



# Medical Device Industry Perspective

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## Why Are We Here?

- Growing need to bring healthcare costs under control with “specific” focus on high profile, high cost cardiology areas
- Hospitals need to become more cost efficient, with specific focus on delivering improved quality outcomes
- Bleeding and access site complications continue to contribute to LOS, adverse outcomes and excess costs
- Vascular complications are twice as likely to occur as the next leading complication-renal failure<sup>1</sup>
- Femoral access has been a traditionally trained procedure, but perhaps it is time to rethink and move towards recognized alternative approaches

<sup>1</sup>Kugelmass A, et. al. *AJC* 2006



## Is It Just About Bleeding?

- Complications attributed to vascular access have the most lasting and meaningful impact to patients
- The periprocedural management of a femoral PCI patient has a direct and significant impact to the healthcare professional and patient
- Socioeconomic impact to the patient, family and caregiver is currently not well appreciated or measured
- Education and training of the HCP in procedural techniques has been traditionally product related/focused



# Current Device Industry Assessment

- Device solutions in the US have been universally focused on femoral access for over 40 years
- Product development has been primarily directed at the therapy spectrum over the past 25 years
- Attitudes and approaches to vascular access have remained relatively unchanged for the better part of three decades
- Currently, radial access requires a small subset of tools and techniques to realize the advantages gained for all stakeholders

# TERUMO® Considerations for TREATT

- Devices utilized in the trial should have an indication for use for radial access
- “Patent” hemostasis should be encouraged and measured to reduce potentiality and occurrence of radial occlusion
- Hydrophilic introducers and recognized pharmacotherapy should be encouraged to reduce occurrence of radial spasm<sup>1</sup>
- Patient preference and experience should be measured
- Site selection should give consideration to quantifying and correlating physician’s radial experience/outcomes

<sup>1</sup>Sudhir Rathore, et.al ,*Impact of Length and Hydrophilic Coating of the Introducer Sheath on Radial Artery Spasm During Transradial Coronary Intervention*; *J. Am. Coll. Cardiol. Interv.* 2010;3;475-483



## What Does The Future Hold

- Changing healthcare climate and patient preference mandates a need for change
- Access site complications being considered as “never” events
- Future device focus towards transradial procedures could produce a paradigm shift towards new and improved procedural methodologies