covered by GORE Guiding Catheter is introduced
Case 2: TIPS in BCS

Essential in Budd Chiari Syndrome
Case 2: TIPS in BCS

GORE TIPS Needle covered by GORE Guiding Catheter is pulled back and „jumps“ into the residual liver vein
Case 2: TIPS in BCS

GORE Guiding Catheter is pulled back and GORE TIPS Needle is getting sharp. Anterotate the needle against the liver vein wall to exit – rotate slightly to the right.
Case 2: TIPS in BCS

0.035” J guide wire (Cook) is placed in the portal vein
5F Pigtail catheter is used to measure the pressure of the portal vein
Case 2: TIPS in BCS

Amplatz Guide wire is inserted
Case 2: TIPS in BCS

Periportal ballooning (8 x 40mm, Boston Wanda®)
Case 2: TIPS in BCS

Central ballooning (8 x 40mm, Boston Wanda®)
Case 2: TIPS in BCS

Insertion of GORE® TIPS Sheath + Dilator
Portal vein angiogram via 10F GORE® TIPS Sheath
Case 2: TIPS in BCS

GORE® VIATORR® Endoprosthesis (8 x 80mm) placement
Case 2: TIPS in BCS

Ballooning of the GORE® VIATORR® TIPS Endoprosthesis (8 x 40mm)
Case 2: TIPS in BCS

Ballooning of the GORE® VIATORR® TIPS Endoprosthesis (8 x 40mm)
Case 2: TIPS in BCS

Final Angiogram
GORE TIPS Set - Conclusion

**Needle**
- Sharp and rigid (but not too rigid)
- Helpful marker (status band) indicates „activation“ of the needle

**Sheath**
- Optimized radioopacity
- Interlocking components allow for smooth liver passage
- Transparent tapered hub eases a save GORE® VIATORR® insertion
GORE TIPS Set

Thank you!
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